

Privacy & Security Tiger Team
Draft Transcript
August 6, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning and welcome, everybody, to the Privacy & Security Tiger Team. There will be opportunity at the close of this call for the public to make comment.

Let me do a quick role 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? Carol Diamond?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Judy Faulkner?

Carl Dvorak – Epic Systems – EVP

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Carl Dvorak? It was Carl. David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

David Lansky?

David Lansky – Pacific Business Group on Health – President & CEO

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Dixie Baker?

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

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Rachel Block? Christine Bechtel?

Christine Bechtel – National Partnership for Women & Families – VP

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

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

Leslie Francis?

Leslie Francis – NCVHS – Co-Chair

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Adam Green?

Adam Green – Progressive Chain Campaign Committee – Cofounder

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Joy Pritts?

Joy Pritts – ONC – Chief Privacy Officer

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Did I leave anybody off? I know Micky is on holiday.

Jamie

Jamie

Judy Sparrow – Office of the National Coordinator – Executive Director

Jamie. Thank you.

Andreas – MITRE Corporation

Hello. This is Andreas ... with the MITRE Corporation.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay. Thank you. I'll turn it over now to Deven and Paul.

Paul Egerman – eScription – CEO

Good morning. It's Paul Egerman. I want to welcome you to our Tiger Team Meeting. I want to thank, first, the Tiger Team members for their dedication, being here and participating in this meeting this morning on a, hopefully, wherever you are, bright and sunny August day. I want to thank the public, who might be listening to our call. There will be an opportunity for public comment when we are completed with the call. We look forward to receiving those comments.

To briefly remind everybody, the Tiger Team was organized at the request of ONC with members from the Policy Committee and the Standards Committee to aggressively meet during the summer months to address a series of very specific privacy and security questions. This Tiger Team has been making actually extremely good progress. We've gone through a large number of issues. Most recently we've been focusing in on issues related to consent and what we will be doing in today's meeting is sort of picking up on the consent issues and trying to see if we can sort of wrap those issues up to complete, sort of like package those issues.

The path that we are on, the schedule that we are on, to make sure everybody understands what the plan is, is hopefully we can complete those discussions on consent today. Then, over the next approximately week we, which really means Deven, will be taking all of the work that we've done and putting it together in the form of a letter of recommendation. So we're going to be switching from basically a PowerPoint presentation that's been guiding our work into letter text with our specific recommendations. We will be circulating that to you, the members of the Tiger Team, sometime next week.

Then we have one more meeting scheduled in August on August 16th, which will give you an opportunity to view all of that material as a whole and to comment on it. Then on, I think it's August 19th, there's a Policy Committee meeting, at which case we hopefully will be presenting the information in the letter.

So that's the overall process. Again, today, the intention of today is to sort of wrap up and clean up some of the issues related to consent and in particular, to respond to some of the questions that were raised by members of the Policy Committee and a few members of the Standards Committee when we did our presentations.

So, unless anybody has some comments about the agenda the first issue on the agenda is what's called the Bullets on Direct Exchange, which is on slide seven. So, Deven, do you want to lead us through this discussion?

Deven McGraw – Center for Democracy & Technology – Director

Sure. So what we have here is the third and fourth bullets here, this is related to the discussion that we had on our last call that the initial topic arose in our discussions about sensitive data and reconciling two recommendations we had made. One being that directed exchange doesn't require additional consent beyond what's already in current law and that sensitive data would a trigger.

We ended up putting up some bullets that started with some good language that was circulated by Wes about the importance of the doctor-patient relationship in direct exchange. We had decided that those would really be better bullets as part of the direct exchange recommendation itself. We also had a fairly extensive conversation about the language and wanting to be clear that what we're doing, at the core of our recommendation is that the fact that we're talking about an electronic transfer of information doesn't change the essence of that relationship and that that's sort of at the core of the way we wanted to express this.

People were not quite 100% comfortable with the language the way that it was, at least not from a consensus perspective, so Paul and I took it off line and have tinkered with the wording of these bullets to try to make sure that folks are comfortable with it. Again, I think we largely had consensus on the basic intent that the absence of a trigger factor doesn't change the patient-provider relationship and the importance of that relationship in the discussions that take place between providers and patients and so we have attempted to do this here now.

We just want to make sure that we got the intent right in this wording and spend a little bit of time talking about it. But consistent with our desire not to eat up large amounts of the call in wordsmithing, we've sort of only got a small amount of time dedicated to this so that we don't fall into that trap, but we do want to get some feedback on what you think about what we've got on here. Really, it's just these last two bullets that are relatively new, just some different wording of the same concepts that we discussed on our call last Tuesday. Does anybody have any—?

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

I have a comment about the third bullet point. I understand the idea of this notion of the importance of a patient-provider relationship and the provider using judgment. My concern is that as these environments expand, even direct exchange I think the volume of requests that are likely to occur in a large environment are such that I'm concerned about the practicality of assuming that in each case the provider and the patient have this meeting of the minds as to what is to be exchanged.

I don't know how you capture that. I just see the reality, which is there's an enormous amount of information that's going to get exchanged and sometimes it will be in advance of an encounter, sometimes it will be the direct result of a consultation or some type of referral, but I'm just a little concerned about how intimate the patient-provider relationship is intended to be in this bullet.

Paul Egerman – eScription – CEO

It's a good comment, John, although I think what we're trying to do in this bullet is to say that our recommendation on directed exchange isn't intended to change that patient-provider relationship. Whatever it is now with where information is either faxed or done on paper, the fact that we're saying you can do it electronically, we just don't mean to change that in any way. So we're not trying to make it harder or easier. We're trying to say whatever it is supposed to be what it should continue to be.

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

I hear John as raising the issue of an increased volume associated with a more ... way of transferring information—

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

That's correct.

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

I think it's an important point. I believe that there are at least some limits on that phenomenon in terms of directed exchange just by the nature of what directed exchange is. It's much different than the likelihood that there will be more sort of ad hoc requests for data associated with the other models of exchange.

But still, I think John's got a good point. There will be an increase in volume and I wonder— I mean when I started ... to this specific language I was trying to balance coming from a model where it sounded like we were saying that every exchange involved a counseling session between the physician and the patient to one that was more dilute and John's making the point we may have not gone far enough. I'd be interested for John to suggest what would be an alternative way of saying this that doesn't disrupt our

fundamental notion that this is about the patient-provider relationship and is more practical or to say our notion is wrong if it got to that.

Paul Egerman – eScription – CEO

I would also like to understand why we think this will increase the volume. This is directed exchange for treatment. It's just like ordering tests. So, I don't think the treatment volume will change as a result of what—

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

I think what will happen here, practically speaking, is that what happens today will ... tests are repeated, information is not exchanged because it's not readily available. What we're talking about, even in a directed exchange, will be an environment where information will be much easier to access for other providers and, therefore, will be accessed in order to facilitate when—

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

Oh, I see. But that is a different case, right? When you say accessed from other providers we're now into a query and response rather than this is what the doctor decided to send proactively associated with the transition in care of—

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

Well, I think that will occur though too though—

W

Even in the query and response model our directed exchange doesn't foreclose that as long as the provider is still in control of making determination as to whether—

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

That's true, so David's going back 100 years now. David's original scenario had to do— Well, no, not his original scenario, but several scenarios had to do with being able to electronically request person-to-person information from a provider and have that come back when the provider looked at the request, so you're right.

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

Just so you understand too, I think as volume goes up the time that people will dedicate to determining whether the request is, what's the word, have the opportunity to review the request will go down. Again, I think volume will still dictate the fact or will affect what's practical or what actually occurs in a practice or in a hospital setting in terms of how they look at releases.

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

How should we go about this?

Gayle Harrell – Florida – Former State Legislator

Well, I have to put my \$0.02 in because I think that anything that backs off that provider-patient relationship and dilutes what you've said here is going to be very negative. I think you've got to make sure that that is understood, that responsibility is there and it's very, very clear there should be no change whatsoever, that the consideration that applies to the paper world also applies in that counseling or whatever needs to happen so the patients are very clear about what's going to be exchanged.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. I mean to water this down any further would be negating the Hippocratic oath. I mean this seems to be pretty innocuous.

Paul Egerman – eScription – CEO

Well, I think to Wes' request, I think the key here is it doesn't necessarily change the patient-provider relationship. What I think it doesn't change is it doesn't change the provider's responsibility to ensure that they are reasonably attempting or reasonably trying to honor the patient's privacy expectations, while still addressing the patient's expectation with respect to providing treatment related information to other providers. I think that was something Judy Faulkner's always said as well is there is this balance that has to be achieved and I think that it's up to the provider to try to take those patient preferences into consideration in total.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's what it says it seems to me.

Deven McGraw – Center for Democracy & Technology – Director

Admittedly, I think everybody inherently gets the balance we're trying to strike here and it's just a matter of making sure that the two ends of that balance are adequately represented and it's depicted. We're just still struggling with the language here, so what I'm going to suggest, John, is that if you want to suggest, if you don't think this hits at the right balance, or anybody on the phone for that matter, please continue to send wording and everyone will have an opportunity to read it and we'll continue to try to pound at this and get it right.

One other thing that I might suggest is that we do have some room, I think, in these recommendations to provide examples, illustrative examples of what we mean, which might be able to help make it more clear.

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

That might solve the problem. If everybody tells me what I'm talking about has already been addressed then that's fine. If we have the opportunity to add examples that clarify this environment then maybe that's all we need to do.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Judy Faulkner – Epic Systems – Founder

I think that's fine. I wanted to look at a different part on it though, bullet three where it says, "Judgment in evaluating which parts of the record are appropriate to exchange." To me, as I read that, I'm thinking of the topic that we had earlier of segmentation and what's doable and what's leaky and stuff like that. I come away with an impression that it's supposing that, in fact, you can say which parts of the record can be exchanged and you can do this and not this and that and not that. I think there's an implication within there.

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

Yes. There is.

Deven McGraw – Center for Democracy & Technology – Director

Yes there is. I mean part of it is also we had an extended discussion, Judy, about how the whole record being sent and sometimes that's what's needed, but sometimes it's just the lab test results, sometimes it's just the care summary. So I was just trying to capture that the judgment is both, about the what, as well as the to whom.

Paul Egerman – eScription – CEO

Yes. I certainly didn't mean to imply the strictness of inference or the strictness in terms avoiding inference that is associated with the segmentation discussion.

Deven McGraw – Center for Democracy & Technology – Director

Right, which we actually have captured there very well I think or we're creeping up to it very well.

Paul Egerman – eScription – CEO

Then that's the fourth bullet?

Deven McGraw – Center for Democracy & Technology – Director

Well, no. No. No. I mean remember that this is sort of a direct exchange in general discussion. We do have some more discussion about the sort of leaky data problem in the sensitive data category.

Paul Egerman – eScription – CEO

What I'm hearing, and I'm sorry if I'm misreading, but what I'm hearing Judy and John say is that that last phrase implying that a provider will take the time to exercise judgment in deciding what to send all of the time implies an active act; whereas, I was thinking of it very much as in the simple case when they're dictating a note and they decide what to put in the note or not. But also, when they started having standard templates for notes and things like that, part of what went into the judgment of creating those things was a general sensitivity and a lot of times if it is a request it comes through staff and staff, depending on what the practice is, staff has been better or worse trained in how to reply, but at a minimum it's the physician's obligation to do that training for their staff.

Deven McGraw – Center for Democracy & Technology – Director

Right.

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

What happens when we get to the point where even in a direct exchange it becomes programmatic, completely programmatic?

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

Well, then it becomes leaky.

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

And you set up programmatic rules that reflect good clinical judgment. I mean, like you do with everything else. I mean what's the alternative, to basically say the provider has no obligation to worry about what data was exchanged because it's too much work?

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

I agree with your point that you use good clinical judgment. That absolutely makes sense to me, but that does undercut the notion that there is this pure patient-provider relationship that is an intimate patient-provider relationship where they try to understand what the patient, he or she, wants rather than an environment where by you do use good clinical judgment to decide what needs to be sent.

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

I think this fourth bullet captures exactly where we're going with this. I mean doctors today, when they fax information to another provider, they do consider what needs to be faxed and what doesn't. This is really a clarification of that statement.

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

Yes. We're worried about the impact of increased volume on the current model.

Deven McGraw – Center for Democracy & Technology – Director

Right. I mean I get all of that, but it doesn't sound like anybody on the call is saying that that relationship isn't important and that the prong of that and the expression of that doesn't need to be in here somewhere in addition to, but without necessarily stepping over a line where it looks like we're suggesting that that conversation must proactively take place at each and every—

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

Yes. I'd like to suggest a one-word change that I think would help in this—

Deven McGraw – Center for Democracy & Technology – Director

Okay.

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

In the third bullet, the second-to-last line if you replace evaluating with determining and my reason for doing that is that that determination might be happening in clinical rules. It might be happening in training the staff. It might be happening— I'm trying to get it out of the implication that there's a specific per-transaction thought process going on here as opposed to the sensitivity of the issue.

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

I would agree with Wes and I would add one thing then to the end. For a given purpose, based upon, I think how Paul has described it, good, clinical practice or accepted clinical practice or something like that.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I just want to say that I think one of the reasons we got to this part of the discussion is that we can't pre-suppose the things that a patient considers sensitive or doesn't want to share. I think what we were trying to do here, if I'm remembering the last conversation, is to make sure that if the patient expresses to the provider that there are things that they don't want to be shared that the provider know and honor that regardless of what "consent" is required. I don't want to lose that, so if you're going to add appropriate to be exchanged by given purpose based on clinical judgment I think we should also say and patient expectation.

W

Exactly.

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

Could we say expressed patient expectations? Because otherwise you get to—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. Sure. You don't have to ... them.

Paul Egerman – eScription – CEO

I think we're getting a little too far and starting to break our rule about wordsmithing, but I guess the—

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

We're meaning ... here.

Paul Egerman – eScription – CEO

Pardon me?

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

I think we're meaningsmithing here.

Deven McGraw – Center for Democracy & Technology – Director

I've been taking copious notes. I actually think we—

Paul Egerman – eScription – CEO

I think we need to move on a little bit, but I think—

Judy Faulkner – Epic Systems – Founder

But, Paul, this is so important I don't know that—

Paul Egerman – eScription – CEO

Okay.

Deven McGraw – Center for Democracy & Technology – Director

But we could spend four hours on these two paragraphs.

Judy Faulkner – Epic Systems – Founder

It might be worth it.

Deven McGraw – Center for Democracy & Technology – Director

No, it's not worth it, Judy, because it's not the last opportunity we have to refine this.

Paul Egerman – eScription – CEO

Yes, we'll an opportunity on the 16th.

Judy Faulkner – Epic Systems – Founder

Can I say two more things then?

Paul Egerman – eScription – CEO

Yes.

Judy Faulkner – Epic Systems – Founder

One is I like where patient's concerns could be patient's expressed concerns so that the physician doesn't have to—

Deven McGraw – Center for Democracy & Technology – Director

We've got that already, Judy.

Judy Faulkner – Epic Systems – Founder

Oh, I'm sorry. I missed that then. Then the other one is on the third bullet we have used the word exchange in this whole thing to mean computer exchanged. We haven't used it to mean paper exchanged as we talk about exchange and so I'm wondering whether, in fact, we need to then say,

because otherwise there are two things; there is an expectation that it means computer exchange, which parts of the record are appropriate. Maybe we should be, as you think this through—you don't necessarily have to do it now, change for given purpose, whether that exchange is done with or without the computer, because you need a way to say that they don't turn to the EHR vendors and ask for things that can't be done because they think they have to.

The second thing in this is lots of times it isn't the provider sending the patient somewhere and saying, "Here's the information that goes." It's the patient showing up somewhere else and the information being pulled over at that time and the patient's provider, who is responsible for this isn't making that choice for the patient. The other provider doesn't know, the new one doesn't know what's in the patient's record and it's all done electronically.

Paul Egerman – eScription – CEO

Those are good comments—

M

Although I think that that's outside of the push of the—

Deven McGraw – Center for Democracy & Technology – Director

It is, but even in Judy's example, as I mentioned earlier when Wes raised query response, direct exchange can occur in a query model as long as the provider still has the control of the decision to release the records.

Judy Faulkner – Epic Systems – Founder

And for most providers they're making that automatic, so when a patient shows up elsewhere, so if I show up at the University of Chicago and say, "Please get my information from the University of Wisconsin," the doctor at the University of Chicago, who is my provider at that time, doesn't know what's in my record and the provider group at the University of Wisconsin doesn't have the opportunity to consult with me.

Carl Dvorak – Epic Systems – EVP

Sometimes the University of Wisconsin will be a collection of specialists and your primary care doctor might actually be somewhere else in a different practice. So I think we have to recognize what the normal use cases are really going to be.

M

But I would call those query models.

Judy Faulkner – Epic Systems – Founder

It's still direct exchange—

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

No, I think we've been distinguishing query as being all forms of requests to reply and not in directed exchange being those forms of requests to reply where the reply is automatic.

Deven McGraw – Center for Democracy & Technology – Director

Yes. I actually—

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

Yes. I think what Judy and Carl have raised is the notion that automatic can happen through people, as well as somewhat through computers.

M

Yes and it can happen directly against an EHR as opposed to an aggregating service of some kind. I think that's an important point, but—

(Overlapping voices.)

M

The decision to push that we've been driving from—

Judy Faulkner – Epic Systems – Founder

Right. In particular, what's going on for many of these is that the way we're talking about it right now is just simply making referrals easier. That's all. What we're getting to, which I think is even more important, is when the patient shows up somewhere else without a referral, without the information and it's an emergency, which is the real life-saving component, it happens here a lot, how does that data come over.

Deven McGraw – Center for Democracy & Technology – Director

Okay. We are actually—

Paul Egerman – eScription – CEO

Let me interrupt this discussion because I want to make sure we get ourselves back on our agenda. First, to be clear, directed exchange does not mean push. Directed exchange is point A to point B and so—

Judy Faulkner – Epic Systems – Founder

This is point A to point B.

Paul Egerman – eScription – CEO

That's ... my comment relative to what David had said earlier. And so also, to be clear, when we show this to you what we're trying to do is show you that we were trying to be response in the last meeting. It looks like we haven't quite gotten the right sequence of words, although Deven has copious notes on this. What we want to do, what I'd like to do is we'll take another cut at this—

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

And we'll send it out to you. Again, remember, you're going to have another chance. The purpose of the August 16th meeting is that will be the time to make sure that we can polish these things and get them exactly right, but I want to make sure because we have some other issues we need to address—

Deven McGraw – Center for Democracy & Technology – Director

Yes and some of the conversation that we've just been having about sort of direct, push/pull is part of the discussion on refining the consent triggers.

Paul Egerman – eScription – CEO

Yes. So I'd like to thank everyone for their comments. I hear what you're saying, Judy and John and David and Wes and Carol. We will do our best to put this together and see if we can come up with something that comes closer. As I say, you'll have another chance at that.

So I'm going to move on to the next slide, because this is where actually, compared to the previous discussion, I think this is a place where we're going to start to have to roll up our sleeves in today's call. The previous slide on direct was all about wrapping up or sort of polishing or completing our recommendation on directed exchange. From there I just want to remind everybody the next sequence was we said, "Well, what are the triggers for consent? If directed exchange does not require consent what does require consent?"

Again, the thing that helped us a lot through this discussion was that patient-provider relationship and so we sort of listed off the things that would cause sort of like a loss of control by the provider out of that patient-provider relationship and so we ended up with these six triggers that are listed here. These six triggers, the way it's listed here, also to tell you how this got wording is we had a conference call. I think it was on a Friday. It was one of these three-hour calls.

