

Tiger Team

July 16, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the Privacy & Security Tiger Team. This is a Federal Advisory Committee and there will be opportunity at the end of the call for the public to make comment. Let me do a roll call. Deven McGraw?

Deven McGraw - Center for Democracy & Technology – Director

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Paul Egerman?

Paul Egerman – eScription – CEO

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Latanya Sweeney? Gayle Harrell?

Gayle Harrell – Florida – Former State Legislator

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Carol Diamond? Judy Faulkner and Carl Dvorak?

Judy Faulkner – Epic Systems – Founder

Here.

Carl Dvorak – Epic Systems – EVP

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Dave McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

David Lansky? Dixie Baker?

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

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Micky Tripathi? Neal Calman? Rachel Block?

Ellen Flink – NYSDOH – Dir., Research in Patient Safety & Quality Initiatives

Rachel is not here, but Ellen Flink is representing her. Hello.

Judy Sparrow – Office of the National Coordinator – Executive Director

Hello, Ellen. Thank you. Christine Bechtel?

Christine Bechtel - National Partnership for Women & Families – VP

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

John Houston? He's there; I know. Wes Rishel?

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

Here.

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

I'm here. I'm sorry. This is John Houston.

Judy Sparrow – Office of the National Coordinator – Executive Director

Leslie Francis?

Deven McGraw - Center for Democracy & Technology – Director

She's on the public line. We're asking John and Leslie to tag-team.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay. Joy Pritts?

Joy Pritts – ONC – Chief Privacy Officer

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

Anyone else? Did I leave anybody off?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Hello. This is Micky Tripathi.

Judy Sparrow – Office of the National Coordinator – Executive Director

Micky. Good. All right. Thank you.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

And Carol Diamond is here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Great. Thank you, Carol. Good morning. I'll turn it over now to Deven and Paul.

Paul Egerman – eScription – CEO

Good morning. It's Paul Egerman. I wanted to say good morning and welcome you to our Tiger Team meeting. It's very impressive that we have pretty much a full house. So many members are participating and I thank you for your dedication. This is not an easy process and we are having some very intense and spirited discussions and I very much appreciate everybody's participation. It's very impressive.

I also want to thank any members of the public, who might be listening in. As Judy Sparrow said, there will be an opportunity for public comment at the end of the call.

To very quickly remind everybody, we are a group that's called a Tiger Team. We're a relatively small group of people that was organized to do some very intense work over the summer months, over July and August, to really assist ONC, the Office of National Coordinator, with some very specific privacy and security issues that have arisen. So that's who we are. Whatever decisions we make are not really decisions. Our decisions are really recommendations that go before the HIT Policy Committee, which, in turn, are recommendations that go before the National Coordinator.

Having said all of that, to very briefly review what the agenda is today and talk about what else is going on, first of all, you will notice perhaps that the slides and the way we're going about this process is not quite as professional as we did it in past meetings. The reason is, unfortunately, there was a contracting issue, a federal contracting issue with the good people at ... and so, at least temporarily, we lost our staff support from ..., which Deven and I are very much hoping and praying will be soon returned.

Deven McGraw - Center for Democracy & Technology – Director

We're working on it.

Paul Egerman – eScription – CEO

Yes. I have absolute confidence—

Deven McGraw - Center for Democracy & Technology – Director

There was a gap in the contract and it lapsed and we're trying to get it reinstated as soon as possible.

Paul Egerman – eScription – CEO

Yes. So I'm sure that will occur. So what will happen during this call is when we get a little bit further down the line you'll see that Deven has volunteered to be like the note taker, so she's going to do her best to like type stuff on the screens. You'll see some of the screens – we became very much of a black and white presentation so you will see that's the underlying reason why.

Now, the other thing that is going on right now is we completed a very robust, a very good discussion on the whole issue of data collection and uses and reuses and we've been circulating the document. A number of people have been red-lining the document with various comments. What we're going to do is, consistent with the ground rules, we're not going to do the wordsmithing of that on this call, but I want to assure everybody that everybody's edits and comments are basically being accepted. If they're not accepted for whatever reason we'll tell you that. They're all being accepted. The only other reason why if you put forward a suggestion that doesn't get accepted, sometimes people will independently put forward basically the same thing.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

I think there was something that Judy Faulkner suggested that it turned out Dixie had said with slightly different words a day earlier. So that would be the only other reason why when you see the final document you might not see your exact wording. But what's going to happen with that, just to make sure everybody understands, is sometime, probably what, over the weekend, Deven?

Deven McGraw - Center for Democracy & Technology – Director

Yes or later today if I can.

Paul Egerman – eScription – CEO

Okay. So later today, but maybe over the weekend, Deven will produce another draft of the document, which, hopefully, incorporates everybody's comments so you'll have another chance to look at that. That will be, hopefully, the draft that we will then submit to the Policy Committee on Wednesday, but even then I do want to remind everybody what our basic process is, which is that sort of like everything we do is still, I would call it, somewhat tentative because the basic process is to walk through all of the issues we need to walk through and then towards the end of our schedule we have an open meeting where we're going to go back and review all of our decisions, because it could very well be that we talk about consent today or maybe when we talk about sensitive data next week there is some new understanding of issues that causes us to want to go back and change something that we did, say, on data collection or to expand it. So there will be an opportunity to look at all of our material as a whole.

There is also an opportunity as people go through these things. One other issue that can arise is basically sometimes people will raise new issues when they look at things. So when that occurs we're sort of like putting them on the parking lot. I know John Houston raised an issue about syndromic reporting I think—

Deven McGraw - Center for Democracy & Technology – Director

Surveillance. It was both, John and Leslie.

Paul Egerman – eScription – CEO

Yes. And we think that's a great issue, but we just view that as something we haven't discussed yet, so we'll put that on the list. I want to assure everybody that the intention is to capture everybody's comments on this. Also, thank you for the comments, because the comments are actually very good. You're making sure that this document is clearer and you're clarifying it and getting rid of the ambiguities and that's terrific.

So before I go on and talk about today's agenda and consent, is everybody okay for the status of that? Are there any comments about what I just said?

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

We're working from a document and I know Deven published a presentation as well. I'm just wondering what is the master document for providing feedback and what are we going to really work from?

Deven McGraw - Center for Democracy & Technology – Director

I'm going to send the latest version that incorporates all of the comments or that I think incorporates all of the comments for you all to look at. Again, I hope to get that out today, if not, over the weekend, but I'm really aiming for today. The idea is for people to, if I haven't gotten the substance right most importantly or if you want to suggest additional wordsmithing changes that would be the time to do it. I think in the future we want to explore, particularly when we get the ... team back, creating a wiki, a site that we can use to comment on documents so that we don't have to worry about people commenting on versions after, in fact, additional comments have already been made. So to avoid a circumstance where, again,

people are commenting on old documents. So we're looking into that, but we weren't able to sort of pull that off for this round of meetings, but we hope to, because that would be much more efficient.

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

But I was also thinking that we have a document and we'd also have a PowerPoint now that are sort of ... I'm just wondering—

Paul Egerman – eScription – CEO

Which is the most recent, Deven, the PowerPoint's or the documents? Which should they be red lining?

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

What's the order of precedence on those?

Deven McGraw - Center for Democracy & Technology – Director

I don't remember doing a PowerPoint on the recommendations.

Paul Egerman – eScription – CEO

So it's a document.

Deven McGraw - Center for Democracy & Technology – Director

I didn't. It's a document. Yes. Don't red line anything you have in your e-mail box now. You should wait. The slides that you got were the consent slides that we're going to talk about today.

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

All right. I just thought there was some overlap between them somewhat, so I was wondering how they all fit together, but that's fine.

Deven McGraw - Center for Democracy & Technology – Director

Well, but I mean anything we do on consent, of course, presumes the set of recommendations that we're sort of finishing the wordsmithing on, but that we basically are substantively in agreement with.

Paul Egerman – eScription – CEO

Okay. So, unless there are other comments, are we ready to move on to consent? The discussion about consent is a discussion that we actually started at our call earlier this week.

Deven McGraw - Center for Democracy & Technology – Director

Yes. It was just on Tuesday.

Paul Egerman – eScription – CEO

It was just on Tuesday. It seems like it was six years ago, but it was just on Tuesday. So the idea is what we were hoping to do, as you see the agenda on your screen, was to really focus today's entire discussion on this entire topic, which is clearly; I don't know if contentious is the right word; but it's certainly a controversial topic. This is an issue where we, as a team, can be doing what we're supposed to be doing, which is to take on the complicated and controversial issues and providing some assistance to ONC on those issues.

Now, the slides, I mentioned we don't have ... involved, but the slides are slightly not quite in the order I want to present, so here's what I want to say: For today's discussion I want to make sure we frame the discussion today. Today we're reviewing consent from the standpoint of a patient's participation in exchange generally, so which is sort of like a yes/no decision. The things that we are not discussing

today are granular consent issues, in other words, consent by type of information. So this gets into the whole issue of sensitive information and that issue we will be discussing. Hopefully we'll be able to get to it next week, but this is sort of more of a general consent discussion.

To go back to the previous slide, Deven and I thought it was helpful to frame this discussion around some fundamental principles and the fundamental principle, which is a principle that we've referenced in our recommendations related to authentication that we think is really important is this comment that is first written here on this first bullet. The relationship between the patient and his or her healthcare provider is the foundation for trust. It says that in the health information exchange there is also a foundation for trust in everything actually, in my opinion—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Before we start going into the slides there are two terms that you used that I don't understand. One is Health Information Exchange. What do we exactly mean by that? Because I know that you said well it's not sensitive data. I think when you speak it implies that we all know what's being exchanged and I'm really struggling with understanding what you mean by that because, in my experience, one of the things that makes consent very difficult to work through is that you really have to know the answer to the question consent to what.

Paul Egerman – eScription – CEO

That's right.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'd really like to understand how you define health information exchange if that's the context.

Paul Egerman – eScription – CEO

Yes. That's an excellent question. Health information exchange is exchanging the information, health information, about a patient from one provider entity to another provider entity.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But which health information? Is it the entire medical record? Is it a referral? Is it just laboratory? This is my struggle with it; that health information exchange has so many ways of being implemented that it would be helpful to try to at least create a concept for ourselves that puts some more context on it.

Deven McGraw - Center for Democracy & Technology – Director

Well, I suggest we continue with the parameters that we set forth in the beginning of this particular round of Tiger Team discussions, you know, beginning with our series of meetings on collection, use and disclosure, limitations, data, reuse and retention. That is that we're focusing on the exchange of information that's required for stage one of meaningful use. Sometimes that's just a lab test result. Sometimes that's a public health report. Sometimes it's response to a need to send quality information to CMS, but that would sort of be our defined universe.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

So that's not implied in the material so far or in the slides, because it says broadly, —health information exchange.” I would just ask that we clarify what we mean very specifically, because without that it's really very hard to have this conversation.

Paul Egerman – eScription – CEO

Okay. So that's a good comment and so we should do that.

Deven McGraw - Center for Democracy & Technology – Director

Yes. That's fair.

Paul Egerman – eScription – CEO

That's fair.

Deven McGraw - Center for Democracy & Technology – Director

I think Paul and I didn't repeat it on the slides. This where the ... folks were always helpful. They always started by repeating the parameters that we'd agreed that we would start from—

Paul Egerman – eScription – CEO

Yes.

Deven McGraw - Center for Democracy & Technology – Director

And we forgot to do that.

Paul Egerman – eScription – CEO

Actually, that's a good comment, Carol, because there are a few other parameters that I want to mention.

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

I think there's a follow-up on Carol's point though. I think there are a lot of exchanges or entities coming together that will have exchange functions or functionality and so there is a little bit of a concern about this being sort of a raised condition, because they're forming as these recommendations are being put together and if we're doing phase one of meaningful use we may find though from a timing perspective that these exchanges that are going to be beyond that are already formed. I think some of them will come back and say, —Oez, I'm now going to have to overlay a whole new set of requirements over top of ... exchange is already formed that didn't exist before,” and so I just think we need to be mindful of that as well.

Paul Egerman – eScription – CEO

Excellent point, John. That is one of our challenges. I guess that's why they put us together and called us the Tiger Team. There is a time pressure here because it's sort of like the train has left the station on a lot of this stuff. There are some interesting challenges.

But picking up on what Carol said, excellent point in terms of defining health information exchange. What this slide is trying to suggest is one of the fundamental principles that we referenced before is the patient-healthcare provider relationship; that that relationship is a foundation and a concept that providers hold the trust and are ultimately responsible. Providers may delegate some decisions, but this is the principle that we've used before and so the idea is just to reference it again. So it says there in the second bullet, —Decisions about patient choice should flow from and be consistent with this fundamental principle.”

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Paul, I'd like to add to that. I think no matter what kind of exchange you're talking about, if it's only dealing with meaningful use in stage one or it's what we anticipate to be stage two, which is going to be much more robust exchange, you have to set that principle, I think; I really have a problem with limiting it just to meaningful use, as defined right now, because that is absolutely the core, fundamental principle that has to go through whatever exchange we're talking about.

Paul Egerman – eScription – CEO

I agree.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

W

And—

Deven McGraw - Center for Democracy & Technology – Director

No, I don't think we were suggesting that as a principle limitation, although it came up in that context. I think when we get to some of the more specific questions on the slide about consent, I think, and the factors that lead us to want to reply or something beyond additional law, that's when it's more important to think about what universe are you talking about.

Paul Egerman – eScription – CEO

Thank you for that comment, Deven, but Carol puts forward the definition of what we mean by information exchange, but another word on the screen that you could ask about is what does this word trust mean, because that means a lot of different things in a lot of different contexts. But one of the things that, to me, trust means is patients trust their physicians. That's a fundamental thing. I don't think they necessarily trust other entities within the healthcare, within the alphabet soup of healthcare entities that we have, but they do trust their physicians and that's got to be our sort of building block.

But to continue on in some of the principles, to make sure that we're building on things that we've already done, I also want to put forward this slide that there is a previous recommendation from this is actually the Privacy & Security Workgroup, which is sort of like our predecessor in some way. That said that patient choice is not needed beyond whatever current law may require in directed exchange from one provider to another for treatment. So what that means is, to pick up the example that Carol gave, a physician or doctor's office orders a laboratory test. You don't need consent from the patient in order to get the test result back from the lab.

If you order a radiology exam, which really is perhaps some outside radiologist reads the x-ray, you don't need consent for the radiologist to transmit the x-ray interpretation back to the primary care provider. If the primary care provider sends the patient to a specialist, a hand surgeon or something, and they have to read the x-ray, it's the same thing. They transmit data related to that treatment of patient. We're saying those do not require consent. That was a decision that was already made from the previous workgroup, so this is not really a discussion about directed exchange as it relates to providing treatment to patients. So we want to make sure that we build on that as one of our foundations.

The other things that I think we need to build on as we do this discussion, we should assume that the fair information practices, the material that we've already agreed to and we're going to agree to, that all of the parties are participating in that policy framework and we should also assume that whatever security rules that we establish, that all of the parties will be doing whatever security and whatever message transport or whatever rules that we establish so we don't have to keep repeating those every place. In other words, those should also be listed here, but we were a little short staffed. We didn't list them, but those are also basic fundamental assumptions that are in place.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Paul, just a question; and I think this gets back to John Houston's question earlier. It would be good to understand what the final deliverable looks like. In other words, how all of this is going to come together as a framework, as opposed to a set of; I understand it's an artifact of the fact that we're trying to go

through these issues one at a time; but a set of independent recommendations that don't nest themselves inside of an understanding that all of the elements of a framework are applied.

