

Privacy & Security Tiger Team
Draft Transcript
July 9, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the Privacy and Security Tiger Team. There will be opportunity at the end of this meeting for the public to make comment. Just a reminder for Workgroup members to please identify yourselves for attribution when speaking.

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

Yes.

Judy Sparrow – Office of the National Coordinator – Executive Director

Latanya Sweeney? Gayle Harrell? Carol Diamond?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Judy Faulkner and Carl Dvorak?

Judy Faulkner – Epic Systems – Founder

Here.

Carl Dvorak – Epic Systems – EVP

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

David 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?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Rachel Block? Neal Calman? Christine Bechtel?

Christine Bechtel - National Partnership for Women & Families – VP

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

John Houston?

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

Leslie Francis is here for John.

Judy Sparrow – Office of the National Coordinator – Executive Director

Right. I'm sorry, Leslie. Thank you.

Gayle Harrell – Florida – Former State Legislator

Gayle Harrell is here as well.

Judy Sparrow – Office of the National Coordinator – Executive Director

Gayle. Right. Let's see, Wes Rishel?

W

Yes. Wes said he couldn't come.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay. Joy Keeler?

Joy Keeler, MBA - HiMSS

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Adam Green?

Adam Greene – OGC/HHS

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Joy Pritts?

Joy Pritts – ONC – Chief Privacy Officer

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Did I leave anyone off? Okay. Thank you. I'll turn it over to Deven and Paul.

Paul Egerman – eScription – CEO

Good morning. This is Paul Egerman. I want to welcome you to our Tiger Team meeting. We have a fairly packed agenda. To quickly remind everybody about what the Tiger Team is all about, we are a group that has been organized to try to respond to a series of questions that came from the Office of the National Coordinator and to respond rapidly we consist of members from the Policy Committee, the HIT Policy Committee, the HIT Standards Committee and also from NCVHS and also from OCR, so that's a pretty broad representation.

We have an interesting agenda today. Basically, as you may have heard, yesterday there was a proposed rule making, a proposed rule issued by OCR and we have a very short presentation from Adam Green on that topic. Then, after that, we are going to dive into the entire issue of limitations on collections, use, disclosure, re-use and retention of data, so it should be an interesting meeting. But why don't we get started with Adam Green?

Adam Greene – OCR/HHS

Thank you, Paul. So, yesterday the proposed rule that implements most of the HITECH provisions into the HIPAA privacy, security and enforcement rules was put on public display. It will actually be published on July 14th and is going to include a 60-day comment period that will end on September 13th. I think a caveat I can make with respect to this is that it's a proposed rule, so don't take it as final. Everything I'm going to say in the next few minutes is subject to potential change and we look forward to receiving a number of comments, potentially including your own.

So I'll go ahead and start off on frame two, some changes to business associates. So, pursuant to the statute, business associates, the HITECH statute in this case, now include or are proposed to include health information exchange organizations, e-prescribing gateways, or other persons that provide data transmission services with respect to PHI to a covered entity and requires access on a routine basis to such PHI. We clarify in the preamble that this still does not include conduits, so an entity that manages the exchange of protected health information through a network, including providing patient locator services and performing various oversight and governance functions for EPHI would have more than a random access to protected health information and this would fall within the definition of business associate in contrast to conduit; that only has random or infrequent access as necessary to support the transport of the information. It's, under the proposed rule, not considered a business associate.

We also include personal health record vendors that are acting on behalf of covered entities, so this should not be seen as all personal health record vendors, but rather, just ones that are basically offering a PHR for a covered entity. This conforms to some earlier guidance that we published December 2008 on this.

Then we also include within the definition of business associate subcontractors that create, receive, maintain or transmit PHI on behalf of a business associate. So any such subcontractor would themselves be considered a business associate and would be directly liable under this proposal under the privacy and security rules.

Additionally, anyone may contract with, as a subcontractor who creates, receives, maintains, or transmits PHI on behalf of them would also be a BA, so it continues to go down the chain as necessary.

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

I have a question, Adam. This is Dixie.

Adam Greene – OCR/HHS

Certainly.

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

When you talked about conduits, is your assumption that the PHI or that the data, the PHI are encrypted when they go through the conduits?

Adam Greene – OCR/HHS

Under our current definition if it's encrypted and, therefore, there's no access then it would strictly be a conduit. If it's unencrypted, but there's not a need to access the information other than on a random or infrequent basis to support the transport services then that would still be a conduit under our proposal. So encryption is not necessarily the line, although encryption would, per se, mean that you don't have any level of access.

Does that answer your question, Dixie?

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

Yes, but it's hard to envision how unencrypted data can go anywhere without there being a risk factor.

Judy Sparrow – Office of the National Coordinator – Executive Director

Can we let Adam finish his presentation? We've got some time for questions.

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

Sure. Sure.

Adam Greene – OCR/HHS

Okay. So what does a business associate have to do? We're on slide three. A business associate must comply with all requirements of the security rule, so these are the general requirements and also the more specific, administrative, physical, technical and organizational safeguards.

A BA only may use or disclose PHI as permitted by the BA agreement or required by law. Required by law would not include a contract provision. Required by law is a federal or state law, but would include regulations, such as potentially, for example, Medicare regulations.

The BA may not use or disclose in violation of the privacy rule. This generally means that a BA may not use or disclose in a way that a covered entity would not be able to use or disclose. There are two limited exceptions, one for data aggregation and one for certain business management functions of the business associate.

Also, the BA must provide electronic access to either the covered entity, the individual or the individual's designee. That's something that we expect the business associate agreement would reflect what the expectations are, whether the e-access should be directly to the individual and/or individual's designees or, in contrast, whether it should be that any requests for the access to the BA gets referred to the covered entity.

On slide four: Business associates must enter into a business associate agreement with subcontractor business associates. There is no need for a covered entity to enter into agreements with subcontractors. Rather, a covered entity has one agreement with the BA. The BA has one agreement with the subcontractor BA and so on.

The BA must take corrective action if it learns of a subcontractor BA non-compliance, similar to the corrective actions that a covered entity or the same, frankly, as the corrective action that a covered entity must take if it learns that a business associate is non-compliant.

Additionally, a business associate is liable for violations of a subcontractor BA, who is acting as an agent within the scope of agency, so agency tends to go towards what level of control is exercised and is available. So this would not mean that there's liability for independent contractors, but strictly for agents acting within the scope of agency.

So, some other provisions besides business associates, going on to slide five: Covered entities and business associates; authorization is required for sale of PHI even if the use or disclosure is otherwise permissible. Currently, under the current HIPAA rule you cannot sell PHI without an authorization unless it's for a permissible purpose. So, for example, if a disclosure is permitted for healthcare operations there is no prohibition on also receiving money for the PHI. Research; this is another area where under the current rule if you're permitted to disclose for research then there's no prohibition on receiving remuneration for the PHI. This proposal will change that and so if it's not permitted by the rule then, of course, you need an authorization. If it is permitted by the rule, but you're receiving remuneration, then an authorization would be required.

There is exceptions pursuant to the statute for public health treatment, payment, fail of a covered entity. So in other words, if a hospital gets sold its records can be sold along with it.

Business associate activities on behalf of the covered entity; this just means that if you hire a business associate to do something there can be an exchange of money related to the business associate doing its function.

To an individual: So, for example, if an individual requests access to protected health information in accordance with the privacy rule you continue to be able to charge the individual a reasonable cost-based fee. The same is also true for an accounting. There are certain situations where an individual can be charged for receiving an accounting of disclosures and there'd be no prohibition on charging for that exchange of PHI, also, where it's required by law.

We've also carved out that where the remuneration is reasonable and cost-based fee to cover the cost of preparation and transmittal, and this would also include research. So, in any situation in which the remuneration is just for the preparation and transmittal and there's no profit, in essence, that is permissible under this proposal.

So, going on to slide six, covered entities and business associates must provide electronic access in the electronic form and format requested if readily producible, otherwise in a readable, electronic form and format, as agreed to by the covered entity and individual. This is actually not that different than what the current rule says. The current rule says an individual can request access, whether it be in hard copy or electronic, in any form or format and if that form or format is readily producible the covered entity must provide it. But, under the current rule, if it is not readily producible then the covered entity must provide a hard copy in a form and format agreed to by the parties. This proposed change would say that if you maintain the information electronically then you continue to have to provide the access in the form and format requested if readily producible, but if you maintain it electronically and you cannot do it in the form and format requested, then you now have to provide a readable electronic form and format, as agreed to by the parties.

So if your EHR, for example, has a PHR functionality built in that would make it readily available to individuals and an individual requests electronic access in that form or format that would be readily producible. However, if your EHR did not have that form of access we're not now suggesting that you have to go out and buy some solution that will provide PHR level access to the individual. Instead, you have to provide a readable, electronic form or format in a form that's agreed to by the parties, so that could be a PDF. That could be a secure e-mail exchange, something of that nature.

You also must provide an electronic copy to an individual's designee, but the request must be in writing and must clearly identify the designee and where to send the electronic copy. The statute calls for clear, inconspicuous language and we want to make sure our people aren't relying on just phone calls to send electronic records wherever the person on the phone requests. So that's why we do have a written requirement here, but this could potentially be to a caretaker, to a PHR, to another provider. You may charge for labor and the media if the electronic copy is provided in a physical media, so if, for example, the electronic copy is provided in a secure e-mail you can't charge a \$10 retrieval fee, but if there is some time related to reviewing the request you are able to recoup those costs. You can't charge for any server time or any overhead costs related to the hardware that's necessary, but if, for an electronic, secured e-mail, for example; but in contrast, if someone wants an electronic copy delivered in physical media, such as a CD-ROM or a flash drive you can charge for the physical media under the proposed rule.

On to page seven: On slide seven the covered entity and BA must agree to a request to restrict disclosures to a health plan if it is for payment and healthcare operations and not otherwise required by law and if the PHI relates to a service for which the individual or a third party, other than the health plan acting on behalf of the individual, has paid the covered entity in full. So this is kind of the statute. We've expanded it slightly to specify that the individual him or herself does not have to pay in full, but you could have a third party pay on behalf of the individual.

In the preamble we do recognize that there may be some challenges in this, including, for example, to what extent restrictions have to be passed on downstream to recipients of information, obviously, not the health plan, but other potential recipients. We particularly raised the example of pharmacies where an individual might go to a provider, request a restriction, but there might be medication related to the health services that are paid for out of pocket. If there is an e-prescription done then by the time the individual gets over to the pharmacy the pharmacy may have already communicated with the health plan to determine what the appropriate payment amount is. So that's one of the challenges that we've identified is does the electronic prescription have to support some means of passing on this restriction. Do you have to avoid electronic prescriptions in this case, which we recognize is not a laudable goal? So that's just one of the examples; I thought the one example most relevant to this group of some of the challenges that we see on this restriction.

So, going on to slide eight: There are a number of other areas of the proposed rule that I won't talk about to this group, but I'll just raise as marketing; fundraising; compound research authorizations, which pertains to where certain research authorizations can be required; in other words, you will not receive clinical treatment without finding this authorization and the ability to combine that to optional authorizations; disclosures by providers of student immunization records to schools based on oral consent rather than a full authorization. There are some changes with respect to deceased individuals, including that after 50 years from the time of death the information is no longer protected under the privacy rule under the proposal; some changes to enforcement; and we've also set forth compliance deadlines and proposed transition periods for business associate agreements. Specifically on that, when the final rule is published, which is going to be still a number of months off, there will be 30 days before it becomes effective and then we're proposing a 180-day period before compliance is required. Then on

top of that we're providing a transition period of up to a year for covered entities and business associates to revise their business associate agreements.

That concludes my rather short summary of the NPRM. I'll now open it up to questions.

Paul Egerman – eScription – CEO

Before we do questions let me just say, Adam, thank you very much for producing this short summary, especially since we're getting it like the day after you produced the rules. I mean you're really on top of things to be able to do this. I just want to say I very much appreciate your efforts. So our questions should really be oriented to understanding the material that Adam has produced, so what questions do people have?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Hello. This is Micky Tripathi.

Adam Greene – OCR/HHS

Hello, Micky.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Hello, Adam. How are untethered PHRs, like Google Health and ... and others treated under this?

Adam Greene – OCR/HHS

To the extent that they're providing services directly to individuals rather than on behalf of a covered entity, they are neither covered entities, nor business associates. Now, it could be theoretically that they serve both functions. It could be that they have a line of business that goes directly to individuals, but they also have contracts with particular covered entities to offer their tool on behalf of the covered entity, in which case they may be a business associate in some respects, but not others. But to the extent of whether they're tethered or not, I don't want to suggest that that necessarily dictates it. It might be more of what their overall relationship is with a particular covered entity.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Okay. So if a covered entity, like a hospital system that had its own patient portal allowed the ability for a patient to upload their information into Google Health is that considered a contract between Google Health, say, and that entity or not?

Adam Greene – OCR/HHS

No. We would not consider that. If Google Health, as a line of service, offered to actually create the PHR solution for the covered entity that would be a different story, but simply the covered entity providing the ability to share information with the PHR would not be acting on behalf of the covered entity.

Deven McGraw - Center for Democracy & Technology – Director

Adam, this is Deven. On the same line of questioning from Micky, I wasn't writing notes quickly enough. You mentioned that you guys had talked about this in some guidance.

Adam Greene – OCR/HHS

Right. Back in December of 2008 when the ONC published the privacy and security and confidentiality framework we also did a series, as part of a toolkit with that. We did a series of HIPAA papers on various health information exchange topics. One of them is devoted entirely to PHRs and talks about this distinction.