Then Deven and I had a Policy Committee meeting the following Tuesday, so we spent the weekend and I wrote down a bunch of stuff really fast. Deven edited it and then we went with it and we presented it this way to the Policy Committee and also to the Standards Committee. Then when we presented to the Policy Committee we realized that we hadn't drafted this correctly and there was a lot of questions. So we were given the direction to clean this up. So that's what we're trying to do.

What you see here on slide eight is exactly what we've already presented to the Policy Committee and Standards Committee, so that's sort of like the existing status. The six triggers, we're not going to go through them in detail because we're going to do that in a minute, the first one relates to health information no longer under control of the patient or the provider. The question on that was what does that mean, control?

The second one was patient's health information is retained for future use by a third party intermediary and there was a lot of questions about that, which was what does that mean, future use?

The third one relates to unencrypted PHI, patient's health information, which I know is not the same as PHI, is exposed to persons not related to ongoing treatment.

The fourth one about aggregation also caused some confusion.

We also had sensitive data, which we addressed last time.

Then we have the sixth approach.

So what we've done with these six triggers is on the subsequent slides we are putting forward a proposal as to how to clean it up a little bit or to clarify it, to come up with some examples. We want to run these by you one-by-one to see if this is correct.

The first slide: Actually, this slide has two triggers. Let's look at the first one. The first one was the concept of control. The question was what does that mean, control? This is something that Deven drafted. She changed this to decision to initially disclose or exchange the patient's health information from the provider's record is not in the control of the provider, so it's really never in the control of the patient in the EHR, but anyway, she put in initially disclosed and she gave two examples, a federated HIO and a centralized HIO. I think there was nothing intended by having the font different for centralized HIO—

Deven McGraw – Center for Democracy & Technology – Director

Yes. There was not.

Paul Egerman – eScription – CEO

So do not infer that that means something about centralized. I think that was just a fonting idiosyncrasy.

Deven McGraw – Center for Democracy & Technology – Director

Yes. I am no PowerPoint pro.

Paul Egerman – eScription – CEO

What I want to do is say what are your reactions to this. Is this great? Is this worse? What do you think about this?

Judy Faulkner – Epic Systems – Founder

I've got a question for you, Paul. So I am a patient and my provider is Dean Clinic and Dean Clinic has little offices all over the place and Dean Clinic is also extended out in kind of a care organization-like fashion to lots of provider groups, who aren't Dean Clinic so that maybe I'm seeing a provider group associated with this, which is called Manitowish Waters, a little, tiny provider group, and it's right next to, it's associated with a Manitowish Waters Dean provider group, which is associated with the great big Dean Group in Madison. Am I going to feel that it is in control of the provider if I read this?

Deven McGraw – Center for Democracy & Technology – Director

If you share within that Manitowish group? Where is the sharing going on?

Judy Faulkner – Epic Systems – Founder

Well, my record is I see a provider, who is not part of Dean, but who shares the software with Dean in one comprehensive record to have better community care.

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

I think the spirit of this is that that would be a consent trigger and I would agree with the spirit of that. If the record is shared outside of the confines of the provider that you, as a patient, have a relationship with at a minimum you need to be aware of that and I think, ideally, you should consent to that, particularly if it's part of a different covered entity. Maybe the distinction is a covered entity. If it's within the covered entity then it's not going outside the control of that provider's organization.

Paul Egerman – eScription – CEO

I wonder if we could divide this in half. Judy is raising an issue that got raised throughout, which is there are lots of care structures that are a challenge and I think when we originally were thinking about this we were more thinking about the examples written here, which are the HIOs, so one way to respond to Judy's comment would be to say the decision to initially disclose the patient's health information for ... not under the control of the provider and is in the control, as an organization that does not provide healthcare.

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

Why do we have the word initially there?

Deven McGraw – Center for Democracy & Technology – Director

I'll tell you why since I am the drafter of it. Again, thinking about the doctor-patient relationship, again, is the foundation for all of this. If a doctor whose record is being shared, either initiates that disclosure out of his or her record or is responding to a query that nevertheless has control over the decision about whether to share the record or not versus the types of models where maybe it's more automatic and we

should talk about that or whether the record is accessible through like a centralized HIO where the provider who contributed the data no longer has any input into how and when it's shared beyond that initial participation agreement that he or she agreed to sign, that those were distinct.

So it's initial disclosure because it's about how the information gets released out of the record that is the trust basis with the patient in that physician-patient relationship. So, to subsequent disclosures down the line, if it's disclosed from one provider to another, the recipient provider then has similar obligations with respect to that record. It's who is the decision maker at the time and when the record holder has the power to make the decision that's when it gets released. It's not—

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

I would agree. Therefore, I would delete the word initially, because no matter when, if the decision to disclose or exchange the patient's health information from the record is not in the control of the provider then that entity should get consent.

Joy Pritts – ONC – Chief Privacy Officer

There had been some confusion in this conversation before about the re-disclosure issue, so I think that we just need to make sure that if that's what you're talking about— Is that where we're going with this is also with re-disclosure? It's a little different than the original conversation I believe.

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

Whoever is holding the record. What you don't want is if provider A discloses it to provider B and then provider B discloses it you don't want provider B not to be responsible for getting the patient's consent.

W

If it's a trigger situation—

Paul Egerman – eScription – CEO

This is a trigger situation.

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

That's right. Yes. Yes.

W

But this is a—

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

Yes.

Paul Egerman – eScription – CEO

... because this is a trigger situation. This is a situation where the patient's record is being sent to some entity that will have this control over it, which is the decision to make other disclosure kinds of decisions. So this is a trigger situation.

Joy Pritts – ONC – Chief Privacy Officer

Yes. I understand that. Just to play it out, and I'm just doing this to be devil's advocate because I want to make sure that we know that I have a ... for this. If I'm a patient in a system where, let's say they obtained patient consent or not, they transfer my information to another provider and in that situation now that provider is in a system where it's not a directed exchange. It's a kind of query response situation. At that point that provider is going to be required to obtain my consent.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think just to maybe complicate life a tiny bit, but to throw a test against this is what if the patient says, “No. I don’t want you to share that information?” In other words, maybe this is describing situations where there is optionality in the sharing and saying, logically, that consent would be required for the optional sharing to occur.

Paul Egerman – eScription – CEO

Yes. I mean that’s correct. If the patient says no, we’re going to get to that in subsequent slides, but clearly, the implication is that if the patient says no then you don’t share it, so the data is never sent to the HIO.

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

I’d like to make another comment about ... mentioned automatically release. For me, a provider organization is responsible for the rules regarding automatic release, so if there’s an automatic release rule and the provider organization has put that in place it still is under the control of that provider organization. It’s not like it accidentally gets out there. It’s their rule that triggered the automatic release, so I would consider that acceptable. If it were acceptable for a person to hit the send button then it should also be acceptable for the provider organization to have a rule and say automatically send this to so-and-so.

Paul Egerman – eScription – CEO

Okay. I understand those comments, but I want to make sure we understand where we are.

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

Right. This is directly related to this one.

Deven McGraw – Center for Democracy & Technology – Director

Yes. No. I think it is too. I think it’s a very good question but, Paul, this is your discussion to manage, so we can parking lot that one, but I do think it’s important to explore it.

Paul Egerman – eScription – CEO

Okay. So getting back to this discussion, we had this issue raise with the word initially that Dixie raised. Where are we on that issue? Are we taking that out or are we—?

Deven McGraw – Center for Democracy & Technology – Director

I think we’re taking it out.

Paul Egerman – eScription – CEO

Okay. So we have that. We also have this issue that Judy raised, which is an issue that gets raised a lot in these things, because the way I looked at this is the examples are good examples. This is really a trigger for consent for participation in a federated HIO and/or a centralized HIO, which, from previous discussions, I think we all agree that should be a consent situation. The patient should understand what’s involved and should have a chance to say, yes or no, I want to participate.

Christine Bechtel – National Partnership for Women & Families – VP

Just to make sure I'm tracking the discussion, so if I give my provider consent to share my information with the HIO, if we take out the word initially then the HIO is going to have to ask me again whether I consent to the use of my information for treatment by another provider, for example? Are we setting up a situation where I'm going to continually be asked to consent?

Deven McGraw – Center for Democracy & Technology – Director

No.

Paul Egerman – eScription – CEO

No. No. Christine, if you go back to the factors ... what are the factors trigger that need my provider to obtain the patient's consent. So the picture here, one picture, is the patient is sitting down with the provider. More likely, the patient walks to the registration desk and has a bunch of papers thrown at them, but however it works, the patient makes a determination. What are the circumstances where the patient has to make a determination? Once the determination is made then it's made. We have other discussions about how the patient can rescind that. We've already discussed that separately—

Christine Bechtel – National Partnership for Women & Families – VP

Got it.

Paul Egerman – eScription – CEO

But this is one of the situations where you have to ask the patient's permission because the idea is the provider holds the record and so the examples are a federated HIO and a centralized HIO, which I said we all agree would be situations where you would have to do it and that goes for situations again— The main topic here is the concept of control and how you define control. So that's sort of like how we're defining control is the ability to basically either disclose or exchange the information.

I want to get to the question that Judy raised—

Deven McGraw – Center for Democracy & Technology – Director

Yes, although to me Judy's question is about what is a provider's record—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And what is an HIO is kind of the other side of the question.

Deven McGraw – Center for Democracy & Technology – Director

Right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Those two kind of blur together more and more.

Paul Egerman – eScription – CEO

Yes. So what I was going to suggest in response to what Judy is asking, because I understand Judy's comment, which is a comment we hear a lot, is well there are all of these interesting and complicated delivery structures. We have accountable care organizations. We have something called the medical home. There are a lot of interesting delivery structures and I don't think that that's necessarily what we intended here with this trigger.

So what I was going to suggest we do as a response may not be a good suggestion, we say it's not in the control of the provider or the provider's healthcare delivery system, which means we're going to have to define what that means, a healthcare delivery system.

Judy Faulkner – Epic Systems – Founder

Well, typically a healthcare delivery system, if I'm that provider in the Manitowish Waters, who is not part of Dean I'm not part of the healthcare delivery system, what they would call the healthcare delivery system I don't think, terminology wise. There has to be different terminology than that, Paul.

Paul Egerman – eScription – CEO

Well, but in your example, Judy, isn't that still directed exchange? I understand—

M

No.

Judy Faulkner – Epic Systems – Founder

It's directed exchange. I agree with that. I'm just nervous at the word the provider's healthcare delivery system, if I looked it up on the Web, would be their ... their owned clinics.

Paul Egerman – eScription – CEO

It's just we have to define it correctly—

Judy Faulkner – Epic Systems – Founder

Yes.

Paul Egerman – eScription – CEO

If we define healthcare delivery system to include accountable care organizations, medical homes—

Christine Bechtel – National Partnership for Women & Families – VP

The one thing I want to make sure that we're not inadvertently doing is we had this hearing yesterday on care coordination and what we definitely want to see happen is regardless of whether you're in a deliver system or not or you're a medical home or whatever, if you're a onesy-twosy, small practice out in the middle of nowhere I still want that person to coordinate with other healthcare providers in the community that I may be seeing whether or not they're affiliated in the system. I guess that we're not talking about directed exchange, but I just want to make sure that in an example where a primary care provider needs to pull together my information from other entities, medical records in order to do population health management or look at my chronic disease over time and monitor my care, whether or not I'm sitting in the office or not, that we don't inadvertently sort of wall that off.

Paul Egerman – eScription – CEO

Yes. So that's what I'm trying to do is figure out a way to do that, Christine. The places where I think we want to do the consent is the federated HIO and the centralized HIO, these things that are not healthcare organizations. They're these other organizations.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

These are the intermediaries that you just—

Paul Egerman – eScription – CEO

That's correct. I'm trying to figure out a way—

Deven McGraw – Center for Democracy & Technology – Director

Well, quite frankly, in Christine's example you could see that can take place. That kind of data pulling together for population health purposes can take place through the release of data by the providers, who control the record. Right? That would be more of a direct exchange, so that doesn't trigger the factors. Whatever label we slap on it, the provider is still in control, the provider record holder is still in control of the decision to disclose and that's sort of the central piece of this.

W

So maybe the factor itself might be clarified, if I'm correct here, to say a patient's information is aggregated by an intermediary outside of a provider's record, blah, blah, blah.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I wonder if we should consider though language of HIPAA and talk about covered entities. I mean we're going to get into definitional issues if we use anything other than words that have fairly precise definitions.

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

... precise ...

Deven McGraw – Center for Democracy & Technology – Director

Okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But it's well understood in operational terms.

Paul Egerman – eScription – CEO

Well, so maybe ... is instead of what I suggested about healthcare delivery systems and the control of the provider or the control of the covered entity that the provider has a relationship with—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Or I was thinking in terms of—

Deven McGraw – Center for Democracy & Technology – Director

No. No. No. No. That's different. It's in the control of the covered entity.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Or when it leaves the control of the covered entity is what I was looking for. Maybe consent is required when it leaves the control of the covered entity.

Paul Egerman – eScription – CEO

No. It's under the control of the providing control of the covered entity.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, the provider is a covered entity, so in other words, if the provider is part of a big, integrated delivery network, which is a unified covered entity, then sharing within that IDN doesn't require any other consent, but if it's to leave that covered entity and be under the control of something outside the covered entity, a new entity of some kind or another, then that would require consent. At least that's the notion I'm exploring.

Paul Egerman – eScription – CEO

Okay. So it's not in the control of the provider or a covered entity?

(Overlapping voices.)

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I would say it's not under the control of the provider's covered entity. In other words, you require consent to leave the control of the providers' covered entity.

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

We've discussed this before, how a covered entity is explicitly provider organizations that are involved in HIPAA transactions—

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

Yes. The issue here is the dual use of the provider term ...

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

Yes. Use provider entity, I think. Yes.

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

Yes. I desperately need to get something on the parking lot here. Judy raised a factor that I hadn't thought about before, which was where different covered entities literally share a common chart.

M

Say that again—

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

Different covered entities, different provider organizations literally share a common chart. That is there is no transfer or information associated with the information being shared.

Judy Faulkner – Epic Systems – Founder

To expand on that, it may be 200 different provider organizations sharing a chart.

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

Yes. I recognize that this is not a part of this discussion, but I think it's such an important one that we ought to at least parking lot it and come back to it.

Paul Egerman – eScription – CEO

Yes. That seems like that's an interesting issue. When that happens it's probably a disclosure issue, but it's not a consent issue.

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

Well, that's what I'd like to get clear in our discussion.

Paul Egerman – eScription – CEO

So what we need to do is—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

... imply that any provider in that entire network has unrestricted rights to the records?

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

Subject to the rules of rule based access and whatever else ... within a covered entity, right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Wouldn't there be consent involved in that? I mean I think it's exactly the right question to raise, I just—

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

Frankly, I think it's addressable. The question is addressable. I don't think it's a conundrum, but I do think we owe it to not get out of this little exercise without looking at it, which is why I—

Paul Egerman – eScription – CEO

Okay. So let's parking lot that. That's a good issue. I still want to see if we can find a way to clean this up so that people are okay with it because maybe another way of doing it is just to say that the decision to exchange the information from the record is not in the control of the provider and is in the control of an entity that does not provide healthcare.

Deven McGraw – Center for Democracy & Technology – Director

Yes. The only thing I don't like about that, Paul, is it presumes that there will be no HIOs run by healthcare organizations.

Paul Egerman – eScription – CEO

Well—

W

That's not the reality of things, because—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right. Or an HIO would set up a one-man shop just to avoid that distinction.

Deven McGraw – Center for Democracy & Technology – Director

Yes. I mean I think it fits some of the models that we're currently aware of, but it's a little too 2010 and not going to stand the test of time is my concern.

W

....

Paul Egerman – eScription – CEO

Well, it seems like there are only two ways to address it. One is to say that to describe something about the entity that ends up having control—

Deven McGraw – Center for Democracy & Technology – Director

Which I actually think is the harder—it's part of what gets us into trouble. I'd like to go back to the foundation of patient expectations and the patient's relationship with the provider, which includes the provider entity and what type of sharing is consistent with what that patient expects. So, for example, I presume that most patients, who are seen in a Mayo Clinic affiliated hospital, think about that as the Mayo Clinic so that sharing within that clinic is not perceived by the patient to be a disclosure outside of the clinic. Now, you guys can tell me if I'm right versus—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's right.

Deven McGraw – Center for Democracy & Technology – Director

I go to my little hospital down the street and the sharing involves a completely different provider that I'm less familiar with.

Judy Faulkner – Epic Systems – Founder

Yes and no. I think in many cases you're right on that, but I think there are a lot of cases where you don't know who the owning provider is. So in other words, there can be an organization; let's say it's SSM, who owns St. Mary's but you know that you go to St. Mary's. You don't know that the record is under SSM.

Deven McGraw – Center for Democracy & Technology – Director

Right. Right. I mean it's—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, yes, although—

Deven McGraw – Center for Democracy & Technology – Director

That's one thing. I mean I get what David has been saying about thinking about consent and expectations, but I'm a little concerned about what a provider who is essentially using one single entity to host their legal medical record. If a patient doesn't give consent to that then ... meaningful choice to the patient because essentially that provider, this is how we share. If you don't like it I'm afraid I can't treat you, because I can't keep your record but for in this way that we've decided to keep records versus HIO situations, where the provider has his or her own record, but also send records to another, to the HIO for sharing purposes.

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

I think it's important for us to keep clear that we're not discussing prohibiting these other models from occurring. We're just saying that if they occur and if I, as a patient, if my provider is going to use that model I, as a patient, should be made aware of it and give my consent.

Paul Egerman – eScription – CEO

Yes. Well, I don't think you have to give consent though. I think it's an issue of disclosure in my opinion.

Judy Faulkner – Epic Systems – Founder

I agree with you entirely, Paul. I think there's a huge difference between consent and disclosure ... differentiation.

Paul Egerman – eScription – CEO

And I think the fundamental problem that we're sort of wrestling with is this somewhat complex, perhaps you call it convoluted organizational structures that exist within healthcare.

W

Right.

Paul Egerman – eScription – CEO

I mean let's look at something that instead of something that's as complex as what Judy said, let's look at something that's actually very simple, like a single community hospital. Well, you go to a single community hospital and say who is the provider and the provider is the hospital, but not really, because the emergency department is staffed by emergency physicians, who are technically a separate group practice, but if you're the patient, to pick up on Deven's comment, you see the hospital as one thing. You don't realize the emergency department physicians have their own group. The radiologists have their

own group practice. You don't view those as separate providers, which is the way I think HIPAA would consider them. You view that as well as it's one healthcare—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But that healthcare organization maintains access control policies that reflect who has the rights to see the record. You don't call that consent.

Paul Egerman – eScription – CEO

I understand that, David, but to try to finish what I'm trying to say is from the patient's expectation standpoint you treat it as one thing. So what I'm trying to say is I think what we need here is some other terminology, some other word to describe that. I tried to call it healthcare delivery system, but there's something else, which is somehow a group of these providers that are operating together and share a common record. If that environment is not a consent trigger it might be a disclosure trigger in the more complex issues that Judy described, but it's not a consent trigger.

Adam Green – Progressive Chain Campaign Committee – Cofounder

There are two concepts in HIPAA that are relevant to this—

Paul Egerman – eScription – CEO

You're going to save me on this one, right?

Adam Green – Progressive Chain Campaign Committee – Cofounder

Yes. One is called the organized healthcare arrangement and that includes either a clinically integrated care setting in which individuals typically receive healthcare from more than one healthcare provider, so think of a hospital and a group practice that operates at the hospital, an organized system of healthcare in which more than one covered entity participates and which the participating covered entities hold themselves out to the public as participating in a joint arrangement and participating in certain joint activities, such as utilization review, quality assessment. That's the one term that already exists under HIPAA to describe these joint activities.