Deven McGraw - Center for Democracy & Technology – Director

Yes. It's a good point, Carol. It's actually articulated much more clearly in the recommendations that were circulated this week on paper that state with certainty that entities involved in health information exchange, providers, third party service providers, should follow fair information practices when handling patient information. Then the specific answers to the questions flow from that, but these consent recommendations, all of them, including, I would argue, even this previous recommendation flow from an assumption that the entities involved are following steps and that there is a framework of accountability, including security and there is a framework of accountability, oversight and enforcement. I think we all recognize that there is still work to do on that, but we've at least recommended that all of the parties need to adopt and implement that.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. In my view we haven't worked on some of those very important elements yet and it has an effect on some of these one-off discussions.

Paul Egerman – eScription – CEO

That's right. Again, you raised another great point, Carol, but part of the reason we were approaching it this way is also related to John's comment. On a lot of these issues the train has left the station. People are asking questions and while it may not be the ideal way to address these issues, it's also not a bad way. If these are the real questions people are being asked, if we can answer them in the process of answering them we develop the basic concepts and thought processes and policies that are used to create the correct framework.

Deven McGraw - Center for Democracy & Technology – Director

I also want to go back, Paul, to something you said earlier about opportunities that we will have later in the summer to try to look at this as a coherent whole and make sure it fits together well and identify where the gaps are that need further work, which then I would expect that the Policy Committee's workgroups, whether it's the Tiger Team, the larger Workgroup; I'm not sure what's going to happen yet after the summer, but there is a continuing body of work that needs to be built here. I don't think anybody disagrees with that.

But we have to be vetting some of this stuff to the Policy Committee as we go. Quite frankly, we're more likely to be able to sort of get by and along the way if we're giving them opportunities to comment on some of what we're working on earlier in the process and get and incorporate their feedback.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. That's why I'm asking about the ultimate deliverable. It would be good to have something skeletal that places all of the issues on the table that we need to get to. Some of it could be highlighted a different way and some of it could indicate that we still have to get to those issues, but to make it clear, every time we speak about these policies, that there are a set of them that need to be working together in order to achieve our objective.

Paul Egerman – eScription – CEO

That's very helpful. You're right, Carol, because it does indeed flow exactly from my comment because I'm saying here we have a previous recommendation from the workgroup about directed exchange not requiring consent. We want a reference that fits. We want a reference that there is going to be some security and message handling policies and so, yes. What you're saying is that in some sense that's the

beginnings of a description of this exact kind of package that you're looking for, what the whole thing will look like when we're done. That would be helpful, so great comment.

So, in continuing on, as I say, we've got this previous recommendation. We've got the assumption that all of the parties are following the policies and all of the parties are following whatever security rules we put together. Then we have these six questions that we put forward and started to answer the first one last Tuesday. When we go through the questions you'll see I rephrased question number one, which is, ~~What~~ "What factors triggered the need for patient consent to participate in information exchange?" That's the first question.

The second question we also changed a bit. What approach should ONC take to a national policy on choice? It's not quite the same as the question before, but it's just reflecting the fact that this is what we do. We advise ONC on what they should do for a national policy. The third question that actually created a somewhat interesting exchange of e-mails between Wes and me that I think people saw was, ~~Should~~ "Should providers have a choice as to whether they participate in models of exchange?" Then we have these final three: Who should educate patients about choice? How and by whom should consent be obtained and managed and consent durability?

So, to dive into the first question; and what's going to happen as we dive into this, this is a process whereby Deven is about to show her unbelievable, flexible series of talent and she's going to share her desktop and help you describe as we go through this.

Deven McGraw - Center for Democracy & Technology – Director

Yes. Cross your fingers, everybody.

Paul Egerman – eScription – CEO

I can't tell you how excited I am to see when the screen changes, but this is the process. The screen is about to change, which makes it hard for me to actually read this, but the question is, ~~What~~ "What are the factors that trigger the need for patient consent, to participate in information exchange?" So you need to be on, actually, the next slide, Deven.

Deven McGraw - Center for Democracy & Technology – Director

Yes. Got it.

Paul Egerman – eScription – CEO

Okay. So, if you're looking at this like I am, you might want to push the Full Screen button on your screen, because it got a little bit small. In looking at this question and reading what people had written on it, what I did was I sort of tried to rephrase it a little bit. The way it was written before, people said, ~~What~~ "What are the factors?"

Somebody would say, ~~Well~~ "Well, you want to know who has control of the patient information." So I wrote this more in the standpoint of this is what a specific trigger would be. So the concept is if patient health information is no longer under control of the patient's provider, and we're saying that triggers a consent decision or a consent circumstance, that's the way I'm trying to rephrase it is what's the trigger. What causes this to happen?

So I wrote that. I wrote, ~~The~~ "The patient's health information is retained by intermediary," as opposed to what was written before. This was a question of where health information is retained. I wrote, ~~Patient's~~ "Patient's information is aggregated with information about the patient from other records." Again, that was partly

also a response. These are all things that were talked about last Tuesday, but it was just rephrased a little bit. The last one is with sensitive data.

So let me pause now and see, first, if people understand what the question is and if they want to comment on these responses or if they have other responses they want to add to these.

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

I did send some responses that are not incorporated here. Do I need to go through those again?

Paul Egerman – eScription – CEO

Yes you do, but you have to put them in this format. In other words, you can't say we need to know what data is involved. If there is specific data—

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

My wording was quite similar to this, but—

Deven McGraw - Center for Democracy & Technology – Director

Dixie, just so you don't think we were completely ignoring your responses, that was not our intent. But some of the incremental responses that people sent, at least in our opinion, fit under these broader categories. So, of course, if you think we're wrong you should point that out.

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

Well, the first one read, “I think that we should acknowledge that it's not just under the provider's consent, but under the patient's or the provider's control.”

Deven McGraw - Center for Democracy & Technology – Director

What do you mean by that, Dixie? We're talking about we do have a universe of provider-to-provider exchange for stage one.

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

Okay. Well, stage one also allows the patient to be in control as well.

Paul Egerman – eScription – CEO

Well, I'm not sure what you mean by control.

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

The same thing you mean in your bullet.

Paul Egerman – eScription – CEO

Yes. Actually, when we put this together there was an e-mail Carol sent that had a better description of control.

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

All I would suggest is that it says the patient's health information is no longer under control of either the patient or the patient's provider.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. This is David. I like that wording, because I do think the patient – we can't ignore patient control of their own data or if we do ignore it we need to carve it out up front as a non-covered case.

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

Okay.

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

I think the principle is important. Sometimes you actually reiterate things merely to emphasize the importance of the principle, but if you look at who has actual control of the data, if the data is in the provider's records it is the provider, who has control of the data. The provider uses, is guided or commanded by policy or law in terms of how it exercises that control in releasing the data, but the patient doesn't have control of this data.

Paul Egerman – eScription – CEO

But we may have a copy of it. They can't be restricted with what they can do with their copy of the data is the question.

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

I understand, but what we're talking about here is the exchange between providers—

Paul Egerman – eScription – CEO

Yes. Wes is right on this. I mean I think about my medical record. I don't really control it. My physician has that record. I can correct it if I have access to it—

Deven McGraw - Center for Democracy & Technology – Director

But I don't see the harm in phrasing it this way—

Paul Egerman – eScription – CEO

I don't either.

Deven McGraw - Center for Democracy & Technology – Director

Especially if we know that in some areas of the country they are experimenting with exchange using health record databanks that are, in fact, patient controlled.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I agree with adding the patient, because for me the consent that's most important here is that it's the patient or the person that has the relationship with the patient.

Paul Egerman – eScription – CEO

Yes.

Judy Faulkner – Epic Systems – Founder

I'm wondering if we should also address something like emergency circumstances. Would that go here? The ones that I have specifically heard people tell me about are ambulance situations and critical situations where patients are brought into the ED. I certainly have heard of ambulance situations where the information could not be shared and the patient suffered.

Paul Egerman – eScription – CEO

Yes. That's a good question, Judy, but that's actually the opposite of this question. That's actually a question that sort of says what are the circumstances in which access to the record is obtained, where consent is not needed.

Judy Faulkner – Epic Systems – Founder

Okay. Are we going to do that?

Paul Egerman – eScription – CEO

We don't have it on the list, but we certainly could and should. I sort of picture doing that as part of the sensitive data discussion.

Judy Faulkner – Epic Systems – Founder

Because on the first one there, when you say patient's health information is no longer under the control of the patient's provider, to me that says patient and ambulance going somewhere in a strange city, not under the care of the provider, need the patient's consent. That's how I read that.

Paul Egerman – eScription – CEO

No. Again, we may need to do some wordsmithing around the concept of control. This is more an issue where somebody other than the provider gets to decide who has access to that data.

Judy Faulkner – Epic Systems – Founder

As long as we keep in mind that people will do very strange things as they misinterpret how we word things.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

That's right. I mean I—

Deven McGraw - Center for Democracy & Technology – Director

We can try to keep that from happening, Judy, but it's not an easy thing.

Paul Egerman – eScription – CEO

Yes.

Judy Faulkner – Epic Systems – Founder

Well, where we recognize it; and I think right now it's the ambulance situation; we should put that on the parking lot.

Paul Egerman – eScription – CEO

Yes.

Deven McGraw - Center for Democracy & Technology – Director

Can I suggest that when we get to the specific discussions about like form of consent and if consent is required and maybe throw that into a break the glass discussion that we don't have in the agenda, but we should.

Judy Faulkner – Epic Systems – Founder

Okay.

Paul Egerman – eScription – CEO

Yes.

Deven McGraw - Center for Democracy & Technology – Director

That should definitely go on the agenda at some point and perhaps temporarily in the parking lot.

Judy Faulkner – Epic Systems – Founder

Right.

Paul Egerman – eScription – CEO

Right. And probably what we need to do, I don't know if we want to necessarily do this now, is we also probably need to wordsmith a little ... this concept of control—

Judy Faulkner – Epic Systems – Founder

Yes. Right, Paul.

Paul Egerman – eScription – CEO

This wording; I think it was Carol that suggested it when we were talking about models and so I sort of picked up on that wording, but I think it's really who gets to decide what's going to happen to get access to the record is sort of one of the issues there.

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

Paul, this is Dixie Baker again. I think that the second bullet out I would say the same thing about the word retained. We need to define that, because there are some functions and maybe capture our words about functions within the business associate agreement because a lot of the functions that an intermediary might perform would require retaining for a certain period of time. I think at one time we had the idea that; I think this is David McCallie's idea; it was retained for some future use rather than what—

Paul Egerman – eScription – CEO

Yes.

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

You know—

Paul Egerman – eScription – CEO

Yes ... the issue was it gets a little bit complicated about whether or not somebody is keeping an audit trail—

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

I think it just really—

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

....

Deven McGraw - Center for Democracy & Technology – Director

Let's let John get in. He's not been able to yet.

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

With respect to that concept of retaining an intermediary, I think some of the forums in which this is going to occur is going to be if there is a community health record or there is a record that is constructed by multiple providers. The idea that there is an intermediary is almost a misnomer. I understand that we were talking about exchanges between providers, but again, I think what we're seeing is that some of what's being designed here is going to be based upon this consolidated record and how do we deal with that in the notion of retaining data, which we know is going to occur.

Then another fundamental question I have is what is, qualitatively, the consent going to be and how detailed is it going to be in such cases—

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

John, I think that's point three here.

Paul Egerman – eScription – CEO

Yes. We're going to get to that.

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

Yes.

Paul Egerman – eScription – CEO

We're going to get to that, John. Your comment about community record in some sense leads to the third bullet here, which is I'm not sure this is the same thing you're saying, but data may be aggregated with information—

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

Yes. Maybe. I look at that and maybe it is, but back to my other point though about the consent; I think part of all of this gets overlaid with the notion that the content of the consent is also going to be very important and then maybe I'll withhold ... when we get to the third bullet point

Paul Egerman – eScription – CEO

I agree, but right now the issue, we're saying, is we already said directed exchange doesn't cause consent. We're saying what does trigger consent.

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

Right.

Paul Egerman – eScription – CEO

What the first three bullets together are saying is, as well, you've got this patient-provider relationship. You've got trust between the patient and the provider. Somehow the patient's record flows outside that circle of trust and now some other entity either is retaining the data or has control over the data or is somehow taking the data and matching it with other sources. We're not saying it's bad; we're just saying there is a consent; that that triggers consent.

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

I don't think the retaining is what triggers it. This is Dixie Baker. I think that, to go back to our expectation principles, I think that the fact that people with no functional relationship to my care have access to my data is what triggers it.

Paul Egerman – eScription – CEO

Again, when I put this together I was simply trying to reflect back what Tuesday's discussion was. So you suggested we don't really need the second bullet?

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

That was from Tuesday's discussion ... of Tuesday's discussion. Yes. You know, you expect that your provider, other providers that your provider might consult with, your payer – you know, there are certain people that are directly related to your care that you assume they have access to your records, but if your

provider is sending it to somebody that you have no idea, that you would go, “Why would they have access to my records?” I think that triggers consent.

Gayle Harrell – Florida – Former State Legislator

I think the aggregation of any information also triggers consent.

Paul Egerman – eScription – CEO

I agree with you, Gayle, but if you could hold onto that issue for a minute, I just want to wrap up what Dixie is saying –

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

To build on Dixie’s point, a real-life example that maybe can tease this out is what IHIE, the Indiana Health Information Exchange, and HealthBridge in Cincinnati both do now, where they are the intermediary. They get lab results from hospitals and they store them on behalf of the physician participants. There are some participants who they deliver; they’re just a router; and they just deliver it via whatever interface they’re using to their EHR. In that case they’re just a pass-through, but for those who don’t have an EHR they are effectively the application that stores in perpetuity the lab results for those particular patients. So it is retained, but it is retained on behalf of the end user, who doesn’t have another application of their own.

Paul Egerman – eScription – CEO

So between what you’re saying, Micky, and what Dixie is saying, you’re both saying to delete that second bullet?

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

No.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

No.

Paul Egerman – eScription – CEO

What are you saying?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Well, first off, I just wanted to ask the group when we think about retained by an intermediary that is one example. The other, I think, that we just need to refine the definition of retained probably relates to what it’s being retained for so, for example, we’re dealing with this in a state where we’re working with their HIE. There are many EHR systems and, indeed, maybe most that don’t well taking unsolicited data from the outside, so even though you’re technically pushing stuff to them, in principle, the intermediary is actually retaining it while the system might, every nanosecond, ping it and then grab the data when it’s available. There may be milliseconds it is actually retaining the data—

Paul Egerman – eScription – CEO

Yes. So, Micky and Dixie, what do you recommend we do to fix bullet number two?

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

For me the key is the exposure. If my physician is sending information to any intermediary where my data are closed; and I don’t want to get into the technical ... if they’re encrypted and they just pass through, that’s fine. But if they’re passing through, but it’s not encrypted, it’s exposed. So any time, if my data are

being sent to anybody that's not directly related to my care and being exposed to, they have access to that they can understand it then that requires my consent.