Deven McGraw - Center for Democracy & Technology – Director

Okay. Great. Thank you.

Adam Green – Progressive Chain Campaign Committee – Cofounder

I can go ahead and send that to the group if people are interested.

Deven McGraw - Center for Democracy & Technology – Director

Yes. Please do.

Paul Egerman – eScription – CEO

That would be great. Thank you.

Judy Faulkner – Epic Systems – Founder

Adam, if the healthcare organization and the PHR, Google or ..., for example, work together to do an interface versus that it's just a general mechanism to upload information, if instead they're working on interfaces together is that considered meeting a business associate agreement?

Paul Egerman – eScription – CEO

That was Judy Faulkner speaking.

Adam Greene – OCR/HHS

Okay. In a case like that I would probably say we would need to see the facts of a particular situation to see to what extent they are acting on behalf. If it's simply ensuring that there's connectivity, but the PHR is really offering the services directly to the individual outside of the particular covered entity then that probably would not. But if it's something much more than simply ensuring connectivity then that could go into the area of acting on behalf of the covered entity. Does that help?

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

This is Leslie Francis. Just on that, there are PHRs out there that advertise that they are directly connected. I don't know what the underlying contractual agreements are.

Adam Greene – OCR/HHS

That's something we'd have to look at. We expect, especially as interoperability increases, that more and more the expectation is going to be your PHR is going to be able to connect to your covered entity and that would not indicate that your PHR is acting on behalf of your covered entity, but if there is some sort of different relationship than that we would certainly look more closely at that.

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

Adam, this is Dixie Baker. You didn't mention, I don't believe, the accounting of disclosures. Did you, in this proposed rule, clarify whether an exchange between a covered entity and business associate organization is a disclosure? Was that clarified?

Adam Greene – OCR/HHS

No. The accounting for disclosures, because it's actually in the statute tied to a different time frame, specifically it's tied to publication of ONC standards, we've done that as a different rule making, so there's going to be some time in the near future a proposed rule on accounting of disclosures that will get into clarifying what is meant by a disclosure for purposes of accounting and more specifically, a disclosure "through an EHR," which is the terminology that is used in the statute.

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

Okay. Thank you.

Judy Faulkner – Epic Systems – Founder

Adam, this is Judy again. If the interface goes the other way and it goes from the free-standing PHR into the healthcare organization then what does that mean?

Adam Greene – OCR/HHS

If it's just a matter that they're connected that may not necessarily mean that the PHR is acting on behalf of the covered entity. Certainly, we can envision a time with NHIN Exchange; we've heard talk of PHRs wanting to be at the table there where they may be regularly pushing things into EHR systems so that the physician or other provider can see both, their own information and the PHR information. That would not, whether it's done at a large scale, like the NHIN or whether it's done at a smaller scale that would not necessarily indicate that one is acting on behalf of the other. Does that answer your question?

Judy Faulkner – Epic Systems – Founder

Yes. Thank you.

Paul Eggerman – eScription – CEO

Other questions for Adam?

Deven McGraw - Center for Democracy & Technology – Director

Adam, this is Deven. I think one of the most significant things that I saw in the rule and that you talked about in your summary this morning for some of the discussions that we've been having lately is the extension of liability under the rule, not just to the two layers where I thought it stopped, but essentially from the subcontractors to BAs are themselves considered to be essentially, I guess, business associates of business associates. So when we're thinking about the business associate agreement as a potential tool of accountability for creating some clear parameters around data use it sounds to me like that's much more possible than we had originally thought.

Adam Greene – OCR/HHS

I'll once again add the caveat this is a proposed rule, so you should keep that in mind. But under the proposal you could theoretically have a business associate at the tenth degree, if you will. Each business associate in the chain is required to have a full fledged business associate agreement with their respective subcontractor.

Deven McGraw - Center for Democracy & Technology – Director

Right. And is it safe to say also that at least as you all have proposed, Adam, that the limitations that are in the initial covered entity to business associate agreement have to be respected down the chain? In other words, subcontractor to subcontractor, three steps removed can't enlarge the scope of what can be done with information if that original contract narrows it. Is that a correct assumption?

Adam Greene – OCR/HHS

I'm going to want to talk about that internally before getting back to you on that.

Deven McGraw - Center for Democracy & Technology – Director

Okay.

Adam Greene – OCR/HHS

Certainly, no business associate down the chain could do anything that would not be permitted by the covered entity and would not be permitted by their particular business associate agreement, but whether,

if you will, the circle of permissible uses and disclosures is always the same or narrowing, that's something that I'll have to check back on.

Deven McGraw - Center for Democracy & Technology – Director

Okay.

Gayle Harrell – Florida – Former State Legislator

This is Gayle. I need a little more clarification on that. How many layers would the business associate chain go down? I mean is this ad infinitum? Also, is it very clear that it has to be exactly the same? Can a business associate of the 15th degree have a different kind of an arrangement as to what gets sold, what gets used?

(Overlapping voices.)

Gayle Harrell – Florida – Former State Legislator

... clarification on that.

Adam Greene – OCR/HHS

Certainly. Right now the privacy rule sets forth a number of requirements for what the business associate agreement between the covered entity and the business associate must state. That includes that there's no use of disclosure permitted that would not be allowed by the covered entity itself so, for example, covered entities under the proposal would be very limited in how they can sell PHI and so the business associate could not sell PHI in any fashion if the covered entity could not.

All of the same content requirements for the covered entity to business associate agreement also have to be included in each subsequent agreement down the chain. So business associate number ten, if you were to ever go that far; and I'm not advocating that people do; but if it ever got to that point, their business associate agreement with business associate nine would have to have all of the same requirements. It doesn't have to be a carbon copy. It doesn't have to be identical, but it has to meet the same content requirements that are found in the HIPAA privacy rule, including that BA10 cannot use or disclose in any way that the covered entity could not.

Paul Egerman – eScription – CEO

I'd also add, if I understood your slide presentation correctly, business associate number one is responsible for the actions of number two. Number two is responsible for the actions of number three and so on.

Adam Greene – OCR/HHS

Right.

Paul Egerman – eScription – CEO

That inherently creates the sort of limitation that I think Deven is asking –

Adam Greene – OCR/HHS

I want to add a caution to that. They're responsible in two respects. One would be if they learn of a practice or pattern of non-compliance then they have to take certain actions, which are the same actions that a covered entity currently has to take, which would be attempt to have the business associate remedy the pattern of practice and if they don't, terminate the agreement. Previously we indicated if termination is unfeasible then you have to notify the secretary that we're proposing to remove that, so that is one level of responsibility.

The other is agency, but I don't want to suggest that agency is necessarily the majority of cases. Under traditional agency law, having nothing to do with privacy, a principle is liable for the actions of an agent and so we're just saying that's the case here. A business associate who, as an agent subcontractor, would be liable for those actions, but if it's an independent contractor relationship, which an example would be you're basically paying for the results, but don't have any control over how the business associate subcontractor actually performs the actions, that would not be an agency relationship and that would not create a level of liability for the upper business associate.

Deven McGraw - Center for Democracy & Technology – Director

Right. This is Deven. Because HITECH extends direct liability to business associates, essentially they're liable themselves for their own misdeeds –

Adam Greene – OCR/HHS

Right. If the question –

Deven McGraw - Center for Democracy & Technology – Director

... by an independent contractor.

Adam Greene – OCR/HHS

Right. So it's a question of whether just the subcontractor is liable or whether potentially both the subcontractor and the above business associate are both liable for the actions.

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

This is Dixie again. I still have two more questions on how this all happens. If I'm the patient and down three or four levels down my person information is sold and it is divulged to people inappropriately, what's my recourse as a patient? Do I go after the covered entity? Do I go after business entity number one, number two, number three to get to number four? What is my recourse as a patient?

Adam Greene – OCR/HHS

As a patient your recourse upon learning of the sale of your PHI would be to file a complaint with the Office for Civil Rights and we would investigate and if we determined that the subcontractor, business associate or whatever entity was involved violated the privacy rule they are potentially subject to sanctions of \$50,000 per violation, in some cases, up to \$1.5 million a year for certain continuing violations. Also, there is another recourse with respect to state attorneys general that they have authority under the statute to also do some enforcement, so that would be your recourse as a patient.

We recognize that as you get to these greater levels there may be less transparency for the patient and that's something that we certainly would welcome comments on how to deal with. The breach notification will also go to all of these, so if there is a breach at the subcontractor level they would be required to notify up the chain and the covered entity would be required to notify the individual.

Paul Egerman – eScription – CEO

That's very helpful, Adam. As usual, you've done an excellent job. I mean I really appreciate this presentation and certainly appreciate all that you are contributing to our work. So thank you very much. I think we could ask a lot more questions, but unfortunately, we have also a fairly packed agenda.

Adam Greene – OCR/HHS

You're welcome. Thank you for this opportunity.

Deven McGraw - Center for Democracy & Technology – Director

Thank you, Adam.

Paul Egerman – eScription – CEO

So I appreciate that and appreciate your continued participation, because you can also help guide us as we go through our work to make sure that we're not doing something that's conflicting or inconsistent with this new, proposed rule.

Moving on on the agenda in terms of the things that we need to cover, I already discussed what's shown on the screen, our goals. What we're trying to do here today is to address some specific issues that have been raised by ONC: Where we are on the agenda is basically we're sort of at the point now of the bottom item that shows on the first page of the agenda, which is framing the issue. In a minute Deven is going to discuss a little bit more about the key issues related to data collection and re-use.

Then what we're going to try to do, if you're on the next page, is we're actually going to try to develop our recommendations on each of these questions. There are nine questions. We hope to get through four or five of those today. If we get through all nine of them we can enter ourselves in the Guinness Book of World Records as an absolutely superior Tiger Team and perhaps get an opportunity for a medal. But I hope we can get through at least four or five of those and start to introduce the topics for our next meeting. So that's what we're going to be trying to do.

As you look at these slides; I'll show you this next slide; you can see immediately the influence of I want to thank Joy Pritts for hiring ... and the people at ... who are just doing a terrific job to help Deven and me and relieve us of a lot of work. So they're putting together these fancy slides for us and that's why all of the sudden things are looking a lot more professional, a lot better.

So what you see here in terms of framing the basic scope of what we're trying to do, to remind everybody, this is really just a reminder; it shouldn't be anything new. I call this our atomic view. When you're talking about health information exchange, the darker blue, assuming you're looking on a color monitor, is public health reporting, treatment coordination, care, quality reporting. Those are the three things that we're mainly focusing on over the summer. The grayed out areas, patient access, research, claims and payment processing, we're not going to be focusing on them over the summer. That's not to say they're not important. Obviously, patient access is clearly extremely important. It's just that we can't do everything in patient access by itself. It's a fairly complicated and interesting issue, so just to remind everyone, it's coordination of care and treatment, which is probably going to be the bulk of our work, but also public health reporting and quality reporting are the major aspects of our scope.

So to talk about framing this, Deven, why don't you take us through this section?

Deven McGraw - Center for Democracy & Technology – Director

Okay. Great. Thank you very much, Paul. Essentially, we want to give folks some background here, because as is always the case, there is both, existing law that pertains to the questions that we're going to ... as well as some work that's been done by ONC and its associated teams, again, all of it relevant to the questions we're discussing today.

With respect to HIPAA and then the HITECH law, certainly there are provisions in law already that cover the collection, use and disclosure and retention of information. I think the Tiger Team members are basically familiar with those, although, certainly as we come up on particular questions if there are issues where people need clarification on what current law provides, we can do that.

What's not on the slide, but is always in play, and if I didn't mention it, I'm sure Gayle would help to remind me and that is that there are state laws that apply in this space as well. It's actually the Data Use and Reciprocal Support Agreement, otherwise known as the DURSA, is an agreement that has been in the works for quite some time now with a particular team of folks that have been working with ONC and it's an agreement among health information exchanges; exchanges as a noun; and integrated delivery systems that are participants in sort of the initial NHIN efforts.

This data use agreement sets out the parameters for participation by these entities and it includes federal participants as well in the NHIN. Again, it was developed by the NHIN cooperative with private sector and government participation. It is based on existing body of law and policy claim work. It's a comprehensive agreement that is intended to ... of health information. It creates a common set of trust expectations into an enforceable, legal framework via the contract largely. It's already completed four rounds of federal clearance. Much of the discussion in creating it really pre-dated the enactment of the HITECH legislation, but it was most recently revised in November of 2009. That's certainly the most recent version that I've read. I suspect there are probably a few others on our Tiger Team who have read it as well. It's not a short contract, but for anybody who wants to read it, we certainly have the resources to share it. It's on the ONC Web site on-line.

I want to provide an example of some key provisions just so you get an idea of some of the decisions that are incorporated into this agreement. Participants who are not federal agencies or covered entities or business associates are required by this contract to comply with the use and disclosure provisions of HIPAA as if they were covered entities. Participants may retain, use and disclose information received via the NHIN in accordance with the applicable law and whatever their own policies are. So in other words, what this agreement governs is what are the terms for exchange through the NHIN once it comes into a participant record, how you then retain, use and disclose information is in accordance with the law that you have to comply with, federal and state, and your own policies. If you terminate your agreement any information that you retained when you were participating in the NHIN, again, it's not as though you have to give that back. That's information that you received, that you were authorized to receive according to the contract and then how you use it subsequently is governed by the laws that apply to you, federal and state, and then whatever your own policies and procedures are.