There's also a separate thing called affiliated covered entities, which is legally separate covered entities that are under common ownership or control, so that could be a hospital system that has a number of subsidiary organizations, so both of these concepts exist in HIPAA and there are certain allowances that permit a greater level of disclosures within the organizations.

Paul Egerman – eScription – CEO

That actually sounds almost perfect, Adam, so thank you for saying that. Now let's go back to this, saying the information is not in the control of the provider or the provider's organized healthcare arrangement. Is that good?

Judy Faulkner – Epic Systems – Founder

Was that the second one you said or the first one?

Paul Egerman – eScription – CEO

That was the first one.

Judy Faulkner – Epic Systems – Founder

Yes. Okay.

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

I've looked at the organized healthcare arrangement definition a number of times in relation to these types of activities. I think the one ... potentially could be it's very transparent to the user; you have a physician practice participating in an HIE, but to the patient it just still looks like a sole practitioner and there really isn't any outward appearance of the level of integration that might be occurring behind the scenes. I've always heard or felt the organized healthcare arrangement had a level of either there was some explicit recognition that it was part of this organized arrangement rather than it being all done behind the scenes.

Paul Egerman – eScription – CEO

Well, shouldn't that be handled with a disclosure requirement for the patient?

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

Well, I think the disclosure requirement absolutely helps it, but I'm just wondering what the threshold is for that. Maybe I'm picking nits, but I've always been concerned at what point is it really established. Is it patient expectation or is it based upon all of the trappings around the practice as well that might make it appear as being part of an OHCA?

Deven McGraw – Center for Democracy & Technology – Director

Adam, what are the ... in terms of holding one's self out to the public as being part of one of these organized healthcare arrangements? Is that sort of a test that has some factors that we could look to or ...?

Adam Green – Progressive Chain Campaign Committee – Cofounder

Well, there are actually five categories of OHCA's. I mentioned the first two and you can be in one category and not another. So the second category has this requirement to hold themselves out to the public as participating in a joint arrangement, but that's not necessarily present for all categories of OHCA's.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Paul Egerman – eScription – CEO

So there are like a ton of issues here, but what we're trying to do is, again, to understand what is this trigger for consent. What we're trying to do is also to address the concern that Judy addressed, which other people have expressed in other situations, because what we really intended to do with the trigger was to go to an HIO. It wasn't necessarily to deal with some of these complex healthcare organizational structures.

So the proposal that is being put forward is to say that this wording is correct. It's not in the control of the provider, but we ... the provider's OHCA. A new acronym, but that's Organized Healthcare Arrangement. It's at least a first attempt to deal with some of this organizational complexity.

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

I would also make it clear that that OHCA needs to be disclosed—

Paul Egerman – eScription – CEO

Yes ... what we need to do is put it on the parking lot, some issues there because to me it is a disclosure issue. It's not a consent issue and so that's something that we should make a separate recommendation on; that there should be disclosure to patients—

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

Transparency.

Paul Egerman – eScription – CEO

Yes, in terms of, in fact, it's part of transparency, but to me it's sort of like the patient should know where their record is located.

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

Yes.

Paul Egerman – eScription – CEO

If my record, if I see Dr. Smith and Dr. Smith puts all of her records with, say, Cleveland Clinic, all I need to know is somebody needs to tell me that.

Judy Faulkner – Epic Systems – Founder

Then the other thing with that is it's kind of volatile. Dr. Smith may be putting her records with Cleveland Clinic, but four days later Dr. Jones may join, who is an ophthalmologist and ten days later Dr. Brown may join, who is an OB and so you don't know who is made up of that group.

W

Yes.

Paul Egerman – eScription – CEO

That's true. So here is where I'm hearing this go: We're going to add to the end of this not under the control of the provider or provider's organized healthcare arrangement to this issue. We're also going to somehow have a separate recommendation on sort of like transparency for OHCA and say that this is a matter for disclosure that patients need to, if a provider is hosting their record as part of an OHCA there's another entity that needs to be disclosed to the patient.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Back to my test around can you opt out of it, does the patient have no control over OHCA related sharing? Is that the assumption?

Paul Egerman – eScription – CEO

Yes. The only control they would have would be to not see the patient—

Deven McGraw – Center for Democracy & Technology – Director

Well, or to ask, but it wouldn't have to be honored. I mean—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So this—

Deven McGraw – Center for Democracy & Technology – Director

... if the provider couldn't do it.

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

What did you say, Deven?

Deven McGraw – Center for Democracy & Technology – Director

So in other words I mean you always have the right to request restrictions on sharing of your record, right? But in a circumstance where we're not recommending that consent be required or there's no law that requires it, it's really up to the provider to determine whether or not they can honor that and still give good care to the patient.

Joy Pritts – ONC – Chief Privacy Officer

There is, just so you know, that in the provisions about notice of privacy practice I believe; Adam, you can jump in here; that there is already not a requirement, but there is an option for organized healthcare arrangements to use one combined notice of privacy practice that describes the entities to which it applies.

Adam Green – Progressive Chain Campaign Committee – Cofounder

Yes. That's one of the main benefits of the OHCA is a single notice and also no need to have business associate agreements between the different members of the OHCA, so those are some primary reasons people enter into them.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I don't know much about these OHCAs, but what would stop an HIO from just deciding it wants to be an OHCA and avoid some of these hassles? What's the barrier to becoming an OHCA?

Adam Green – Progressive Chain Campaign Committee – Cofounder

We have an FAQ exactly on that point, which is can a health information organization participate as part of an OHCA. The answer is no. A HIO, by definition, cannot participate as part of an OHCA because the privacy rule defines an OHCA as an arrangement involving only healthcare providers or health plans, neither of which I think a HIO qualifies as.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Okay. That's exactly what I wanted to know.

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

I think that assumes though that there's a separate entity that's actually running the HIO. I think back to the earlier part of the conversation, there could be, I guess, a model where the HIO is sort of a federated group of providers all working in conjunction—

M

I don't see that as being, if in fact, all of those providers are in an OHCA then I don't see that as being much different than them having a common record. I mean technically there are some differences in how the data gets swapped around, but the issues and the expectations of the patient would seem to be the same.

Paul Egerman – eScription – CEO

Was Gayle or somebody else trying to get in on this?

Gayle Harrell – Florida – Former State Legislator

Yes. I was trying to ask because I have the very same concern; that you could have an HIO decide that they want to be an OHCA. Now, are there protections for the patient within the OHCA? Are there privacy protections? For instance, say I don't want my record in that OHCA shared, my abortion record for instance, if I had one, with the ER doc or someone, the radiologist, who happens to be my neighbor down the street. Is there the ability to say, "don't want my record shared outside my direct provider."?

Adam Green – Progressive Chain Campaign Committee – Cofounder

The answer is that you can request that restriction, but there is no obligation for covered entities. They can tell you, “No, we’re not going to accept that,” or they can say, “Yes, we’ll accept that request,” and then they have to follow it.

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

As I recollect the privacy rules, there is very little detail about what really an OHCA is ... on the definition a few criteria, if I’m not mistaken, correct, Adam?

Adam Green – Progressive Chain Campaign Committee – Cofounder

Right. It’s definitional and then it provides certain things that aren’t necessary, such as you can have a single notice. You don’t need to have separate notices. You don’t need to have business associate agreements between them, so those are some of the primary functions.

Paul Egerman – eScription – CEO

Again, just to make sure everybody is ... the reason we’re putting forward the concept of OHCA is simply to clarify our recommendation on this point.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

Because the place where we really want the consent is these federated and centralized HIOs. Those are the examples that we gave and that’s really what we want.

Deven McGraw – Center for Democracy & Technology – Director

Yes. I agree, Paul. I think we’re just struggling with trying to think of the universe that exists today, as well as models that might arise in the future and one of the things that is appealing to me about the OHCA concept is that there’s a degree of clinical integration among the participants. And maybe in some cases they share financial risk and may increasingly do so under healthcare reform models and so I think it’s an example. I think we need to say in our recommendations that ONC and the office ... need to keep an eye on these models to make sure that we’re not creating a situation where an entity that looks and walks and talks like an HIO can’t just call itself an OHCA in order to get around having to ask patients for their consent to participate.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right. So just to be the cynic, this makes HIOs even less likely to survive. I mean if all of the data sharing is so much easier and simpler and less burdened with consent issues if you’re an OHCA then there will be lots of OHCA’s, but very few HIOs.

Deven McGraw – Center for Democracy & Technology – Director

I disagree. We’ve actually allowed for HIOs that maintain provider control of data to not have to be bound by consent requirements. The other thing is that, in fact, most HIOs that I’m aware of are giving patients some choice.

Paul Egerman – eScription – CEO

That’s right. Our job is not to try to change the competitive landscape in terms of what is happening in healthcare. I mean these things called OHCA’s, they exist and you see it in the legislation where there are things called accountable care organizations and that’s the way it all works.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. We're building them left and right, so I totally agree. I'm just saying that that horse being out of the barn makes the ... issue somewhat of a moot point.

Paul Egerman – eScription – CEO

Well, I think that would be interesting, but I think right now it's not a moot point. Who knows how it may end up in the future. My question is are we coalescing around this concept that ... or the provider's okay. We may have to wordsmith a little bit, but the real issue there was sort of the carve out, some of these interesting healthcare structures so that we're very clear; it's sort of like the non-healthcare entities that we're really aiming to consent discussion towards.

Deven McGraw – Center for Democracy & Technology – Director

Yes. No. That's certainly consistent with my notes.

Paul Egerman – eScription – CEO

Okay.

Deven McGraw – Center for Democracy & Technology – Director

Jumping ahead to Dixie's question that we put on the table on an automatic release is the same as control.

Paul Egerman – eScription – CEO

Okay. So do you want to move to that question, is that what you said, Deven?

Deven McGraw – Center for Democracy & Technology – Director

Well, yes, because I think it's wrapped up in its decision to

Paul Egerman – eScription – CEO

I don't know what that means, an automatic release.

Deven McGraw – Center for Democracy & Technology – Director

It's done by a rules engine for example. Right, Dixie? Am I phrasing that right?

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

That's right. That's right.

Adam Green – Progressive Chain Campaign Committee – Cofounder

If I can add, I don't know if HIPAA would ever allow a provider to forfeit control over disclosures of their record. They can't turn their record over to someone else and you decide how this is going to be disclosed, so the argument is that the rules engine is the instrument of the physician's control, not that it's—

Paul Egerman – eScription – CEO

Yes. Let me give an example. I don't know. How does this work in practice?

Judy Faulkner – Epic Systems – Founder

In practice, a patient may show up at an ED, a place that that patient has never been to before and is not part of the OHCA. I like that word. And be in distress and may tell the ED provider there or the ED physician that their normal record is somewhere else.

Paul Egerman – eScription – CEO

But that's a directed exchange situation.

Judy Faulkner – Epic Systems – Founder

I thought that's what the question was how does that work—

Paul Egerman – eScription – CEO

I don't see how that—

Judy Faulkner – Epic Systems – Founder

But then there's a rule engine that manages that all.

Paul Egerman – eScription – CEO

I still view that as directed exchange. I don't see that—

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

HIEs today create the ability for a provider to access or request information from a pool of data that is available without any more consent from the original data than what was already given when it made that data available. It may have put it in a central repository. It may have put an entry into a central repository that has data available—

Paul Egerman – eScription – CEO

If it did all of those things that's a consent situation, right?

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

All right. So right now the question is how does it happen right now. Right now it happens typically by there being a legal agreement between all of the entities that are participating that you, as the entity requesting the data, will follow the rules of practice that we've all agreed to. It's a common policy and providers only enter into it when they believe that the HIE is getting compliance with this agreement. They may also implement some rules, such as we do or we don't—we do have an engine that honors patient's consent requests, but that varies from place-to-place.

Paul Egerman – eScription – CEO

What happens is when a patient consents to participate in an HIE they're consenting to all of that also.

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

That's right.

Paul Egerman – eScription – CEO

And so that's not directly related to this discussion. That's how the HIE or the HIO works—

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

I thought that was your question. I'm sorry.

Paul Egerman – eScription – CEO

And so I don't understand Dixie's concern about rules based.

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

It's not a concern. I think it should be included. Let me give you an example for a quality monitoring organization. Healthcare organizations routinely send clinical records to quality monitoring organizations

and they shouldn't have to have a doctor push a button every time a record is sent there. If that organization has an agreement that that quality monitoring organization is going to help them monitor the quality of their affairs—

Paul Egerman – eScription – CEO

I just don't understand how that relates to this issue of control.

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

They should be able to set that up as a rule in the rules engine, such that the information is automatically sent to them.

Paul Egerman – eScription – CEO

That might be, but that's not an issue of control here.

Deven McGraw – Center for Democracy & Technology – Director

Actually, Dixie is not arguing—I'm putting words in your mouth, Dixie—I don't think she's arguing that that isn't direct exchange. I think she's saying that it is. I was just pushing on this a bit to make sure that everyone on the team was comfortable that control by a provider could still be exercised through some sort of automatic means.

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

Yes. That provider set up some rules that they set up. Always send this. Yes. Exactly right, Deven.

Paul Egerman – eScription – CEO

Okay. So that's helpful. So let's get back to this first bullet. We have six of these we have to go through.

Deven McGraw – Center for Democracy & Technology – Director

I was starting to look at the time too, Paul, but I sort of feel like this one is such a strong driver of consent concern—

Paul Egerman – eScription – CEO

I know.

Deven McGraw – Center for Democracy & Technology – Director

That I'm hoping—

Paul Egerman – eScription – CEO

This is the guts of our discussion.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

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

It is, Paul, I want to be real clear. Deven and I both ... it is bullet one where we have in there the word control we want to just clarify that that control may be exercised through an automatic trigger that the provider sets up.

Deven McGraw – Center for Democracy & Technology – Director

Right.

Paul Egerman – eScription – CEO

Okay. I'm fine with that.

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

It's really granting ongoing consent in a sense. Each release doesn't require re-consenting. You could establish an ongoing process that could be automated, which will be automated.

Deven McGraw – Center for Democracy & Technology – Director

Right.

Paul Egerman – eScription – CEO

Okay.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Paul Egerman – eScription – CEO

So—

Deven McGraw – Center for Democracy & Technology – Director

I think we're good with this one.

Paul Egerman – eScription – CEO

Are we happy with this one? Are you happy with this, Judy?

Deven McGraw – Center for Democracy & Technology – Director

Keeping in mind you'll be able to look at how it got worded.

Paul Egerman – eScription – CEO

That is correct. We've got to do a little wording on it. Deven is correct; I shouldn't be rushing us through this. This is like the guts of the whole thing, because getting back to this issue of control, again, part of the strength of how we're approaching this whole issue is we're focused on the patient provider relationship and trust and realize the provider has control of the record and that's why there's the trust relationship between the patient and provider and so we're describing the situations under which the control changes and that requires consent. So this is the guts of what we're saying.

Judy Faulkner – Epic Systems – Founder

You asked me. You said my name there, Paul. I think three things: One, considering the OHCAs, I think it's really good that we're doing. Two, that we keep thinking it's not just referrals out. Keep remembering it's request in. And three, that we make sure that as we do this we're not doing something that inadvertently implies that it has to be automated segmentation until we decide whether we're doing that or not.

Paul Egerman – eScription – CEO

Yes. I think we already decided that issue. That all makes sense.

Judy Faulkner – Epic Systems – Founder

Okay.

Paul Egerman – eScription – CEO

Okay. So I think we're ready to move on to the second bullet. Your turn, Deven.

Deven McGraw – Center for Democracy & Technology – Director

So this second one is one that we had put on the list of triggers and a patient's health information is retained for future use by a third party or intermediary, i.e., not the patient or the provider. We got some questions about this and so Paul and I were wondering is this just another way to describe, to sort of surface our concerns about centralized HIOs and, therefore, maybe it is captured in the first trigger.

The other thing that I thought of is we've got a whole set of recommendations that are deeper in your slide deck and that we came up with a month and a half ago on third parties and intermediaries and expressly acknowledging that there are circumstances under which they need to retain data for accessible future uses. In fact, they should not retain data, be permitted to retain data beyond what is needed in order for them to perform the function that they've been asked to perform and any associated, administrative functions. So in order to avoid having this one be looked at as some requirement for consent any time it's sent to a business associate, what is the real concern that we're trying to get at here that is different from the control issue?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think I may have been guilty of introducing this language in one of the earlier discussions. The spirit of what I was meaning to accomplish I think is now rolled up into our bullet point number one. It's essentially, in my mind, what is the definition of an HIO. It's an entity that accumulates information about the patient outside of the control of the provider's record and makes that available in the future to people, who claim they need access to it.

I don't think centralization versus federation is relevant. I think if the HIO makes the information available through some mechanism, whatever the technology is, that it would qualify to fall under what the spirit of this was addressing, which says that since that information is now being made available to an entity outside the provider's organization or OHCA then it would require consent. But I think, Deven, I agree with you that it is now covered pretty well in bullet number one.

Deven McGraw – Center for Democracy & Technology – Director

Is there anybody else who sees a concern that would trigger consent that isn't really well covered in number one and is covered also in our recommendations about third party retention of data?

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

When David first came up with this one he had the word unspecified before future use. I think that that's important. I think the ability for a provider to send or otherwise share information with a third party to be put in a large database in the sky for some unspecified future use that is not in any kind of agreement is different from number one.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But I think it kind of comes to the definition of what is an HIO. They're building in access to the record for unspecified future purposes, but that's what an HIO is.

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

Right, but I don't think that that's captured, that they're going to retain it is captured in number one.

Deven McGraw – Center for Democracy & Technology – Director

Right. But, Dixie, we have said they shouldn't, that third parties should not be able to retain data beyond what's necessary for them to perform the functions that they've been asked to perform under their business associate agreement.

What I'm a little bit uncomfortable with saying, we've said they shouldn't—

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

Yes.

Deven McGraw – Center for Democracy & Technology – Director

But if they do then the patients then have the burden of protecting his or her own data by either opting in or opting out. It really sort of takes a bad situation and says to the patient you should solve it versus relying on our primary recommendation, which is under fair information practices there should never be unspecified future uses for which you are holding data.

In terms of sort of David's example of the sort of centralized repository where if you need the data you can get it, I think we've got that covered under the control issue, but that's what I keep getting back to is I worry that the way we've got this, if we re-word number two and say it's retained for unspecified future use then that cuts against a recommendation that we've made that that shouldn't happen. And that should be the primary policy recommendation.

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

I think it really gets into the realm of governance, which I know is in this parking lot— I don't know which parking lot, but it's in there. When we speak of consent and the need for consent, in my mind that always translates into some regulation or something enforceable downstream. When we talk about fair information practices we all know that fair information practices have been articulated and documented, in fact, for years, but are not followed. So that bothers me to say, "Well, we got it in the fair information practices." Therefore, they're going to do it because I would argue they probably won't.

Paul Egerman – eScription – CEO

I think we've got to be careful about using consent to enforce privacy or security policies.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I agree.

Paul Egerman – eScription – CEO

I think that's not the ... consensus on consent. You've especially got to be careful that we don't treat it like some kind of administrative nightmare where you've got to sign over things that you don't even know what they are. So my question is this: Another way to ask the question Deven is asking is how does it help us to have this second bullet here? In other words, what is the situation that it covers that wasn't already covered by the first bullet?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I think Deven said it a couple of times. I think our real issue here is the retention of data by a third party and I think, as she's articulated, we've said before they should not retain it unless it's fulfilling a specific purpose and they should be limited to that purpose. I think that would serve us better. I worry that every time we bump up against an issue that raises privacy and security concerns the tool we bring at it is always a discussion about consent and I concur with you, Paul, that the protection of the patient; I mean consent is one piece, but it has to include the other elements of privacy and security, including requirements about how to handle or not handle the data.