Paul Egerman – eScription – CEO

... are you saying that bullet number two should be—?

Deven McGraw - Center for Democracy & Technology – Director

Yes, but I guess, Dixie, that I'd ask for you to think about the set of examples—

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

I think number three. I think number three covers what I just said.

Paul Egerman – eScription – CEO

Yes, but I just want to stick with number two for a minute, okay?

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

Oh.

Paul Egerman – eScription – CEO

If the information is retained; when I read this I thought this was what was like the centralized model

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

Well, but it looked like ... function. They retain it long enough to do their clearinghouse function, you know. But that's not retaining over time, which I believe is what you're trying to get to.

(Overlapping voices.)

Paul Egerman – eScription – CEO

It's an issue of wordsmithing this a little bit. If it's retained, like a permanent store—

M

It's what it's retained for.

Paul Egerman – eScription – CEO

Yes.

M

Right.

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

Yes.

Paul Egerman – eScription – CEO

I think we raise the question of if it's outside of the current authorized treatment planning and healthcare operations then it's being retained for some future use. That's the issue, to me anyway—

M

So if it's retained for the purpose of future use or treatment—

Paul Egerman – eScription – CEO

Right.

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

David used the word unspecified on Tuesday and I think that's exactly the right term

Paul Egerman – eScription – CEO

Yes. Good point, Dixie. Thank you for reminding me.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

So this is interesting because in this case, if you take the Indiana model or Cincinnati, where I don't believe that they get any extra consent to do what they do because they believe that all of what they're doing is just providing lab results back to the providers via a different mode. I shouldn't say that. So they don't think that they need any extra consent beyond what exists in the paper world today. By this definition we would essentially be saying that they should be getting consent because they are retaining it; not unspecified, so I guess that's the caveat, unspecified. You're right. I'm sorry.

Paul Egerman – eScription – CEO

Well, Micky, in the case of a lab result it had to be ordered by someone, so it's being retained for delivery, for that purpose.

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

And it's related to the person's care.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right. If that's our question, who can see it, if it's just the ordering physician and that's a direct messaging model, if anyone who has proper authorization can see it that's now into the data aggregation point

Paul Egerman – eScription – CEO

That's a good point, David. Let's look at what was written by bullet number three.

Deven McGraw - Center for Democracy & Technology – Director

Yes. I've got it. Okay.

Paul Egerman – eScription – CEO

I would rephrase this a little bit, the patient's health information. The control over who has access to patient's health information. The decision about who has access to patients' health information is not under control of the patient's provider.

Deven McGraw - Center for Democracy & Technology – Director

Isn't that number one?

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

Yes, that's number one.

Paul Egerman – eScription – CEO

Okay. So what is number three here?

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

Exposure. I wouldn't call it access. I'd say exposed to.

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

I think that what we're really doing is distinguishing something that Paul has made in sort of a bigger framework, which is we're distinguishing direct data exchange from other exchange. In the case Micky described, an HIE becomes not only the transmission mechanism, but also the storage mechanism for directed exchange. That's just another role that this technology provider plays, vis-à-vis some receiver, some physician, who was the receiver of a directed exchange.

If, on the other hand, that retained data then becomes available for lookup by third party providers, whether for treatment or for other purposes, that should require the consent of the patient.

Paul Egerman – eScription – CEO

Yes. So the issue is – I don't know if I've got you right, Wes. I'm looking at what's now in the third bullet. The patient's health information exposed for reasons not related to treatment—

(Overlapping voices.)

Paul Egerman – eScription – CEO

Is really exposed persons or entities—

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

For reasons beyond a directed exchange.

Paul Egerman – eScription – CEO

Or that were not directly delegated by the provider.

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

Yes. Wes, it seemed like your point was more a control one. I mean, but I don't want to—

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

I think, as far as I understand; and my mind does wander; but I think we're talking about what are the factors needed to obtain patients' consent. I think we have pretty well agreed that for directed exchange the consent is implicit in the consent to treat. If I refer someone to a cardiologist I don't need additional – the cardiologist doesn't need additional consent to send the report back to me.

But I would argue that the mechanism by a delivery may involve retaining the data somewhere, just as if I'm a physician and I'm using a remotely hosted EMR. The data gets stored in the cloud of that EMR. That by itself doesn't trigger a need for additional consent. However, if that retained data becomes available to other physicians, whether for treatment or for some other reason that I can't even imagine, that does require the patient's consent.

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

Is that because the decision making about that data being released is now out of the original, treating provider's control?

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

By definition, releasing it to a third, to another provider outside of the purpose that's covered by HIPAA consent should require more consent. I mean at least it sounds that way to me.

Gayle Harrell – Florida – Former State Legislator

I also want to bring up the fact that if you're just sending the package and the package arrives at the destination, if there is an audit trail kept, even though the PHI may not be exposed, you still have PHI, because if it's coming, say, from an abortion clinic to a primary care doctor that in itself exposes the PHI.

Deven McGraw - Center for Democracy & Technology – Director

That's right. I mean that's why, Gayle, that's one of the reasons why we're trying to not use just the term PHI. I actually tried to deliberately say that it's health information because if an audit trail gives you enough to match a patient with a health condition or a piece of health information, whether that's through an audit trail, whether that's through a patient lookup, that's in essence what I intended by saying patient health information—

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

I think that's a really important issue. I hope we can address it at some point in the agenda as a specific issue and not have it come up as we go through each of the issues.

Deven McGraw - Center for Democracy & Technology – Director

Which one, Wes?

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

The issue of the fact of a transmission from a certain source may itself be protected information.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

It could be, although I also want to remind everybody that one of the premises of this is that all of the parties are complying with whatever policy and security rules we put in place. So that's just an observation.

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

But, Wes, is there a consent there that you think is required? I mean ... disclosing—

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

Well, taking Gayle's point of view I can say I can think that as a patient I may feel differently about the consent I give to the abortion clinic than the consent I give to the foot doctor. We need to recognize in our policies that making sure the data is encrypted in between wouldn't alleviate the need for that consent.

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

Yes. Yes.

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

Because it's the fact of the transmission that is the concern; however, I'm just hoping we have a place on the agenda where we can segregate out that issue, talk about it completely, because the balancing audit trails versus the need for privacy ... is a different topic—

Paul Egerman – eScription – CEO

So, if you would give me a two or three word description of this topic what would it be?

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

It would be—

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

... channels.

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

You've already raised it. You've already said that we'll discuss next week more fine-grained consent. You've already got the principle on the table, I think, that the consent may be specific to providers rather than generic to all providers in HIE, so I'm almost thinking that the rest of this issue is more about examining our approach with regards to the fact of a transmission as opposed to the contents.

Paul Egerman – eScription – CEO

Okay. That's helpful. Let's get back to the third bullet, which is the bullet I guess Dixie is suggesting. Are people comfortable with that the way it's written? Any other comments on that before we go on to the fourth bullet?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I wonder if; this is David; in the third bullet when you said not released and related to currently consented treatment or payment for care, the word current or ongoing or something like that should be in there.

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

I agree.

Paul Egerman – eScription – CEO

Okay. Ongoing treatment. Okay. The next bullet is the aggregation bullet. This is, again, what was talked about last time. We just did our best to clarify that because I think in one of the e-mail exchanges, I think it was Wes, was ... the definition of the word aggregated, so—

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

I don't think that aggregating information, I mean this is basically what an EHR does, right? But I think that—

Deven McGraw - Center for Democracy & Technology – Director

No, not from other provider records, Dixie. I mean an EHR—

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

I think it is. I think an EHR is always from multiple sources, but if you would use—

Deven McGraw - Center for Democracy & Technology – Director

No. I think—

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

For me it is if that information is then used for something other than my treatment or my payment, if it's used for some other thing then it requires my consent.

Paul Egerman – eScription – CEO

All I can tell you is that's different than what was said on Tuesday. People thought this would trigger consent.

Deven McGraw - Center for Democracy & Technology – Director

Yes. No. I actually had a different model in mind. John, were you about to say something? Maybe you were about to—

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

Yes. I think there is a number of ways this occurs. I mean I think of situations where not only do you have a community record, but you might have a group of providers that contribute to a separate covered entity of providers that will separately contribute to a common record.

M

Yes.

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

In that case the patient would have a relationship with each provider, but there would be some type of community record that would be established. So that record could be used for a whole variety of purposes by each one of those providers. It may necessarily need to be and each one of those uses might be permissible under HIPAA, but we still have a community record, which is contributed to by everybody.

Deven McGraw - Center for Democracy & Technology – Director

Right. I don't think we're suggesting here that such aggregated types of records wouldn't be allowed if we, you know, again, if the right decisions were made about fair information practice, etc. But to me, if there's a community record aggregated it's different and a copy of my provider's record that's accessible to others I would actually like to have consent over whether my information is in it.

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

I absolutely agree.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I agree. The way we've analyzed this in the past is whether or not it's a different covered entity. In other words, aggregation within a covered entity is covered already by that covered entity, but when you cross into the boundaries of a different covered entity then you're—

M

This is what this is all about—

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

Yes. Yes.

M

This is about separate covered entities.

M

I'd like to comment that this is becoming a more common model than I might have ever imagined.

M

It's a very common model.

M

Yes.

M

A lot of times I can think of several EHR vendors, whose products are frequently offered in a model where the medical data is shared across covered entities, even though the administrative data is specific to a covered entity.

Paul Egerman – eScription – CEO

Deven, I think that; I'm just looking at what you're typing here; the point is that the aggregation is happening outside of the covered entity, not that the records are coming from a different covered entity.

M

Well, the record is a community record. It's contributed to by multiple covered entities.

M

Right.

Paul Egerman – eScription – CEO

And the control of the record may rest outside of the covered entity as well.

M

Right.

Paul Egerman – eScription – CEO

Or in a new covered entity that's different from the treating physician's covered entity, the contributor of the record is different from the controller of the record.

Deven McGraw - Center for Democracy & Technology – Director

Well, right. We've got the control piece. Suffice it to say these are not mutually exclusive factors, right? They could all be operating.

M

Right.

Paul Egerman – eScription – CEO

To simplify this, the fundamental concept is we want to trigger consent whenever information is aggregated from more than one covered entity.

M

But then this goes back to my comment earlier about what is that consent and how much granularity can—

Paul Egerman – eScription – CEO

We're going to do that in the next question. We're going to talk about that.

Deven McGraw - Center for Democracy & Technology – Director

Is it more clarifying or more confusing to say a copy of the patient's information is aggregated?

M

I think that's a red herring.

Deven McGraw - Center for Democracy & Technology – Director

Okay.

W

Yes.

M

That gets worse.

Judy Faulkner – Epic Systems – Founder

This is Judy. Could I step through an example and see what you say about it? So you have a hub organization and it is maybe a multi-specialty hospital and clinic, but it's sharing its records and it's software, which happens all of the time, as someone just mentioned, with others in the community, maybe a member of small provider organizations so that they create a community record, but they're individual healthcare organizations all sharing a community record, so as the patient goes to the primary care doctor or maybe the patient specialist, the system is also the system that the hub uses and anybody who sees that patient has access to that record—

M

Not only has access to it, but they contribute to that record—

Judy Faulkner – Epic Systems – Founder

And contribute and it may be that when studies are done, because they're always doing studies to make sure that their decision support criteria are the right criteria and stuff like that. How does that get covered here?

Deven McGraw - Center for Democracy & Technology – Director

In other words, the way that it would be covered would be that it's a factor that triggers some level of patient choice. It doesn't mean that such a model couldn't be well constructed using fair information practices with strong policies, but I think that what we're saying here is in those types of aggregate, multiple entity models the patient should have some choice about whether their record is part of it.

Judy Faulkner – Epic Systems – Founder

Then the question I would have above that is if the patient has a choice and says no, but that's the way the two systems work, then what happens?

Paul Egerman – eScription – CEO

Well, actually, we're going to get to that in a minute—

(Overlapping voices.)

Paul Egerman – eScription – CEO

... information exchange—

Judy Faulkner – Epic Systems – Founder

Yes.

Paul Egerman – eScription – CEO

If the patient says no it means that their data can't be sent.

M

Actually, it's more basic than that. I'll be honest with you. If a provider signs up for the type of environment that Judy described, if a patient says, "I can't consent to that," the provider in most cases honestly would have to say, "Then I can't treat you, because your record is part of a PNE record and that's the way that it is."

Paul Egerman – eScription – CEO

It could be.

W

Yes, because it's not really being sent. It's shared.

M

It's shared. It's part of the record. It is the record.

M

But it's accessed across covered entities and this, I think, calls out for this treatment.

M

But then my point is that the consent almost ... the patient if you don't like this model we can't treat you. That's the consent that has to occur, I guess, in my mind.

W

I've got to say that

M

Right. That is happening increasingly. I talked to a CIO this morning, who has exactly the setup that Judy was describing—

W

Yes, but I think our responsibility as an advisory body is not to try to fit into what is happening, but to put forward what we think are the right policies that protect patients.

M

Right. No. I completely agree with that. I was just pointing out that this is increasingly common.

Paul Egerman – eScription – CEO

Yes. And it will get more common with the emergence of a ... care organizations, which, by definition require cross—

M

That's correct.

Paul Egerman – eScription – CEO

Covered entity data sharing, you can't be an ACO without that.

W

And I think as we protect the patient we have to protect both, the patient's privacy and the patient's health. We have to be aware of that.

Deven McGraw - Center for Democracy & Technology – Director

Well, of course, but there are ways to cross entity share data effectively and efficiently without necessarily aggregating it in a common community record.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

But to Judy's point and, I think, Wes' point, it is absolutely happening today. It is incredible. I think it's amazing how much is going on today in just this forum. So you need to be cognitive of that, because it really all, honestly, is an all or nothing and we can't be naïve to it either. By the way, the whole ... exception safe harbor is really, honestly, in my mind has caused a lot of this to occur because ... is allowing providers to basically contribute EHRs to—

Paul Egerman – eScription – CEO

Yes. It's interesting. When you mentioned ..., Micky, it gave me an idea as to how to handle this. We may want to put this like on a parking lot for discussion, because we're talking about entities and covered entities and we do this in like a very legalistic way, but what we may want to do is to deal with some of the examples, like what Judy is proposing, to find what I might call a virtual organization where you see a physician and the physician really isn't a member of, say, UPMC, but somehow they exist within the UPMC umbrella. They use the UPMC records system. I'm not sure that that's necessarily aggregation, as long as the patient understands it.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Right. That's within one delivery entity—

Paul Egerman – eScription – CEO

It's a delivery entity—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Right.

Paul Egerman – eScription – CEO

I love what you just said, Carol. The way to fix this on the aggregation is instead of saying ... the delivery entity.

M

Yes, but recognize this. A lot of providers are sponsoring these types of records for community physicians who are themselves independent of provider and so each one of them has a separate relationship with a patient.

Paul Egerman – eScription – CEO

Okay. I think those are good comments. I'm worried though that we're spending a lot of time on this. It's excellent discussion. We need to have more discussion on it, but—

Gayle Harrell – Florida – Former State Legislator

I have a comment on this. From the patient's perspective, the whole discussion always starts from what would the patient expect. What is the patient's expectation of what will happen with their records? Here the transparency comes in. If a patient doesn't know or give consent that that is happening and this is not what they're expecting, then we are really breaching that trust relationship with the patient if they don't know that same consent to us.