The other thing that I think is worth noting about the DURSA is that it does create some limits on how participants can use it, for what purposes. So participants are permitted to exchange message content, i.e., protected health information, for the following purposes only: Treatment. Payment, although this is limited and again, we're not focusing on the payment pieces here, but it's going to be relevant to future discussions. Healthcare operations under HIPAA, but it's limited only for the first two categories of healthcare operations, which, for those of you who are familiar with the definition, there is about eight different components to it. It's the first two and those are largely related to care coordination and quality assurance. It has to be for the subject patient, not for your patient base overall. Specific public health activities and reporting. The quality reporting that's required for meaningful use. Then, of course, disclosure that's pursuant to an individual's proper authorization.

Now, there's a lot more in the DURSA, but we wanted to pull these pieces out to provide you with some background of some work that has already been done that is quite relevant to the discussions that we're going to have today in terms of what our recommendations would be to the Policy Committee.

Again, to remind us, we're dealing with the questions that we're trying to provide recommendations to the Policy Committee at the July meeting; those questions broadly are what limits should be placed on the collection, use and disclosure of PHI by providers and what limits should be placed on the use, disclosure and retention of PHI by third party service providers, also sometimes known as intermediaries. Then we

have some sub-questions that we distributed to you ahead of time. We did get some initial comments from Leslie Francis and John Houston at NCVHS, but rather than circulating it, since we have Leslie fully on the call today, she'll be able to contribute herself to those discussions. I think in the future; Paul, you can correct me if I'm wrong; we're still hoping to be able to resolve remaining issues that we can't resolve in these calls, e-mails in the interim, so notwithstanding that, I think folks with the short week didn't have quite as much time to get us feedback. We hope that you will continue to do so in the future.

Paul Egerman – eScription – CEO

That's fine. One thing I would add, Deven, is when people have feedback they should feel free to send it to all of the members of the Tiger Team ... should not just send it to Deven and me, because that actually slows it down. We're going to read it. Feel free to send your comments to everybody. We want to give you a chance to have a discussion.

Deven McGraw - Center for Democracy & Technology – Director

Yes. Okay. Does anybody have any questions about anything that we've talked about in the framing, if I said anything about the DURSA that doesn't comport with your understanding of it? Speak up.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. Just zoom way out; in light of what we heard from Adam this morning discussing the proposed changes for the privacy rule, these questions should be framed as what in context of that, as extensions that would particularly focus on HIE for meaningful use, which might go further than the privacy rule?

Deven McGraw - Center for Democracy & Technology – Director

Yes. I think that's right, because I don't think that we are – well, I mean if people want to frame their particular comments in terms of wanting a specific modification to the privacy rule I would suggest that that's off the table, but we have to assume current law and, of course, while the proposed rule is just a proposed rule, I think we should think about that as sort of a possibility of the policies that are either already in place or proposed to be in place and think about if we have specific recommendations that are either on top of that or maybe they do go directly to the proposed rule.

I'm not sure if that answers your question, David. I mean we have to take current law into account, but I happen to think that these questions go to what's beyond is already in current law we might want to see in terms of some limitations. To me, Adam's presentation suggested that there may be ways through BA and subcontractor agreements to enforce some of the policies that we would like to see enacted, but it doesn't answer the question; it only arguably answers the question of how. It doesn't answer the question of what.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Okay. That's helpful. I just think that there is a lot of connection between the two based on what we heard this morning.

Deven McGraw - Center for Democracy & Technology – Director

Yes. Absolutely. Okay. So, given that, we have sort of the first sub-question within the broader two over-arching questions that we want to try to answer and that is should the exchange of PHI for treatment be limited to treating the individual, who is the subject of the information and not necessarily your other patients?

So, just for folks who are not familiar of the definition of treatment under HIPAA, which was not changed by HITECH in any way, which is treatment basically means any treatment and is not limited to the subject

patient, so a provider could look up the PHI of patient A's siblings in order to treat patient A or the PHI of patient B, who is unrelated to patient A, in order to treat patient A. So, certainly the DURSA draws some lines here and so we have put up a couple of options. This is not to say these are the only options, but these are some options that we thought of to start the discussion.

One would be exchange of PHI should be limited to the treatment of the individual who is the subject of the information. This is essentially the limitation that's in the DURSA where exchange can take place for treatment if it's treatment of the patient who is the subject of the information that you are either collecting or disclosing.

Another potential option is sort of maybe I would call this the status quo, exchange of PHI may include any treatment and is not limited to the individual who is the subject of the information.

Now, before we begin the discussion I want to remind folks that we are having an over-arching policy discussion, but recognizing that we may, depending on the model exchange that we're talking about – in other words, as you'll see on the bottom of this slide, there is a set of over-arching policy recommendations that we're talking about, but we're also raising the possibility that the policy recommendation may, in fact, be slightly different depending on the model of exchange that we're talking about.

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

I have a question, Deven. This is Dixie Baker. I actually looked up this in the law, the definition of treatment and it wasn't clear to me whether that includes diagnostics and preventative care.

Adam Greene – OCR/HHS

This is Adam. I can confirm it does. The definition of healthcare that feeds kind of the definition of treatment includes diagnostic care.

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

Okay. I didn't dig deeply enough then. Thank you, Adam.

Adam Greene – OCR/HHS

Yes. There's always another layer to the onion.

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

Yes.

Judy Faulkner – Epic Systems – Founder

This is Judy. The concern that I have on this is, for instance, newborns and mothers. If I understand it right, you can't look up mother information from the newborn or newborn information from the mother. I believe from what I hear from the physicians that that's essential for appropriate treatment.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I think you could extend that; that there might be other genetic relationships where there is equally critical, albeit, maybe less common clinical interplay between two subjects.

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

This is Leslie Francis. But that's exactly the kind of situation where patients may be deeply concerned about leakage of information. For example, within a family if one sibling has been tested for Huntington's

and the other one does not want to be tested for Huntington's it would seem inappropriate to have that information leak through an interchange when historically, of course, everything would have been siloed.

Judy Faulkner – Epic Systems – Founder

This is Judy and I agree with you. I do think there should be an exception though for maternity.

W

I think you also get into some STDs and people who may not want a chain. If you're going to talk about HIV or STDs, how far down that chain do you go in opening other people's records?

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

That was the other example John Houston and I used in the comments we sent Deven.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

W

I think it becomes very dangerous without consent.

Deven McGraw - Center for Democracy & Technology – Director

I want to remind folks to; this is Deven, just to remind myself; make sure you introduce yourself before you make a comment for the public, who may be listening on the call and want to know who is speaking.

Paul Egerman – eScription – CEO

Deven, do you want to introduce Linda's ...?

Deven McGraw - Center for Democracy & Technology – Director

Oh, yes. Thank you very much. So, we have the assistance of ..., which Paul mentioned earlier and which is terrific. If we can, Allison, switch to the shared desktop with Linda Koonce of ...? She can help us. When it looks like our discussion is coming to some recommendations then she's going to help us by making note of them so that we're not counting just on minutes. What we want to avoid is spending endless time wordsmithing in this process, but we do want to keep a very close record of where the discussion is going and where we may be developing consensus, which will help us be prepared to refine recommendations in later meetings and then present them to the Policy Committee, as well as share them with people who are not able to be on the phone.

Paul Egerman – eScription – CEO

And also, in some senses, two options are shown. Those are sort of exclusive options. The first one says you're going to limit treatment to only one patient. The second option says you're not going to do that. So that's basically what we're talking about right now. Those appear to be the two choices, although maybe there's another choice where you limit it and you ... your limits lower –

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

This is Dixie Baker. I apologize for not sending my written comments. I didn't know we were supposed to, but my recommendation is between those two. I think it should include the PHI of the individual receiving the treatment, plus PHI of other individuals that may have a direct relationship and value in treating that individual.

Deven McGraw - Center for Democracy & Technology – Director

Dixie, this is Deven. So who makes that call?

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

The physician. The professional. The licensed professional.

Deven McGraw - Center for Democracy & Technology – Director

Would you limit that to family members or leave it to the professional to determine if there is a need to know?

Gayle Harrell – Florida – Former State Legislator

This is Gayle Harrell. I have a real issue with opening it up without consent ... people.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

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

I think I would add Gayle's. I agree with you. Even if it's family I think consent should be there.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. As I worked through these questions last night the question of consent kept coming up. I know we've postponed that until a later session, but I assume the context here should be what can occur without explicit consent other than the treatment of the patient. Is that the way we're to interpret these questions, Deven?

Deven McGraw - Center for Democracy & Technology – Director

Yes. Basically. Because if you think about what current law says about consent, which is under federal law, assuming we're not talking about substance abuse treatment, treatment information, treatment, payment and operations data can be exchanged for that purpose without the need to get consent, but of course, in some states and particularly for some types of sensitive information, there is a requirement to get patient authorization first.

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

Deven, this is Leslie Francis. We should flag for later consideration when we go back to consent the question of granularity. For example, if there is going to be all-in or all-out the question might be ... about whether people would consent to have their records shared for treatment with some purposes to others, for example, for genetic ... they would limit who those others might be –

Deven McGraw - Center for Democracy & Technology – Director

Leslie, I'm just going to interrupt you. I acknowledge that it is very hard to separate these discussions and I think it's a good idea for folks to say, to sort of signal that they be accepting of limitations and beyond that with patient consent, but not to get into too much detail about the parameters of that consent because it's going to be a little diverting from the main topic, I think.

(Overlapping voices.)

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

This is Dixie Baker. I suggest, so that we can move on, we simply attach to number one without explicit consent and move on.

Judy Faulkner – Epic Systems – Founder

This is Judy and I think that the problem still stays with mother and newborn, in which case the mother, who, I think for almost all of us, we can't imagine a mother who doesn't want the child taken care of well.

From the physician's point of view you have to know if the mother has an STD. You have to know the medications, because you may harm that child if you don't know that. That mother may not be able to give consent and I think in that case, from the instant before the child is born it's considered part of the mother and the instant afterwards that information still needs to come across if the mother is unable to give consent. I think it's okay if the mother says no, which I can't imagine, but I think that if the mother is unable it should be a presumed yes.

Deven McGraw - Center for Democracy & Technology – Director

Well, and I think that, Joy and Adam, you can help me out here, but certainly for newborns the parental consent laws are clear for minor treatment. Maybe we just need to note that.

Paul Egerman – eScription – CEO

But, Deven, the example that Judy is giving is ... like a pediatrician treating a newborn –

Deven McGraw - Center for Democracy & Technology – Director

Right.

Paul Egerman – eScription – CEO

Needs to know does the mother have a sexually transmitted disease or needs to know there is some substance abuse issues. That's critically important information, so that's information about the adult, not ... presumably an adult; it could be a minor too, but that's a whole other issue, presumably an adult.

(Overlapping voices.)

Gayle Harrell – Florida – Former State Legislator

This is Gayle. That's where the consent of the mother comes in and normally those kinds of things are done pre-admission.

Deven McGraw - Center for Democracy & Technology – Director

Yes. I think that I see –

(Overlapping voices.)

Gayle Harrell – Florida – Former State Legislator

... the mother is not capable.

Deven McGraw - Center for Democracy & Technology – Director

This is Deven. I think the tricky part is when the mother doesn't consent. Right? Is that what you're getting at, Judy and Paul?

W

There's always the ability to go through the courts for a minor and you can do that very quickly if there is a life threatening issue or something that is absolutely imperative that a doctor needs to know. The doctor can immediately go to the court and get an injunction and get the ability to do that.

Deven McGraw - Center for Democracy & Technology – Director

Okay. Let me see, without getting into too much detail in this recommendation, it sounds as though with the exception of needing mother's information to treat newborns, which I kind of want to put off to the side for a second, that the basic rule of exchange of PHI being limited to treatment of an individual, who is the subject of the information, unless you have the consent of the patient to have their information accessed

or disclosed for treatment of others, is that sort of where we're landing, without carving out the newborn issue for a second?

W

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. Could you restate that Deven? I just missed the details.

Deven McGraw - Center for Democracy & Technology – Director

Yes. No. That's okay. It's essentially recommendation number one: Exchange of PHI should be limited to treatment of the individual, who is the subject of the health information unless you have the consent of the subject for broader use, putting to the side the question of access to maternal information in order to treat infants, newborn infants. The reason why I'm carving it off to the side is I feel like; I don't know about the rest of you; it would be helpful to actually find out if the folks on the DURSA coordinating committee thought about this before they put in that treatment of the subject only restriction.

Christine Bechtel - National Partnership for Women & Families – VP

Deven, this is Christine. I agree and I was thinking; I mean there is probably some clinical people, people with clinical backgrounds who ... could be helpful. You may have covered this, but can you remind me of the recommendations we make will we have an opportunity to solicit some public input on them in case we're not making a decision with all of the information we might need?

Deven McGraw - Center for Democracy & Technology – Director

Yes, although it's not through formal means. I mean we have the public comment period here. Paul and I talked about using the blog, the FAVA Committee Blog, to try to solicit input from the public on some of our recommendations we're considering in between our meetings, which we have not done before, but we certainly would like to do so. Then, of course, when things get presented to the Policy Committee we get feedback too, but there isn't sort of a formal comment period. It's really only through informal mechanisms and of course, it would be great if members of the Tiger Team could do a little outreach to their networks where there are pertinent issues like this one where we really should get feedback from some other folks before we would move forward. Does that make sense?