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

I'd like to add a little bit to that which is Dixie's concern, which is that I think really what we're charged with is bringing the fair information practices into more use by deciding how to apply them, at least in the FAQ that ONC is preparing for their HIO grantees. We're trying to make this more prominent. Frankly, most people that I know have looked at fair information practices say, —I can't figure out what the heck that means." So we're trying to be more concrete, apply it in a more concrete way and promote them, frankly.

Gayle Harrell – Florida – Former State Legislator

To add to that too, I'd like to say I know it's in the parking lot, but when we come to this whole discussion of governance I think that's where we really need to step up to the plate with some very strong recommendations.

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

Okay. I'm fine.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

David Lansky – Pacific Business Group on Health – President & CEO

Can I go back to your question about whether this covers the ground. I think the areas of applications and uses that I'm worried about in this discussion we haven't talked about and I'm hoping that you can all reassure me that they're covered. There are a lot of places where there are aggregate data sets, like clinical registries and clinical trials and other places where IRBs often provide approval for data sharing. And there's this whole paradigm of learning health system and information and sharing through aggregation that, for example, take something like the ACC registry for the cath lab.

You can imagine the implication of our language being that each push of data from the registry of the patient's information from the cath lab to the registry should be subject to the consent. And that implies we have so many consents that will be required that you end up with a blanket consent. We've talked about this in the past. It is effectively meaningless. You're essentially saying to the patient, —By, I've got 20 places I have to report your data and here they are. See page 16." It's not a meaningful consent so I don't know how we create kind of a balance between the uses of information to these third parties for clinical improvement and observation and even in the case of personal care and clinical trials that isn't such a burdensome consent paradigm that it's not meaningful.

Deven McGraw – Center for Democracy & Technology – Director

Well, David, we have taken these issues on in only the frame of stage one of meaningful use, so largely treatment and the reporting of quality measures and certain public health reporting, all of which, we presume, for the most part is directly done out of the provider record, but where it's not and where that reporting takes place out of an HIO, in other words, we have not dealt with the research questions because we started with a discreet set of exchange scenarios or use cases. We know we need to get to that.

David Lansky – Pacific Business Group on Health – President & CEO

Our implicit intention; I guess I'm looking at the language on our slides and perhaps in our letter; as we said earlier in this call, the word providers is pretty wide open and I don't know that we're able to constrain, but by applying our language to specific settings, institutional forms, organizational types, as opposed to uses we're going to have a difficult time in a very evolving space. I look forward three, four, five years and think of our language as setting some precedent. I'm just worried that—

Deven McGraw – Center for Democracy & Technology – Director

Except it's not just about providers, David. We in fact started, so if you look at slide number two in the deck, but the first substantive slide, we sort of have already said we've created a bit of an artificial universe that these recommendations apply to and we have to be very clear in our recommendations that that's the set of use cases that we were dealing with and the frame for all of this, because while these might provide a helpful jumping off point for those discussion about research, comparative effectiveness, clinical research, those have bigger issues and we would probably use these to jump off some, but we might come to some more nuanced conclusions.

Paul Egerman – eScription – CEO

Essentially, David, as I listen to your comment I think you've got an interesting comment, which I've heard a number of other people make in other formats, but I think your comment actually justifies removing this bullet, because this bullet could be interpreted to mean that any quality database, any registry needs patient consent and I don't think that's what we intended.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But David's question was double-edged in that if the consumer's data is being sprayed all over the place and we say is that a good thing, does the consumer not have some right to know where that data is going and why it's going there? If we take away any notion of consenting around it then all that happens completely under the covers.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Right.

Deven McGraw – Center for Democracy & Technology – Director

There's consent and there's transparency. I think all I'm saying is that we have a set of recommendations within a particular frame of purposes and there is a whole host of other stuff. We need to be very clear about what these recommendations are applying to and where additional work needs to be done so that people don't assume that this is the final word of the final word, if even that ever happens. But we heard some of David's comments from Chris Chute on the Standards Committee. We've heard it from others. There's sort of a very complicated set of issues with respect to certain quality improvement efforts and research that go beyond the sort of stage one of meaningful use exchange requirements and for which some clear guidance is needed, I think, but we didn't tackle it yet.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Right. In the mean time I just want to make sure we don't lose some of the elements that we've been discussing about what we believe are good information handling practices for the exchange of clinical records for healthcare delivery. In other words, in order to sort of take into account those additional issues I want to make sure we do what we need to do on the exchange issues.

Deven McGraw – Center for Democracy & Technology – Director

Right. For treatment, right?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. Yes.

Deven McGraw – Center for Democracy & Technology – Director

One universe at a time, but they're in a close parking lot. I mean they're absolutely out there and there is a lot of activity and uncertainty and there's some more work to be done.

David, I mean I think we're getting rid of this bullet because we've got it covered already or even for the use cases for which we intended it to be applied.

David Lansky – Pacific Business Group on Health – President & CEO

Well, I'm hearing you say that the context established elsewhere in our presentation will address the thing I'm raising as a concern.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

David Lansky – Pacific Business Group on Health – President & CEO

I also hear there's a question about disclosure versus consent and clarifying ... summarize whether disclosure to the patient of the various uses of information will address some of the concern and I've heard us all say that the fair information practices that go beyond consent remain critical to both, identifying and making sure there's an enforcement mechanism around. So that's all good. I guess I'll just leave it and when we get to the written text then we'll come back to it.

My concern the way our slides read is the slides are very broad in their language and if I'm a provider I was meeting with some surgeons yesterday discussion registries and consent, for example, specifically and they're really concerned that they want to continue to facilitate the push of data to the registry and this discussion just read as a set of slides with basically say you have to go to your patient to get permission to do that.

Deven McGraw – Center for Democracy & Technology – Director

Right.

David Lansky – Pacific Business Group on Health – President & CEO

So I will hold this thought for further use.

Deven McGraw – Center for Democracy & Technology – Director

Thank you.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think David said it really well, but I think we should come back and revisit that question. What role does the patient have in governing participation in these extracurricular activities that don't have any direct effect on the healthcare that they paid for? It's a great question to come back and visit.

Deven McGraw – Center for Democracy & Technology – Director

Yes and just so you don't think that we won't be having any fun anymore after the summer, it's on the list. Okay. I think we are ready to move on to the next one.

Paul Egerman – eScription – CEO

Great. The next one, the third consent bullet, which says, "Patient's health information is exposed to persons or entities for reasons not related to ongoing treatment or payment for care." When we start to think about examples of this one I guess there were a number of concerns.

We wanted to reconcile it with our slides, recommendations on slides 31 and 32, which already deal with the idea that you have to have business associate agreements and deal with any kind of an arrangement where some other business entity has access to unencrypted PHI, but the question is is this really a

consent trigger? I mean if you make it a consent trigger does that mean patients have to give consent if you want to use like an interface engine or something? That helps you transform from one format to another.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So again, the spirit of this I think is pretty clear. Those providers sending data out to aggregating entities, who aren't involved in your care in some way, which might cover the registry case that David Lansky just brought up, we want to know about that. I think that's the spirit. Again, we seem to be backing off from those use cases and saying we're going to come back and visit them later.

Gayle Harrell – Florida – Former State Legislator

Yes, which has a real concern for me.

Deven McGraw – Center for Democracy & Technology – Director

It has a real concern that we're revisiting them later?

Gayle Harrell – Florida – Former State Legislator

No, a real concern that we're backing off things that we had discussed in length and I don't want to see us watering down if there's an absolute conflict in what we said previously versus what this is saying then that's one thing, but we seem to be backing off a lot of things.

Deven McGraw – Center for Democracy & Technology – Director

Well, I don't think it's backing off, Gayle. I mean we didn't actually spend a lot of time. We spent one call on these triggers, which doesn't mean they weren't well intended, but we didn't have a lot of time to think about wording them to be very clear about what we intended and so I for one am struggling to figure out, again, given our frame of just stage one of meaningful use, what we're talking about here.

Given that and given the recommendations that we've already made about when third parties or intermediaries have access to data to perform legitimate functions with data, I'm not sure that I could, standing up in front of the Policy Committee say what is the concern here that we're trying to reach within that framework of stage one of meaningful use that isn't already addressed by the control issue. That's what I'm struggling with, Gayle.

I'm not intending to back off on any of this. I just don't know what this deals with. If it's the registry issue then I think it's not within our stage one frame and we've got to parking lot it. It doesn't mean it goes away, but we haven't sufficiently discussed it to put it on here I think.

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

I think most of the registries that health information are sent to, I think, are public health.

M

No, not legally.

Deven McGraw – Center for Democracy & Technology – Director

No.

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

They're not legally public health?

M

No. They're private, most of them.

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

Well, some of the examples that have been brought up in public health reporting and I want to be clear that we're not talking about any kind of consent around public health reporting, right?

Deven McGraw – Center for Democracy & Technology – Director

Right.

M

Right. I mean they might be for the public's health, but they're not public health.

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

I think what's going on here is that we started this group in the ... time about six weeks ago when we started the Tiger Team and we were focused on HIOs and sort of non-HIO directed exchange. Okay? Then over the course of six weeks we have come to recognize that the same language that we concocted in that context has implications for registries, for clinical research for all kinds of things that initially weren't in our focus and we're coming back and re-examining them from that point of view.

That being said, I'm just having trouble getting context around this slide. I've read it over three or four times and I end up thinking about it. My mind wanders. So this a revision to what we collected previously, is that right?

Deven McGraw – Center for Democracy & Technology – Director

Well, it's looking. I mean if we want to present our final recommendation on what are the triggers for additional consent beyond law for the stage one meaningful uses of exchange we're just trying to make sure that—

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

Yes. No. I mean I was following it on the previous slide and then I got lost on this slide.

Deven McGraw – Center for Democracy & Technology – Director

This information, this is exactly the set of recommendations that we initially put before the Policy Committee, that they accepted, but with the caveat that we would continue to refine them and there were lots of questions raised about what these triggers mean. So the trigger is on there—

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

So now when you go back to the slide we were on—

Deven McGraw – Center for Democracy & Technology – Director

There it is.

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

Okay. So they have not yet been revised? We're planning to revise them?

Paul Egerman – eScription – CEO

That's what we're doing right now.

Deven McGraw – Center for Democracy & Technology – Director

Yes. That's what we're doing now.

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

Okay. So for revision. Okay. Thank you.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think the spirit here is that we were really concerned about the purpose to which this data was put, but we clumsily specified that it was just triggered by the actual transfer of the data. So transfer of data, for the purposes of a registry that improves the quality of care, no one in the long run is going to object to that. That exact same data flowing to a marketing agency that makes money for the provider, because they sold advertising rights to your record to pharmaceutical companies, there would probably be a lot of people that would object to that.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So the question is what is the purpose to which the data is being put that is at issue I think. I think I would say that there are certain of those purposes, which ought to require patient consent. There may be other purposes, which it doesn't require consent. I don't know that we've captured anything remotely like that here, unfortunately.

Deven McGraw – Center for Democracy & Technology – Director

Well, that's right, but also keeping in mind that marketing is not on the table. It's only with respect to the exchange that's required for meaningful use. We have artificially constrained our universe—

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

Okay. Well, there's no IRB than exchanges in meaningful use, right, in stage one meaningful use?

Deven McGraw – Center for Democracy & Technology – Director

None. None. None at all. No research. No payment, quite frankly. None of the other uses that are often characterized as secondary.

Paul Egerman – eScription – CEO

Yes. These trigger slides are thinking of a much broader set of cases than—

Deven McGraw – Center for Democracy & Technology – Director

In many cases, yes. So I guess I submit that we acknowledge that this concern arose out of, I think David's right, purposes that are not part of stage one of meaningful use. So we remove it for the purposes of recommendations related to stage one of meaningful use.

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

But save it for—

Deven McGraw – Center for Democracy & Technology – Director

Yes –

Gayle Harrell – Florida – Former State Legislator

With the caveat that this is further discussed—

Paul Egerman – eScription – CEO

That's right, Gayle. In fact, if you read down to the bottom of this slide we're going to suggest that we add a recommendation that says we may add subsequent triggers when we start to consider exchange beyond stage one of meaningful use.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I just want to say I think David is right in saying that the thing that we were worried about here has to do with, and I think it's what led to this bullet, quite frankly, how the information is used and what information is collected. I think as long as we put it in the context of what we said before around purpose specification and collection limitation and use limitation that we can get at these issues in an appropriate way, without trying to come at it here, I think, a little bit

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

I think that's right, Carol.

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

I think this one in particular may be inappropriate for stage one because some of the reporting to CMS is not related to payment for care or treatment.

Deven McGraw – Center for Democracy & Technology – Director

Right.

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

So I definitely think this would not be a good one for stage one.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I agree with all of the above, but remember that the HIOs that are being built will be built and up and running and accomplishing purposes that go beyond stage one. I mean they'll be doing things that aren't specifically required for stage one and we were asked to address some of those functions, as I understood, from ONC because some of this is targeted at helping the state HIOs, HIEs know what to do. So they're doing things beyond stage one—

Deven McGraw – Center for Democracy & Technology – Director

Yes.

M

That's true, although we do have a consent trigger.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But that's how we got in this conundrum, right? I mean—

Deven McGraw – Center for Democracy & Technology – Director

Yes. It's exactly right, David, but it's with too big of a primordial soup of issues to try to tackle consent for every possible use and disclosure through that frame without kind of laying this groundwork. It's sort of back to the old dilemma of kind of where do you start and still try to provide to be somewhat responsive to what ONC was looking for.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right.

Gayle Harrell – Florida – Former State Legislator

David, I think we're going to get to that conversation next, because, as David says, there are HIOs up and running and we want to make sure that we address the concerns of the patient right now that's out there and they're seeing these things happen now.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

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

Yes. I agree. I think there are some things that if we don't make any statements about at all they're going to be more and more institutionalized within HIOs and it may be too late to address them downstream.

Deven McGraw – Center for Democracy & Technology – Director

So noted. We've been working fast and hard and here's where we are.

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

Yes.

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

As a matter of policy, we don't do anything. We recommend to the Policy Committee. It recommends to ONC and ONC does, so ... it's not likely to get out anyway.

Paul Egerman – eScription – CEO

Your description is correct, Wes, although ONC does seem to be requesting our assistance—

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

No, but I'm pointing to the question was how much do we regard meaningful use phase one as our brief and anything else is exceeding it or how much, because if we exceed our brief then there is some danger that all of our wonderful, good times we're having together will go for naught.

Paul Egerman – eScription – CEO

That's helpful. So, Deven, I think we've got an agreement on this one.

Deven McGraw – Center for Democracy & Technology – Director

Yes. I think we do as well.

Paul Egerman – eScription – CEO

Do you want to lead us through aggregation?

Deven McGraw – Center for Democracy & Technology – Director

So the original trigger is what's on this slide here. Patient's information is aggregated outside of a provider's record or record of integrated delivery system/ACL; maybe we could put /OHCA; with information about the patient from other external medical records. Here I'm just wondering what might be the concerns about aggregation that are not already covered by trigger number one, which we spent a lot of time on on this call clarifying what's meant by control and who's the provider. It seemed as though to me we were always thinking of this bullet as centralized HIO and so I'm proposing that this bullet is already covered by number one and doesn't need to be an independent trigger.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Well, Deven, I would say this: I think that structure makes the policy determination in that once you have comingled and put everything together the model that we put forward, which is that the patient and their treating providers make decisions about what to share and how to share it, starts to get very difficult to implement. This is one situation where I think I would encourage us to make a statement about not promoting models where that kind of control between the patient and any particular provider is compromised.

Paul Egerman – eScription – CEO

I understand that, Carol, but the question is is this the place to do that statement. In other words, isn't this redundant with our first consent trigger? I don't see how you can do the aggregation that you just described without first having to control this in the first trigger. Would a better place to handle this be in like a disclosure recommendation that if this is occurring, as part of transparency patients need to know this and maybe it's something they need to know when they make the consent decision, but I'm not sure if by itself it's a trigger.

Deven McGraw – Center for Democracy & Technology – Director

Well, we've already said that consent has to be fully informed and fully educated.

Paul Egerman – eScription – CEO

Yes.

Deven McGraw – Center for Democracy & Technology – Director

I guess, Carol, I would ask if it's better articulated as an example of trigger number one.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Well, I think we should really be understanding the full circle of what we're talking about here. It's not just what information is aggregated. It is also what that implies for who and how it's accessed downstream.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Sure.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

So if you think about that situation it creates less ability to address that and I think some of the examples we talked about on the call earlier about clinical judgment and sharing ... etc. it begins to get impossible to implement in that model. I just want to make sure that we're thinking about it fully, not just around where the information goes, but what happens once it goes there in terms of the policy implications of who can access it and when and how and how much.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I agree, but I think that, again, begs the question of what is an HIO and what kinds of access policies are required of the HIO, because I think I may have been responsible for this word aggregation as well in the earlier discussion. What I meant by aggregation was that records or knowledge of the records from different providers, who are not part of the same OHCA, I guess we would call it now, have information comingled in some way. That's an HIO, so the question really becomes—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Not necessary an HIO.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, not necessarily, but in the case that we're focusing on I think it would fit the definition of the HIOs in our bullet number one, which we haven't defined and we haven't specified because it's not part of meaningful use stage one, I assume, what the requirements on the HIO are for access control and use purpose and so forth.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Well, it's really an issue, David, I think of whether and how the HIO model either fulfills or undermines the provider's ability to do what we ask them to do—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Which is the real issue.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right. So—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

If the architecture of the model or the way that information is comingled basically makes it impossible for the provider to do what we ask, then there is a policy determination that gets made in the model that is counter to what we have suggested.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Are you talking about the architectural model?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'm talking about the way the information is aggregated and accessed. So if you're in a model where everybody has to submit their data, everybody also has to agree and that data is comingled. Everybody also has to agree to the same set of policies around access and use and sharing. It's just the nature of it and I'm suggesting that that can compromise some of the policy recommendations we've made previously.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. I mean I might like to debate that with you, but I think it would take us way of track, so I'll table that for now. I mean I understand your point. I'm comfortable that we are covering as well as we can with the scope that we've restricted ourselves to if we eliminate this bullet and just roll it up into an eventual definition of what an HIO is.

Deven McGraw – Center for Democracy & Technology – Director

Carol, does that suit you or—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

For me it's not really about the bullet. It's not losing the downstream implications of some of these things because it's one thing to say the provider-patient relationship is paramount and the provider should exercise judgment and the patient's requests need to be honored and then not to say anything about things that we think might compromise that I think is worrisome.

Gayle Harrell – Florida – Former State Legislator

I agree with you, Carol.

Paul Egerman – eScription – CEO

I think that maybe a discussion about models for HIOs is relevant, because there may be some implications or interplay between technical models and some of these policies, but at this level of policy we're saying that consent is required when that record is made available to this HIO entity, whatever that turns out to be. That's our bullet number one.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes and on your first comment I would say yes, because I think models make policy.

Paul Egerman – eScription – CEO

Well, yes, where models are affected by policy. Right.

Deven McGraw – Center for Democracy & Technology – Director

So it sounds to me; and someone correct me if I'm wrong; that some of the concern that you're expressing, Carol, is not just about whether centralization is a trigger for consent, but more about sort of other fair information practice policy considerations that arise in those models. Am I over—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. Deven, I would say my concern with centralization has never centered on consent. I mean it raises the stakes for a lot of other things; loss of large amounts of data; the breach risks go up. There are a lot of things that I think in fair information principles have an impact on that where the stakes go up significantly.