Paul Egerman – eScription – CEO

It's an excellent point. The flip side of that point, Gayle, is lots of times the patients expect and understand it's a single delivery organization and are actually surprised that there are multiple entities involved. So it's an interesting issue.

Here's what I want to do with this, because this is one of these issues we could spend half an hour or an hour talking about. I'd like to leave the aggregation issue where it is. It's like we have a parking lot, which we've really got to talk about accountable care, virtual organizations, definitions of delivery entities and the context of this and probably a lot of other issues. It's an interesting and subtle issue. The aggregation issue, I think, was more raised from the concept of if you have some of these, if you have an HIO that really is taking data from unrelated sources for whatever reasons and putting it together that that perhaps is something that triggers consent.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I really align with where Gayle's comments were going. I just want to say that in our work, particularly on the issue of consent, we found rather than thinking about this in the sort of opt-in/opt-out construct, which I think, unfortunately, blinds a lot of issues or blends a lot of issues together, that it was much more helpful to try to use a construct that distinguishes between general consent and independent consent. General consent is meant to be sort of you are asked to participate in a particular data collection or use of your information or disclosure and then independent consent, when a reasonable person's expectations would not anticipate that their information would be used this way. It's rooted in the principle that choices be proportional, so the more sensitive, the more exposing or the more, sort of, inscrutable.

In other words, if the patient can't see it, the more specific and discreet the consent that's required. We use that construct in the common framework for network personal health information as it particularly applied to people who would sign up the first time for a personal health service that might be hosting their information and then requiring independent consent if there was some other collection or use that would be unexpected by a reasonable person.

Paul Egerman – eScription – CEO

Right. Excellent comments, Carol. If I understand you right, what we're talking about is closer to general consent. We're talking about if the provider is participating in a model that is like a centralized model and has some of these attributes then that triggers consent. There are a lot of other issues we've got to talk about, but that's sort of a general consent.

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

This all goes back to that idea of, back into Carol's point that the form, substance and the way the consent is structured, because part of my fear here too is when we deal with granularity I'm not sure whether there's a way to even interject that into this type of a model—

Paul Egerman – eScription – CEO

I agree, but we're not talking about granularity today.

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

Yes, but we have to recognize—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But I do think that one thing we have a responsibility to do is to define the parameters of consent, which is to say we spent a lot of time trying to go through what the issues are, but there has to be transparency about the issues that would influence the consumer's decision. The choice should be meaningful. It should be amendable and revocable, but it's contextual, but it's proportional. You know, there are all of

these sorts of elements. The worry here, obviously, is when you just say consent; and this is why I've encouraged us to really read some of the consent policies; it's not clear what you mean and it's not clear that it's actually helping the situation.

Paul Egerman – eScription – CEO

I understand those comments. Those are all extremely helpful comments. So, getting back to the question at hand, which is the factors that would trigger consent, we've got some issues on this fourth bullet related to aggregation that we need to define.

I want to move to the fifth bullet and find out what are the issues that people want to raise. The fifth bullet, again, repeats what we said on Tuesday, which is simply to say if the exchange is used to transmit sensitive information that would also trigger a consent situation. We don't have to define specific data. We just said whatever NCVHS says is sensitive, but if it's involved with sensitive information that would be also a trigger.

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

The other point, and it sort of relates to the aggregation more too, which is kind of what Wes said, is the secondary use of your data, like if I opt-in, say, to an HIO and say that's fine with me that my data be exchanged in this HIO and then that HIO ends up disclosing my data for purposes other than just that exchange that secondary use triggers an additional consent. The same thing about aggregation of data; I give my consent to aggregate the data, but before they can use those data for anything else it should require, in my mind, a secondary consent.

Deven McGraw - Center for Democracy & Technology – Director

Dixie, when you say for that secondary use of data are you talking about uses that, in fact, we might already require consent under law, like—

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

Yes. Yes. Probably secondary is a bad use of term because it's taken on some baggage in our industry, but if there's a second, if there's a chain of two situations that both require consent, the first consent can't take care of both of them, right? Again, the best example I can think of is the opt-in. If I opt-in to an HIO and then that HIO ends up deciding to aggregate my data and sell it to some pharmaceutical company or something, I didn't opt-in to that. I opted into my physician using that HIO to exchange my information ... it's a second

Paul Egerman – eScription – CEO

Well, here's another way I would address that or ask you if this is the way you want to address it. We're listing these factors. Do you want to say the sale of de-identified data would be a factor that triggered consent?

Deven McGraw - Center for Democracy & Technology – Director

I should let Dixie answer the question, but I have to say that I want us to continue to address de-identification policy as one.

Paul Egerman – eScription – CEO

I understand, but that could be an issue though that she says triggers consent.

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

Yes, but that's really not the primary issues I'm trying to make.

Paul Egerman – eScription – CEO

Okay. So if it's not, then can we address it when we do the de-identification discussion?

Deven McGraw - Center for Democracy & Technology – Director

I think, Dixie, actually your comment; I don't think we were trying to imply with these factors that one consent would necessarily take care of it. I think we were just here trying to identify the factors that would lead us to recommend consent beyond what would be required in current law, some form of consent. Then when you get to the questions about what does that look like in more detail, then I think you have to consider whether it's informed, whether it's meaningful. Is it layered with respect to how it's presented to consumers?

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

I think I agree with you. I think the point though that I think is more common, more likely to happen is you get somebody's consent for; and I'm going to avoid the whole payment thing; that was a bad example. You get somebody's consent to opt into an HIO and then that HIO, as a business, takes on an additional business, aspect to its business model, whatever it is that I didn't know about when I consented for my information to be sent there. Then I think that we need to capture that a second consent, even though it's down—

Paul Egerman – eScription – CEO

Let's talk about that, Dixie, a little—

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

Later in time, you have to—

Paul Egerman – eScription – CEO

Dixie. Dixie.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Isn't that, in effect, captured by point two? I'm sorry. This is Micky. I'm sorry to interrupt, but point number two basically says if an ... future use would suggest I need new consent.

Paul Egerman – eScription – CEO

Yes. And also, we have a question about the durability of consent.

Deven McGraw - Center for Democracy & Technology – Director

Right, in a later bullet.

Paul Egerman – eScription – CEO

So when we get to the durability of consent we can talk about issues about how you can withdraw consent and what happens—

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

But I think we need to capture the fact that when a second condition arises, even after ... consent, you have to get the second one. I don't think the second bullet captures it at all. No.

Judy Faulkner – Epic Systems – Founder

This is Judy and I'm a little confused by this because of how things work together and what's "anded" and what's "ered." If this is saying that any sensitive information, so anything that goes across that maybe you're sending from one provider to another and information about, say, an STD goes across because

that is what the patient is being treated with and the drugs for it and everything else, then are you saying that for most cases when provider A sends information to provider B, because electronically that information may go across you will probably always need the patient's consent then?

Paul Egerman – eScription – CEO

I don't necessarily mean always. What this says is at least once, if the patient's record has sensitive data the patient has a choice as to whether or not the data, the entire record would be transmitted over. How that's handled would be an issue of choice for the patients.

Judy Faulkner – Epic Systems – Founder

Okay. I think most healthcare organizations, just to be safe then, would read that as you better get the patient's permission whenever you transmit the information.

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

I don't know how you overlay this over the fourth bullet, this idea of getting additional consent for sensitive data sharing when you have this community record.

Paul Egerman – eScription – CEO

We're not talking about additional consent. We're just talking about is this a criteria that lets you consent to participate at all, yes or no?

Gayle Harrell – Florida – Former State Legislator

In Florida, for instance, you have to get additional consent for anything such as HIV, STDs, abortions, behavioral health, mental health—

Paul Egerman – eScription – CEO

I wonder if what we should do with this is the same way of approaching the de-identification sale; we should take the whole issue off for now.

Deven McGraw - Center for Democracy & Technology – Director

Into our sensitive data ...?

Paul Egerman – eScription – CEO

Yes, because it triggers a lot of discussions. I mean—

W

Well, it's required by law in many states.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

Oh, I understand. What's required is required.

Deven McGraw - Center for Democracy & Technology – Director

Yes. Definitely. This is above and beyond law.

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

It might be additional level of protection, but necessarily, consent.

Paul Egerman – eScription – CEO

I think listening to all of these comments it makes me understand this is next week's discussion ... we get to it and it's a complicated issue, so let's—

Deven McGraw - Center for Democracy & Technology – Director

I actually had an idea about addressing Dixie's point.

Paul Egerman – eScription – CEO

Okay.

Deven McGraw - Center for Democracy & Technology – Director

If maybe one of the factors was a significant change in the original circumstances or the circumstances that supported the original consent—

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

Perfect. Thank you, Deven.

Deven McGraw - Center for Democracy & Technology – Director

I'll write it out.

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

Yes. Very good. Very good.

Paul Egerman – eScription – CEO

Let me ask, besides these issues, are there any other issues that should be listed here that we haven't done?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

I wasn't able to make the call on Tuesday, so maybe this was already covered, but I'm just wondering why on the fifth point, just looking ahead to how concrete we're going to be in the recommendation is the idea that we specifically don't want to say that it is sensitive information, as defined by state or federal law, but that we want to have some other separate, sort of, authoritative list, whether it's NCVHS or something that would define it or are we saying that this needs to be locally defined?

Paul Egerman – eScription – CEO

Well, in terms of the sense of data, I think what we're trying to say is we're not going to be the ones that are going to define it, so we'll use either NCVHS or we'll use whatever the state and local people use.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Okay.

Paul Egerman – eScription – CEO

It's just that we're just going to call it sensitive. It's like we have enough issues on our plate. We don't have to deal with that one. We'll use somebody else's definition of what's sensitive.

Deven McGraw - Center for Democracy & Technology – Director

Yes. In essence, we didn't have the discussion in that level of detail, Micky, because we knew the sensitive data conversation was coming, so—

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

This is Dixie. I have a question about the first bullet. Does that mean that if the provider uses a business associate to help them do whatever that that would be part of the patient's consent?

Paul Egerman – eScription – CEO

No it doesn't.

Deven McGraw - Center for Democracy & Technology – Director

I certainly wouldn't read it that way, Dixie. I read it as, and this gets to sort of the definition of control vesting with decision making authority. I think when a provider hires a business associate to perform a function on his or her behalf and carefully circumscribes in the business associate agreement what the data can be used for that's still the provider exercising his or her decision authority.

Paul Egerman – eScription – CEO

Okay.

Deven McGraw - Center for Democracy & Technology – Director

Did that make sense?

Paul Egerman – eScription – CEO

Yes. So, getting back to this list, are there any other issues, any other factors that trigger that we haven't listed?

Deven McGraw - Center for Democracy & Technology – Director

We will probably get some from the Policy Committee too.

Paul Egerman – eScription – CEO

I'm sure, but there have got to be others. I mean I can think of one that's not listed, which is if the patient is prominent. In other words, you've got a politician, a professional athlete, an entertainer—

Deven McGraw - Center for Democracy & Technology – Director

You know what? I actually don't think we need to set policy for institutions in that regard where we are saying, as a group, that those people are more special than others. I suspect that institutions—

Paul Egerman – eScription – CEO

Will set their own policies?

Deven McGraw - Center for Democracy & Technology – Director

Will set their own policies in that regard.

Paul Egerman – eScription – CEO

Okay.

Deven McGraw - Center for Democracy & Technology – Director

I don't think it's right to say these people deserve, from an over arching, national policy matter, special treatment of their data.

Paul Egerman – eScription – CEO

That's a good point.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I think when we get back into the sensitive data question this may come back up too, because the definition of what's sensitive may be a function, a little bit, of who you are, what you do. It may not simply be the traditional census type of domain.

Paul Egerman – eScription – CEO

Okay.

W

I agree with that and my experience with compliance officers in healthcare organizations is that they will be as conservative as possible in any interpretation.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

That makes sense.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

I'm just trying to clarify as I'm looking at the last bullet. I'm trying to clarify in my mind what the second bullet means then. So is it that the future use is unspecified, meaning that the current use is unspecified and that's where it would trigger consent or is it that a use in the future is different than the use that was originally consented, which actually brings us down to the last bullet?

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

The second bullet is the retaining. If they retain it for some unspecified future use they should have your consent.

Deven McGraw - Center for Democracy & Technology – Director

Yes. The last bullet to me; this is Deven; presumes that there already was some consent and is a circumstance under which you'd need to get more versus number two is saying you may not have to get consent under law, but if the situation is one where the patient's health information is being retained for some unspecified future use then you need consent for that arrangement at the outset. Does that make sense?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Well, I was just trying to figure out what does it mean is being retained for unspecified future use; that literally the consent form says we may use it for other things that we're not able to specify now? I just don't understand.

Deven McGraw - Center for Democracy & Technology – Director

No. No. That you would have to get consent in the first place—

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Right.

Deven McGraw - Center for Democracy & Technology – Director

Where there is an intermediary or not intermediary necessarily, but where you have an exchange situation where that patient's health information is being retained. So it's not that you got consent in the first place and then you have to think about whether the consent form was complete enough. It's a treatment, payment or healthcare operation's exchange that ordinarily you wouldn't have to get consent,

but it's using a model where that information is being retained for potential future use. So I think what we're saying here is that that is distant enough from the original patient-provider-trust relationship that that on its own could trigger a need to get consent.

So I think I've been struggling, but having said that, I've been struggling a bit with retained for unspecified future use too and I'm not suggesting that I have a different way to verbalize it, but I'm thinking about how we sort of struggled with this concept of data retention in our previous set of discussions and where we understood that in some cases there are legitimate business reasons for organizations to have to retain data in order to perform a specific function that they've been asked to perform and then to do administrative tasks that are directly related to that particular task. That, to me, is not the retention that we're talking about. What we're talking about here is a circumstance where at one polar end we're going to create an HIO and we're going to pull all of the data together because we foresee that it would be easier down the road to access, use and disclose it for multiple purposes if it was all in one place.

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

I had problems with the term by an intermediary. I think for this one maybe what we're talking about is retaining the information for a purpose that's not specified in the agreement, between the controller of the data and whoever. We call it an intermediary here, but they could be a business or anybody.

Deven McGraw - Center for Democracy & Technology – Director

But that, to me, I—

Paul Eggerman – eScription – CEO

That's a good point, but I think that's getting into a little bit of wordsmithing on this and—

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

Well, I'm trying not to do that. I'm trying to say that I agree with Deven; that retain for unspecified future use doesn't have much meaning, but if you tie it to— And we are talking about an intermediary, a secondary, a third party there, right?

Deven McGraw - Center for Democracy & Technology – Director

Yes.

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

That third party retains it for some purpose other than what their business agreement says that they are supposed to be using the data for. That should require consent.

Deven McGraw - Center for Democracy & Technology – Director

Yes, but it's a little more complicated for me than that, Dixie, which is to say that we've already said in our earlier recommendations that nobody should be able to retain data—

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

Oh, I see.

Deven McGraw - Center for Democracy & Technology – Director

Beyond what they need it for. Maybe I just answered my own question, but I don't want people to be able to say and to come together in an HIO and not be very clear if they are, in fact, going to be retaining data in the HIO why they're doing it and be doing it for a very specific reason that is supported by the providers that are joining it. It's the sort of concept of we're going to bring all of the data together again and hold it in one place—

M

Yes, in case somebody needs it in the future.