Christine Bechtel - National Partnership for Women & Families – VP

Yes. We can certainly do the informal outreach as well. I think the other ways of getting some public input are good. We might just, by the end of it, come back to the question of whether it's possible to do like an RFI from the Policy Committee, which I know we're planning to do on meaningful use. Once we have our comprehensive set and people see how they interact together and with the design considerations it might be something to think about for later, but let's keep going.

Deven McGraw - Center for Democracy & Technology – Director

Okay.

Adam Greene – OCR/HHS

Deven?

Deven McGraw - Center for Democracy & Technology – Director

Yes?

Adam Greene – OCR/HHS

... can I just throw out some considerations?

Deven McGraw - Center for Democracy & Technology – Director

Of course.

Adam Greene – OCR/HHS

The first is one other option to consider is in our guidance we talked about that if a patient doesn't want their information to be used for the treatment of others they can request a restriction, which, under the HIPAA Privacy Rule there's no requirement that the provider accept that request. But another option would be instead of making it ... consent that you provide the option of any restriction, so kind of the opt-in/opt-out of looking at things.

Another consideration is just to keep in mind infectious disease where, especially if there is some strange, clinical situation, knowing what the treatment of others in the immediate area may be very important –

Deven McGraw - Center for Democracy & Technology – Director

But, Adam, wouldn't that be considered a public health use versus treatment?

Adam Greene – OCR/HHS

No. A disclosure to a public health authority would be public health, but within the first days where you're just talking about using another individual's treatment information, that wouldn't fall under our public health. I think that that's something different.

Deven McGraw - Center for Democracy & Technology – Director

Can you just check on that? Only because I thought I read in the proposed rule of the different public health uses that contact tracing or communicable disease notification was part of it, but –

Adam Greene – OCR/HHS

To a public health agency.

Deven McGraw - Center for Democracy & Technology – Director

Okay.

Adam Greene – OCR/HHS

You know ... CDC, that sort of thing. That would fall under public health, but it may take some time for CDC to recognize that there's an outbreak in an area whereas ... you may want to do it knowing that some other patients have the same clinical symptoms may be a more immediate need.

Deven McGraw - Center for Democracy & Technology – Director

Right. Well, your comment, Adam; this is Deven; is making me think of a question I'm going to throw out to the group, which is whether this restriction, this limitation on treatment exchanges, if this is one where model matters. So if you're talking about directed exchange from a provider's record where they're in control of it would we put this same limitation on that type of exchange versus the ability in sort of a query response, federated or centralized model? To me it's different, but I'm not sure if the other members of the team share it and so that would get to, Adam, so I would be much more comfortable with a provider using his or her own patient records than going out and querying other records to do their own sort of public health surveillance after one of their patients shows up with an STD.

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

Well, the truth is; this is Dixie; in these other models a public health agency would probably be the one that did that. So I think it's most likely to be applicable to the direct model, but I think it's a valid exception and should be acknowledged.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. This is David. Deven, could you clarify? In the directed exchange model are you referring to, does that mean push specifically, that provider A pushes the PHI to the other provider versus the other two models, when the other provider has to query for the data?

Deven McGraw - Center for Democracy & Technology – Director

Well, to avoid the word push, because I love that term, but I'm reminded by Judy and Paul that it's not exactly an appropriate way to describe it. So when I think of directed exchange it is provider vetted, to use a term that Latanya once used. So, in other words, you might get a query from somebody from the record, but the provider decides whether to send it or the provider initiates the sending on his or her own discretion.

To me those are both push models, because ultimately, the control still is with the record holder and the action is taken by the record holder, but I don't know. That's still push to me, but I understand that some folks don't want to call it that because it's two slightly different actions.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So you're making a distinction; this is David again; on who has final control of the decision for the release, whether it is the requester or the responder?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. Deven, this is Carol. I think you put your finger on it, which is that once the control over access moves to another party the provider doesn't have the same role to play and I think that is a significant change.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

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

Yes it is.

Paul Egerman – eScription – CEO

But the issue of this part of the discussion, I want to be careful that we don't continually revisit the definition of the models. We did that in our last meeting. We sort of agreed that these definitions are so much helpful to us in some ways, but the boundaries between life federated and centralized ... some cases federated and directed ... those are unclear boundaries and a lot of exchange exists in the hybrid –

Deven McGraw - Center for Democracy & Technology – Director

And I totally agree, Paul, which is one of the reasons why I'm trying – I mean I used directed exchange when I started, but Carol actually clarified it very nicely for me and it's more of a control issue.

Paul Egerman – eScription – CEO

That's exactly right. So the real issue is do the various models have an impact on the recommendation that we're making here.

Deven McGraw - Center for Democracy & Technology – Director

Right.

Paul Egerman – eScription – CEO

And it would appear that they don't –

Deven McGraw - Center for Democracy & Technology – Director

No. It appears that they do.

M

Yes. I think that we're confused about the details of the models or who has control and whether that affects this decision or not.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

The reason I say it doesn't is if you look to the centralized model where all ... the issue is still the same question. Should exchange be limited to the treatment of an individual? So in that example there is accessibility to other individuals, but still the question is is the access still limited to a single individual? It's the same question, it's just that the provider has possibly more alternatives in the other models.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, it may be the same question, Paul, but the person who answers it or the entity that answers it is different in these models. I think that is big. Look, this is the reason why I think these three models, breaking them out this way and trying to create policy for any of them is going to be very difficult, but I want to just say that the big issue here from a policy perspective is who makes the determination about when to share information –

Paul Egerman – eScription – CEO

No. That's not the question. That's not the question that I asked –

(Overlapping voices.)

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

It is. Can I please finish?

Paul Egerman – eScription – CEO

I'm sorry, Carol. No. We have some issues that we have to address –

Deven McGraw - Center for Democracy & Technology – Director

I get that, Paul, but I actually think that Carol's framing is critical to resolving the issue.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, so just let me finish here, okay? We may feel differently about the options on the table if we know who is making the determination about whether or not to respond with the information that's being requested and that is an issue of who has the control over whether or not to respond. I do think that plays into our answer around which of these two options we would recommend.

Deven McGraw - Center for Democracy & Technology – Director

This is Deven. Let me frame the question to the group a little bit better. I mean looking at the recommendation that we have on the table is a sort of exchange of PHI limited to the treatment of the individual, who is the subject, unless you have the consent of that subject for further use where the provider is in control of decisions about disclosing information from her record are we saying that you can't disclose information from your record except with respect to treatment of the individual who is the subject, which would definitely be a narrowing of HIPAA, versus wanting to only apply that policy in models where the record holder is conceding some or all, some control over that decision.

M

I'm confused.

Deven McGraw - Center for Democracy & Technology – Director

So in other words, without acknowledging that there are hybrids between centralized and directed I'm focusing on sort of the ... of control here. For me this is partly because I do, admittedly, have greater concern over models where the record holder has conceded some control over decisions about disclosures from the record and those are the ones that I think need to have more parameters placed on them versus where you have the provider/record holder in a vetting role and either initiating the disclosure or making a determination to respond to a particular request. Maybe that's not shared with others, but I think that's the game changing, different from patient expectation piece of this for me.

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

This is Dixie. I agree with you. Deven, and I think that Carol's point is really, really important. I think that that's what should be the two boxes ... is whether the HIO makes the decision or the provider or the individual makes the decision.

Gayle Harrell – Florida – Former State Legislator

This is Gayle. I can tell you that when you put that second entity in there, decision making prospect, no matter what model it is, the game changes ... from ...

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

And that's really the important connection I think.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I think that's especially true in the absence of clear consent. Otherwise we say we'd rather trust a provider to make the right decision than a system that doesn't understand granular consent.

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

But that's a good point, David. Because since we phrased it as we want number one, except with consent, it probably doesn't matter because in any case they need to get the consent.

Deven McGraw - Center for Democracy & Technology – Director

Well, no. It would be consent if it wasn't about the subject of the information.

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

Right. But if it's the subject of the information then the exchange is allowed anyway.

Deven McGraw - Center for Democracy & Technology – Director

That's right. For treatment.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. This is David again. The way I'm hearing it is in the absence of consent if we would want to put ... restrictions on the queriers ... get data about a different patient, very tight restrictions, if the querier can ask another provider, where it sounds like we're willing to put more of burden on that other provider to decide whether the data can be released, absent explicit consent otherwise.

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

But if we have, assuming we have identity controls in there, right?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. I am assuming everybody is who they say they are.

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

Everybody is who they say they are. Then even if it's the HIO that gives you the information, shares the information, exchanges the information, it still is the information of that subject and nobody else.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But we're specifically asking about queries for someone other than the subject.

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

No. We said that that can't happen without consent.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I thought that was the question within the directed exchange model. Do we want to modify that opinion? That was Deven's lead-in question. Does it make a difference which model?

Deven McGraw - Center for Democracy & Technology – Director

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And I thought we were leaning in the direction that it does make a difference, because if it's a provider making the decision to expand the release of information to a different patient, a different subject, then we are more comfortable with that than we are if it is a database making the decision.

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

I'm not. I—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's why I'm trying to bring this out because, depending on how you say it; it either makes sense or it doesn't make sense.

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

Yes. I think it's the same in all three. Without that second party's consent the information shouldn't be shared.

Gayle Harrell – Florida – Former State Legislator

This is Gayle and I agree with Dixie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

When you say it that way it makes sense to me too. This is David. Carol, what do you think?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'm confused now.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I'm sorry.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I mean I think that we are not smart enough to think of every permutation that happens in the course of clinical care to say unequivocally that the determination by the provider and the patient on both ends of this question has to only happen one way. In other words, I'm all for sort of the patient authorizing the query, but the provider on the receiving end of that, if they are the ones being asked whether or not they can release that information it creates a different kind of a stop-gap than relying on a third party to answer the query, regardless of patient consent. In other words, I think there is an issue here that is different than consent.

Let's not forget also that consent for release of records, these things can say a lot of things, including whether or not the patient, at some point, might agree to getting information about a significant other or what have you. I think the stop-gap of having the provider on the receiving end of that query making the determination of whether or not to respond is an added protection.

M

I'd like to also echo that. Our privacy ... is very explicit that it falls to the provider that's making the disclosure to decide whether or not to do this. It's a discretionary matter I think that is very relevant from our perspective to this discussion.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Right. And that determination cannot be made if there is somebody else making the decision about releasing the records.

M

So what basically we're saying is in the models other than directed exchange this issue is a little bit more difficult, but are we saying that as a result we're going to change our policy recommendations?

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

I think we're saying it's a little easier; that they absolutely need to consent in anything but the directed, but we may be more lenient in the directed model.

Deven McGraw - Center for Democracy & Technology – Director

Yes. That's what I think we're saying.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But I think with Adam's clarification, which is it's the provider that needs to make a determination about the disclosure ultimately, I think that that is a policy statement that needs to be a part of our recommendation. I don't think it's our job to say you can't possibly do that with this model or that model, but I think the provider being in control of their data and answering whether or not to disclose information is a requirement in this policy.

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

This is Dixie. Do you, Carol, when you refer to a provider are you referring to a provider organization?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. The entity who's got the information and who is going to make the determination about whether or not to share it.

Gayle Harrell – Florida – Former State Legislator

This is Gayle. I'm going to have to leave the call. I have to get on an airplane. But, Deven, or someone, if I could give you a call maybe later this afternoon or tomorrow, I would like to pick this up, because this is a great concern to me

Deven McGraw - Center for Democracy & Technology – Director

Okay. Sure. Yes. Don't call me on Saturday, Gayle, but –

Gayle Harrell – Florida – Former State Legislator

I'll call you on Monday. How about that?

Deven McGraw - Center for Democracy & Technology – Director

Okay.

Gayle Harrell – Florida – Former State Legislator

Okay. I'll call you Monday.

Deven McGraw - Center for Democracy & Technology – Director

Thank you. So let me try to re-frame the recommendation here. In models where the provider is not – when the provider has control over disclosures from the record – I'm sorry. Hold on.

M

We need to distinguish, Deven, between the querying provider and the responding provider, I think, here.

Deven McGraw - Center for Democracy & Technology – Director

Right. I'm just trying to figure out how to phrase it here. So we started with a limitation on exchange that would be narrower than HIPAA and say that you can't exchange PHI for treatment unless you're doing so for the individual who is the subject of the PHI or you've got the consent of the subject for broader access –

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

Of the subject that you want to use, right? That's a different –

Deven McGraw - Center for Democracy & Technology – Director

That's right. The subject of the record.

M

The expanded subject. Yes.

Deven McGraw - Center for Democracy & Technology – Director

But we would not apply this limit when the provider is in control of making the determination of whether to disclose the data. It's not perfectly worded and I would want to tinker with it. Again, we still have the newborn issue too –

W

Deven, you know what? I actually don't think it should be an either/or. I think this is a big policy fork in the road for any of these exchange policies that we're going to discuss, which is in a query whether or not the

provider has control over whether or not to respond. I will tell you, even in the analog world, even let's use phone calls; providers get a lot of phone calls for records or from other provider offices and if it's someone they interact with regularly they respond differently than if it's someone they don't interact with regularly.

Deven McGraw - Center for Democracy & Technology – Director

Right.

W

I do think this issue of having the entities being asked for the data making the determination about the disclosure is a big policy consideration, I think, for a lot of our recommendations. I wouldn't say that it's an either/or. It should, according to Adam's clarification as well, be part of the requirement in responding to this.

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

It really is a separate slide, if you will.

M

And I think the question about which provider is making the decision is relevant. You could imagine, for example, an HIO with a centralized database hiring a nurse who fields all of these calls –

W

I think that's not what we're talking about.