I'm actually also saying that depending on how it's implemented it could undermine or make impossible some of the policy recommendations we previously made.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Okay. I said I'd stay out of it, but I changed my mind. I think centralization is something of a red herring. I think you could meet all of the policy requirements that we've talked about with a model that centralizes relatively more of the information. I think it's absolutely impossible. I think it's a technology issue that's an independent access. It does have security implications, but again, they're technology implications. I mean we centralize in a data center here where I work many, many hospitals' records and it's well protected. It's more protected in that setting than it is if it was distributed out—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I don't think we're talking about centralization in the context of a legal enterprise. I think what we're talking about, again, is outside of the health delivery entity and that is a different issue and it raises all of the concerns we had about how the information is used, what is stored, how long it's stored, where it's stored. You know, it triggers all of those things. I don't think anybody's talking, at least I'm not, for health information exchange, about the issue of centralization in terms of how an enterprise manages its own information.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So what are you proposing, Carol, for this trigger?

Deven McGraw – Center for Democracy & Technology – Director

I'm interrupting because I actually don't think Carol is talking about it as an independent trigger—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Okay.

Deven McGraw – Center for Democracy & Technology – Director

But expressing concerns about the model. So in other words, I think we can remove it and, Carol, please correct me if I'm wrong. I think we can remove it as an independent trigger for consent because the consent piece is already well covered. I think what Carol is saying is that with respect to some of the other recommendations that we have made on fair information practice, the application of fair information practices to third parties or intermediaries that this particular model of third party or intermediary raises more concerns.

We've got some recommendations that cover this. We probably have not mined this area quite enough and probably won't have sufficient time to before our August meetings and we may have to, as with the application of fair information practices in other context outside of stage one, as well as continuing to sort of expand on, for example, what transparency means in this new environment. Lots of sort of implementation of FIPs issues that we just haven't gotten to I think we need to parking lot that, but do so in an express way.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I agree with your clarification, Deven, although I would say that at least for me it's very hard to uncouple the model from the policy discussion because a key way to fulfill the data protection and privacy protection elements that we've been discussing all of the way along comes down to some of these model issues. It doesn't have to be today, but I would just say that I think people always have a tendency to think about the privacy policy as policy issues and then model and technology issues as model and technology issues. I guess I'm just saying they are so interrelated and we should bring to bear the full spectrum of protection opportunity that there is.

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

I think I agree with both, Carol and David, because I think that this is an example of an area where we really do need to specify both, address both, security and privacy policies, because there are different security policies relating to different models.

I would also like to say that I think what we have not captured in this first bullet that I think Carol is and I certainly am bothered by is the ongoing use of the information by an HIO. That doesn't dictate whether it's centralized or federated, because if they have an ongoing ... ongoing use of the data I think that requires consent beyond the first bullet. I mean you can give your consent for your physician to send your information through an HIO to another organization or to make it available to other providers for the purpose of treating, but the idea of an HIO having ongoing access and exercising their access for ongoing other uses is what I think is problematic.

Paul Eggerman – eScription – CEO

Yes. I think that's what the first bullet says—

Deven McGraw – Center for Democracy & Technology – Director

Well, no, I don't think it does. Dixie, I think your issue is getting at the fact that our fair information practice recommendations on intermediaries scratch that surface, don't dive in as deeply as I think some of us would want to. So again, what I'm suggesting is that we put a marker down in our

recommendations that we are going to continue to look at those issues rather than suggesting that ongoing use is a trigger for consent when we've already got a set of recommendations that suggest that all of that ought to be very limited.

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

Well, I think that consumers should be able to consent to one without the other. I think a consumer should be able to consent to bullet one without giving consent for ongoing use. I think that's a second level

Rachel Block – New York eHealth Collaborative – Executive Director

Could I ask a slightly different question? I'm sorry if this was covered. I've been on most of the calls, but I have missed some portions of some calls. There are HIOs and then there are HIEs, which could occur outside of an HIO.

Deven McGraw – Center for Democracy & Technology – Director

Right.

Rachel Block – New York eHealth Collaborative – Executive Director

So to me one of the advantages of an HIO is that there is an O that can be held accountable through contract, BAAs, regulations, whatever, but there is a lot of HIE that occurs outside of the Os. So did we have; I don't want to take us down a road here if there was sort of a conscious decision to describe this only in the context of things, which might occur within HIOs, but I think one of the other tricky things we're going to have to deal with and this discussion prompts the point, is that there are a variety of HIE activities, which could include all of these things that may occur outside the context of an O. We're going to have to weigh in at some point, I think, in terms of whether we think that's okay and what we would suggest as an accountability mechanism under those circumstances.

Deven McGraw – Center for Democracy & Technology – Director

Yes. We haven't addressed it, so here's what we've said, Rachel: We've said our recommendations are only about exchange for stage one of meaningful use. We've said that direct exchange doesn't require consent beyond what existing law would already require and we've looked at triggers for when there ought to be additional choice for the patient on whether they participate in it or not.

We've said that we think business associate agreements, that that is an enforcement and the accountability tool has improved greatly, but it's still probably not sufficient to govern all of the types of exchange that will go on out there and that more is needed and we've punched governance to the side—to the near side; in other words, we know it's needed, but we haven't touched it yet. So there's sort of been a limit. We have both, deliberately limited ourselves, often under much protest, to a certain set of circumstances in order to get started and to put some concrete recommendations on the table, but I don't think all of what you've raised, Rachel, has been covered yet, but we haven't ruled any of it as being not important.

Paul Egerman – eScription CEO

Hopefully that answers your question, Rachel.

Rachel Block – New York eHealth Collaborative – Executive Director

Yes. I think it's just to make the point that this whole conversation has been talking about what HIOs are doing and that these things are happening outside of HIOs today.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Rachel Block – New York eHealth Collaborative – Executive Director

I don't know if it's the same point Carol was trying to make, but it may be a similar point that I don't think that what we're describing here is today limited to HIOs. At some point we do have to come back to how to frame the accountability framework and also say that there may be some of these things, which we don't think should be occurring outside of that accountability framework.

Paul Egerman – eScription CEO

Those are all good comments. I also just want to return to the slide on the screen, the agenda. What we're supposed to be focused on is agreeing on these triggers, so the trigger that we were talking about was the, I'll call it, aggregation trigger. So it seems like there are some concerns about this, the whole topic of aggregation, but if I heard it right is there an agreement that we would remove this as a specific trigger?

Rachel Block – New York eHealth Collaborative – Executive Director

Are you going to state it in another way within that first bullet, Paul, or are you just eliminating the whole conversation about it?

Deven McGraw – Center for Democracy & Technology – Director

We're not eliminating the conversation. I think we're going to wrap it into the first bullet. The other thing that I want folks to do, because we have not looked at the recommendations that we made on third party intermediaries and fair information practices in a very long time and I think people are kind of forgetting that we made them. I'm not suggesting that they're perfect and not in need of some additional attention, but they will be part of the package of recommendations that I'm pulling together and will receive the emphasis that because we've had to focus narrowly on consent we need to be reminded that we actually did raise concerns about third party, how HIOs use data going forward once they get it. It's more of a marker than a definitive statement, but it's in there and we will do future work on this if I have anything to say about it.

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

I would be more willing to leave number two as a consent and move one to a transparency issue. I don't think bullet one addresses the issue of aggregation, either virtual or physical aggregation.

Paul Egerman – eScription CEO

I don't know what you mean by addressing it. The issue is a trigger for consent. I don't think you can—

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

Right. I think it should be a trigger—

Paul Egerman – eScription CEO

Let me ask you a question, Dixie. How can you do aggregation unless you have control of the data?

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

You can have control of the data without doing aggregation.

Paul Egerman – eScription CEO

I understand that, but the question I'm asking is why is this needed as a trigger—

Deven McGraw – Center for Democracy & Technology – Director

Separate from number one.

Paul Egerman – eScription CEO

Pardon me?

Deven McGraw – Center for Democracy & Technology – Director

As a trigger separate from number one—

Paul Egerman – eScription CEO

Yes, why do we need this separate? In other words—

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

That's what I just answered you, Paul. I said you can do number one. You can allow the exposure to a third party without that third party aggregating the data, so you can do number one without doing –

Paul Egerman – eScription CEO

When I talk about number one I'm not talking about number one on the slide. I'm talking about the first one, number one, on the previous slide, the issue of control.

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

Right. Well, yes. Show me the previous slide.

Deven McGraw – Center for Democracy & Technology – Director

Okay. Hold on.

Paul Egerman – eScription CEO

Okay. Decision to initially disclose/exchange of patient's—

Deven McGraw – Center for Democracy & Technology – Director

And initially is gone

Paul Egerman – eScription CEO

The decision to disclose/exchange the patient's health information from the provider's record is not under the control of the provider or the provider's OHCA.

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

Again, today you can turn over control of data to a third party without that third party aggregating—

Paul Egerman – eScription CEO

Yes, but can you do it the other way around? Can you have a third party aggregate without it having control?

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

Yes. No. You can't aggregate without having control.

Paul Egerman – eScription CEO

Okay. So my issue is if you can't aggregate without having control why do you need aggregation as a separate trigger?

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

Because aggregation is a separate act.

Paul Egerman – eScription CEO

Yes, but understand it's covered by the first, by what you say—

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

It's not. It's not. Let me give you an example where if you have an HIO that has a business associate agreement with three different providers and they separately manage and have control over each of those repositories, the data from provider A, B and C, but they never aggregate the three, separate from aggregating it and doing other things with it.

Paul Egerman – eScription CEO

I understand. In other words, you can have control without aggregating.

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

Right.

Paul Egerman – eScription CEO

My question is can you have aggregating without control?

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

... No. You can't aggregate without control, but—

Paul Egerman – eScription CEO

Then that means it's covered by the first bullet. We should just list it as an example.

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

I think it's a separate level of consent and I think that—

Paul Egerman – eScription CEO

... write it twice when it's aggregation? I mean—

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

No. It's a totally different thing. Let me try again. If I gave consent to allow my provider to give control of their outsource, outsource the management of their data repository to a third party—

Paul Egerman – eScription CEO

Well, that's—

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

That's fine with me, but if that third party then comingled my information with five other institutions and does all sorts of analytics and other things, other than just outsourcing the data to them that's a different thing.

Deven McGraw – Center for Democracy & Technology – Director

But, Dixie, if they're doing that—okay, so I see what you're saying. You're saying that there ought to be two layers of consent?

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

Well, what I said was I would be perfectly happy making the first – yes, I think it should be two layers of consent.

Paul Egerman – eScription CEO

That's a different concept than we've had before. I think you're going to get a lot of resistance to that. How do the two layers work? Do they have to sign twice if I'm a patient? Do I have to—?

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

We've discussed this before, Paul. We've discussed it in the context of sensitive information.

Paul Egerman – eScription CEO

Do other people want to have a second layer of consent? I'm just curious if other—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

What do you mean by a second layer? Can you clarify that?

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

Well, what I'm saying is a patient should be able to give a consent for their provider to share their information and even give control of their information to a third party without, at the same time, allowing that third party to comingle it with other information. That's all I'm saying.

Paul Egerman – eScription CEO

If it's ... issue of whatever the capabilities of that HIO are. In other words, if you've got disclosure or transparency you can find out if I give consent this is what they do or this is what the flexibilities are that they allow me to do.

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

Well, it's—

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

I'd like to suggest that we're confusing purpose with technical architecture.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I agree.

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

I mean comingle or not; comingle is a physical characteristic of the data or it's a way of describing the retrieval, but what I hear is that it's one thing for me to – I don't even think I necessarily know when my provider uses a business associate. I don't know whether they use ... or ... for my EHR, but if they're going to take my identified data and put it into the state quality repository then there's some level of disclosure or consent that's needed with regards to that, probably according to state law. In Minnesota it's disclosure

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

I would argue that this number one on the slide that's shown now is nothing but what a business associate does and does not require consent.

Paul Egerman – eScription CEO

We already agreed on this slide.

Deven McGraw – Center for Democracy & Technology – Director

We already agreed that number one is going away, Dixie.

Paul Egerman – eScription CEO

Yes, number one on slide ten.

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

The one that you have on the screen right—wait a minute—

Deven McGraw – Center for Democracy & Technology – Director

Trigger one is the control trigger ... the bullet that's—

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

No. I'm talking about the number one on page nine.

Paul Egerman – eScription CEO

Yes. She wants to go back to the discussion we already had and repeat it.

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

No, I don't want to go back and repeat it.

Paul Egerman – eScription CEO

But you're saying you don't think that's a trigger.

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

I'm saying that if you think about it, the decision to disclose or exchange a patient's records where it's not in the control of the provider really equals handing it over to a business associate.

Paul Egerman – eScription CEO

We already had that discussion, Dixie. We're not going to repeat that.

Deven McGraw – Center for Democracy & Technology – Director

Dixie, I think that's not what was intended and it's probably an issue of wordsmithing. How about if we work on the wordsmithing of this in order to get the centralized HIO point and allowing patients to have some choice about whether their data is part of it –

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

I think we need to capture the ... consent for aggregation across multiple provider organizations and we haven't done that in the first bullet on page nine.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think isn't that going to come down to what the definition of an HIO is, that one of its purposes is to aggregate data across organizations or at least to make access available to data across organizations, whether it's aggregated or mingled or whatever? I think it keeps coming back to what is an HIO.

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

Yes.

Paul Egerman – eScription CEO

I would also just be very careful that we're not using the consent policy to make other privacy and security policies that we want to make. I mean we have some very serious concerns about aggregation, but I don't think that consent will necessarily be the place that we can implement that. Maybe there are other vehicles that we need to do to implement those concerns.

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

I think that that is consumers' primary concerns, the aggregation of their information and use of that aggregated information for other purposes—

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

I think their concern is I think they have a secondary concern some, or at least their advocates do, about the risks associated with breach as associated with aggregation, but at any rate I do think the other thing I wanted to say is, David mentioned about defining HIO. I think we will never define the limits of the purposes of data in an HIO. Just as soon as we do someone will come up with a business proposition that buries it. We have to describe HIO in a very abstract sense for our purposes and then talk about use.

(Overlapping voices.)

M

... some of the things Dixie is worried about.

Paul Egerman – eScription CEO

I want to get back to the question that we have, which is the issue of aggregation, the second bullet on slide ten. The proposal is to eliminate that bullet because it's already covered by the control bullet. In other words, you can't aggregate unless you have control, so that's not a new trigger. Putting this here doesn't cause a different action, so the proposal is to take this off as a trigger, but to include some examples and wording as part of that control bullet. That's the proposal.

Deven McGraw – Center for Democracy & Technology – Director

Well, and also to resurface this discussion and some of the recommendations that we have on fair information practices, so it's not all about patient consent.

Paul Egerman – eScription CEO

Okay. That's the proposal.

Joy Pritts – ONC – Chief Privacy Officer

When we're rethinking this piece of this I think the medical home concept that you were discussing a little bit earlier comes into play also to make this consistent with that discussion.

Paul Egerman – eScription CEO

Didn't we handle that with the whole issue of the OHCA?

Deven McGraw – Center for Democracy & Technology – Director

And providers can—

Joy Pritts – ONC – Chief Privacy Officer

But what I'm saying is that, yes, you handled that with that OHCA, but it also applies with this one, so if you're—

Paul Egerman – eScription CEO

That's correct.

Joy Pritts – ONC – Chief Privacy Officer

... let's just—

Paul Egerman – eScription CEO

That's correct. You're right, Joy, because that's one of the things. There were two issues that were problematic about this and that was one of them, which is we tried to add the ACO, but it was like it ended that same whole discussion about medical homes and other medical healthcare structures as to whether or not that was intended, which is really not what was intended.

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

So, Deven, what you're really proposing is to roll this up into number one on page nine?

Deven McGraw – Center for Democracy & Technology – Director

Yes.

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

Okay. I'm okay with that. I just don't want it dropped entirely.

Deven McGraw – Center for Democracy & Technology – Director

Oh, my goodness, no.

Paul Egerman – eScription CEO

Okay. Assuming there's agreement on that—

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription CEO

Then we'll move on to the next one, which I hope is simple, but maybe it's not. It has to do with sensitive data. Basically what we just said is we want to remove this bullet in light of the recommendation that basically we spent the four hours on on Tuesday, which is we already discussed what's going to happen with sensitive data. It's confusing to list it here.

Deven McGraw – Center for Democracy & Technology – Director

Yes. Well, because it looks like the mere presence of it in the record was itself a trigger for consent. So it's not an independent factor in other words.

Paul Egerman – eScription CEO

That's correct.

M

Refresh my recollection. The recommendation from last Tuesday's call, what was that again exactly?

Deven McGraw – Center for Democracy & Technology – Director

We'll get there. Okay. So we said when it's direct exchange there is no additional requirement beyond what the law would already require to obtain the patient's consent to exchange information, but of course,

we've got those bullets about doctor-patient relationship and consideration of the patient's expressed preferences, etc.

M

Okay. I just—

Deven McGraw – Center for Democracy & Technology – Director

Okay.

M

I would agree.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Paul Egerman – eScription CEO

Okay.

Deven McGraw – Center for Democracy & Technology – Director

The next one—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

This may be food for thought, but it seems to me that the word consent can be construed conceptually and also tangibly. I think the way we're referring to consent is the document that the patient signs that says, "Yes, I agree," but the nuance of those additional bullets sort of imply that the patient's okay with whatever information is being shared.

I just offer it because every time I hear somebody say consent and then I think about what we said, which is just because the document isn't signed doesn't mean that the provider-patient relationship isn't paramount and that the provider and the patient aren't having a discussion about whether or not the patient is okay with it, specifically if the patient says, "I'm not okay with it." I just offer it because I think it's a nuance we're going to have to articulate carefully in whatever document this ends up in.

Deven McGraw – Center for Democracy & Technology – Director

That gets back to those two bullets that we started the call off with and I think we're getting close, but we haven't got it worded quite right ... everybody.

Joy Pritts – ONC – Chief Privacy Officer

Does written consent alleviate your concerns, that term?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

No. I'm actually saying it heightens them.

Joy Pritts – ONC – Chief Privacy Officer

Yes.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'm saying exactly the opposite; that we have said there are certain things, like I send my patient to go have an x-ray and the radiologist is going to interpret the films. We're saying that doesn't require written consent is our sort of statement; but we're also saying that in those other two bullets on consent that the

provider-patient conversation about how information is shared and the patient's expressed concerns and the provider's judgment be honored. The interpretation of the word consent can either mean the written, which I think we're referring to, but it can also mean the agreement of the patient simply.

I just think we have to find a way to explain that nuance because I think we mix things sometimes. Every time I hear somebody say consent is not required I say, —But wait a minute. If I say to my doctor I don't want you to send whatever to this specialist that I'm going to we're saying the provider should honor that.”

Deven McGraw – Center for Democracy & Technology – Director

If the provider can do so. I mean again—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

They don't have to under HIPAA apparently.

Joy Pritts – ONC – Chief Privacy Officer

Right. So that's, I mean I understand the distinction and that's why I was asking if the term written helped—

Deven McGraw – Center for Democracy & Technology – Director

No, it doesn't. It doesn't.

Joy Pritts – ONC – Chief Privacy Officer

I would like to finish my statement for a second here, which is that I think you're making a distinction that you believe and that the group has said that the individual's permission or thoughts or desires and the physician's should always be taken into account. A lot of that is what we would call implicit consent.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Right. Exactly.

Joy Pritts – ONC – Chief Privacy Officer

So you're making a distinction between the fact that you don't have to have it in writing doesn't mean that you don't have to have any.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Exactly. Right.

Joy Pritts – ONC – Chief Privacy Officer

That's why I'm trying to say that from my perspective using the word written consent says it makes it clear that that's the only thing that you're referring to is this written documentation as opposed to implicit.