Deven McGraw - Center for Democracy & Technology – Director

Somebody might want it in the future and to me that on its own ought to trigger some ability for the patient to have some choice about whether their data is in or out.

(Overlapping voices.)

Carol Diamond – Markle Foundation – Managing Director Healthcare

But we also want to make sure that our sort of view on consent doesn't trigger blanket ... which is, —~~Okay~~, if I have to get consent I'll get consent for anything and everything," and sort of go against the other elements we talked about. So when we get to a discussion of what's involved in defining meaningful consent I think we should come back to that.

Paul Egerman – eScription – CEO

Yes. Unfortunately, Carol, when you're speaking there's a little bit of a – I don't know the right word—

M

I think she's at a ... parlor or something.

Carol Diamond – Markle Foundation – Managing Director Healthcare

It does what?

Deven McGraw - Center for Democracy & Technology – Director

It's ... in a very ping-pong way.

Paul Egerman – eScription – CEO

Yes. A ping-pong noise. I'm sorry. I hate to ask you this, but is there any chance you could like call back?

Carol Diamond – Markle Foundation – Managing Director Healthcare

Yes. Sure. I'll be right back in.

Paul Egerman – eScription – CEO

If you don't mind because there's something on the line.

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

I agree with Deven. This is not something you get consent for. It's something that shouldn't be allowed. You shouldn't be able to retain information for some unspecified future use.

Paul Egerman – eScription – CEO

Is our issue here just that we've worded this? We need to figure out how we word this better?

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

I think it's what Deven said. It's—

Deven McGraw - Center for Democracy & Technology – Director

Yes. It may be that, in fact, we've already said very clearly that these types of sort of unspecified data retention arrangements shouldn't occur.

Paul Egerman – eScription – CEO

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I was the one who originated this notion of future unspecified purpose and I agree that the wording is too vague to be useful the way it is right now, but what I was thinking of is in contrast to the permissions that are granted under TPNO, if the provider is putting that data away somewhere, outside of his own record, for a future TPNO then it needs consent. Future use period, but I'm thinking TPNO. By this I would mean a community repository, for example.

Paul Egerman – eScription – CEO

Well, yes, but here's another way, David. I could look at this entire issue of third party intermediary and data retention. Isn't the real issue what's in the first bullet, that somebody else has control?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

Paul Egerman – eScription – CEO

That's the real issue.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

And so I think as long as you've got that issue you don't need that second bullet at all.

Gayle Harrell – Florida – Former State Legislator

I would disagree. I think people—

Paul Egerman – eScription – CEO

I'm sorry. Can you repeat what you just said, Gayle?

Gayle Harrell – Florida – Former State Legislator

Retained somewhere.

Paul Egerman – eScription – CEO

Gayle, I somehow missed the first part of what you said. Could you say it again, please? Did you say you agree or you disagree?

Gayle Harrell – Florida – Former State Legislator

Yes. I disagree. Probably if you could ... any kind of reference to retention of data – I would disagree. I think you've got to address the retention of data. If an HIO is using a hybrid model or a centralized model and patient information is being retained in that model, patients don't expect that. They don't know about it. They don't expect it.

Paul Egerman – eScription – CEO

Okay. So then why don't we leave it in? But then our problem is the word unspecified.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

Let's take out the word unspecified.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. I want to make a technical side point; that it's access to data regardless of the pathway that that access has to go through, whether it's centrally retained or a copy is, I think, technically interesting and has lots of security implications, but it doesn't have privacy implications. Access is access, regardless of how many links you had to go through.

Paul Egerman – eScription – CEO

Yes. I understand that comment and when we get done with this I'm going to try to wordsmith a little bit to get to that concept. What I'd like to do is ... first, I appreciate your comment, Gayle. We will continue the retention of data. That was an excellent comment. When I look at these bullets I just want to say is there anything we haven't covered that we should cover?

Adam Green – Progressive Chain Campaign Committee – Cofounder

One area that actually ties in a little bit to what's been discussed is whether the purpose of the exchange or the permitted purposes, so for example, is the exchange limited to treatment. Does it allow payment? I don't know if that's a potential factor.

Paul Egerman – eScription – CEO

Well, it could be. I would like to write in some of the context what are the factors that cause, that trigger consent. In other words, what would be the things that it would do that would cause you to say, —“I've got to do consent.”?

Adam Green – Progressive Chain Campaign Committee – Cofounder

Right. I guess I'm just asking would there be limited scope exchanges that, just based on a limited scope, if that would be a factor.

M

Meaning they would not require consent or—

Adam Green – Progressive Chain Campaign Committee – Cofounder

Right.

Deven McGraw - Center for Democracy & Technology – Director

I actually think that you could, using these factors as indications of greater risk, construct an exchange model that would be more true to the original doctor-patient-trust relationship that is the sort of foundation for all of this. That wouldn't necessarily trigger any of these.

M

Right. Or, alternatively, you trigger them, but you have to give some explanation to patients and providers why they should feel comfortable with it. I mean I don't want to necessarily say that we're going to limit people to doing this, but if you trigger it then you've got to somehow win the trust of the participants; that this is what it's doing.

Paul Egerman – eScription – CEO

Agreed. But the question I had asked was is there anything else that we haven't listed, any other comments? If not, I'm going to push this on to the next slide, which is going to be very interesting.

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

The only thing that I might suggest is that we capture what Gayle and I keep coming back to; anything else, any activity that the patient would not expect to be happening.

Paul Egerman – eScription – CEO

Yes. I mean I understand the concept, but that's a hard one to write down in a way that I think is—

Deven McGraw - Center for Democracy & Technology – Director

What if we tried to capture that essence back in our fundamental principle about –

Paul Egerman – eScription – CEO

Oh, that's a good way to do that.

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

Yes. Excellent idea.

(Overlapping voices.)

Paul Egerman – eScription – CEO

That's a good way to do that. Excellent idea.

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

Good. Excellent. Yes.

Deven McGraw - Center for Democracy & Technology – Director

Okay. I don't want to go back on the slides right now, but I will insert it.

M

What's the fundamental principle? Could you restate that?

(Overlapping voices.)

Paul Egerman – eScription – CEO

There's a patient-provider relationship. One of the fundamental principles is we've got to operate according to what patients' expectations are. Patients should not be surprised.

M

Absolutely.

Paul Egerman – eScription – CEO

I mean that's the big criteria. In other words, would a patient be surprised if they learned something and you hadn't told them, so the ... would the patient be surprised if they found out their data was stored someplace else. That would be the fundamental principle. We need to track those things.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I just want to say I don't think that's difficult to define, because it's actually rooted in consumer protection law and I'm sure Deven can cite the law, but the basic framework of a reasonable consumer's expectation is not foreign in consumer protection law.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Eggerman – eScription – CEO

But that principle will help us quite a bit.

Deven McGraw - Center for Democracy & Technology – Director

And the reasonable man/woman is all over the law period. So—

Gayle Harrell – Florida – Former State Legislator

You can always reference it as the Paul Tang principle.

Paul Eggerman – eScription – CEO

Yes you can, I suppose. So since people haven't told me new bullets, I'm going to move on to the next slide, which is the one where we have to like fasten our seatbelts, this whole issue about choice. Can you move on to that, Deven?

Deven McGraw - Center for Democracy & Technology – Director

Yes. You're on it. You're on it on my screen.

Paul Eggerman – eScription – CEO

I know everybody has an opinion, so how are we going to come to a conclusion on this is a little mystery to me. I know some people think that we shouldn't be even asking the questions, but we were asked the question, so I think as an advisory committee, we've got to answer it somehow. Although, I did take the liberty of changing the question before we would answer it. The question is, "What approach should ONC take to a national policy on choice?" I think this question is related to what we just said on the previous slide. So, assume for a moment that there is an exchange model that exists and it's triggered consent.

Now, this is not at a granular level. It's more of like a very general level to participate. What are the options? The options are you could do opt-out. You could do opt-in. There is an option written here that ONC would allow providers and HIOs to establish their own choice models with opt-out as a minimum.

There's another option that's written here, which is sort of to say let's let people decide how they want to handle this themselves. I don't know if that's correct in terms of describing a completely local decision.

Those are like four choices and what does anybody want to say on this topic?

Gayle Harrell – Florida – Former State Legislator

I want to go back to the original question. Are you talking about just exchange intermediaries who would say what approach should ONC take on a national policy on choice, on choice for what level—?

Paul Eggerman – eScription – CEO

For information exchange, participating in the information exchange.

Deven McGraw - Center for Democracy & Technology – Director

When one or more of the factors on the previous page is present, right? Okay.

Paul Egerman – eScription – CEO

That's right. In other words, you've read the previous page and let's say, for example, you tripped one of those factors, so you have an exchange intermediary that retains data, so that trips one of the factors. Now what do you do?

Does the patient have a choice to opt-out? Does the patient opt-in? Is it the third thing where the providers and the HIOs can establish whatever they think? You've got to do at least an opt-out. Is it like— There are too many models. We can't figure this out. People need to do whatever they think.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

This is very confusing to me, because I feel like we just spent the last two hours kind of talking about this. I mean when we say additional consent is needed on the previous slide we're not saying the patient should be given a choice about whether or not to participate. We're saying additional consent is needed. I feel like we've defined it in a pretty granular way. I guess I'm just wondering what it is we're talking about here.

Paul Egerman – eScription – CEO

We're talking about opt-out versus opt-in.

Deven McGraw - Center for Democracy & Technology – Director

Yes, but I also think you're right, Carol. We have already set up some factors where we think the patient ought to have some choice about whether or not to participate and so basically what this slide is asking is are we saying that ONC is going to set national policy requiring choice or recommend that when these factors are present that a choice be made about choice. I mean that local decision option, one might argue, is really not on the table because we've already said we think some choice should apply in certain circumstances.

W

Yes.

Paul Egerman – eScription – CEO

But it's also important— You said something, Carol; I want to make sure; the way I'm looking at this is it's a choice to participate. So again, if you trigger one of the factors on the first slide, the previous slide, so let's say data is stored at the intermediary, a choice by a patient not to participate means none of the data will be sent to that intermediary.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Right.

Paul Egerman – eScription – CEO

So in other words, it's like a gating thing. Nothing will happen. There might be other choices made if you decide I do want to participate. Then you might have a whole slew of other things that you'd have to decide, but as you say, if it's this choice or the highway, I'm taking the highway. That's what says this. This is all-in or all-out at this level.

Judy Faulkner – Epic Systems – Founder

This is Joy and I'm wondering whether we should look at it differently. Should what we did before be consent that always has to happen, but if those situations aren't there, this is how you do consent?

Paul Egerman – eScription – CEO

I'm sorry. I missed the last part, Judy.

Judy Faulkner – Epic Systems – Founder

Well, in other words, what if those situations don't occur?

Paul Egerman – eScription – CEO

Then there's—

Judy Faulkner – Epic Systems – Founder

I'm just a regular patient and my data, I live in Madison, Wisconsin and I show up in San Diego at a hospital there. Do I have to give consent or not if none of those things are triggered?

Paul Egerman – eScription – CEO

The answer is no you don't, because if you show up in San Diego and it's directed exchange then there's no choice.

Judy Faulkner – Epic Systems – Founder

Okay.

Paul Egerman – eScription – CEO

This is still—

Judy Faulkner – Epic Systems – Founder

This is only in these circumstances.

Paul Egerman – eScription – CEO

Only in these circumstances.

Deven McGraw - Center for Democracy & Technology – Director

Right. And of course, again, we're talking about these circumstances above and beyond what current law might require.

Judy Faulkner – Epic Systems – Founder

Okay.

Paul Egerman – eScription – CEO

That's correct, because there may ... there may be state laws on some of this stuff.

Judy Faulkner – Epic Systems – Founder

Then I think that the biggest trigger here is that bullet that says sensitive information, which could be embedded in all sorts of things that the organization may or may not be aware of and they can't figure it out electronically and therefore, this probably, as I mentioned before, would be considered to be the standard that they're going to use for everyone.

Paul Egerman – eScription – CEO

Yes. And so the—

Deven McGraw - Center for Democracy & Technology – Director

Except that we sort of put that sensitive data issue, Judy, in the parking lot.

Judy Faulkner – Epic Systems – Founder

Yes, with that exception.

Deven McGraw - Center for Democracy & Technology – Director

Right.

Paul Egerman – eScription – CEO

So, getting back to the choice model, I just want to make sure we're all ... the discussion. The discussion is we assume for a moment one of the factors on the previous slide has been tripped, so it's a centralized model in there since the data is stored at an HIO. Then the question is when that occurs; and remember, these are HIOs that are probably funded by the federal government or possibly funded by the federal government. What approach should ONC take to a national policy on choice to participate in that type of a health information exchange? That's the question that we're asking. It's a question that's apparently asked of ONC all of the time.

Gayle Harrell – Florida – Former State Legislator

First of all, I want to say what we are recommending should be on a policy level. We have, again, I bring up the tenth amendment; every state will have to address this—

Paul Egerman – eScription – CEO

I was looking forward to your doing that actually.

Gayle Harrell – Florida – Former State Legislator

I can't wait to be there to do that at the state level in Florida. However, I think after a large, public debate this is an issue that is going to generate a lot of large, public debate I can assure you and every state will have to address it. I think on the federal level what we have the power to do as a recommendation to ONC is to recommend to them that they recommend a certain level and, of course, states will individually address that, but my sense of things and listening to my constituents out there, you have to have an opt-in model. I think you come to patient expectation. This is new ground to patients and what is their expectation? They want to have a say in what happens to their PHI. If it is being moved around, if it's being stored, if any of those things happen that triggers the consent issue that we just discussed, patients want to opt-into that. They need total transparency as to what's going to happen. They need to be educated on it and then they want the choice of either opting in or opting out or not participating. They want to know that in order for that to happen they have to say it can happen.

Paul Egerman – eScription – CEO

I appreciate that, but I'm trying to understand what your recommendation is, Gayle. Are you saying ONC should have opt-in as a national policy or are you saying that it's just sort of like have guidance or something on an opt-in, but the states and local people can make whatever choices they want?

Gayle Harrell – Florida – Former State Legislator

I think the ONC has to recognize that states have the power to make those decisions and that they should set what they consider the optimum level. They should recommend opt-in; however, acknowledging that states may choose not to do that.

Paul Egerman – eScription – CEO

When you states are you talking about the state legislature or are you talking about can individual HIOs say, —I know ONC says opt-in, but we already set ourselves up as opt-out and opt-in is going to be kind of a hassle. We need to grow fast and opt-out will grow us faster and so we're going to ... ONC."

Gayle Harrell – Florida – Former State Legislator

I think each state should make that decision and it should be done by the state legislature after public debate.

Paul Egerman – eScription – CEO

I actually don't have any trouble with that. Any time there's a public debate on anything the state legislature decides. That makes sense.