M

So we need some notion of a provider with a relation, a treatment relationship with the subject –

W

Yes. I think that's what we're talking about.

M

I think that needs to be clear.

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

I agree with Carol. It's really an umbrella issue. It shouldn't be bundled in this question. It should be kind of the preface to all of these questions.

Deven McGraw - Center for Democracy & Technology – Director

Dixie, in what way? I don't think I understand what you're saying.

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

Like there should be a question that says who should decide, who should be responsible for deciding whether to release information that is requested. You could say what we just said, that it's the provider that holds the information for that patient or something like that. But it's like sort of a definition of the bottom. It's the answer to that whole bottom blue stripe.

W

I think it's going to be a policy recommendation, which is more over-arching than simply whether or not the information about someone related to the patient can be released. I think we're going to find that as we go through these issues who is answering the request is going to make a big difference in our view. I

think the over-arching recommendation is, especially again, I'll say with Adam's clarification about response is the ultimate responsibility for disclosure resting with the provider, I think the over-arching policy issue to clarify is to say that the provider who has a relationship with the patient is ultimately accountable for disclosure and therefore, needs to control the release of records, which is basically what happens today in the paper world.

W

Right, which is true. I think I mean I'm just trying to figure out how that works in some of the models that the states are – how we're going to provide guidance to the states that are developing models where there is some sort of conceding of control by agreement. So in other words, the providers are not making individualized decisions, necessarily, about what flows from their records, but a collective decision about sort of terms of access, use and disclosure.

W

Right. And that may cover some data and some forms of information sharing, but it won't and shouldn't, I guess, cover everything.

W

That's right. So in other words, if the fundamental principle is the provider with the patient relationship is responsible for and should be in control of decisions about release of information from those records, a provider can concede this control, but if we wanted to say that a provider can concede this control, but that ability to delegate in a treatment context should be limited to sharing the exchange of information for the individual, who is the subject of the PHI versus sharing that information for another person unless you've got individual A's permission. Does that –

W

I mean I don't know how everybody else feels, but I don't know that we necessarily need to go there. I think it's enough to say that ultimately, by law, the provider is accountable for the disclosure of information and should be in control of that disclosure. I don't know. I mean people may feel differently. I feel like it's not – we're getting into the weeds of the weeds if we go on to, in these situations, it's okay to delegate it; in these situations it's not. I don't think we can think of every permutation.

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

Yes, but I think that the whole concept that Deven just expressed; and this is Dixie Baker; that the provider who holds the record, really, because its too hard to decide across an HIE who is responsible for whom, but the provider who holds the record for that individual is ultimately responsible for deciding, making the decision on whether to release it and share it or not is the basic premise.

W

Yes.

M

So I'm trying to understand how to ... this recommendation, how we phrase this. I mean we're saying exchange could be limited to the treatment of the individual, the subject of the PHI and also subject to approval from the record holder.

Deven McGraw - Center for Democracy & Technology – Director

No. I got the impression that where the group was leaning was to a more affirmative statement as a recommendation; that the provider with the patient relationship is accountable for determining what gets disclosed from that patient's record.

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

But we're recommending that as a more over-arching recommendation and then come back to this specific recommendation.

M

Okay.

Deven McGraw - Center for Democracy & Technology – Director

Okay. So let's assume that we've done that because I didn't actually really hear any objection. So what would the specific recommendation then look like? In other words, so then we're saying that it's really the decision of the provider about when to disclose information for treatment purposes, because –

M

Right, but then—

Deven McGraw - Center for Democracy & Technology – Director

... policy. So essentially, it's number two, but with a clear statement that it's the record holder's obligation to make that determination.

Adam Greene – OCR/HHS

Deven, this is Adam.

Deven McGraw - Center for Democracy & Technology – Director

Yes?

Adam Greene – OCR/HHS

Maybe it would help also to clarify kind of an individualized decision, because when you enter into initial contracts for health information exchange you're often times making kind of global decisions on how you're going to be exchanging for treatment. What I'm hearing here is that there is interest in more individualized treatment in this particular set of circumstances.

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

This is Leslie Francis. I think that's a very important question because once the provider says it's in the exchange, at the outset, it sounds like the recommendation has just gone full circle to say well then, the provider ... so it can't.

Deven McGraw - Center for Democracy & Technology – Director

Unless, Leslie, we were to say that as a policy matter we think that providers can contractually permit disclosures from their records for treatment purposes, but only when it's treatment of that individual, the patient who is the subject of the record as opposed to leaving it just up to the full discretion of the provider.

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

This is Dixie. Maybe what we're coming to, I think, is a number one with two exceptions, one for directed and one for the others and the one for the exception with directed is except the provider decides that they need to see these other records and the exception for the other two is unless they have the consent of the others.

M

Right.

Deven McGraw - Center for Democracy & Technology – Director

Right.

W

No. But I think if we just say you need the consent of the patient we've taken away the stop-gap of the provider, who is in the position of disclosing the information, making a determination.

Deven McGraw - Center for Democracy & Technology – Director

This is Deven. I thought Dixie made a distinction and applied the piece about requiring consent for a record to be used for broader than just treatment of the subject of the record in context where the provider has ceded some control.

W

Right.

M

Maybe –

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

That to an extent would apply to the federated end and centralized and optionally to the directed, but the directed would have the exception that if the provider felt that it was in the patient's best interest they could make that determination. They have control.

M

Maybe there's a way to phrase this without referencing the models

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

Yes.

M

The way you phrase it is you say if limited to the treatment of the individual with the following exceptions. The exceptions are if you have consent of another patient or if you have approval from the record holder of another patient. Those would be the two exceptions.

Joy

You know, my sense is that we should make the policy recommendations that we think are in the best interest of the patient and the provider and not try to contort ourselves into these three models. I agree with the recommendation of not talking about the models.

I think the recommendation is that the disclosing provider; let's call it that; who has a relationship with the patient, needs to make the determination about whether or not to release the records and not go into whether they've ceded that control or allowed somebody else to make the determination. Ultimately, accountability will rest with them and it's an additive policy protection, which is to have the provider make a determination about whether or not to respond to these requests.

Deven McGraw - Center for Democracy & Technology – Director

Feedback on that?

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

I don't understand that.

M

Yes. I don't understand how it answers this question is what I don't understand.

W

Joy doesn't want to answer this question.

M

Pardon me?

W

She's posing a larger principle.

W

Yes.

Joy

I'm posing the principle, but I'm posing it in a context of this question as well.

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

We already agreed on the principle.

M

Yes. I think we agreed on the principle. I was trying to answer the question.

Deven McGraw - Center for Democracy & Technology – Director

Well, good. I mean we have agreement on the principle, so, Linda, let's get that down. So the principle being that the provider or record holder ultimately is the one who needs to make the determination about what gets disclosed from the record, right?

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

Right. Yes.

Deven McGraw - Center for Democracy & Technology – Director

So then the question – Carol is suggesting we should end it there, so in other words, the answer then to the question of whether there'd be limits on exchange of PHI is no expressed limit, but a dependency on the record holder to make those determinations in accordance with their policies and the law that they have to follow.

W

And the individual, right?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. So what happens with it when there's an unattended health information exchange present and that record holder is not available?

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

Well, or the HIO is the record holder –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. Right.

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

I think we need to capture that the treatment relationship with the patient; we need to capture that so that the HIO can't arbitrarily decide.

Deven McGraw - Center for Democracy & Technology – Director

Yes. Actually, Linda already put that in for us; provider with a patient relationship is ultimately responsible for making the decision on what gets disclosed from his or her records, right? Because there will be multiple providers with treatment relationships and each is responsible for the records of the patients they treat.

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

For the records that they hold, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But that means then the provider would never release records to a health information exchange prior to a request and that a provider has to gate every release in real-time?

W

No. I don't think it means that at all. I think it means that ultimately the provider is responsible for making the determination with patients about what information to share. If a provider decides that there is certain information that's always going to be shared, as happens in many HIEs, then that's the determination of the provider and the patients that they're treating, but I don't think we can possibly go into all of the permutations of what information is standardly released and what information is not in this specific question that we have, which is information about someone related to the patient. I think what we're saying is both, that the individual and the provider, who want the information, have to agree – the patient has to agree and the disclosing provider has to agree and not go into the details of how each model would do that.

Joy

This is Joy. Ignoring the models, what you just said differs from what the recommendation is, because the recommendation is that the provider with the patient relationship is ultimately responsible for making the decision. There is no consultation with the patient in the recommendation at this point.

W

Yes.

M

But I don't think that's right, is it?

Joy

Well, I'm saying that this is what is requested here and I'm not sure that's the intent.

M

Yes.

W

No. I thought you were saying the provider with the patient relationship and the authorization of the patient, so maybe I missed something.

Deven McGraw - Center for Democracy & Technology – Director

Well, in part because we were suggesting that we have part of this as this bifurcation of consent after we've had some discussions about whether we want to put any expressed limit. We're trying to sort of shape the landscape of consent to what before we get to individual authorization questions.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. I think we've –

Deven McGraw - Center for Democracy & Technology – Director

Quite frankly, if we made it, to me, I'd like to continue to defer that piece because it's a big enough issue that we have to continue to discuss it I think when we have some dedicated time to doing so.

David, I'm sorry. I didn't mean to interrupt you.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I'm just thoroughly confused. I apologize. I maybe haven't had enough coffee.

W

You're not alone.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It almost seems like we need scenarios to act out here. It's gotten so confusing. I find myself reflecting back on episodes of *House* or TV shows where the whole show hinges around discovering hidden data and it can get really complicated. So it's not surprising that we're confused, but it seems like the specific issue here is assuming there is data available and the provider would like information about someone other than the patient being treated, related, then would we allow permission? What would be the constraints for that? We're saying that in general no access to the other patient's data would be allowed with the exception that if you make direct contact with a treating provider that treating provider could decide, under other rules, under his standard responsibilities, to release that information.

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

Except a default is with consent.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, we've taken consent out. That's where it gets so hard.

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

I don't think so. I think that was our going in position is that consent is required to use somebody else's information and now we're working on with the exception of if the provider decides that it's life critical or whatever. But I think the going in position is getting the person's consent, obviously.

W

I agree.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. Without consent it doesn't make a whole lot of sense to even ask the question.

W

I agree. The provider's willingness to disclose the data is not a substitute for the patient's authorization.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right.

W

Well, now I'm confused.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Whether direct or not. I mean –

W

Well, let me give you a scenario and I'm hoping to flesh this out a little bit. So if the individual, because we're promising this, we're trying to keep the consent issue out of this – so if information is uploaded, is generally available through some sort of exchange and a provider, who is treating a patient with, we'll say, XYZ disease says, "You know, I'd like to see the records of other people who have XYZ disease just because I think that would be a good thing to do," and he doesn't have relationship with those other people is that something that would be allowed or not allowed under this?

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

No, not without –

W

No. Not allowed.

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

Not allowed without consent.

Deven McGraw - Center for Democracy & Technology – Director

Let me, just so we can close on this and try and move on, we've got a clear statement about the provider with a patient relationship to be ultimately responsible for deciding what gets disclosed out of the record about patients. I'm ... the consent thing because I just want to close something out here. Are we suggesting that where the request comes in by another provider for a record that is where the requesting provider does not have a treatment relationship, but it's Joy's example, we want to make sure that the provider has the patient's consent before that gets released? Certainly, folks seem to be comfortable with that. I mean the maternity issue we may have to explore in a little more detail, but are you guys also saying that you want to have patient authorization for any query for an authorization being a very specific requirement, by the way, under HIPAA for any request for information, even for treatment purposes where both providers are treating the patient for each and every instance?

W

No. No. I don't –

W

We don't have to go there.

W

We're not there.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

We're talking about other patients.

Deven McGraw - Center for Democracy & Technology – Director

Then I think I need to understand where the consent point is coming in. Again, we're trying not to resolve that issue here, but I feel like if we could tie that end down we might be able to move on.

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

I think we've decided. I think we agreed upon and somebody raised it, but a while ago we agreed that, number one, exchange of PHI should be limited to the treatment of the individual who is the subject of the health information except with the consent of the second individual we agreed upon and this provider stuff is more equivalent to a break the glass scenario, where the doctor decides that, "really need to get to this information," like Judy's example of the mother.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I had that same thought. This is closer to a break-the-glass scenario than anything else.

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

Yes, but we need to capture, number one, with consent because that part we did agree upon.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

The spirit is that you can't go exploring other people's records unless there is either expressed consent to do so or it's an emergency –

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

Right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

You have to put that in ... –

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

Yes.

Deven McGraw - Center for Democracy & Technology – Director

Okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And knowing full well that it's an emergency is not an excuse in and of itself. I mean it's regulated by all sorts of other HIPAA rules.

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

Right.

Deven McGraw - Center for Democracy & Technology – Director

I'll just put break-the-glass on the whiteboard for us, which is to say from my own experience it's a slippery slope and we should come back to that issue at some point and really define it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

Deven McGraw - Center for Democracy & Technology – Director

Okay.

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

Comma, except with consent of the other person ...

M

So if we took break-the-glass –

W

Wait – and the control of the disclosing, and the agreement of the disclosing provider. Maybe that's already –

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

No. If they gave their consent that should be fine.

W

No. See, I'm saying it's not an –or." I'm saying it's an –and." In other words, to go back to the consent issue, if there's broad consent that's agreed to by the patient for information exchange and we all know what some of these documents look like and this scenario comes up it is protected to that patient for the provider who controls their information to decide whether or not or how to respond to the request about someone other than the patient that's being treated by the requesting provider.