Deven McGraw – Center for Democracy & Technology – Director

Yes, but the problem with that, Joy, is that it gets back to the conversation that we had earlier about implied consent to me is not just about whether the consent was in writing, but also about whether the provider, in his or her judgment, feels that he or she can send the data because they know of no expressed preference to the opposite from the patient. Because sometimes the expressed conversation doesn't take place, but the doctor sends the lab results because they're doing so because it's consistent in their clinical judgment with good patient care and they don't have any reason to suspect that the patient wouldn't want it to be sent.

So I think that's why the writing thing is not the distinction here. Implied consent may be the better concept, but I think it's not just about do I have it in writing or not, but it takes on other dimensions. When I'm acting on the patient's behalf I may do things that I haven't necessarily asked the patient about.

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

Does it make sense to almost make; I don't want to say glossary; that's the wrong term—

Deven McGraw – Center for Democracy & Technology – Director

No.

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

But describe all of the ways different consent can occur? I mean I hate to say that, but—

Paul Egerman – eScription CEO

We actually talk about the form of consent in the next slide. I wonder if we should delay this discussion until then. Does that sound right to you, Deven, or do you want to continue this?

Deven McGraw – Center for Democracy & Technology – Director

No. No. No. Yes. Let's do it within the sort of form of consent. But that's only when consent is required, so—

Paul Egerman – eScription CEO

Yes.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But I do want to say I think John makes a good point and it's something that we have all struggled with when we talk about any issue, which is to find a way in this, whatever the final write-up is, to really define the terms we're referring to, by the way, not just consent. It applies to a lot of things. I mean our discussions are very deep and we end up sort of understanding the terms because we've talked about them for four and a half hours, but they still end up as a bullet, right now on a slide. I think we do have to think about how to explain a lot of the terms behind some of these statements.

Paul Egerman – eScription CEO

Good point.

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

Yes, because I think some of what happens, honestly, is when we move these recommendations forward what happens is people that aren't privy to these conversations don't have the same starting point as we do or ending point that we do. So they may question them as well. I find that with NCVHS all of the time. You have something in a subcommittee and you talk about it. You bring it to the full committee and people ask the same questions de novo, because they're not privy to the conversation.

Deven McGraw – Center for Democracy & Technology – Director

Right. That's fair.

Paul Egerman – eScription CEO

Good points. So, Deven, do you want to take us through the last two bullets?

Deven McGraw – Center for Democracy & Technology – Director

Yes. The last two are we had initially on the consent triggers a significant change in circumstances supporting an original patient consent. I guess we're suggesting deleting this because it feels repetitive. In other words, whenever a trigger applies choice attaches. It's not that the patient makes a choice when a trigger doesn't apply and the patient is not required to make an express choice or give expressed consent and then later down the road when the circumstances change and there is a trigger there is no consent. When a trigger applies consent is required.

So I just didn't see the need to separately express the significant change, so we're suggesting deleting it unless folks feel strongly otherwise. Then we want to add again; Paul alluded to this earlier; a statement that says we may add subsequent triggers when we start to consider exchange beyond stage one.

Gayle Harrell – Florida – Former State Legislator

I would just clarify when we make our first statement when consent is required, when the triggers are there, that we say whenever a trigger takes place so that a feeling ... is the trigger may not be there now, but should it happen later, that the consent is then required.

Deven McGraw – Center for Democracy & Technology – Director

Yes. That's fair. Good point.

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

Except that the reason we put this in here, I think, we had the discussion before about how a trigger could occur multiple times and it wouldn't require consent every time.

Deven McGraw – Center for Democracy & Technology – Director

Oh, I see. Okay.

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

... you know saying that.

Deven McGraw – Center for Democracy & Technology – Director

Okay. That's a good point and I think maybe rather than putting it as a separate trigger we just explain what we mean by when a trigger applies and make it clear that a trigger applies—

Paul Egerman – eScription CEO

Yes. That's a good solution. It's a little odd as a trigger, but I think we do have to respond to it, as Dixie and Gayle are saying.

Deven McGraw – Center for Democracy & Technology – Director

Yes. Agreed. Okay. I think we can move on.

Paul Egerman – eScription CEO

So that was an excellent and rich discussion. Do you want to do this slide, Deven, or am I doing this one?

Deven McGraw – Center for Democracy & Technology – Director

Well, this slide is the same.

Paul Egerman – eScription CEO

Okay.

Deven McGraw – Center for Democracy & Technology – Director

This slide is the same. These are we say that when there's a trigger patients should have a choice about participation and the choice needs to be meaningful. So what we've got that's new, Paul, is what you've keyed up for us.

Paul Egerman – eScription CEO

Yes, but the comments; before we go into what I keyed up here; there are two comments about this. One is when we put this forward, particularly the Policy Committee, but also Policy Committee and Standards Committee, people liked this. This really came from Carol and Markle Foundation. The people did like this quite a bit and it's important to notice when you look at it that one of the things we agreed to that makes sense is advanced knowledge, time to make choice. That is one of the criteria.

The other thing, just so nobody is caught by surprise, when we write this up there's a good chance we're going to take out the word choice and put in something else, like consent. The reason is, as we discussed previously, the patient's right to choose has meaning in other debates and so we're trying to just steer away from that a little bit. So it might get rephrased a tiny bit, but ultimately I just wanted to acknowledge that this was very strong in terms of what it says and it's a good guideline.

Now, what happened was when we presented this to the Policy Committee and also the Standards Committee there was a slide afterwards where we said we couldn't come to a conclusion ... on opt-in. We said that there were two statements and, as you may remember, Dixie and Gayle wrote a very sort of heartfelt presentation as to why they felt opt-in was correct. Then what happens, as I say when we presented this in front of the Policy Committee, almost the entire discussion was simply on this one issue, which is unfortunate, because people lost track of a lot of the other issues that we raised and the Standards Committee wasn't quite that extreme, but it was a fair amount of discussion. We got some national press and it seemed like the national press only reported on this issue.

We felt that our recommendations would be better if we actually made some decision on this concept of the form of consent and so I thought I'd give a shot at it, so I wrote up something that has a lot of words that basically says when any of the triggers that are described the form of consent must be a meaningful consent. Then I reiterate, which includes a requirement for advanced knowledge. Patients must have an opportunity to provide consent before any of the patient's data is made available to a third party information organization.

We may want to wordsmith that and take out the expressed and third party information organization, maybe not. This requirement, I said, can be met with an opt-in form of consent. Then I wrote alternatively, providers can provide clear disclosure statements and provide opportunity to opt-out before making available patient's data. In either alternative, patients must have an opportunity to make a consent decision before their information is made available to the third party information organization.

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

Isn't that a lot of words to say opt-in? I mean if you say you have to have the opportunity to opt-out before the data is made available what distinguishes that from opt-in?

Deven McGraw – Center for Democracy & Technology – Director

What that means is if you don't opt out you're in. If it's an opt-in you would not be in unless you opted in.

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

I don't hear that. Alternatively, providers can provide clear disclosure statements and provide the opportunity to opt out before making available patient's data.

Deven McGraw – Center for Democracy & Technology – Director

Yes. To me the distinction is the question of a default, Wes. All of it is done ahead of time and so people might look at that as an opt-in, but ultimately there is a period of time and a deadline. If it's opt-out in advance you're presumed if you don't take the affirmative step to opt-out your data is in. If it's an opt-in in advance you're not going to be included unless you have opted in by the deadline, although you could opt-in later after the fact, but as ... after that time is expired what's the default with respect to that data.

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

Let me just put this in the context of some specific examples. Let's suppose that we have an HIO and one of the things that we're doing, which is very common, is to originally accept lab data and forward it under a directed exchange model and retain that lab data so that it's available for lookup later on. Okay?

M

I'm sorry. Who retains the data?

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

The HIO.

M

The HIO. Okay.

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

So that if someone comes to the emergency department and we can find out they've had uncontrolled blood sugar for a while that's very helpful. Now, I don't understand how opt-out works in this model. That is to say is it the case that the HIO would be screening all data coming from the lab, doing the directed exchange and then not recording, not making that data accessible because— I don't understand where the deadline is that these time periods start from basically.

Deven McGraw – Center for Democracy & Technology – Director

Wes, let me ask you about your model. Where is the trigger?

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

I don't understand. The trigger for consent?

Deven McGraw – Center for Democracy & Technology – Director

Yes, because you said it's doing the directed exchange.

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

The directed exchange doesn't need a trigger for consent, right?

Deven McGraw – Center for Democracy & Technology – Director

Right. This model in Paul's proposed approach only applies when there is a trigger, when—

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

But the trigger then is that the data, which was sent for one purpose is being made available to other providers for treatment that wasn't anticipated in the directed exchange.

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

It's being retained.

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

Retained. Yes. I mean for practical purposes access is being—

(Overlapping voices.)

Paul Egerman – eScription CEO

Here's my answer to the question: Assume the trigger has been triggered. Assume the trigger situation occurs. That means that you have to have a consent. It's best to think about what's the impact if the patient doesn't give consent. If the patient doesn't give consent it means that the patient's data is not sent through that HIO. It's sent some other way.

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

... I mean there's a legal requirement for the lab to deliver the data to the first recipient or those that were specified on the order and the HIO is a business associate of those, of the lab, so it has to deliver that data legally.

Paul Egerman – eScription CEO

When you say legal requirement of the lab to deliver then you're also taking this out of the context of this discussion.

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

I'm saying that the contexts are right now, every day, mixed together.

Paul Egerman – eScription CEO

No. No. I'm just saying that the lab, according to HIPAA, is the provider. If the lab is using the HIO, well that's just a different environment. I mean the patient doesn't have a relationship with the lab and so that's all. I actually don't understand how that works.

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

It's still a directed exchange.

Paul Egerman – eScription CEO

I think it's probably still a directed exchange.

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

The problem is that as a matter of practice in some of the most successful, economically self sustaining HIEs that we have, data that is first obtained on the basis of directed exchange is retained and used, made available for query.

Paul Egerman – eScription CEO

So, in that environment, Wes, how do you picture it working in an opt-in form?

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

Well, I don't know that there are any examples that have used opt-in, but if I did imagine it it would be that they would have a list of patients who have affirmatively worked with some agent to opt-in to all exchange, all of the non-directed exchange characteristics of the HIO. That agent probably is not the lab. It's probably usually the primary care provider, but it's one of the complications of opt-in that we have situations where that lab test may have been ordered by a provider who does not even participate in the HIO.

Paul Egerman – eScription CEO

So the environment you described is a very complicated environment and it raises a whole series of other issues in addition to this form of consent issue. What I'd like to suggest we do is consider this proposal first from the standpoint of the simpler environment, so maybe simpler, maybe not, but if you look at the kind of environment that Carol was talking about where there's some centralized HIO that perhaps even aggregates data, so this is an environment—

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

So far that's no different than what I've described.

Paul Egerman – eScription CEO

Well, it is in a way. Let me get to that, but we get to one of these environments that is particularly problematic from a privacy and security standpoint, centralized HIO. It's aggregating data. Maybe it's aggregating data across multiple episodes of care. It's getting all of the data. So the idea of whether it's an opt-in or an opt-out decision, the impact should be the same, which is a patient should be able to say don't send my data over there. I don't want my medical record going there.

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

Just clarify: You're not saying that that eliminates the ability to do directed exchange. You're saying that my record should not be available later.

Paul Egerman – eScription CEO

No. I'm saying my data should not go to that HIO.

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

Don't send my data to the HIO at all. So the scenario is the lab now has a direction not to send data to the HIO, but the HIO is the business associate that's delivering data.

Paul Egerman – eScription CEO

This is a patient's relationship with the provider and if the trigger – let's leave the lab because it's a complicated one with pharmacy also. Let's leave the lab and pharmacy to the side for a moment.

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

... data we're exchanging out ...

Paul Egerman – eScription CEO

Well, it's not all of the data we're exchanging. I'm sorry. There are exchange environments—

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

No. I would say percentage wise it's probably no more than 85%, but fine.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I was wondering, Paul, first of all, I like what you've written here, but I understand Wes' concern as well. I think that practically there are real issues there. I wonder, and maybe this is wordsmithing, but I wonder if we were to reword it to say instead of saying made available to a third party information organization it said made available via a third party organization, which would essentially say the third party organization cannot release the data until consent is present, even though it might actually have it due to these other arrangements where the data has passed through. So instead of available to make it available via.

Paul Egerman – eScription CEO

Well, it seems to be—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That changes things, I realize, but it might be closer to reality and yet still get the spirit of what you're saying here, which is that until meaningful consent is presented the data isn't available to people via the third party organization.

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

Right. I think—

Paul Egerman – eScription CEO

Well, it's an interesting issue, but it's an important one—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It is.

Paul Egerman – eScription CEO

Really, what we're talking about here is not really the form of consent. We're really talking about what is the impact if you decide not, if you don't give consent, so whether it's opt-in or opt-out, what is the impact of deciding not to consent, to participate –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So to me—

Paul Egerman – eScription CEO

I think it should be that the third party organization doesn't get the data at all. You're suggesting they can get the data; they just can't use it for some purposes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes—

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

Here's the problem: Those organizations are doing double duty. They are both, a business associate of let's ... out of the lab. Let's say that this physician has decided to meet their meaningful use for transitions of care by sending CCDs through from their EHR, through the EHR to the recipient of the patient on the transitional care, another physician, a nursing home, whatever. Okay?

Now, if I'm a physician and I'm in the HIO I probably made a deal with the HIO that says I don't have to worry about whether you have consent from the patient and do something different. You're my business associate. I have to send this data. You've taken responsibility. You are guaranteeing that you will help me fulfill my responsibility to deliver the data. Okay?

The problem: I don't think we can get out of tying consent to something besides physically having the data get to the organization in the first place. We can talk about retention. We can talk about access. We can talk about something else, but a rule that's as simple as you can't send the data to this HIO unless the patient has consented or at least the patient, if the patient has withdrawn consent according to the model, is fundamentally going to create consternation for HIEs that are already doing this dual role.

Paul Egerman – eScription CEO

So you're suggesting, if I understand, Wes, let's say I'm a patient and I get this consent thing and I read it and I say, "I don't want to do this. I don't want my data aggregated. I don't want this stuff. I disagree." You're saying my provider can send my medical record, my CCD information to the HIO anyway?

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

In fact, the HIO is also the business associate that's delivering that data to the other thing then you can. The question is not—

Paul Eggerman – eScription CEO

Okay. What do other people think about this?

Deven McGraw – Center for Democracy & Technology – Director

I actually think that the small compromise that David suggested ... will accommodate many more models that we have out there, but still essentially accomplish—

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

But I'm not buying into I mean David explained ... by meaning it had to do with access as opposed to first. I mean the problem I had was that ... seemed to apply to both, the case of the business associate relationship and the case of the HIO relationship.

Deven McGraw – Center for Democracy & Technology – Director

Oh, no. I mean I think that we're already assuming that consent is only going to apply to a trigger and the existence of a trigger relationship for one aspect of the business doesn't—

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

And the problem I'm having with this wording is that it says you cannot send the data to this organization absent consent.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Paul Eggerman – eScription CEO

Yes. That's—

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

That totally denies what was already said elsewhere.

Deven McGraw – Center for Democracy & Technology – Director

Well, let me ask then, assuming we could get this worded right and what we're talking about is saying that what's important here is that when consent is triggered it needs to be in advance; that the patient's choice needs to be exercisable in advance, regardless of whether it's opt-in or opt-out, right?

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

I mean I still have trouble equating those – not equating consent in advance with opt-in. I understand you're saying that in one case they're notified in advance and if they don't do anything the data flows. In the other case they have to do something.

Deven McGraw – Center for Democracy & Technology – Director

Right.

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

So I guess that's just in the past opt-out, I haven't understood failure to opt-out as an explicit event with data starting to flow immediately and so, yes, I think it's okay.

Deven McGraw – Center for Democracy & Technology – Director

So then I'll put a friendly amendment on my own reformulation, which is to say that if you already have an existing model where the patients were not given that choice in advance are we suggesting that you have to make sure that they're aware of that opportunity, whether it's opt-in or opt-out?

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

Yes. Absolutely.

Gayle Harrell – Florida – Former State Legislator

I'm having some issues, as you probably thought I might. This is the closest to an opt-in, as long as the consent that you have to take action that is not posting. What I see happening in a situation like this is you post a sign at the door that says, "Your information will be shared unless you sign a document that says we won't share your information."

Paul Egerman – eScription CEO

I think we've already discussed quite a bit about what we mean by meaningful consent.

Gayle Harrell – Florida – Former State Legislator

Exactly. I see that happening and to me that is not meaningful consent. I think really people need to understand what they're getting into and not a sign on the wall that says your information will be exchanged.

Deven McGraw – Center for Democracy & Technology – Director

Yes. That's never been acceptable, Gayle, under our recommendations.

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

Yes. I have to agree. The fact that it's happening doesn't mean that it's what we've been recommending. I mean—

Deven McGraw – Center for Democracy & Technology – Director

That's right. So in other words, if it's truly meaningful by all of the standards we've got and people have advanced time to make the choice –

Gayle Harrell – Florida – Former State Legislator

To me it would have to be a written choice. You would have to sign. You'd have to check.

Paul Egerman – eScription CEO

That's where the difference is here, Gayle. The issue is, what I was trying to do, completely unsuccessfully, but what I was trying to do was to listen to what you were saying and Dixie was saying and to think through the whole thing and just say, "Well, gee, the requirement to have advanced knowledge and an opportunity to make the decision is really the correct thing to do."

The decision also has to be sort of like proportional or commensurate or whatever the right word is, with the exchange circumstances. So thinking through those things it did occur to me that there are some situations where a healthcare organization might say opt-out is better because we are doing the example that Wes gave with the lab and the fundamental issue is nobody is deciding they don't want to do it. To

get to a situation where you've got 99% of your people opting into something is administratively burdensome. It's easier to keep track of the one percent who don't want to do it and so it's to give a little bit of flexibility, but it's also to be clear that you have to have advanced knowledge.

Gayle Harrell – Florida – Former State Legislator

Advanced knowledge is a sign on the wall.

Paul Egerman – eScription CEO

Well, advanced knowledge, whatever that means. I mean this is ultimately the responsibility of the providers to do this.

My other thought process is both providers and state governments could choose how they want to, whatever they want to do to improve this. So it turns out at the Standards Committee meeting I happened to be on a plane flying home with John Halamka, who is Co-Chair of the Standards Committee. We were talking about this as related to directed exchange and he made an interesting comment. He said in Massachusetts and Boston there's such a privacy culture that exists in the community. He said, "We don't have any choice but to do opt-in on everything. We do opt-in on all kinds of stuff that we're not required to do because that's the function of our culture."

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

I thought Massachusetts had a strict opt-in law on the books, at least for things like HIEs.

Paul Egerman – eScription CEO

It could be, but his comment that I thought was good was you've got to take into consideration what the culture is and the community and the patient population that you're dealing with also. But that's what the intention here was and so if you don't think it's a good compromise that's—

Deven McGraw – Center for Democracy & Technology – Director

Yes. The other recommendation—

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

We're going to go about this. We've certainly made opt-out look a lot more like opt-in in this round. We're going to go around again and then Gayle is going to say there's only one thing and that's opt-in. This is going to go on. I haven't seen any interest from Gayle whatsoever in moving from that point.

I for one believe that it has to be responsive to differences in state law, differences in state, difference in culture and things like that. We've done an awful lot to strengthen opt-out and the stuff about they're going to put it up on the wall and that's acceptable, that is in direct conflict with what we're recommending. The whole point of meaningful consent is meaningful consent. I don't believe that we should subject the committee to any more time discussing this if the only way we're going to come to a reconciliation is to have Gayle agree with anything except opt-in, because she's made it clear she will not.

Paul Egerman – eScription CEO

I understand and we don't have to have unanimous agreement, but we should discuss things enough that people understand it.