Deven McGraw - Center for Democracy & Technology – Director

Right. This is Deven. I don't think that we're in a position at all to trump state law, but I actually would put something slightly stronger from a national policy level on the table, which is to say that if ONC is going to set a national policy on choice then I think they ought to try to promote it through all of the tools that they have to do so. So that would include the federal funding conditions, the tools that it has in its disposal, maybe even we should talk as a group about whether we'd want to suggest even changes ... to HIPAA, but let's just say for now our recommendations go to ONC. I'm suggesting national policy that ONC uses the tools that it has to encourage, but I actually would go with option number three, giving states some flexibility, but requiring them to, at a minimum, when the conditions are triggered from the previous slide, at least give patients an opt-out. But I would put some conditions on that opt-out. That would make it essentially almost be as strong as an opt-in, which is to say there is plenty of patient education, time for patients to actually exercise their right to opt-out, but at the end of the day if they don't the presumption is that they're in.

Paul Egerman – eScription – CEO

Okay. So we've got one person who is pretty strong on opt-in; one is strong on option number three.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I don't understand again what we're talking about. Are we saying, is this a discussion only about the conditions that were triggered in the previous slide?

Paul Egerman – eScription – CEO

Yes and whether or not to participate in the exchange as a consequence.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

So when we say consent is needed in that slide, for those conditions, now we're debating whether it's consent or whether it's opt-out?

Paul Egerman – eScription – CEO

That's correct.

Deven McGraw - Center for Democracy & Technology – Director

Well, actually, I don't think that opt-out is not consent, but it's not prior consent. I mean although one could construct an education and transparency regime around choice where people say there is a 30-day advance, a 30-day, 60-day, 90-day advanced notice period before the structure is operational, where people have the right to say, "I don't want my data in it." When you haven't heard from somebody it's presumed to be in.

Carol Diamond – Markle Foundation – Managing Director Healthcare

Yes, but what's in it? Is it just my demographic information? Is it my full medical record? Is it just sensitive data? I'm really struggling with what it is we're trying to decide.

Paul Egerman – eScription – CEO

Couldn't we just simplify that and say it's PHI?

M

Yes. Or the other thing you could do, since we make reference to meaningful use in stage one is I think, for the sake of this discussion, is assume that it's a CCD or a CCR. It's a summary of the record, which is—

M

I wouldn't—

Deven McGraw - Center for Democracy & Technology – Director

... health information so we get out of patient health information or identifiable health information so we don't fall into the trap of limitations that might or might not be PHI.

M

Yes. Okay. IHI. I think that's a better choice. I think that's the breadth that we ought to take at this level. We may refine it at some point.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I guess I'm wondering how we could be saying that a third party could aggregate information beyond the expectation of a reasonable consumer and wait for that consumer to trigger both, the notice and the consent at their next health interaction.

Deven McGraw - Center for Democracy & Technology – Director

Okay. That's a fair point, Carol.

Paul Egerman – eScription – CEO

So, Carol, that may not be an argument that would say opt-in or—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I think what we've done on the previous slide is more important than opt-out or opt-in. I'm just going to tell you guys, for all of the years that I've been working on this I think trying to boil it down this way tends to obfuscate the issues and doesn't really get to meaningful policy. But I—

Paul Egerman – eScription – CEO

I agree 100%.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But I do think, and it's consistent with our ... where the consumer's information is being aggregated by some third party that the construct of both general consent and then independent consent for things that are unexpected by a reasonable consumer is an important one.

Paul Egerman – eScription – CEO

Okay. So if I heard you right, let's see if this is right. I wrote your name next to Gayle's name in my opt-in side of this question.

Carol Diamond – Markle Foundation – Managing Director Healthcare

I know you're trying to pin it that way, Paul. I guess I'm just saying that I believe that what we are saying on the previous slide, where we need to have consent it is meaningful consent and the consumer has meaningful choice and it's not dependent on waiting for the consumer to have another healthcare interaction where they might be informed that this is happening.

Paul Egerman – eScription – CEO

Yes, they need to be told before it happens.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think that Carol said the right phrase there, meaningful consent. If we have an opt choice it needs to be a meaningful choice. Deven, I think, went and itemized some of the ways that we could give guidance or recommendation on what is meaningful choice. I think that's what it's going to boil down to. I personally, if it was up to me, would prefer an opt-in model, but given the need to build these systems quickly and given the benefits from them, I think it's probably practically going to be an opt-out model, but it's opt-out with meaningful choice, not an opt-out—

M

I think we've got the three points to combine here and we're there. We've got Carol's term, meaningful choice. We've got Deven's elucidation of how choice might be meaningful, either with opt-out or opt-in. We've also got Deven's point about this is not just a line on a piece of paper that we expect ONC to actively support the point of view that's expressed. Then we have Gayle's point about it's finally more than likely in most states a decision that will happen at a state legislature. I can't help but believe there are some states where the legislature just won't act, but generally, if they do act that rule—

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

Let me ask a question as it relates to my fourth bullet point in the prior slide, because if a patient presents for services and there are fair information practices as to how that practice participates in a global or some type of shared record, what is that considered? I mean I guess if the patient doesn't want his or her record to be part of that then they can go somewhere else for treatment, but if they do go to that provider for treatment there is no other choice but their record be part of that common record. How does that fit into this whole consent?

Paul Egerman – eScription – CEO

That issue is sort of like a side issue, John, in terms of the common record when that's the only record, because I think that community record relates to the concept of what is the delivery system, what is the delivery network, which is sort of a different issue.

What we're talking about right here is the sort of more bread and butter, meat and potatoes, whatever the right expression is, situation that clearly does exist where there is HIOs and, for example, they are centralized. They retain data. They do all of these things. When that occurs what choice is all about is a patient saying, the ability to say, —No way. I don't want my data put over in that database.”

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

But, Paul, let me just say this: This is bread and butter too. I think—

Deven McGraw - Center for Democracy & Technology – Director

John, can I—

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

Hold on. Wait. Let me just speak. I think I have to rely on Judy Faulkner a little bit, but these are the models that are occurring in the United States on a fair number today and so we do need to be more cognizant of the fact that this model exists and it is just occurring today. It's not theoretic or in small number.

Paul Egerman – eScription – CEO

Yes. We can talk about that model—

Deven McGraw - Center for Democracy & Technology – Director

But let me ask you—

Paul Egerman – eScription – CEO

... we're talking about right now.

Deven McGraw - Center for Democracy & Technology – Director

John, when NCVHS's Privacy & Security Workgroup and the whole NCVHS actually issued its recommendation to ONC that the patients ought to have a choice about whether or not their information is part of the NHIN what were you guys envisioning?

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

Well, I think that's different. Again, when it's part of the NHIN that is the rollup; I mean that is this idea of a master exchange, I guess. I'm talking about the fourth point that we made here today, which is that you have this community record that might exist in certain areas. It does exist in certain areas, in certain contexts.

Paul Egerman – eScription – CEO

Here's my response to that, John: I think that's a good issue and I think there are some ideas about how to address that, but I want to address that as a separate topic.

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

Okay.

Paul Egerman – eScription – CEO

I'm just saying that's not what we're addressing right now. What we're addressing right now is the health information exchange models or organizations that trigger these other issues. I'd like to try to see if we can settle that and then we'll talk about that issue. That issue is going to be ultimately an issue that we could actually solve using some of these concepts that Dixie and Carol put forward about patient expectations. If patients understand that they're part of the community delivery system then it becomes a lot easier and so we just have to apply some of those principles to that model and understanding that model. Then we can talk about it.

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

Does there need to be a single answer, if you will, for all of the bullets on the previous slide? Does it have to be the same approach for all of them?

Paul Egerman – eScription – CEO

Yes. In other words, I would say if any of those things trigger a choice what is the choice. What should ONC take? I mean I suppose you could say under these circumstances we want you to opt-in and under these we could do opt-out. That would be an answer you could give too.

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

Deven, would you mind putting up that slide? I'd like to see our bullets again. Thank you.

Deven McGraw - Center for Democracy & Technology – Director

Sure. Yes.

Judy Faulkner – Epic Systems – Founder

I agree with Deven on the third one. I like that because different providers have different types of information, but more, I like it because I think patients have two expectations that we have to constantly keep in mind. They have an expectation for privacy and they have an expectation to be kept healthy. The reason I like the third one is I think it balances that well.

Paul Egerman – eScription – CEO

Okay.

Deven McGraw - Center for Democracy & Technology – Director

So even after I put that on the table, I'm starting to get; I mean this is the purpose of these discussions, right; I'm getting persuaded by some of the conversations about maybe not answering this question so specifically. So we have specifically said ONC should create national policy, in other words, choice. Some patient choice is required when any of the circumstances under slide one are present and ONC should promote that choice and such choice needs to be meaningful with full transparency and education, but not go into whether it should be opt-in, should be opt-out, give some discretion to local providers as to how that gets done, but it has to be meaningful choice.

Paul Egerman – eScription – CEO

Deven, just a second, let me just challenge you a little bit on that, which is you say ONC should develop a policy, so when ONC turns to us and says, —“Okay. You're our advisors,” what should that policy be?

Deven McGraw - Center for Democracy & Technology – Director

The policy should be the patient should have some choice about whether or not to participate when these types of circumstances are present—

Paul Egerman – eScription – CEO

Yes, but then ONC says to us, —“Everyone says what does that look like. Is it opt-in or opt-out?” What should we say?

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

I think our point should be that neither model is necessarily meaningful; that the meaningful nature of the model is more important than the specific mechanism.

Paul Egerman – eScription – CEO

Could we define some criteria for meaningful, like, for example, a time window during which a choice can be made, the ability to make the choice outside of an urgent need for care?

W

Before we get there I just want to say that I like Deven and Wes' comments. I totally agree with that, but I will just point out that individual choice is one of the fair information principles—

Deven McGraw - Center for Democracy & Technology – Director

Right.

W

And that no matter what the model, some level of choice, even if you can decide not to participate, some level of choice is one of the fair information principles. I think the situations that we have on the next bullet, as Wes says, can be made much more meaningful without boiling it down to that ... simplified construct.

Paul Egerman – eScription – CEO

So the argument is we want to do this thing that we call meaningful choice and then we want to put forward some attributes of that to explain what that means?

W

Yes.

Paul Egerman – eScription – CEO

And among the attributes are sort of like no surprises to the patient or—

W

Yes, and also the choice is proportional, if that's clear. The choice should be proportional to what the consumer is being asked to do. I think in the previous slide we have some of the situations where you elevate the need to have consumer control and consent.

M

But choice should be proportional.

Paul Egerman – eScription – CEO

Yes. The concept of surprises should be that somehow the choice should be given before the action is taken.

W

Yes.

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

I don't understand what that proportional means. I know you just explained it, but I still don't know what you're talking about.

W

It's a pretty common construct, which is to say you can get somebody ... to do things that you describe around a use or a disclosure of information. If you want to go beyond that, in other words, if there is particularly sensitive information, if it's going to another entity that has different policies, if there is a disclosure that's particularly sensitive the detail of how a consumer consents to those things should be proportional to those requirements.

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

Oh, I see. Commensurate, not proportional; I don't see any proportional aspect of that. But I also, through the years I've read a lot of proposed legislation and etc. and I'd like for us to be more specific about the education too.

Paul Egerman – eScription – CEO

Yes. We're going to get to that in a minute, Dixie.

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

Oh, okay.

Paul Egerman – eScription – CEO

There is a question on that. I just want to stick with this issue for right now.

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

I thought it was because I see education in that issue.

Paul Egerman – eScription – CEO

Yes. So we're going to get to that in a minute.

Judy Faulkner – Epic Systems – Founder

I'd like another one in there, which is the method of choice should not harm the patient's health.

Deven McGraw - Center for Democracy & Technology – Director

What does that mean, Judy?

Judy Faulkner – Epic Systems – Founder

It means that we shouldn't create situations where because the patient has to make a choice and didn't do so because of lethargy, which is going to be the biggest problem, would have done so, didn't do so and now when there is a need for that data it can't go over.

Deven McGraw - Center for Democracy & Technology – Director

Do we get that when we talk about consistent with patient expectations? The only reason why I'm

Judy Faulkner – Epic Systems – Founder

Well—

Deven McGraw - Center for Democracy & Technology – Director

I'm bucking against the harmful to health is that it somehow suggests that it's an either/or proposition and—

Paul Egerman – eScription – CEO

Well, there's another issue also with it, Judy and Deven, which is interesting. In some of the material I've read on this, some people say this consent issue is frequently a dispute between medical paternalism and individual sovereignty. So there's this fear if you say if it's not harmful to health that gives you an opening for medical paternalism, for a physician to say the patient doesn't want to do this with something, but I think it's better to do it this other way, so I'm going to go ahead and do it—

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

That's what I—

Paul Egerman – eScription – CEO

That actual dispute between medical paternalism and individual sovereignty sounds like an odd sequence of words, but it is, I think part of the core of some of—

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

Gee, I thought of that as the reverse of the case Judy was describing. Maybe not.

M

I thought of it—

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

Medical paternalism is more often a way not to release data than it is to release it, to send it, right?

M

I don't think so.

Paul Egerman – eScription – CEO

I think it could be. It could be anything.

Gayle Harrell – Florida – Former State Legislator

This is Gayle ... my phone is

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

Doctor knows best.

Deven McGraw - Center for Democracy & Technology – Director

Gayle, we can't hear you very well.

Gayle Harrell – Florida – Former State Legislator

I've been off. My phone went dead, so I had to switch phones, so I'm jumping in again and missed part of that conversation, but I think you have the break-the-glass legislation that allows physicians to have access in emergencies and things of that sort. You get into a real issue between what patients want done with their data versus what the paternalistic physician may feel, although I run a healthcare facility and side with physicians most of the time, I think you have to really look at this from the patient perspective.

Paul Egerman – eScription – CEO

So let's go back—

Judy Faulkner – Epic Systems – Founder

That's what I'm trying to do, Gayle, but I think that when you have patient expectations you have patient expectations for both, privacy and for healthcare. I think in the context that we have it here we're considering primarily privacy. Sometimes I think the patients don't realize that if they don't make a choice they may harm their health.

(Overlapping voices.)

W

Maybe it's not an extreme situation where someone says I have to break the glass, but wrong decisions are made because they don't know that they should have made different decisions.

(Overlapping voices.)

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

Judy, that's exactly what I was trying to get to when I mentioned education. You know, the need to completely inform the patient of the implication of their decisions is essential.

Paul Egerman – eScription – CEO

Yes. That's consistent with what we mean by meaningful. I mean it's an informed decision.

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

Yes, fully informed both sides, the health side and the privacy side.

W

Yes and I'm—

Paul Egerman – eScription – CEO

One has to be careful with the expression informed. I made a comment in another call, which is I did this very, very minor surgical procedure last week and I got three pages of documents to sign called informed consent.

W

Well, that's what it's going to end up being.

Paul Egerman – eScription – CEO

Yes, which is frustrating it.

W

Once you get the lawyers writing it they're going to put in so many things into there that the average patient will not be able to read it.

Paul Egerman – eScription – CEO

What you do when that happens is some people read it and some people just ask the doctors if it's okay. He says yes and they sign it.

W

Yes. That's what I'd do.

Deven McGraw - Center for Democracy & Technology – Director

Why don't we think about what I've written on the slide so far? ... the point

Paul Egerman – eScription – CEO

Can you slow it up a little bit or something?

Deven McGraw - Center for Democracy & Technology – Director

What?