M

Are you saying that if I'm a patient and I say I want my information given to this physician my personal physician can override my decision and not provide that information?

W

No. No. I'm saying if you've expressly consented to that particular request that's one thing, but we haven't really gotten to consent yet and what you might have instead done is signed a form saying you consent to have your record shared generally in an exchange and this particular scenario I think is situations in which things change. It becomes a sensitive condition, whatever, it's a minor. I don't think we understand what the patient's authorization or consent looks like yet and I guess all I'm saying is it is also protected for the patient to have a request for their information being made by someone who is not treating them to go through their provider.

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

I think the HIOs just become ineffectual

W

Well, I don't necessarily know that that's true, Dixie. I mean I feel like we could make these statements, but carve out for some further discussion on whether there are any conditions on a provider sort of ceding this ultimate authority through contract for an HIO, for example, or some sort of more central exchange. Carol didn't want us to go down that line, to go down and parse that too finely, but there was also, I didn't think, any disagreement on the call that that's entirely possible. But what we're doing here is ultimately making a statement about so the record holders are responsible and similar to the earlier set of recommendations we made, that's a delegable authority that providers can make and they've got to make the judgment call for that, how that takes –

W

Right.

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

So if I have the patient's consent to give my information to an HIO then you are also saying that the provider can say, "Yes, HIO, you do have my agreement to share this with those people."

W

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But then that means any provider could search the HIO for whatever he wanted.

W

Right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Then they're sharable? That doesn't sound right.

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

If the individual gave their consent for that –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But no, they gave their consent presumably for treatment purposes and this is not related to your treatment. It's treatment for somebody else.

Joy

This is Joy. I think we can capture some of this by breaking this out of element. I'm just trying to clarify what I think has been said and I'm sure you will let me know if I haven't I have no doubt about that.

I think that the policy recommendation here, as written, is a little confusing and I would say the exchange of PHI for treatment should be limited to the treatment of the individual who is the subject of the information –

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Joy

Okay. Then I would put a period there, because what I think comes after that are some separate, perhaps, policy recommendations or recommendations that could be made separately so that it's a little clearer, because the consent one, you're going to have this exception in everything we discuss and so we're trying to avoid having that in-depth discussion on that right now. We could just presume that this is happening. The premise here should be that you're talking about exchanges without the consent of the individual.

W

Right.

Joy

And that we could get into these other parameters after that, because I think it raises a really good point that they could be captured separately.

Then a separate policy recommendation here is this last thing, which is that the provider with the patient relationship is ultimately responsible for making – well, except what you're saying is the provider and the patient, the provider with the patient relationship is ultimately responsible along with the patient for making the decision on what gets disclosed. Is that what is meant there?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, I think that's the spirit, but that's fairly vague. Can the provider override the patient? Probably not, except for public health.

Deven McGraw - Center for Democracy & Technology – Director

Yes. My suggestion is to leave those two, even though it's a little vague and we may need to flesh out some more details, particularly on the topic of consent, when we get to it, which we're getting there very soon. But if we sit with those, Linda, can you do a hard return between those two sentences, please? Sit with those two recommendations on this piece and see if we can't, because I felt like the group liked both of those statements and we may need to clarify them a bit more as we go, but I think we should, unless Paul objects, try to see if we can't tackle ... first.

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

Would you consider adding to what gets disclosed to whom and for what purposes?

Deven McGraw - Center for Democracy & Technology – Director

Yes. I mean that's law.

M

All of this is law, isn't it?

Deven McGraw - Center for Democracy & Technology – Director

Well, I mean that's the state of the current law, so sure. Does anybody have an objection to that?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Which sentence were you adding it to, Dixie?

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

The bottom.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

The bottom. Yes. Okay. No. No objections from me anyway.

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

I'm taking it, David. You have to take it where you can get it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I have several colleagues on the phone who might think differently.

Deven McGraw - Center for Democracy & Technology – Director

I don't hear them.

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

Good.

Deven McGraw - Center for Democracy & Technology – Director

All right. Paul, let's see if we can do another question.

Paul Egerman – eScription – CEO

Okay. So if we go to slide number 11 ... the slides, I wonder if we can do this. It's a little hard to read with the small font. Could we get the other presentation or is this it?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

You might make it go full screen. It might –

Paul Egerman – eScription – CEO

Okay. So here is what this is saying; I guess I shouldn't ask for that.

Deven McGraw - Center for Democracy & Technology – Director

Be careful what you wish for.

Paul Egerman – eScription – CEO

That's right. So here's what it is on the screen: In order to facilitate a PHI request how should the relationship between provider and patient be confirmed? This is the relationship between the requesting provider ... considerations. Should you just trust the requesting provider? Is trusting the requesting provider sufficient? There was like four alternatives that were written or maybe there are others. One alternative was trust the requesting provider. The second was get an attestation for the treatment relationship. The third one was obtain some other affirmation demonstrating treatment relationship. Number four was, I guess, a contractual agreement. So those are the four options. I know NCHVS people had a comment on this. I don't know if you're still on the phone, Leslie, but –

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

I'm here. This is Leslie Francis. This comment comes from John Houston, who in his experience at Pittsburgh believes quite firmly that three and four are really unworkable given the wide variety of arrangements that are likely to be there and ... the ... organization should be held to having corporate controls in place for governance oversight process to be sure that

Paul Egerman – eScription – CEO

Okay. So that's a comment that suggests option number one. Am I understanding that correctly?

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

Option number one coupled with controls on attestation and oversight by somebody like

Deven McGraw - Center for Democracy & Technology – Director

Right. Like an audit trail, for example. This is Deven.

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

Exactly. Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I assume that audits are a given here, but it might not hurt to call that out.

Paul Egerman – eScription – CEO

So the assumption is, assuming that there is security that validates identity and that there's an audit trail ... access?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. I think those would be assumptions that we should state.

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

Right. That was the assumption of John's and my comment.

Paul Egerman – eScription – CEO

Somebody just said something. I didn't quite get that. Could you say that again?

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

This is Leslie Francis. The audit trail and the opportunity to oversee the presence of the audit trail was an assumption of John's and my comments.

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

This is Dixie. I think it's not just audit trail, because that's not something a patient really can see, but rather an accounting for the disclosure. In my notes I went so far as to say that the accounting of disclosure should be automatically provided to the patient.

Paul Egerman – eScription – CEO

So let's, first of all –

Deven McGraw - Center for Democracy & Technology – Director

We definitely have to touch that last one. We only --- that.

Paul Egerman – eScription – CEO

Linda is running. I think we should go to that white board view of this now because we're starting to get some things that perhaps we should write down. Thank you.

I just wanted to make sure I've got this right. So far what I'm hearing is people like the idea of trusted provider. They just have like two or three caveats; that there is security in place so that we know the correct identity. There is an audit trail and there is basically accessibility to that audit trail –

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

No. Not audit trail. An accounting of disclosure.

Paul Egerman – eScription – CEO

An accounting of disclosure. I'm sorry.

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

Right.

Paul Egerman – eScription – CEO

And accessibility. I think that's good.

Deven McGraw - Center for Democracy & Technology – Director

I'm going to use my co-chair prerogative to parking lot the accounting of disclosure recommendation. It's a big issue, number one.

Number two, OCR needs to come up with some regulations on it. I mean I just think it deserves a session, if not of its own, where we have more time to talk about it.

Joy

This is Joy. From what I've heard it sounds to me like people were saying trust the requesting provider, assuming that they are HIPAA compliant, HIPAA security compliant. Is that accurate or not?

Paul Egerman – eScription – CEO

Yes. That's what I'm hearing, to trust the requesting provider assuming there is correct HIPAA compliance and controls or whatever the right words are.

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

Well, I was going more towards the attestation, which is still trusting the provider, but trusting them to be more than just a provider, but to assert that they; if I understand it; I'm not the lawyer; but I think attestation just means they say, —I have a relationship," right?

Deven McGraw - Center for Democracy & Technology – Director

Right.

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

That's what I would go with.

M

Yes. I was going to say that I think they should make a statement at least once as to why they're accessing the record.

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

Yes.

W

Yes. I agree with that and it shouldn't be that dissimilar from what patients are already asked to essentially attest to.

M

Providers.

Deven McGraw - Center for Democracy & Technology – Director

Providers.

W

Yes.

Adam Greene – OCR/HHS

This is Adam. Just to clarify, HIPAA actually does include a verification requirement that states that you must obtain any documentation, statements or representations, whether oral or written, from the person requesting the PHI when such documentation, statements or representation is a condition of the disclosure under HIPAA. So if that hasn't been applied in this context necessarily, but there's some requirement in HIPAA to ensure people are attesting to why they're providing something.

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

Good.

M

Is the requirement to attest why it's being provided or why it's being requested or are those the same thing?

Adam Greene – OCR/HHS

The requirement is by the requesting provider and it's just attestation that that provider has a treatment relationship –

M

Yes.

Adam Greene – OCR/HHS

Some relationship with the patient that we're doing this. It's almost like it's a variation of some of the comments that were made in the previous discussion. The provider is not cruising through the documents looking at them. If he's looking at a record he's doing it because he's saying, "We got a relationship with the patient."

M

Yes. I think that's what most EMRs would do.

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

Do we assume HIPAA security and privacy?

W

Yes.

W

I'm going to try to recapture that here, which is the ... recommendation is that the requesting; and again, jump in; I'm not trying to put words in that aren't accurate; the requesting provider should attest of their treatment relationship with the individual at least once and should be compliant with the HIPAA security rule –

W

And privacy.

W

And privacy, of course.

M

Isn't that sort of essentially a combination of number one and number two?

W

Yes. I think so.

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

Yes, it really is. These are sort of additive I think.

M

Right. Right. Each one is an additional restriction.

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

Yes.

M

We're saying go as far as two, but not as far as three or four.

W

Right.

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

Yes.

M

So, just to be precise, I believe, to make sure that we're all in agreement, there are some systems, for example, that would require electronic evidence of a visit or an encounter before access to the record would be granted. That would be more like number three or number four and we're saying that's unworkable?

Deven McGraw - Center for Democracy & Technology – Director

Well, no. I don't know that we're saying that. I would set these as policy minimums.

M

Yes. We're not saying don't do it. I see what you're saying. Yes.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

M

Deven's point is a good one. Basically, an organization could say they want to do something more than this.

M

Yes. They could set a higher standard.

M

There's nothing that stops anybody from setting a higher standard.

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

And whoever is writing here needs to change that one to two.

W

Let's just not even put a number on it because it's a combination.

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

Right.

W

So I'm going to read this slowly, I think, and correct me where we feel it's necessary: The requesting provider, at a minimum –

Deven McGraw - Center for Democracy & Technology – Director

At a minimum, Linda.

W

Should provide – this is slow –

Deven McGraw - Center for Democracy & Technology – Director

It's not you, Linda. I'm sure it's the network.

W

Should provide attestation, some attestation. You don't need it. It could be like clicking a box, right?

M

Right.

W

Okay. Some attestation of their treatment relationship with the individual at least once. And then we can say this ... recommendation assumes that the requesting provider is HIPAA compliant. Does that work?

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

Except for the at least once. I think we should kind of once per request or –

W

Yes. Okay.

M

You could say something like an episode or –

W

Episode of care?

M

Yes.

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

Yes. That's good. Episode of care.

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

This is Leslie Francis. Make sure that the HIPAA compliance flag ... the governance for John, because if HIPAA compliance doesn't come with appropriate oversight there would be concern.

W

Do you mean oversight in addition to OCR oversight?

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

Well, let's just call it whatever you get to when you get to governance, which I know is later on the table. There may be a question whether OCR oversight is regarded as sufficient governance.

Deven McGraw - Center for Democracy & Technology – Director

We will white board that one for later.

Paul Egerman – eScription – CEO

Okay. So let's return to what's written here. Do we have a consensus around this policy recommendation?

Deven McGraw - Center for Democracy & Technology – Director

I think so.

W

I'm not able to open that URL unfortunately. Could somebody just read it?

Paul Egerman – eScription – CEO

Sure. Requesting provider, at a minimum, should provide some attestation of the treatment relationship with the individual at least once per episode of care. This policy recommendation assumes that the requesting provider is HIPAA compliant.

W

Good.

W

Good.

Paul Egerman – eScription – CEO

Okay. So, not hearing any objections and being afraid to ask any questions about the models, let's move on to the very next question.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Just one point. Can I just make one point of clarification? Again, I think this has come up again and again. I heard you, Paul, say people could choose to do more than that; in other words, there may be sensitive cases or what have you and that is true only if the control of the information rests with the provider who wants to do more than that. It's harder to do if there's a blanket agreement for information to be shared and the information is already put somewhere and a third party controls it.

W

Although, Carol, you could also foresee a circumstance where a group of providers, such as an IHI could agree to a higher level of attestation for their data sharing.

Paul Egerman – eScription – CEO

That's true.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. They would all have to agree to the same level if the information was shared only through collecting information centrally. They could, in fact, agree to this level; in other words, they could employ different levels if they had specific needs if they have some control over how the information is shared. That's my only point.

Paul Egerman – eScription – CEO

Those are good observations, but having achieved this rare and wonderful moment of equanimity on this recommendation –

W

... the recommendation—

Paul Egerman – eScription – CEO

I wanted to enjoy that and, if you don't mind, why don't we move on to the next question?

W

Revel in it.