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

I'd like to say something here. Paul, you and Deven, this directly addresses my principle concern. It was that unless an individual has the opportunity to provider or not consent in advance then it cannot be meaningful, the first point in the previous slide. I think this is a good compromise here.

My only suggestion would be in the sentence right next to the end I know everybody on this call realizes this, but I think we should put, just in case, because we will be briefing this and publishing it, make it the opportunity to opt-out before making patient's data available for purposes other than treatment. I know we know it's only –

Paul Egerman – eScription CEO

What's you're speaking to is what I call the second issue. There are two issues with this proposal. One issue is the opt-in versus the form of consent, the opt-in or opt-out. The second issue is the impact of the decision, whatever the form is. So that's the variation; what you just said, Dixie, is the variation of what David McCallie said.

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

Right.

Paul Egerman – eScription CEO

So that's the second issue. Let's separate the discussions. Let's do them one at a time. Let's first see what consensus we have as to the form of consent and then let's see what the consensus is on the impact of the non-consent, because no matter what the form is there's still going to be non-consent and we need to understand what those are.

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

I was just trying to clarify. I mean this whole consent thing has to do with a triggered event. The triggered events are all not related to direct revision of care.

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

I just sent an e-mail that has some rather modest revisions to the language that I think help to clarify.

Paul Egerman – eScription CEO

But before we do that e-mail, Wes, I'd like to finalize the issue in the form of consent. So we've heard Gayle say that she very much wants opt-in. I just want to ask is there anybody else who wants to say that.

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

I just have to say that what I've heard Gayle say is nothing but opt-in is acceptable. I'm not willing to say I don't want opt-in. I'm willing to say that I believe there has to be some flexibility.

Paul Egerman – eScription CEO

Let me rephrase what the question is. In terms of this approach to this opt-in/opt-out discussion, in terms of the recommendation on that are people comfortable with this approach? What other comments do we have about what it says here?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'm wondering why we have this slide. What's covered here that wasn't in the meaningful consent?

Deven McGraw – Center for Democracy & Technology – Director

That's a good point, Carol.

Paul Egerman – eScription CEO

It's a good point, but for some reason it's the only thing the process people are asking about this issue.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I mean it's our job to articulate the issues as clearly as possible, but it seems like all of these criteria are in the meaningful consent parameters that we define, so the much more important thing here is that we provide policy to give people guidance that is meaningful and that protects patients. I guess I have expressed this before; I think this opt-in/opt-out thing is really, really a way to rob people of understanding how to implement these protections in a way that protects patients. I think we've gone closer to that with the parameters for meaningful consent, but it is so ... so poorly understood that I really believe it would be good for us to define what we believe consent looks like in the situations and with the factors that we think may make it meaningful and make that our policy recommendation.

Deven McGraw – Center for Democracy & Technology – Director

Yes. I agree.

Paul Egerman – eScription CEO

So you're saying that we should skip this all together?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'm saying I don't understand what's in this slide that wasn't in the previous one.

Paul Egerman – eScription CEO

Yes. In one sense I agree, but in another sense it's just—

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

I believe there is a distinction described here. Maybe it's because I'm not looking at the previous slides—

Paul Egerman – eScription CEO

We can put it back one.

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

But I believe that the distinction that's described here is the notion of the process, the opt-out process can be meaningful. I mean the opt-out model can be meaningful. As I recall, the previous slides went three times around the block to avoid using the words opt-in and opt-out.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Well, that's right. All of the meaningful choice elements were always meant to apply regardless of the default.

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

I understand, but we still, I think whether we think it's that important or not, we owe it to our listening audience to come down on the issue of opt-out. Either it's never permissible or is permissible with meaningful disclosure and whether we choose to repeat some of what we mean or, better yet, cite what we mean in a way that's easy to understand. I mean I agree with Carol that the issue of opt-in/opt-out has hidden and confused all of the issues of meaningful disclosure. I believe we are fixing that, but that doesn't mean we can get away from answering this question what about opt-in or opt-out.

Paul Egerman – eScription CEO

I agree with what Carol says and I agree with what you just said, Wes. In other words, what Carol says is in one sense we shouldn't need this slide. It's like frustrating. But the issue is, as Wes said, no matter what we do people want to know opt-in or opt-out. They're going to ask us that question. I'm trying to

simply answer that question and I think this answers it in a way that's not inconsistent with the previous slide.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

In this case we're talking opt-in or opt-out only when the triggers—

Paul Egerman – eScription CEO

Yes.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription CEO

The first sentence is, "When any of the triggers that are described on slides nine and ten." Obviously, we'll fix that to whatever the correct slide numbers are.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I would argue we've already implied basically that if the triggers are not there it is at least, this is for directed exchange for the care of a patient, regardless of whether or not there are triggers, there is implicit consent and that implies at least an opt-out. I mean this is what troubles me about trying to make it dichotomous this way for one situation and not others is that that confuses people more.

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

I guess it gets down to whether we consider HIPAA consent to be meaningful consent or not.

W

No. That's—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I think we're providing guidance on what meaningful consent is.

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

I think we are. The question is are we taking a position that HIPAA is wrong?

Deven McGraw – Center for Democracy & Technology – Director

No.

Paul Egerman – eScription CEO

No, we're not. We're taking a position, because I don't think HIPAA necessarily covers all of these

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

No, it doesn't, but the directed exchange it does.

Paul Egerman – eScription CEO

Yes. This doesn't affect directed exchange. This is solely related to the triggers.

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

I was just talking to Carol.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, Wes.

Paul Egerman – eScription CEO

It's solely related to the triggers.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I guess I'm saying we're so focused on consent only in situations where the triggers are that I think we've robbed ourselves of the sort of what does that mean when the triggers are not there. It does have implications. I think we should, in both cases, in either case express what is meaningful choice for people, meaningful consent.

Paul Egerman – eScription CEO

I agree with that. In some sense, Carol, though, I said there was like two issues. You're raising a third issue, which is what happens when the triggers aren't there, because there's clearly situations where there's no trigger and it's not directed exchange. That's just stuff we haven't really talked about yet.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

No. I'm saying even in directed exchange we've implied that there is at least implicit consent and that the patient has the ability to say no. We've said that.

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

Where have we said that the patient has the ability to say no?

Paul Egerman – eScription CEO

I don't understand. How does that relate to what's written here?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Because it's an implied opt-out, where we say it is in the bullets, where we say the patient and the provider should make a decision about the patient-provider relationship is paramount and the patient's wishes should be fulfilled by the provider.

Deven McGraw – Center for Democracy & Technology – Director

We don't say that, Carol.

Paul Egerman – eScription CEO

That's not what that says. I think that's not the issue.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

In that other slide when we started the call that's what we said.

Deven McGraw – Center for Democracy & Technology – Director

Not exactly. I mean this very new. We had a lot of discussion about the patient-provider relationship and making sure that even in directed exchange circumstances the patient's known concerns about data are given some consideration, but we stopped short of saying that if the patient says no that the provider would be required to honor that, which is beyond today what's required in the law, in part because it's sometimes difficult for the provider to honor it. We didn't go any farther than that quite frankly, as a team for recommendation.

Paul Egerman – eScription CEO

Right. So I'd like to return to what's written here on the screen. What I was simply trying to do was to answer the opt-in/opt-out question in a way that was consistent with what we said about meaningful choice as it relates only to the triggers, because fundamentally my belief is in one sense what you said earlier, Carol, that Deven agreed with.

In one sense I agree with it too. We shouldn't have to do this. All we need to do is really say meaningful choice, but the point is that everyone is going to ask this question and this is providing some additional level of clarity, which is opt-in works. Opt-out only works in the case of the triggers when you have some ability for the patients to have knowledge in advance and make their decision before whatever happens happens.

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

Paul, I think that that's important. This slide does capture the context of that it has to happen before the event happens; whereas, the list of bullets is out of context. So I think that the value that this slide provides is that it does provide the context for it as being before the information flows from point A to point B.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But isn't that in the bullet?

Deven McGraw – Center for Democracy & Technology – Director

Maybe not as emphasized, but it's in the bullet.

Paul Eggerman – eScription CEO

It's in the bullets, but all I could tell you again, Carol, is all that happened in the Policy Committee was a discussion about this exact issue. We talked about the bullets and that's what we got written up on in the press. This gives us a vehicle to get past that and get back to the bullets. I don't think it's—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

It really gives us a vehicle for getting back to one bullet, which is that it's in advance—

Paul Eggerman – eScription CEO

And you have to do all of meaningful choice.

Deven McGraw – Center for Democracy & Technology – Director

Right. So maybe the other way to frame it is if, in fact, the choice is meaningful and there is advanced knowledge and time to make it and all of these other factors are present—

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

Yes. That's good, Deven.

Deven McGraw – Center for Democracy & Technology – Director

Okay. For an opt-out that meets all of these is it permissible for states, HIOs, provider organizations to do an opt-out that meets all of these prompts is I think what the question is on the table. Is there anybody beyond Gayle who would object to that? I'm sorry to put you on the spot, Gayle.

Gayle Harrell – Florida – Former State Legislator

I can tell.

M

Deven, would you please restate that one more time?

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

Yes. I'm not sure what you're asking.

W

Me neither.

Deven McGraw – Center for Democracy & Technology – Director

Okay. So what I'm trying to say is that what we're trying to do is to see if we can make a statement on opt-in or opt-out beyond what we've been able to do in the past. If we emphasize that patient choice should always meet all of the factors on number 11, including time to make it in advance, can we say as a consensus that the choice of opt-in or opt-out, as long as it meets all of those factors, can be up to the states, the individual HIOs?

Judy Faulkner – Epic Systems – Founder

I'm a little nervous about that. A couple of things: One is if you look at those numbers again, with 307 million of their population we're talking about the 7 million, who are very concerned and need to be

Deven McGraw – Center for Democracy & Technology – Director

Judy, I'm saying that it's acceptable to do an opt-out.

Judy Faulkner – Epic Systems – Founder

Okay. But I'm worried. Here's what I'm worried about. The last three bullets, I think that choice is proportional to commensurate with the exchange circumstances. I'm not sure. How do we define what that means so people don't worry about that? The last three bullets; I like the first four. The last three are vague.

Deven McGraw – Center for Democracy & Technology – Director

Okay. Well, to be honest, we put the consistent with patient expectations for privacy, health and safety in there in response to concerns expressed by many on the call, you included, that we take into account the fact that patients would want data to be shared in many circumstances.

Judy Faulkner – Epic Systems – Founder

Yes.

Deven McGraw – Center for Democracy & Technology – Director

Maybe it doesn't belong in here, but that's why it's in there.

Judy Faulkner – Epic Systems – Founder

Okay. Well, I guess maybe it's the one that starts with choice is proportional and must be consistent. That kind of comes under full transparency or education. I think that is a subset of that, but I don't know that each organization can say it is absolutely consistent with patient expectations, because that's a hard thing to do. But we can say that it's fully transparent and educational.

Paul Egerman – eScripton CEO

Judy, the way I look at those issues; maybe I looked at it wrong; is that the form of choice and the amount of attention you put to this whole thing has to also relate to what is really happening. If you had an exchange at all all it did was kept track of immunization status against whooping cough. You might be less concerned about it than if it is an exchange that has multiple episodes of care, complete diagnostic

information, medication information. It aggregates data. What is going on also should have an impact on how you handle the situation is the way I interpreted that.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. I like the fact that it implies that not every circumstance has to be handled exactly the same way. I think that's what proportional means. I think that's a good thing and people know that it's not an explicit requirement. It is a sentiment that says handle the situation appropriate to the consequences. I think it makes sense.

Gayle Harrell – Florida – Former State Legislator

This is Gayle. I'm going to put my \$0.02 in here too. I think that as these are the definition of meaningful choice is very important and I'm in total accord with that definition. I think patient expectation is primary and you need what patients expect to happen, what they expect, how their data to be treated is very, very important. I think I would want to see at least some words in there if you want to wordsmith that a bit, fine. But I want to make sure that we do have something in there that relates to patient expectation as to what is going to happen to their data.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I agree with that. I also want to flag that I think consent should be revocable should be added.

Paul Egerman – eScription CEO

Yes. I agree with Carol. I wanted to make that point as well, so I'll second that one.

Deven McGraw – Center for Democracy & Technology – Director

Okay. I think we've got that later, but we'll list it here.

Paul Egerman – eScription CEO

Sure.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

It should be here. The other thing I want to flag for a downstream conversation is the sort of slippery slope and break-the-glass. We have to define that or not include it, because that can be interpreted to be a lot of things.

Gayle Harrell – Florida – Former State Legislator

I agree with you.

Judy Faulkner – Epic Systems – Founder

Here's my hypothetical situation: I'm a patient and the organization, to the best of its ability, did what anyone would consider full transparency and education, but it didn't match my expectation as the patient for privacy, health and safety. That's my concern, that in the way it's written they don't know what is in my head for expectations.

Gayle Harrell – Florida – Former State Legislator

I think we've had a lot of conversations in the Policy Committee, Judy, with the Paul Tang principle, shall we call it, on what patients reasonably expect. I think there is a pretty consistent view out there on what a patient reasonably expects in the way of privacy of their records currently in the paper world.

Judy Faulkner – Epic Systems – Founder

Well, then if we could say consistent with patient expectations as defined in where it currently says, —Here’s what it is,” that’s one thing. But to leave it vague—

Deven McGraw – Center for Democracy & Technology – Director

Well, Judy, I’d be perfectly happy to take it out.

M

I remember a discussion on reasonable expectations that Deven led a while ago—

W

Yes.

M

That it’s a concept in law and—

W

Okay. Stick the word reasonable in there then.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

W

Yes. It should be reasonable expectations—

Judy Faulkner – Epic Systems – Founder

Then I would feel much better about it.

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

None of these are measurable, Judy. I mean ... patient and transparency either, but personally I think that the patient expectations bullet is one of the most important ones there.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Judy Faulkner – Epic Systems – Founder

I’m okay as long as you add the word reasonable. Then I think this is much, much better.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Okay. I would just say on that that it should be reasonable expectations and it is a concept in consumer protection law and the key factor in determining in that paradigm whether consent should be additional or above and beyond whatever the original agreement was whether or not based on an entity’s actions and relationships with a consumer, whether or not a reasonable person would be unaware of the practice in question.

Paul Egerman – eScription CEO

That’s really good. That’s very helpful, Carol. It actually relates to Gayle’s thing about like the sign. That’s very helpful.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Anyone who is interested in a full explanation of these, I would refer to the document in the common framework, CP3, which goes into detail on all of these actual bullets.

Paul Egerman – eScription CEO

So what I'm hearing though is to insert the word reasonable between with and patient.

Judy Faulkner – Epic Systems – Founder

Yes. That makes a huge difference.

Paul Egerman – eScription CEO

Okay. I'm also hearing to take out the must address, break-the-glass scenarios. Break-the-glass becomes really not a consent issue, but a separate topic.

Judy Faulkner – Epic Systems – Founder

Yes. I think that's very helpful.

Paul Egerman – eScription CEO

Now, the other observation I would make is the discussion about opt-in/opt-out causes us to reread this very carefully. That's probably a very healthy thing, right? That we did that and hopefully that will cause other people to do that too. I view this past discussion as very important and very good in terms of making sure we understand what this means to meet meaningful consent or meaningful choice.

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

It sounds like you're wrapping up, which is good. I'm not trying to stop that, but I would like to know at least that the proposed minor changes that I sent around are considered in the—

Paul Egerman – eScription CEO

Yes. I'm going to get to those, Wes.

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

Okay.

Paul Egerman – eScription CEO

I'm ... the form of consent from the impact of a non-consent. So if it's okay, let's return to this slide. Deven made an alteration. Maybe you should repeat what you are suggesting, Deven, and see if we have a consensus around it.

Deven McGraw – Center for Democracy & Technology – Director

Well, it was almost a whole scale alteration. It wasn't exactly this language. Let me try to: When any of the triggers occur the patient's consent has to be meaningful. We've said this all along and it has to include all of those factors. When choice adopts all of those factors the form of choice, whether it is opt-in or opt-out, can be determined by the state or HIO versus saying nothing on opt-in or opt-out, but leaving the form of choice in terms of the default, having some flexibility there and opt-out being acceptable, but above all, choice has to meet those factors, including being in advance.

Paul Egerman – eScription CEO

Including advanced knowledge, so we also emphasize the advanced knowledge requirement.

Deven McGraw – Center for Democracy & Technology – Director

... advanced knowledge, but making sure that that's not the only factor. Right. And whether we've got at least a majority on that.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Can you explain then what the practical difference is, like the operational reality of this? How are they meaningfully different?

Deven McGraw – Center for Democracy & Technology – Director

So I think the only difference is what's the default.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

No—

Deven McGraw – Center for Democracy & Technology – Director

It all has to be in advance.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes.

Deven McGraw – Center for Democracy & Technology – Director

It all has to have time. It all has to be done outside of an urgent need. It can't be compelled. It has to be with full education. It's just when that time has passed and if you've done nothing as a patient is your data part of the model or is it not. That's the only difference.

M

Yes.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Don't both of these imply that it's not if you haven't made that choice in advance?

Deven McGraw – Center for Democracy & Technology – Director

No. Well, no. No. I mean that's in advance to opt-in.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'm totally confused.

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

I had a hard time too, Carol, because I think we all agree that opt-out has been used historically in many cases as a way to avoid providing any meaningful consent, but here's a scenario that would illustrate the difference I think. I'm a patient. I come in to Dr. Welby's office as part of the intake if I'm a new patient or because I haven't done it before if I'm an old patient. Someone has to do something to make me aware of what data exchange will happen and that I have a choice. Then one of two things happen. Either I say yes, I say no or I don't answer. In the case where I don't answer I've got to think about it. I've got to talk to my husband about it, whatever. Okay?

In the case where I don't answer, after a certain amount of time, my permission is assumed; whereas, in opt-in there is no time limit. My permission is never assumed until I explicitly give it.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Gayle Harrell – Florida – Former State Legislator

What I foresee happening is that there will be a giant sign on the wall that says—

Deven McGraw – Center for Democracy & Technology – Director

There can't be a giant sign on the wall. It doesn't meet our requirements.

Gayle Harrell – Florida – Former State Legislator

Or you are given a piece of paper along with the 14 other forms that you fill out for your history—

Deven McGraw – Center for Democracy & Technology – Director

I still don't think that meets our requirements.

Gayle Harrell – Florida – Former State Legislator

And you are given a piece of paper along with everything else and then you turn in your everything else and you've been informed.

Paul Egerman – eScription CEO

Well, in the first place, that's true for opt-in or opt-out, right? I mean those abuses can happen either way, because you're going to sign a bunch of forms when you get to the doctor's office anyways. It doesn't matter whether one of those happens to be an opt-in or not.

Meaningful consent can be applied or avoided in both, the opt-in and opt-out model.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

W

Absolutely.

Deven McGraw – Center for Democracy & Technology – Director

Yes, which is why that part of it is so important to stress. We're running out of time here. I'm inclined to say that we should frame the letter to stress the very important things that we agree on, which is the consent has to be meaningful and has to have all of these pieces to it. It can't be a sign on the wall. It can't be a check the box amidst an array of papers, because whether that's opt-in or opt-out that's just not acceptable.

Gayle Harrell – Florida – Former State Legislator

I absolutely agree with that.

Deven McGraw – Center for Democracy & Technology – Director

And that's where we're going to get.

Paul Egerman – eScription CEO

So what are we going to say about opt-in and opt-out?

Deven McGraw – Center for Democracy & Technology – Director

We're going to say it's ridiculous to frame the policy in terms of that choice because the more important aspect of it is all of this other stuff. I'm sorry that that's not sexy headline stuff, but it is much more important from a policy standpoint.