W

Well, if you mean patients include both privacy and health, I'd feel more comfortable if it said patient expectations for both, their privacy and their health, because otherwise they don't—

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

... as well.

W

I'm sorry?

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

I just see health and safety.

W

And safety. I agree with you because I think in the end where we're going to get into big trouble is if these rules are going to impact the health care. I think they're going to have too many scared healthcare organizations and that's where it's going to harm us later on.

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

That's what I would say. I would prefer those words in there instead of the pros and cons, because it sounds like one is a pro and it's really about you—

Judy Faulkner – Epic Systems – Founder

Risks and benefits?

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

No. Well, yes. That would be better than pros and cons. Yes. Yes.

M

But I think stating it in terms of the positives, you know, the positive of privacy and the positive of health; that sums up risk and benefits.

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

I agree.

M

I like Judy's formulation.

Paul Egerman – eScription – CEO

Okay. So let's look at this for a moment from a different level, which is this has been put forward by Deven and by Carol as sort of this concept that we're going to do meaningful choice. That's different than what Gayle said earlier, which was she made a clear statement for opt-in.

W

No, I disagree actually. I can think of situations in which opt-in is not meaningful.

Paul Egerman – eScription – CEO

Okay. Now I want to go back to what Gayle said. We've got all of these triggers. The data is being retained someplace else. What do you think, Gayle? Are we answering the question or are we avoiding the question with this statement?

Gayle Harrell – Florida – Former State Legislator

I think you've got to make the choice opt-in or opt-out. As far as the recommendation, as far as using the policy levers that ONC has, which I think we should absolutely use, transparency, education, all very much a part of whether you are opting in. If full transparency and education is done I think we've seen probably 95% of people opt-in. Very few people will not opt-in. However, I'm still fully an opt-in person. I think you've got—

Paul Egerman – eScription – CEO

So would you then take this statement and add another sentence to it? Would you say this is fine, but if any of that stuff we saw in slide one happens there needs to be an opt-in style of consent?

Gayle Harrell – Florida – Former State Legislator

Yes. Absolutely. I mean that's where I am. I'm one voice.

Deven McGraw - Center for Democracy & Technology – Director

Yes. I'm not there. I prefer not to specify ... to say that it's got to be choice and it's got to meet those parameters.

Gayle Harrell – Florida – Former State Legislator

Opt-in is a choice.

Deven McGraw - Center for Democracy & Technology – Director

So is opt-out if it meets those parameters.

Paul Egerman – eScription – CEO

Let me ask you this, Deven. I'm listening to what Gayle said. Actually, I was influenced by what Gayle said. Let's say you've got an intermediary where the data is stored. That's the kind of thing that a patient would be surprised by. If you have opt-out what does that mean? It means the patient can opt-out after the data is already been moved.

Deven McGraw - Center for Democracy & Technology – Director

I get what you're saying. I guess the pieces of the choice have to be proportional to or commensurate with what the patient is being asked to do, but I guess I might reword that to be the particular scenario involved. I would, quite frankly, want for people to opt-in to models like that and maybe we do need to be specific, but I actually presumed that that's the choice; that if a model like that was present, given that it's such a significant deviation, in my view, from the doctor-patient relationship, I think the only meaningful choice in that scenario is for people to be asked first, before their data would be part of it.

Gayle Harrell – Florida – Former State Legislator

Agreed.

M

I agree, but I think there's a complicating issue we'd have to consider or we have to be very clear about, which is that a lot of what has been written and discussed assumes that it is the intermediary that is the mechanism by which the patient's choice is enforced—

Paul Egerman – eScription – CEO

Which is an excellent issue. It's why we framed this discussion ... patient provider ... the intermediary.

M

So I think that we have to clearly relate the current formulation to our specifically denying that having the intermediary enforced choice is the equivalent to having the provider enforced choice. Then I think the rest of this flows.

Paul Egerman – eScription – CEO

I missed you at the end—

M

Too many negatives in there, huh? All right.

W

I'm not sure I understand.

Paul Egerman – eScription – CEO

I don't understand. We're really only talking right now about the discussion between the patient and the provider and whether the data gets sent through the exchange.

M

Right. So that fact of what we are talking about is what I think needs to be very clear as we go forward. In other words, I think many people will be coming in to reading our recommendations from a point of view that all that they have read about choice is not focused on the transfer between the provider and the HIE. It's focused on what the HIE does to enforce choice. I look at all of the work that IHE has done, for example. It assumes there's an intermediary with a decision rules engine that's doing this.

Paul Egerman – eScription – CEO

So the way to do this perhaps, let me put forward a suggestion. We've got this definition of meaningful choice. Then we should say something like under the circumstances described under question number or if the triggers occurred described under question number one the provider should offer their patients a choice, an opt-in choice, a choice of whether to opt-into that type of exchange.

M

Yes. I think that's fine right now.

W

Yes.

Paul Egerman – eScription – CEO

In other words, I'm not trying to take away any of this meaningful choice discussion, but I'm also listening to the very practical comment that Gayle is saying and it seems like everybody is agreeing. If it's centralized data, if we did these things it seems like opt-in is the only solution that works. Otherwise you find out two years later that your data is in some place you've never heard of before. That's not a good thing.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

The other parameter I want to put on the table for meaningful choice is also that the consent is not compelled and it can't be used for discriminatory purposes. We have a policy on this in the common framework as well.

Paul Egerman – eScription – CEO

The thing that's important here is we've got two sentences or two concepts here. One is the definition of meaningful choice and the second one is if you trigger the tripwire of question number one, providers have to offer opt-in choice to their patients.

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

Any of them?

Paul Egerman – eScription – CEO

Any of them. Right. Any single one of them. So that may cause us to want to review if that—

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

Yes.

Judy Faulkner – Epic Systems – Founder

I'm just guessing that I've had some experience with maybe coverage of about ten million patients. That's kind of an off-the-top-of-my-head guess.

Paul Egerman – eScription – CEO

A small number, huh?

Judy Faulkner – Epic Systems – Founder

Yes, that's a big number. Some of the healthcare organizations will just make sure that they are putting everywhere this is what we do. We share your records with anyone who we deem is appropriate to share your records with. That's a statement that they make. They don't have people opt-in and they also don't have people opt-out, because they're saying this is what we do. If you're going to work with us, if you're going to be a patient here you have to accept this as how we operate and those are some very prestigious organizations.

On the other hand, just to keep going on this, some of the groups we have, who have worked in states that have opt-in have found it so onerous that they have gone to their states to say will you please change the state laws.

Paul Egerman – eScription – CEO

But, Judy, when you're talking about these prestigious organizations that have these policies, those are for policies within their delivery network—

Judy Faulkner – Epic Systems – Founder

No. That's not correct.

M

I think the boundaries get pretty broad.

M

Yes. So it might be, Paul—

Judy Faulkner – Epic Systems – Founder

The boundary gets very broad. It is very difficult to say where the delivery network begins and ends.

Paul Egerman – eScription – CEO

Yes. I think—

Judy Faulkner – Epic Systems – Founder

I'm not saying this for the delivery network. I'm saying this for outside of the delivery network.

Paul Egerman – eScription – CEO

Look at Indianapolis. I mean it's essentially every hospital in Indianapolis.

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

However, I think we all know of common practices that we don't think should be common practices.

Paul Egerman – eScription – CEO

Right. Just because it happens doesn't mean it's good.

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

Exactly.

W

Correct.

Judy Faulkner – Epic Systems – Founder

True, but I think we shouldn't ignore people's experiences, intelligent people trying for the best care for their patients, who have tried different ways and come up with conclusions that we should not ignore. I—

Paul Egerman – eScription – CEO

So you're saying there's this concept in the second sentence. You don't like it. Is that what you're saying, Judy?

Judy Faulkner – Epic Systems – Founder

... actually ... conflict of the second sentence.

Paul Egerman – eScription – CEO

The second sentence is if you trigger the things we talked about on question number one that it's an opt-in situation.

Judy Faulkner – Epic Systems – Founder

I just like that last, that bullet that is in there that says, "Allow the organizations to establish their own models with opt-out as the minimum standard." I like that. I think that that both, has privacy and healthcare in it. That's what our experience has been that the healthcare organizations are tending to even when it wasn't that way to begin with. They either don't go for interoperability because it's too onerous or they go to try to change the laws.

Paul Egerman – eScription – CEO

Yes, but again, that may not be what is the right policy. It is the easy policy in some ways for the provider and in most cases it is the best policy for the patient, but it opens the door towards potential abuses, which is why we've been asked to address these questions.

Judy Faulkner – Epic Systems – Founder

Well, that's part of the balance if it is best for the most then I think that that's something we still have to keep thinking about.

(Overlapping voices.)

Deven McGraw - Center for Democracy & Technology – Director

Okay. I think John keeps getting drowned out here.

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

I just have to support Judy on this one. I mean I think that practically speaking I hear from physicians all day long dealing with issues just like this within my organization and the over arching comment is that we just want to treat patients and you're getting in my way. The patient is more likely to be offended by the

fact that they can't get at information and so there has to be a practical way to cover those people that, frankly, do want to be part of it. In the lion's share of the cases that is exactly what the patient not only wants, but expects is that that data is going to be available.

Paul Egerman – eScription – CEO

So let me ask you, Gayle, what do you think about all of this?

Gayle Harrell – Florida – Former State Legislator

I have a major problem with it. I think patients want to know and want that option of opting-in. You will get 90% or maybe 95% or 99% of people who will do that and maybe people choose not to be one of those ten million people that Judy is talking about, but they need to have the choice. We want this to be successful and I think as a national policy and using the levers that the ONC has at its disposal to assist in moving that down the road, although there are state's rights and states will make decisions on this, which I absolutely believe that they should have the ability to do that, but I think as a national standard that we can't enforce by law, we can only enforce with the levers that are available to us, we need to be opt-in. I'm not budging off that. I think—

Paul Egerman – eScription – CEO

Let me throw an idea out. I don't know if it's a good idea, but let me throw an idea out. So, we've got this thing that we're going to define meaningful choice. We start down a path of what you suggested, Gayle, saying if we triggered any of these issues it would be opt-in. Suppose we said if we triggered any of these issues it's really important that patients have advanced knowledge so that they're able to make a decision. That advanced knowledge could come in one of two ways. It would be either an opt-in decision or a clear transparency, advanced description of what the process is to make it easy to opt out.

M

But the opt-out, honestly, in a lot of cases is going to be that they're going to go somewhere else for services.

Paul Egerman – eScription – CEO

It's going to say what?

M

That they're going to end up going somewhere else for services.

Paul Egerman – eScription – CEO

Well, but we are being asked to make a policy recommendation that would say that's not what it should boil down to. If our recommendation is that opt-out is an option that must be made available or that we recommend be made available—

M

Yes.

M

Then you're saying that you can't be told to go to another city and don't get sick in Indianapolis.

Paul Egerman – eScription – CEO

A premise of this part of the discussion is that we're all in agreement from the previous slide; that there are circumstances under which a patient is given a choice. I think we also understand the choice is

whether or not to participate in the exchange, whether or not their data is going to be sent to this other entity—

Deven McGraw - Center for Democracy & Technology – Director

Well, more specifically, Paul, it's whether or not to participate in an exchange that triggers those situations.

Paul Egerman – eScription – CEO

That's exactly right, so that's already the decision. So the decision is now what form does that take under those circumstances. Is it opt-in? Is it ..., which is what Gayle says? Is it well, there's transparency. People are notified in advance and then they can opt-out. What form does that decision take?

Deven McGraw - Center for Democracy & Technology – Director

Okay. So can I suggest something? I think what I'm hearing on the call is that with respect to; and I don't know if you guys are seeing the same screen I am, so hopefully this will make sense—

Paul Egerman – eScription – CEO

You need to shrink your font.

Deven McGraw - Center for Democracy & Technology – Director

I know. I tried to do that. So all of the pieces that are still on the white part of the bottom of the slide that are sort of the parameters of meaningful choice and the circumstances that have to be taken into consideration and the protections that have to be built in, I don't hear people disagreeing with that. Where we're not able is, one, whether or not we should specify should it be opt-in, should it be opt-out, should it be totally local. Some folks want to specify and some think that those parameters are sufficient. For those who want to specify there is a difference of opinion between opt-out and opt-in. I think we won't get consensus on that.

W

I would agree on that.

Deven McGraw - Center for Democracy & Technology – Director

And that that's what we present to the Policy Committee; is that we do have consensus that it needs to be meaningful choice as a patient when the circumstances on slide one are present and that meaningful choice has some parameters to it and we explain what those are, but that in terms of whether there needs to be a national determination of whether that's opt-in or opt-out was a matter of some disagreement among the group and we can present that there were some very strong and powerful and strongly held arguments made in favor of opt-in, similarly, strong arguments made in favor of opt-out and some folks feeling as though how the choice in terms of those parameters gets defined is less important than making sure that it's meaningful.

M

I wanted to ask Deven if she would go so far as to say that choice must be offered.

Deven McGraw - Center for Democracy & Technology – Director

Yes. We already –

Paul Egerman – eScription – CEO

We already said that.

M

Okay. Well, that's beyond what some systems do, so—

(Overlapping voices.)

Deven McGraw - Center for Democracy & Technology – Director

... there has to be some choice.

Judy Faulkner – Epic Systems – Founder

Well, it depends on what the choice is. Is the choice about when we talked about aggregation of information as we get to the accountable care organizations and that concept and other independent physicians, who are working together, even though they're all separate, does that mean that we're saying they have to have an option to un-segregate the records, which may be impossible? You may be in a position where you've said what has to be done is impossible to be done.

M

That's my point, Judy, which is that you may not be able to deliver the character of that organization to the patient—

Paul Egerman – eScription – CEO

Yes, I don't think so. I think we can structure this in such a way that you can do that right, because the accountable care organization and the community held record, those are also covered entities. Those are not intermediaries the way we are thinking of them, so I think we just—

Judy Faulkner – Epic Systems – Founder

Well, but let's look at it one step beyond that. Let's say it's not accountable care or community, but it is the organization, the hub organization stretching out to anyone in the community, who says, —I can't afford an electronic health record. I want to have it for meaningful use. Can you share yours with me even though we don't work together much?"

Paul Egerman – eScription – CEO

I still think that can probably be accomplished. I know exactly the models that you're looking—

Judy Faulkner – Epic Systems – Founder

Okay. Because I think it's important to protect that model. The other thing I think—

Paul Egerman – eScription – CEO

I think there is because there are the concepts that we have to figure out how to define, like virtual delivery organizations. If a patient participates in a medical home, deals with an accountable care organization that—

Judy Faulkner – Epic Systems – Founder

Or even not an accountable care organization, just with an organization that's sharing its EMR.

Paul Egerman – eScription – CEO

Yes. There are a lot of ways to address that.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

I would just like to offer just a general comment and caveat though; that we shouldn't assume that because certain actions have been taken in the market that those reflect the policy decisions that the

customers really wanted. They are confined or limited in many, many cases by what a particular vendor may offer them and they make a large market decision and they compromise on a whole bunch of stuff.

Paul Egerman – eScription – CEO

Excellent point, Micky. That actually relates to the point I was about to make. Where we are on this discussion; we're in agreement on this concept of meaningful choice. We don't have an agreement on this business of opt-in or opt-out. We have some strong view points. I have an observation though. The observation I have is one of the reasons why I think there is some resistance to opt-in is that there are already things in place ... disrupt what's already in place.