Paul Egerman – eScription – CEO

Yes. Let's move on to the next question and see if, perhaps, we can get some momentum and do some more because we don't necessarily need to argue the issue about the minimum right now.

W

I'd like to do one housekeeping detail here real quick. Carol, if you get on ONC's Web site, if you type in "HIT Policy Committee" and you use the link on that site it works. I had the same problem.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Okay. I'll try it. Thank you.

Paul Egerman – eScription – CEO

Good. Thank you.

Judy Faulkner – Epic Systems – Founder

This is Judy. I've been in and out ... time permits, but I missed –

W

Yes, Judy. This could be problematic.

Judy Faulkner – Epic Systems – Founder

Can I just ask you a question though? Did you define what episode of care is for the ambulatory environment or not?

Paul Egerman – eScription – CEO

No. That's a great question, but we could put that on our parking lot, but I don't think we need to do that for this recommendation.

Deven McGraw - Center for Democracy & Technology – Director

I don't either. That may be a level of detail that could be ONC's to resolve.

Paul Egerman – eScription – CEO

Yes.

Deven McGraw - Center for Democracy & Technology – Director

If it needs to be.

Judy Faulkner – Epic Systems – Founder

In the in-patient environment it's very clear. In the ambulatory it's very –

Paul Egerman – eScription – CEO

Yes. It's an excellent question.

Deven McGraw - Center for Democracy & Technology – Director

Yes. Good question, Judy. Thank you. Sorry about that. I just wanted to avoid a circumstance where we've got something resolved, but that's a good question, so my apologies.

Paul Egerman – eScription – CEO

Thank you for joining us after the wedding. Congratulations.

Judy Faulkner – Epic Systems – Founder

No, I'm not getting married.

Paul Egerman – eScription – CEO

I didn't know. I'm sorry.

W

... I've not set up ... yet, so—

Deven McGraw - Center for Democracy & Technology – Director

Okay.

Paul Egerman – eScription – CEO

Deven, the next question.

Deven McGraw - Center for Democracy & Technology – Director

Okay. All right. So, will providers who are not covered by HIPAA be permitted to access PHI through an HIO? This is already arguably somewhat model dependent in its current phrasing.

W

So we may need to rephrase the question?

Deven McGraw - Center for Democracy & Technology – Director

We may need to rephrase the question. One could even rephrase it should data exchange with non-HIPAA covered entities be permitted and if you've got a non-HIPAA covered entity what do you do. What additional requirements ought to be in place?

We know that even not all providers are covered by HIPAA. It depends on whether they electronically ... service. Certainly there are others also. The PHR question that came up earlier about recall that we are trying to limit this set of discussions to exchange among providers, so we're really talking about the class of providers, who are not covered by HIPAA.

Paul Egerman – eScription – CEO

It might be helpful to give a few examples.

M

Yes. Could you clarify which providers those are?

Paul Egerman – eScription – CEO

...

Deven McGraw - Center for Democracy & Technology – Director

Adam, Joy, do you want to help me out?

Adam Greene – OCR/HHS

This is Adam. There is a certain list of standard transactions and for providers the most relevant would be billing usually, so if you, for example, only do cosmetic surgery and don't go through insurance at all you may not be a HIPAA covered entity because you don't electronically bill. If you're a small practice; and I think under Medicare law small practices are still permitted to do hard copy billing; then you could theoretically, if you choose to do only hard copy billing and only hard copy exchange you can get around HIPAA compliance. You're not required to comply with HIPAA. Whether it's realistic that these entities would be involved in health information exchange is very much another question.

Paul Egerman – eScription – CEO

What about entities like social workers or physical therapists? Are those HIPAA?

Adam Greene – OCR/HHS

If they do any electronic billing, which, if you do electronic billing you have to do it through HIPAA standards so there is kind of separate HIPAA transaction, so if they don't have any insurance relationships including Medicaid, then they theoretically may not be HIPAA covered entities.

Deven McGraw - Center for Democracy & Technology – Director

But their coverage is not because they're not physicians. It's because they don't bill electronically.

Adam Greene – OCR/HHS

Exactly.

Deven McGraw - Center for Democracy & Technology – Director

So lines don't get drawn that way.

Adam Greene – OCR/HHS

Right.

W

In at least the D.C. area there are a lot of dentists who cannot accept and file insurance on behalf of individuals.

W

Isn't that the truth?

Deven McGraw - Center for Democracy & Technology – Director

Okay. Good point. Washington D.C. dentists.

W

Yes.

Deven McGraw - Center for Democracy & Technology – Director

So the options that we have on the table, providers who are not covered by HIPAA can exchange PHI, but you said they have to be covered by privacy and security rules. I'm trying to massage around the model dependency way this was initially framed. If you're not covered by HIPAA you can't is option number two.

Option three is we're not going to worry about this. All providers can exchange and if they're covered by HIPAA they're covered and if they're not, they're not. Period.

W

Adam, correct me if I'm wrong, but isn't number three the way things are currently under HIPAA?

Adam Greene – OCR/HHS

Under HIPAA you are right; you are permitted to disclose to another provider for treatment, for example, without regard to whether the other provider is covered by HIPAA.

W

Oh, really?

W

I missed that. What did he say?

Adam Greene – OCR/HHS

That under HIPAA currently you are permitted to disclose to a healthcare provider even, for example, without regard to whether that receiving provider is a HIPAA covered entity.

Deven McGraw - Center for Democracy & Technology – Director

Right. Okay. Thank you. Sorry about that. My mind was racing ahead to the next comment and I missed that clarification.

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

I have a question about; and this is more general; should we be referring to IIHI rather than PHI?

Adam Greene – OCR/HHS

The difference is IIHI is basically protected health information except for employment records and information under FERPA.

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

Well, the key point is that even if you are not involved in the HIPAA transaction, HI needs to be protected. PHI is restricted to those. Especially in this particular question we're really talking about IIHI I think.

W

Well, in terms of the way the question is phrased.

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

Yes. In general we're really talking about if there will be non-HIPAA entities through these HIOs then we really should be prescribing policy regarding identifiable health information, not just PHI.

Deven McGraw - Center for Democracy & Technology – Director

Okay. That's fine.

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

My comment about this is I kind of like number one, but I don't know how it would be enforced.

M

Yes.

W

Yes.

M

Yes. I like number one as well, but wonder about enforcement. I mean it's tempting to say if you use X12 you come under HIPAA. If you use this HIO you come under HIPAA. Why not make it symmetrical? But that would require law.

Leslie Francis, Ph.D., J.D. – NCVHS – Co-Chair

John's suggestion was approval. This is Leslie Francis. John's suggestion was agreement by the non-HIPAA covered provider to accept HIPAA requirements.

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

You know, the DURSA that you went over earlier, Deven, does include a requirement that they meet the HIPAA if they are not a covered entity. How is that enforced?

Deven McGraw - Center for Democracy & Technology – Director

Right. Well, it's contractually enforced. If you don't abide by the rule you can have your sort of privileges to exchange be terminated.

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

So maybe this should be parallel to what's in the DURSA.

Deven McGraw - Center for Democracy & Technology – Director

Well, this may be one where; I'm trying to sort of think this through in the context of this just may be one of those areas where there is an enforcement capability in the form of a contractual agreement that can bind providers who come there and agree to exchange data in those types of models. It just doesn't exist when you're talking about a sort of directed exchange from one provider to another where provider B is not covered by HIPAA, unless provider A decided I'm not going to exchange with anybody who doesn't commit to abiding by HIPAA, even if they're not covered or even if they're not technically covered by it.

Christine Bechtel - National Partnership for Women & Families – VP

Deven, it's Christine. This is a sort of half formed thought and I think it's not perfect, but what about enforcement through HIEs that in order for them to be able to participate in the NHIN or in NHIN Direct that this is the agreement they have to have in place with their providers?

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

Yes, which is like a DURSA for NHIN Direct.

Christine Bechtel - National Partnership for Women & Families – VP

Yes. Right. I guess it's a question to ONC whether there are similar kinds of arrangements now that in order for an HIE certainly to have a grant or contract from ONC they have to agree to this and maybe there are some other mechanisms that we could employ for enforcement.

Joy

Was that a question?

Deven McGraw - Center for Democracy & Technology – Director

Well, you know, one thing that occurs to me; this is Deven. I'm not letting Joy answer.

Joy

Thank you.

Deven McGraw - Center for Democracy & Technology – Director

You're welcome to and I'll just shut up, but it occurs to me that we can have, that we do have some criteria like with the meaningful use requirements, for example, that we could think about making sure that data exchangers that are participating in the meaningful use program agree to abide by HIPAA, whether they're covered or not.

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

Yes.

Deven McGraw - Center for Democracy & Technology – Director

So maybe where we're coming to here is a potential stage two policy recommendation that meaningful users agree to comply with HIPAA privacy and security rules.

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

That's actually a phase one.

Deven McGraw - Center for Democracy & Technology – Director

It's not.

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

That's right. You took it out. That's right. It used to be.

Deven McGraw - Center for Democracy & Technology – Director

Well, I think we just assumed that everybody would be covered by HIPAA.

W

But I think, Deven, that's still going to miss a host of providers, who don't participate as meaningful users. I think it's one good option, but there are probably three or four that we would want to recommend.

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

Right. So another one might be -

W

I'm going to jump in. Can we have a general principle, a general policy and then maybe the levers for doing it?

Deven McGraw - Center for Democracy & Technology – Director

Yes. Okay. Good idea. A general policy of providers who exchange identifiable health information should comply with privacy and security rules.

W

I think you were going beyond that. Not to put words in your mouth, but it seems like you were saying that they should be ... I'm thinking should comply; that only pertains to people who are subject to them, so –

Deven McGraw - Center for Democracy & Technology – Director

Well, but how do you get subject to it? Right? So for providers that are covered entities they have to. They're covered. So then we have other tools for requiring those providers, who are not already covered by the rules, to comply and the meaningful use criteria could be one.

W

Okay.

Deven McGraw - Center for Democracy & Technology – Director

NHIN conditions of participation could be another. I'm not sure –

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

I like that. Can we recommend that the DURSA be extended to apply to NHIN Direct?

Deven McGraw - Center for Democracy & Technology – Director

Well, that's complicated. It's a pretty complicated agreement. It doesn't mean we couldn't get there, but it sort of feels like a bigger discussion to me, but DURSA in its entirety, I'd want people to be able to read it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics Yes. I think that radically complicates the spirit of NHIN Direct.

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

Yes it does. Maybe we just put the contractual –

David McCallie – Cerner Corporation – Vice President of Medical Informatics I mean HIPAA is big enough. I don't think we need to throw the DURSA into this debate do we?

Deven McGraw - Center for Democracy & Technology – Director

We're not going to right now David.

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

We're talking about mechanisms though –

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

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

So maybe like an NHIN contract of some sort.

David McCallie – Cerner Corporation – Vice President of Medical Informatics Yes. Yes. That would be one. Would this apply only to nodes or HIOs that are connected somehow to NHIN? I would assume that will take several years for that to happen. There will be many HIOs out there not connected to NHIN that will be participating in meaningful use.

Deven McGraw - Center for Democracy & Technology – Director

I'm not sure I'm answering your question, but you just gave me an idea, David, for a third prong here, which is conditions of federal funding to state HIEs. I don't know if it's too late to even impose those, but –

W

I like that.

Deven McGraw - Center for Democracy & Technology – Director

So it would be, Linda, funding conditions for state HIEs.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Okay. Just –

Deven McGraw - Center for Democracy & Technology – Director

... answer your question, David, which is –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

No, but I like that. That's the direction I was headed. I'm just concerned that in many states there may be 50 or 60 of these HIEs that are loosely federated together in some way. I don't know what the definition of a state HIE is going to turn out to be.

W

Yes. I mean I think we can only speak to the strings that are on the federal funding that goes to the state. It should be federal funding generally so that you cover state HIEs. You should cover beacons. You should cover blah, blah, blah.

Deven McGraw - Center for Democracy & Technology – Director

Yes. Good idea.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right.

Deven McGraw - Center for Democracy & Technology – Director

Linda, did you get that? So federal funding conditions; we could probably just leave it at that.

Adam Greene – OCR/HHS

This is Adam. I have two questions.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Adam Greene – OCR/HHS

The first is is the general policy that they should comply with privacy and security rules generally or only with respect to that particular IIIHI?

M

Hmm.

Adam Greene – OCR/HHS

Then the second question is if it's limited to that IHI do they have to have a privacy officer in place? Do they have to create a notice of privacy practices? An alternative is to talk about uses and disclosures and safeguards.

Deven McGraw - Center for Democracy & Technology – Director

Yes. I mean it's a big question about what pieces of the protections that are in HIPAA we would want to apply to each and every participant.

W

Well, you can tailor your answer to the question that you posed, which was the collection, use and disclosure. That limits the elements. It doesn't adjust the security, but you could add that on too, I guess.

Deven McGraw - Center for Democracy & Technology – Director

Right. I mean I'm not sure, Adam. Can you be more specific about broader application of all of the rules to a provider to collect, use and disclose PHI, how that could be problematic for non-HIPAA covered providers? Because I'm sort of struggling with what I wouldn't want them to do.

Adam Greene – OCR/HHS

I'm trying to figure out, for example, if you have a single case where you want to exchange information is the second provider going to say, "If I receive this one patient's information I now also establish a privacy officer. I have to establish policies and procedures."