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

I'm sorry. So are you suggesting that we take out the language on opt-in/opt-out?

Deven McGraw – Center for Democracy & Technology – Director

Well, somebody else frame it in a way that's going to get us to consensus, because I've tried about—

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

See, I just think that—

Deven McGraw – Center for Democracy & Technology – Director

And I don't seem to be able to do it, so I'm—

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

I don't think we're going to get to 100% consensus, but I've never heard any sort of polling of the group on whether outside of how people line up on the wording. I think during the process of doing that some other concerns were addressed, but—

Paul Egerman – eScription CEO

Are you asking to call the question, just poll the group and vote on this?

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

Yes, I think we need to do that. I mean I think of consensus as being 80% or 90%, not 100%.

Paul Egerman – eScription CEO

So the question is should our recommendation include a statement that says—

Deven McGraw – Center for Democracy & Technology – Director

Opt-out if it meets—

Paul Egerman – eScription CEO

Opt-out is acceptable if it meets criteria and all of the meaningful stuff and it's got advanced knowledge.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

So I am just going to say that even with Wes' example about the time period being if you walk away from the doctor and say, "I want to think about it," or, "I want to talk to my husband," or whatever the example he used was, what is a reasonable time?

Paul Egerman – eScription CEO

Before information is made available.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, but what is a reasonable time period? How long do you have to think?

Paul Egerman – eScription CEO

What we're trying to do here is simply call the question, so I assume the fact that you're asking that, Carol, your vote would be no.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

My vote is I still don't fully understand the difference and if the difference hinges on how long somebody has to wait before your information is shared by default in an opt-out, my feeling is we should say something about that instead of sort of leaving it up to—

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

I wonder if there is any familiar option on recognizing that as a necessary work item in order to get beyond this point.

W

Yes.

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

So I guess the question would be given that that's in the parking lot near the entrance ramp or something, what would you say?

Deven McGraw – Center for Democracy & Technology – Director

In other words, making a note that we will give due consideration to what's meant by advanced knowledge sufficiently in advance; that we haven't turned it into something that's not meaningful.

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

There is some precedence in other laws around, like lemon laws and stuff, where you get a certain window of time to—

Deven McGraw – Center for Democracy & Technology – Director

Lemons are bad because it's only three business days.

Paul Egerman – eScription CEO

So does it help to do what Wes is asking for and poll people or are we not able to do that?

W

I don't understand exactly what you're polling us for.

W

I don't either. Again, I don't understand the difference here.

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

Yes.

Paul Egerman – eScription CEO

You don't understand the difference between opt-in and opt-out?

W

No. I don't understand what you're asking.

Paul Egerman – eScription CEO

What we're asking is a variation of what's written on the screen. Can we say that opt-out would be acceptable if it met all of the meaningful consent criteria, including advanced knowledge?

(Overlapping voices.)

Paul Egerman – eScription CEO

And as a result, providers, HIOs and states have a choice between these two

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

Could I try to phrase it a little differently?

Paul Egerman – eScription CEO

Sure.

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

Vote yes if you believe that opt-in is the only acceptable approach; there is no approach whereby when a patient has sailed—

Paul Egerman – eScription CEO

... vote no.

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

You want that to be a vote no? Okay. Vote no if you feel that any scenario with a patient has failed to affirmatively provide consent, is unacceptable.

Vote yes if you think that subject to some refinement the particular things stated on this slide create the conditions that allow there to be a time limit after which the information is allowed to flow in the absence of an explicit patient response.

Judy Faulkner – Epic Systems – Founder

I've got a question here. What about organizations that are already doing this?

Paul Egerman – eScription CEO

We're going to address that separately.

Judy Faulkner – Epic Systems – Founder

Yes. That's going to be a biggie.

Paul Egerman – eScription CEO

No matter what we have to address that though.

Judy Faulkner – Epic Systems – Founder

Yes.

Paul Egerman – eScription CEO

So does everyone understand how Wes suggested framing this?

Judy Faulkner – Epic Systems – Founder

I understand, but I'm not sure of Wes' example. Your example about the patient, who wanted to decide, then there's a trigger event. The physician has to send—

Paul Egerman – eScription CEO

No. This is not directed exchange. This doesn't apply to directed exchange. One of the wordings that I suggested was to say that this applies to those information flows related to the trigger of consent.

Judy Faulkner – Epic Systems – Founder

Yes. The only thing I would add to that is I think it's unclear a little bit that it doesn't ... as I would think say almost nine and ten and that it's not directed exchange. However—

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

I'd like to suggest that the chairs consider a specific form of response from us now, which is we state yes or no and then state any things that we think need to be clarified as opposed to just asking questions.

Paul Egerman – eScription CEO

Okay. Why don't we start with you, Wes?

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

Yes.

Paul Egerman – eScription CEO

Okay. Who wants to go next?

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

I would like to have the option of voting to do exactly what Deven recommended.

M

Which would be what?

Deven McGraw – Center for Democracy & Technology – Director

Which is that opt-out is acceptable as it meets all of these criteria subject to further elucidation on what's sufficiently in advance.

M

That's what I thought we were voting on.

Paul Egerman – eScription CEO

Yes. So that's a vote yes.

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

No. What I wanted to vote for, which she said earlier, was to not mention opt-in/opt-out at all, but to emphasize the requirement that all of those bullets on the previous page be met.

Paul Egerman – eScription CEO

Is that your current recommendation, Deven?

Deven McGraw – Center for Democracy & Technology – Director

That was one I had given up, but you guys are making another attempt, so—

M

So, Deven, you would vote—

Deven McGraw – Center for Democracy & Technology – Director

You would vote no because you don't—

M

You would vote no; you're not willing to accept the proposition on the table.

Judy Faulkner – Epic Systems – Founder

I support what Paul wrote, as it is. If it gets modified with Deven's recommendation that's fine. I prefer Paul's as is; modified is okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I would vote yes, as long as it's clear that the consent decision is revocable.

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

That's one of the bullets.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, well, it's not on the slide, but—

Deven McGraw – Center for Democracy & Technology – Director

It's not on yet. It will be.

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

I would vote yes. The only caveat would be with regard to Wes' is that rather than a simpler time when an event also might trigger the fact that the patient has not opted out, so if there's some event that would cause somebody to believe that the patient's consent has occurred then it should occur.

Judy Faulkner – Epic Systems – Founder

Can you give an example of that please, John?

Deven McGraw – Center for Democracy & Technology – Director

Yes. I have no idea what you mean by that.

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

I don't know. Maybe I can't think of one. I just don't think a time frame, a set time frame is the answer because it's implicit. I mean if they don't opt-out they don't. They show up for an appointment where their record is going to be used –

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

Outside of directed exchange now.

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

Yes. Okay. You're right. Never mind. I agree. I would just do a yes.

Gayle Harrell – Florida – Former State Legislator

I guess I might as well vote my no. I absolutely agree with meaningful choice and everything we've put there. I think that is absolutely essential that patients have meaningful choice. I think that in order to exercise that they should opt-in; they must have the ability to opt-in. I have great fear that in the long-run how meaningful choice is going to be interpreted and the reality of the situation as to what it's going to mean really makes it necessary for patients to have the ability to opt-in.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

My question then, I really am still stuck on not seeing the difference here again. I think it's the time frame for when if you haven't said anything when the window closes there's really not an issue of opt-in or opt-

out. I think that's a separate policy issue that we should discuss. So I am completely seeing these as almost saying exactly the same thing if they're opt-in or opt-out, but Wes asked a question and I guess it's worth thinking about. Could you envision any circumstance, any circumstance in which there has been an attempt to obtain meaningful consent and for one reason or another it hasn't been possible, there the patients' information should go?

Gayle Harrell – Florida – Former State Legislator

Well, I think they said the break-the-glass kinds of things when you're in an emergency room and you're comatose or whatever.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes.

Gayle Harrell – Florida – Former State Legislator

There are times when you do for the patient's life and safety have to use the break-the-glass scenario. No one has ever said that that should not happen. I absolutely feel that there are times when that would be necessary.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Right. Again, I think for me the issue is to really understand the difference here. I am very worried that the difference is really one of a different policy matter, which is to say when does it go anyway. I think that's something we should talk about and I think we should talk about break-the-glass too, as opposed to seeing either of those as actually being the difference between the opt-in and opt-out as we've written it, because I don't think they are.

Paul Egerman – eScripton CEO

So I'm writing you down as a no.

Deven McGraw – Center for Democracy & Technology – Director

I actually would put her in the same category with Dixie, as maybe raising concerns about when you do feed the beast and give them an answer of opt-in or opt-out, whether you detract from all of the other recommendations that we've made that are so much more important.

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

So should we have an abstain then? I mean yes, no or abstain?

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

I would like to be able to vote for our statement, not including ... in opt-out.

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

So you're then voting no on this, is that right?

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

Yes.

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

Okay.

Paul Egerman – eScripton CEO

Who else haven't we heard from? David Lansky, are you still there? Rachel? Anybody else who hasn't voted, who would like to vote, who would like to say anything?

Joy Pritts – ONC – Chief Privacy Officer

I would, but I'm not allowed.

Paul Egerman – eScription CEO

Thank you, Joy.

Deven McGraw – Center for Democracy & Technology – Director

You're going to ultimately be the one to advise David on what to do with this.

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

Joy, do you think we are compelled to directly address opt-in/opt-out in our position statement on this?

Joy Pritts – ONC – Chief Privacy Officer

I think that whatever guidance you can give; I'm going to be totally unhelpful here; whatever guidance you can give would be helpful.

Paul Egerman – eScription CEO

Joy, that was extremely helpful.

Joy Pritts – ONC – Chief Privacy Officer

Yes.

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

I think it's a real concern that the opt-in/opt-out becomes a distraction from the fundamental message we want to—

Deven McGraw – Center for Democracy & Technology – Director

I agree with that, especially when the distinction that we're making, I don't think is a distinction of opt-in/opt-out.

Paul Egerman – eScription CEO

Let's finish the voting. Deven, do you want to vote on this?

Deven McGraw – Center for Democracy & Technology – Director

Yes. I'm becoming concerned that by making a choice we're distracting from the important message about the meaningfulness of the choice.

Paul Egerman – eScription CEO

So that's a vote no.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription CEO

Okay. Then I vote yes.

Deven McGraw – Center for Democracy & Technology – Director

Again, but it's a vote for I'm steadfastly stubborn about what the important discussion is that needs to be taken.

Paul Egerman – eScription CEO

I understand. So we've got a five to four vote. Just like the Supreme Court.

M

No. No. I wouldn't support something on a five to four vote.

Deven McGraw – Center for Democracy & Technology – Director

Yes. We're aren't as torn on this as we were before, but—

Joy Pritts – ONC – Chief Privacy Officer

Can I ask if the four who did not vote yes, if there is at least a consensus among those four as to how you would word a recommendation so that you could put potentially two on the table?

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

I like what Deven said a while ago where she included at the beginning that it's important to meet all of the criteria on the previous slide, including the requirements for timeliness of the advanced knowledge. Then she said, in which case, it would be up to the state or the HIO to decide how those would be met, but to avoid getting into the tabloid, first-page article about opt-in and opt-out and yet, our message would be the decision, the consent needs to meet all of these bullets.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But would you change our

M

... to decide on this to be out tomorrow. I mean that's not—

Paul Egerman – eScription CEO

I understand, Dixie, that we could change your vote to yes if we had Deven's wording in it?

M

It couldn't be yes then. The proposal there is not to decide the question, all right?

Joy Pritts – ONC – Chief Privacy Officer

If I hear what Deven is saying, and I'm sure she will correct me if I'm not saying it accurately—

Deven McGraw – Center for Democracy & Technology – Director

I might like the way you say it better. Go ahead.

Joy Pritts – ONC – Chief Privacy Officer

It's that the people in the four group want to say individuals should have meaningful choice. Meaningful choice needs would meet these criteria period. They would not say anything about opt-in or opt-out. Is that correct?

Deven McGraw – Center for Democracy & Technology – Director

Either that or the one thing that I did say that when all of those other issues are present the form of choice, whether opt-in or opt-out, is less important.

Joy Pritts – ONC – Chief Privacy Officer

Okay. So, to reiterate, the subgroup, the four group, would say we would support; individuals should have meaningful choice – what was the last thing you said?

Deven McGraw – Center for Democracy & Technology – Director

Should have meaningful choice. It needs to meet all of the prongs on that previous slide, including the revocableness that we don't have listed and in particular, be made in advance.

Joy Pritts – ONC – Chief Privacy Officer

Okay. What was the last item though?

Deven McGraw – Center for Democracy & Technology – Director

Well, the last item was when all of those are present it is of far less consequence whether the default choice, whether it's offered either as an opt-in or an opt-out.

Joy Pritts – ONC – Chief Privacy Officer

Oh, I see what you're saying—

Deven McGraw – Center for Democracy & Technology – Director

It's no different.

Joy Pritts – ONC – Chief Privacy Officer

The key element is the informed part, informed choice, not the means of obtaining that, of exercising that choice.

Deven McGraw – Center for Democracy & Technology – Director

No. I mean I don't consider it to be means. I consider what's the default when the patient says nothing, notwithstanding all of those other pieces.

Paul Egerman – eScription CEO

The impact is almost identical to what the yes people are saying, I think.

Deven McGraw – Center for Democracy & Technology – Director

Yes, but I mean I just want to be really careful about this. It's not as though I don't see that there could be a meaningfully structured opt-out, but I very much worry that that's the lead statement in the article, in the policy and then suddenly we've got these opt-outs that are meaningless.

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

And we've totally lost.

Deven McGraw – Center for Democracy & Technology – Director

Any more so than if we just said opt-in we could have a bunch of opt-ins that are totally meaningless.

Joy Pritts – ONC – Chief Privacy Officer

Okay, so let me say this: I think the five-four distinction is that we have a vote of nine at least on part of this.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Joy Pritts – ONC – Chief Privacy Officer

And I will stand corrected because I'm really not trying to drive this conversation; I'm just trying to summarize it. I think all of you have said that individuals should have some meaningful choice. Meaningful choice would include these following characteristics.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

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

Yes.

Joy Pritts – ONC – Chief Privacy Officer Is everybody in agreement on that?

W

Yes. I agree—

Paul Egerman – eScription CEO

That's correct.

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

I'm sorry. I dropped off the call, so I didn't hear the statement.

Gayle Harrell – Florida – Former State Legislator

Okay. I have ... and I don't know who it was who said that you're not going to get Gayle in on opt-out. I absolutely agree the key to the whole thing is meaningful choice and I'm 100% there.

Joy Pritts – ONC – Chief Privacy Officer

Okay. So let's work on that. That's where we were, Wes. What I was saying is I think the five and four are very close and I'm not trying to put words in this group's mouth, but I'm just trying to summarize what I think I heard, which was that all nine agree that individuals should have meaningful choice and meaningful choice—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Is defined by those bullets, right.

Joy Pritts – ONC – Chief Privacy Officer

Is defined by those bullets. Is everybody in agreement on that?

M

Yes.

Deven McGraw – Center for Democracy & Technology – Director

Yes. We already put that up for the Policy Committee and they agreed.

Joy Pritts – ONC – Chief Privacy Officer

Okay. So you still agree to that, so that's one part. Now then, we have uniform recommendation on that. Then the next one is among the group there is some disagreement I think; I don't know; about whether you should even talk about what the best form of that choice should be.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

No. I think where we are is that I'm not sure and I think Deven said this and I've been struggling with it. I'm not sure if we get all of those parameters defined I'm not sure what the difference is between them talking about opt-in/opt-out. In other words, if all of those criteria are met and if we're worried about time periods let's talk about time periods. That's not an opt-in/opt-out issue.

M

It's a question. I mean I see it as a question of does there finally have to be an act by the patient or not?

Paul Eggerman – eScription CEO

Wait. Wait. Wait. We're starting to rehash the discussion and we're actually a little bit past time, so—

Joy Pritts – ONC – Chief Privacy Officer

We're not rehashing, can I just say the question is is there a substantive difference if all of those criteria are met and if so, what is it?

Paul Eggerman – eScription CEO

That's a good question, but getting back to what you're saying, Joy, we have to give time for the public to make comments too, are you heading in the direction you want to head in terms of getting information you want in terms of summarizing?

Joy Pritts – ONC – Chief Privacy Officer

Well, we got part of it, but I know that we need to let the public comment here, but I was trying to identify the areas where everybody agreed and then I think we can have another area where people may not agree wholly, but to the extent that there is full agreement that's useful to know.

Paul Eggerman – eScription CEO

Yes. I think there's full agreement on meaningful choice.

Joy Pritts – ONC – Chief Privacy Officer

Right. And, Carol, I think what I have heard in the past has been the difference is really largely one of paperwork and of administrative burdens. I don't know enough on that to be able to know the implications of that, but there are people who feel very strongly about that. I've heard it both ways; that it's difficult to implement and opt-in because you have to get a signed piece of paper from everybody and then you have to maintain that. I've heard it from other people that say once you have the system in place if you're going to have a system it doesn't really matter. I've heard all of the opinions on that. I really don't know what the answer is on that and I would not even pretend to express an opinion on it.

Paul Eggerman – eScription CEO

Okay. This has been an extremely interesting and helpful discussion. The full four hours have been terrific. I hate to be cutting it off when people are very energized, but we do have to give an opportunity for the public to make comments. Before I do that, again, I want to thank everybody for hanging in there and for putting forward interesting and enthusiastic comments. Deven and I will still write this up somehow in the form of a textual document. We do have one more meeting on the 16th. This will give people an opportunity to answer all of the issues.

Deven McGraw – Center for Democracy & Technology – Director

Yes. We'll get that out to you next week as early as I possibly can so that you have plenty of time to read it before the meeting and maybe we can even have some dialogue on it depending on whether there's time to do that; e-mail dialogue, but—

Joy Pritts – ONC – Chief Privacy Officer

Deven, it also seems to me that there is an area here that Carol raised, which is what really are the practical implications of is there a difference between opt-in and opt-out. I'm going to see if we can't find somebody in this office who might be able to at least identify some people who might be able to either talk to you or something.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Joy, that should be fun. The context of the meaningful choice criteria we have. We know that there is a material difference without those criteria.

Joy Pritts – ONC – Chief Privacy Officer

Yes, I know, but—

Paul Egerman – eScription CEO

... helpful.

Joy Pritts – ONC – Chief Privacy Officer

Okay.

Paul Egerman – eScription CEO

So those are helpful comments. I understand that Judy Sparrow had to leave, so there should be somebody, I think, from Altarum on the line, who can open the line to the public if the public wanted to make any comments.

Operator

Our first comment comes from Lester Kepper with LHK Quality Associates. Please proceed with your comment.

Lester Kepper

The unsaid word here is how are the benefits going to flow, not only to the patient, but to the people that have to do the work and the paperwork that was implementation and then how it's going to be done.

Paul Egerman – eScription CEO

Thank you, Les. Very helpful.

Operator

We haven't any more public comment.

Paul Egerman – eScription CEO

Well, great. I just wanted to take a moment again to sincerely thank everybody. I feel a little badly I had to cut off some very interesting discussions that were going on, but I did want to make sure there was a chance for public comment. We do try to run the meetings and end the meetings on time, so thank you very much, especially; Judy Sparrow is not on the call; but thank you, Judy and Joy and the people from Altarum, who helped us. We've made great progress and discussions will continue.

Deven McGraw – Center for Democracy & Technology – Director

Thank you, everybody.

Participants

Thank you.

Public Comment Received During the Meeting

1. If a CE doesn't know when consent is needed, then they are not fulfilling their role as a CE. Aggregation is a purpose of use... NOT A TRIGGER. I thought the HIT Policy tiger team was to create guidance, not new law.