Deven McGraw - Center for Democracy & Technology – Director

I'll have to say that—

Paul Egerman – eScription – CEO

That's an observation.

Deven McGraw - Center for Democracy & Technology – Director

Yes. I'm not a person who minds disrupting existing arrangements if I think it's needed to do so in order to advance what I think is the right result from a policy standpoint, but having read that paper that ONC developed that examines what ten different localities have done and sort of the care that some of them took in constructing the models, it's not entirely clear to me that those that had some very clear parameters about how data could be exchanged, some very strong educational components that still use the federated systems, so there was still some provider control of data and then what they layered on top of that was an opt-out that that necessarily struck me as wrong.

Paul Egerman – eScription – CEO

Well, it's interesting because we've got these—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But that doesn't trigger any of the parameters on the previous—

Deven McGraw - Center for Democracy & Technology – Director

That's a good point, Carol. I realized that as it was coming out of my mouth.

Paul Egerman – eScription – CEO

Yes, but wait a second. Here's the issue: We've got these two sentences. On the second sentence we don't have agreement on opt-in or opt-out. The one concept that I was going to try to throw out; I don't know if people like it or don't; would be to say for organizations who do not currently have a choice model, if any of those things that are described on the first question exist then ONC recommends, suggests opt-in.

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

No. No.

Deven McGraw - Center for Democracy & Technology – Director

No. No. No. No. No.

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

No. No. We have to acknowledge that—

Paul Egerman – eScription – CEO

Universally nobody like it. Okay.

(Overlapping voices.)

Paul Egerman – eScription – CEO

If nobody likes it we don't need to talk about it.

Judy Faulkner – Epic Systems – Founder

But, Paul, underneath it, you have a pretty good point, which is if they're already there and they're already doing it and it's already working very well and they have set aside patients why are we forcing them to change it when there is not a problem.

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

There are things that are going on now that if I, as an individual, could opt-out of you better believe I would.

W

Absolutely.

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

So I don't think that any of us—

Judy Faulkner – Epic Systems – Founder

I think that's fine if you can opt-out. I think that's fine. But it's basically if the opt-out mechanism is working why not let it—

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

... Judy, it doesn't exist and I don't think that we should establish, as a going in position, that our policy has to be consistent with what exists today or we wouldn't be here.

Paul Egerman – eScription – CEO

Good point.

Judy Faulkner – Epic Systems – Founder

I agree with you, Dixie. Good point.

Deven McGraw - Center for Democracy & Technology – Director

So, Paul, should we vote count?

Paul Egerman – eScription – CEO

Well, I think there's not consensus, but if we want to we can.

Judy Faulkner – Epic Systems – Founder

I don't know. Vote counting is worse—

M

I don't—

(Overlapping voices.)

Deven McGraw - Center for Democracy & Technology – Director

Gayle, what do you think?

Gayle Harrell – Florida – Former State Legislator

As far as I'm concerned, if I'm a minority of one I—

Paul Egerman – eScription – CEO

I don't think you're a minority of one, Gayle.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

... minority of one. I think my recommendation would be for you guys to ... this discussion and write it up, because I don't think we've really gotten it right yet in the slides.

Deven McGraw - Center for Democracy & Technology – Director

All right. Tell me, because we don't have time, what's not right in the slide, because this is our last meeting before Wednesday.

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

There's one more point that I think we agreed on, Deven, that you might capture and that is that we don't need a single answer for every bullet on the previous slide. I think we agreed on that.

Deven McGraw - Center for Democracy & Technology – Director

Well, I thought that was the proportional choice, commensurate choice.

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

Well, we seem to still be talking towards a single answer for every bullet. I thought we reached agreement that it didn't have to be the same answer for every bullet.

M

And I don't think we have consensus on every bullet.

M

Yes and—

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

Right. What I'm saying is I think we have consensus that there could be different answers for each bullet on the previous slide.

Deven McGraw - Center for Democracy & Technology – Director

Different answers as for opt-in or opt-out and we don't have agreement on opt-in or opt-out?

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

Yes. I thought you and somebody, maybe David, both suggested that we may not have the same answer for every one of those bullets.

Deven McGraw - Center for Democracy & Technology – Director

I did suggest that, but I suggested it in the context of meaningful choice in certain circumstances that seem to me to be so deviated from the original doctor-patient relationship that to provide people with meaningful choice would mean opt-in.

Paul Egerman – eScription – CEO

... because we're running a little bit short on time—

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

Yes.

Paul Egerman – eScription – CEO

Here is what I'm going to report, I'm going to suggest that we're going to report. Tell me if I've got it right or wrong. We're going to make some statements about this concept of meaningful choice. On the issue of opt-in and opt-out we're going to say we did not have a consensus; that we have some members who are very, very passionate that opt-in is the way to go under the circumstances described on the previous question. Other people disagree and there is also a view that there are people who have a non-opt-in solution already working and there's no reason to disrupt it. So that's what we're going to report.

M

All right. I think you should—

Paul Egerman – eScription – CEO

Is that accurate?

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

No. I don't agree with the last statement you said; that there's no reason to disrupt anything that—

Paul Egerman – eScription – CEO

There are some people who think that.

Deven McGraw - Center for Democracy & Technology – Director

... people who feel that way, Dixie.

Paul Egerman – eScription – CEO

I'm just reporting there are some people who think that.

W

Well, there may be no good reason to disrupt it. The folks I know, we know those folks who have had opt-in and have changed it to opt-out. They couldn't tolerate opt-in.

Deven McGraw - Center for Democracy & Technology – Director

Okay. Time has ceased for—

Paul Egerman – eScription – CEO

Yes. What I'm just trying to do is to reflect what I'm hearing. What I'm hearing is we don't have a consensus. We have strong feelings for opt-in. There are feelings for opt-out. There are feelings for things are working and it's not right to change it on this issue. That's what I'm hearing.

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

Right.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Paul, this is Micky. I think this issue of the installed base and current practice is not about opt-in versus opt-out. It's ... so, for example, in the models in the particular ... we've been talking about the opt-out could only be represented by a patient deciding I'm not going to get care at this practice anymore, because they're not even given an opt-out option.

Paul Egerman – eScription – CEO

Right. That's—

Deven McGraw - Center for Democracy & Technology – Director

Well, that's right, but we did say that when the circumstances on slide one are present choice should be required with some acknowledgement that we need to do some further work to refine that aggregated category.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But ... individual choice is always required. Right? You always have to tell a person what's happening to make sure that they have some ability to say I don't want that.

Paul Egerman – eScription – CEO

You're saying that's the way it ought to be, Carol? It's not necessarily that way today.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes and it's one of the fair information principles. In other words, regardless of those triggers, some form of individual notice in choice is always the right thing to do.

Deven McGraw - Center for Democracy & Technology – Director

Well, and under HIPAA you have to, at a minimum, give people notice that they can ask for their information not to be shared.

Paul Egerman – eScription – CEO

But I don't think –

Deven McGraw - Center for Democracy & Technology – Director

It doesn't have to be honored unless ... that circumstance where you're paying out of pocket in full.

Paul Egerman – eScription – CEO

Right, so that's kind of a pointless benefit. It's a feel-good benefit.

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

The whole notion of privacy practice is if you scratch something out they don't have to do anything about it.

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

Paul, back to your summary, I thought that you correctly described the state of the committee. I'm not sure that it's feasible, but it would be helpful if you could give a one-sentence addition that describes why they feel passionately that way so that it is clear to the Policy Committee what the issues are that need to be grappled with in order to resolve the issue—

Paul Egerman – eScription – CEO

That's a great suggestion, Wes.

Deven McGraw - Center for Democracy & Technology – Director

That's a great suggestion. Keep in mind that Paul and I will be surrounded by a number of members of the Tiger Team in the Policy Committee meeting, so we'll certainly be vocal.

Paul Egerman – eScription – CEO

So, in terms of doing the one sentence as to why, here's what I'd like to ask is the people who believe in the different views draft it for us. Gayle, you believe in opt-in. Why don't you draft one? You can do more than one. We'll even let you do two sentences why you believe that.

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

No playing favorites here.

Paul Egerman – eScription – CEO

Well, is there somebody else who wants to draft that?

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

No. I meant giving her two sentences.

Paul Egerman – eScription – CEO

Okay. Then the view that gee, it really should be opt-out, I guess, perhaps at a minimum, who wants to draft that? Are you advocating for that, Deven? Pardon me? Deven's got a ton of work to do.

Deven McGraw - Center for Democracy & Technology – Director

I advocated I don't like being boxed into the choice. I think our much stronger—

Paul Egerman – eScription – CEO

You advocated not taking a choice. Is there anybody who wants to talk—?

Judy Faulkner – Epic Systems – Founder

Deven, if you want to do that one I would be happy to work with you.

Paul Egerman – eScription – CEO

Yes. I wouldn't ask you to do—

Deven McGraw - Center for Democracy & Technology – Director

... drafting the opt-out. I'm not in favor of opt-out.

Judy Faulkner – Epic Systems – Founder

No. I'm agreeing with you. I think it should be whatever they want to do.

Paul Egerman – eScription – CEO

Okay. So why don't you draft that, Judy? If you could draft that one or two sentences?

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

I would like to help—

Paul Egerman – eScription – CEO

Okay. So I think that would be fine.

Judy Faulkner – Epic Systems – Founder

Okay.

Paul Egerman – eScription – CEO

If you could either work with Judy or, if you want, John, you can write your own too. We'll just—

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

I'll try to dovetail on what Judy's doing.

Paul Egerman – eScription – CEO

Will do. As long as you guys keep it short we'll present your views because I think that's—

Deven McGraw - Center for Democracy & Technology – Director

I mean anyone can chime in if they'd like. We can pull them together. We just want to make sure we have at least one from—

Paul Egerman – eScription – CEO

Yes. I mean my goal is – we have a couple of goals. One is we'd love to get to consensus. If we don't have consensus we're trying our best. We want to make sure that you people are ... everyone has heartfelt opinions on these issues and you've put a huge amount of effort into this. I want to make sure your opinions are reflected, so anybody—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

One point I'd like to make, which is sort of to the conclusion of what we're saying, even on the parameters of choice that we have in this slide is that models that do not trigger these issues raise fewer concerns.

Paul Egerman – eScription – CEO

Yes.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

We already did that in the last presentation. There was an agreement on that.

M

I think that I'm going to keep harping on this. I don't think the difference between central and federated is a relevant issue, Carol. I think that's what you're trying to suggest.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

No. I'm—

Paul Egerman – eScription – CEO

No. I think she's talking about directed exchange.

M

Okay. Okay. Got you. I agree with that.

Paul Egerman – eScription – CEO

I hate to be—

(Overlapping voices.)

Paul Egerman – eScription – CEO

We're running a little bit behind, a little short on time. I don't know if I have the courage to do this, but there was actually one other question that I was hoping to get to today. I don't know if it's an easy one or not. If we could do it in two minutes we could try this third one, which is do providers have a choice of participating in an exchange model or can a provider simply say, for whatever reason, I don't like this thing. I'm not going to send my data. I wrote that as yes/no. I'm not sure I know what local decision is. The way I look at it, it's hard enough to get providers to do things when you require laws on them, pass laws on them. If they're not comfortable, we haven't convinced a physician that this is the right thing to do, I don't know how you're going to force them to do it.

M

Yes. I agree.

Deven McGraw - Center for Democracy & Technology – Director

I think providers have to have absolute control over ... decide what they want.

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

Yes.

Paul Egerman – eScription – CEO

Fundamentally, the comment that I put in my e-mail to Wes I think ... important comment. It's for us to succeed with this information exchange thing and the whole issue of privacy and security of electronic records we really have to win the trust of consumers and physicians in the medical community. We have to win their trust. We have to convince them that it works.

Deven McGraw - Center for Democracy & Technology – Director

You're writing my statement for me, Paul.

Paul Egerman – eScription – CEO

But I think to the extent that we include that as a fundamental principle of what we're trying to do, that also strengthens our approach.

Deven McGraw - Center for Democracy & Technology – Director

Yes. To me you just gave a logical answer to this question given the fundamental principle we already put on the table about the provider holding the trust—

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

Yes.

Paul Egerman – eScription – CEO

Yes, but I mean the other alternative is if we answer this question no then what a provider will do, whether it's an opt-in or opt-out structure, will tell all of the patients to opt-out. It's sort of a waste of time.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

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

And then they have to have a course of action to do if their patients do all opt—

Paul Egerman – eScription – CEO

Yes. So good. We actually made terrific progress today, believe it or not, for a Friday. We got through three of these questions. We came to an understanding on this nearly impossible question of choice. This is really extraordinary progress. I want to congratulate everybody.

M

You've got to love deadlines.

Paul Egerman – eScription – CEO

You've got to love deadlines, but also, we've got to love the public, because this might be a topic that people want to say something about. Hopefully somebody's got some insight that will maybe disappear some of our agreements if somebody has a good idea something.

Judy Sparrow, if you can, why don't we open the lines for public comment?

Judy Sparrow – Office of the National Coordinator – Executive Director

Sure.

Deven McGraw - Center for Democracy & Technology – Director

Yes. And, Chris, we can go back to the regular slide.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes. Okay. Operator, could you please ask the public if anybody wishes to make a comment?

Operator

We do have one comment.

Judy Sparrow – Office of the National Coordinator – Executive Director

Great. If that person could please identify your name and your organization, please.

Fassel Corissen

This is Fassel Corissen. I'm an Independent Healthcare Consultant. The consent policy discussion seems to be getting into granular, technical details. Should the Tiger Team consider going forward, adding a senior level developer or database administrator to possibly help understand and clarify that they'll be deploying a consent logic for ...? Early in the discussion, for example, the Tiger Team discussed today the policy of transaction data retention. Some of this is already being managed with HL-7 transaction logging, so whether you're allowing data to be kept only in a browser's temporary cookie session or written directly to a database has a lot of profound implications across healthcare. I think there needs to be some technical input and expertise to help the Tiger Team make a deployable policy. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Any other calls or comments?

Operator

I don't have any other comments at this time.

Paul Egerman – eScription – CEO

Well, let me just thank everybody again. This has been a very terrific, especially terrific. It was a fascinating discussion and we're dealing with very difficult issues. I appreciate your efforts. For the people who have the homework assignments to write things up for us, which I guess are Judy, John and Gayle, if you could get that to Deven and me – it would be great if you could do it by the end of the day today if that's possible.

Gayle Harrell – Florida – Former State Legislator

You're not going to have it today. I'm sorry.

Paul Egerman – eScription – CEO

Could you do it by tomorrow?

Gayle Harrell – Florida – Former State Legislator

Probably.

Paul Egerman – eScription – CEO

Okay. If you could that by tomorrow that would help us a lot, because we've got to get all of our stuff together by the end of the day on Monday in order to get it over to Judy Sparrow to put it all together for the Policy Committee, so whatever you can do would be appreciated.

I want to just thank you again for a fascinating and spirited conversation. Of course, I want to thank Judy Sparrow for her support and Joy Pritts and say thank you again. Have a good weekend.

Public Comment Received During the Meeting

1. Tense is important here. Shouldn't consent be obtained BEFORE these factors occur?