Deven McGraw - Center for Democracy & Technology – Director

To be honest, that's a good point, Adam, but I actually think that our particular levers for enforcing the policy options don't really accommodate one-offs, because you're either in meaningful use and you're in for a lot of ... or you want to participate in the NHIN, which means it's going to be more than one patient or you're getting federal funding, likely. With those one-offs we don't have them covered arguably.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Okay. So just devil's advocate or trying to understand the edge cases here, if we allowed one of those solo, one-off providers to access this, the HIE, and pull down IHI are they then free to disclose it in whatever way they want, because they're not covered by any HIPAA privacy constraint? Could the publish it in the newspaper?

Deven McGraw - Center for Democracy & Technology – Director

Well, I think the technical answer to your question is yes, but I think we should think about the recommendation that we set forth in the answer to the first question, which is putting providers in control of their data and so there's that stop-gap of them deciding when it's appropriate to share data with another provider for a particular purpose and who that provider might be, number one.

Number two: Where that decision might be delegated to an entity like an HIO, since they are ultimately responsible for the terms of that contract, arguably, I think they wouldn't. You'd want to be careful. Does that mean you're not going to have the rogue person going off and publishing something in the newspaper because they don't have to comply with HIPAA, although they still have to comply with the law?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, I mean a provider would be crazy to delegate any authority to an HIO if that could occur without –

W

Their knowledge.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right or without punishment. That would be the death of HIOs in a heartbeat.

Deven McGraw - Center for Democracy & Technology – Director

I completely agree. I guess what I'm saying, David, is it's not like it's not possible for that to happen, but I think based on some of what we've already said it seems we've put the guardrails around making that highly unlikely. But we should continue to test these recommendations against those types of scenarios.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So are we uncomfortable by saying that non-HIPAA covered providers; I've got too many negatives –

Deven McGraw - Center for Democracy & Technology – Director

See, this is hard.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It is. I'm looking at number one, no, number two. Providers not covered by HIPAA are not permitted. Are we uncomfortable with that choice? Is that just too restrictive?

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

Actually, that would be my choice. It's too hard –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's kind of my choice.

Deven McGraw - Center for Democracy & Technology – Director

I think the question came up about how it could be enforced and in circumstances where my provider wants to just share information with my non-HIPAA compliant dentist, like—

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

One of the things I thought about; this is Dixie; is that in cases like that that other provider could become a business associate.

Deven McGraw - Center for Democracy & Technology – Director

Yes, but my dentist ... the information to do something on behalf of the primary care provider.

Paul Egerman – eScription – CEO

Deven, the answer to your question goes back to the question itself. The question is non-covered, non-HIPAA compliant or providers not covered by HIPAA, are they committed to access PHI through an HIO? In other words, you can share information with the dentist, just not through an HIO.

M

Right. This is where the model may make a difference. The directed –

Paul Egerman – eScription – CEO

If it was a directed exchange –

M

It would be okay.

Paul Egerman – eScription – CEO

You would be okay, because the presumption is there's a relationship and so since we're focused on exchange through an HIO you could decide, as Dixie said, that option number two is reasonable. It doesn't prohibit the example that you just brought forward.

Deven McGraw - Center for Democracy & Technology – Director

Yes. I think that's right, Paul. I just was trying to, from the very beginning of the conversation I tried to broaden the lens a little bit so that we were engaging this question not just at a model specific level, but in a greater capacity. But certainly, I would agree. It sounds to me that the group is comfortable with the expressed question that's based on this ... has answered number two. No, we don't think they should be permitted to participate in an HIO and exchange data through an HIO if they don't at least agree to comply with – hold on a second. Step back.

Number two basically means that HIO participation is restricted to HIPAA covered providers.

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

Right.

Paul Egerman – eScription – CEO

Right.

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

Right. Because it's the only one that can be enforced.

Paul Egerman – eScription – CEO

Right.

Deven McGraw - Center for Democracy & Technology – Director

Okay. Then I guess I'm not so sure I'm comfortable with that. I would want them to be contractually obligated in order to participate.

Paul Egerman – eScription – CEO

Well, that would be a way to alter—

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

Restrict it to those plus, if they're not HIPAA covered then they have to sign a contract that has the similar or equivalent safeguards regarding the use and disclosure of the data.

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

A contract with whom?

Paul Egerman – eScription – CEO

With the HIO in order to—

Deven McGraw - Center for Democracy & Technology – Director

So how about a friendly amendment to keep the general non-model specific recommendations that we've already got on there, but add to it that with respect to HIO types of models, so non-directed exchange, then participants have to at least agree to be bound by HIPAA.

Paul Egerman – eScription – CEO

Yes. Although – okay. That's fine.

M

Or could be bound by equivalent constraint to HIPAA.

W

Yes. It should be HIPAA, state law and the HIO policy requirements.

M

Yes. That's right.

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

Maybe we put that with our first general recommendation because it's not specific to this one either, right? Well, I guess it is.

W

It is.

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

It is. Yes.

Deven McGraw - Center for Democracy & Technology – Director

So actually, Linda, it's HIO model. With respect to HIO models, participants should be required to comply with—

W

Hold on a second there.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

With respect to HIO models that involve aggregation of data, non-direct HIO models, because somebody is going to consider directed exchange via a messaging system to be an HIO I suspect. I hate to bring it up. I'm sorry. A footnote.

Deven McGraw - Center for Democracy & Technology – Director

I don't understand what you mean, David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, it's the difference between directed exchange where the respondent that's making the decision versus an aggregation model where you are querying a service and there's not a directly responsible respondent releasing the data. It's the difference between asking a person versus asking a database.

Paul Egerman – eScription – CEO

It's an interesting issue, David. I suggest that we—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It's thorny. I'm sorry.

Paul Egerman – eScription – CEO

Put that to the side because we're also running out of time. Maybe if you could send Deven and I an e-mail on that we could figure out how we could try to word that because—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Sure.

Paul Egerman – eScription – CEO

I think what we need to do is simply capture the—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

Paul Egerman – eScription – CEO

I think we're close to an agreement. Let's see if we can capture this agreement.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. Yes. I just was nervous when you say with respect to HIO models, because we have to define what that includes or not.

W

Yes. I'm confused about the definition of HIOs too.

W

Okay. Is it more with respect to query response ...?

Deven McGraw - Center for Democracy & Technology – Director

I actually think it's modeled where the provider is ceding some control through either a participation agreement whereby they're going to, say, agree not to make sort of individualized disclosure decisions, but to bind themselves to a participation agreement. So that's a sort of federated model HIO. It's a hybrid HIO. It's anything where the provider isn't exercising direct control of a disclosure decision.

Paul Egerman – eScription – CEO

Yes. I think that's the essence of it is direct control of the disclosure by a provider.

W

Yes.

Paul Egerman – eScription – CEO

However we craft the language, that's the distinction that matters I think. It's relevant to the previous discussion we had that we kind of got stuck on earlier.

W

Right.

Adam Greene – OCR/HHS

This is Adam. Just to clarify, all of this is limited to the context of where there's no consent, so a patient can still consent to have their information sent through direct exchange, for example, to their non-covered dentist or something like that.

Deven McGraw - Center for Democracy & Technology – Director

That's right.

Adam Greene – OCR/HHS

Okay. Thank you.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Or better yet, put it in their PHR and let them disclose it. A lobbying point here. I'm sorry.

Deven McGraw - Center for Democracy & Technology – Director

That's okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

You will hear it again from me. I promise.

Deven McGraw - Center for Democracy & Technology – Director

I'm counting on it, David. I'll be disappointed if I don't hear it again.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I won't let you down.

Deven McGraw - Center for Democracy & Technology – Director

Okay. I think we're done with this slide.

W

No. We've got to clarify this last sentence, because it doesn't make any sense right now. I'm sorry.

Deven McGraw - Center for Democracy & Technology – Director

Okay. With respect to HIO medical providers receiving control, they don't have directed control over the disclosure –

M

I know how to fix it. A contract that holds the non-HIPAA provider – a contractor is required to hold the non-HIPAA provider accountable to HIPAA state laws and HIO requirements.

Deven McGraw - Center for Democracy & Technology – Director

But we want everybody accountable for the HIO requirements, so a contract binds participants to –

M

Yes. Binds participants. Great.

W

All participants, right?

Deven McGraw - Center for Democracy & Technology – Director

Yes. No. Yes. Thank you, Linda. Great job.

Paul Egerman – eScription – CEO

Okay. Terrific.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

So are we done with this question, Deven?

Deven McGraw - Center for Democracy & Technology – Director

I believe we are.

Paul Egerman – eScription – CEO

Okay. So we have completed three of the nine questions. Our goal was to do four and we are out of time, unfortunately. Here's what I would like to do: Assuming Linda is done typing, let's quickly go to the next question. If you could put that up on the screen ...?

Deven McGraw - Center for Democracy & Technology – Director

Yes. Slide 13.

Paul Egerman – eScription – CEO

Slide 13. Almost there. Okay. So here is slide 13. The next question is this one. It's a very interesting question, which I interpreted to be also sensitive to the model. It says, —~~bw~~ should public health reporting be handled?" When I read this I thought it really meant how should public health reporting to public health agencies be handled. It's very important this is reporting to public health agencies.

The issues here, the options were that the record holder could authorize whether or not basically an intermediary could do automatic, electronic disclosure pursuant to whatever the lawful public health reporting requirements are.

Another option was the HIO could just establish their own policies as to whether or not they're going to automatically notify public health agencies of these issues.

Maybe there are other options. Again, we don't have time to discuss this, but the reason why I wanted to bring this up on the screen is what I was going to ask people to do as part of their homework for the weekend and for Monday would be to consider this question and if you have a view on it, to send us an e-mail with whatever you want to say about it so that hopefully if we can do that we can have some discussion. We have six questions left to go. We need to somehow make some faster progress. So my first request will be that you would do that.

Then I'd request once you've done that that you look at the next question and do the same thing. How should quality reporting be handled? So the issue there is really a similar question in terms of what we want to do with that.

Then somebody is advancing the slides for me, but you could certainly do the same thing with any of the other questions. What I'm asking for homework is that you consider at least two of the remaining six questions and actually write up what your thoughts are and hopefully we can get some e-mail discussion going back and forth that will allow us to formulate our viewpoints in advance of our next conference call.

The next conference call is scheduled for –

Deven McGraw - Center for Democracy & Technology – Director

The 13th.

Paul Egerman – eScription – CEO

Tuesday the 13th at 10:00 eastern time. So, before I open the call for public comment, before I thank everybody, does anybody have any other comments for today? Deven or any members of the team have any other comments?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I wonder if circulating in a forum that would make it easy for e-mail response if some of the decisions that we made earlier today would also be a good idea.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

In other words, re-reading them with a little time maybe we have additional thoughts or comments or clarifications.

Paul Egerman – eScription – CEO

Sure, but I want to remind everybody that ... we don't revisit our decisions.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Oh, I see.

Paul Egerman – eScription – CEO

I mean you can certainly clarify because I mean if you had an issue the e-mail is the right way to do wordsmithing, so if there's something written there that you didn't think captured it right, that's the case. But what I really want to do in this Tuesday meeting is see if we can get through these remaining six questions.

When we get all done with everything; when I say all done with everything I'm talking about not just this issue, but all of the issues; we are going to go back and look at everything as a whole, because once you complete this you may go back and realize that some of those earlier decisions you made don't make any sense now based on some additional understandings that have come through as we've gone through other issues, consents, sedimentation and some of the other issues that we're talking about or certainly when we get to governance we realize that some of the stuff we did maybe is unenforceable.

We can certainly do what you're asking for, David, which is to circulate it, but what we're really looking for would be wordsmithing changes to improve what was written.

W

So we will get a summary?

Deven McGraw - Center for Democracy & Technology – Director

Yes.

W

Okay. I'm not able to make the Web site work still, by the way, so I'd appreciate it. Thank you.

Paul Egerman – eScription – CEO

Okay.

Deven McGraw - Center for Democracy & Technology – Director

Yes. No. We'll definitely do that.

Paul Egerman – eScription – CEO

Any other comments or questions?

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

I think this has been a good discussion. Good job.

Deven McGraw - Center for Democracy & Technology – Director

Yes. No. Thank you, everyone, for your very good participation today.

Paul Egerman – eScription – CEO

Yes. We're making progress.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

We're learning how to do this and learning how to work together, so I feel very good that we made progress and identified a number of issues.

Judy Sparrow, could you open the line for public comment?

Judy Sparrow – Office of the National Coordinator – Executive Director

Sure. Operator, can you see if there are any public comments? If there are, if they could just please state their name and organization and keep it to a three-minute limit. Thank you.

Operator

There are no public comments at this time.

Judy Sparrow – Office of the National Coordinator – Executive Director

All right. Thank you, operator. Thank you, Paul and Deven and everybody.

Paul Egerman – eScription – CEO

Yes.

Deven McGraw - Center for Democracy & Technology – Director

Thank you, Judy.

Paul Egerman – eScription – CEO

Yes. Thank you, Judy. Thank you, Joy.

Deven McGraw - Center for Democracy & Technology – Director

Enjoy the wedding.

Paul Egerman – eScription – CEO

Enjoy the wedding and everybody else have a good weekend.

W

All right.

Participants

Good-bye.

Paul Egerman – eScription – CEO

Okay. Good-bye.

Deven McGraw - Center for Democracy & Technology – Director

Great job.

Public Comment Received During the Meeting

1. Since all HIOs will be required to comply with state and federal privacy and security laws it seems unnecessary to include Question 3 in your policy recommendations. Whether an entity is defined as a HIPAA covered entity or not, simply by participating in the exchange they will be subject to the privacy and security rules.