Privacy & Security Tiger Team
Draft Transcript
June 16, 2011

Presentation

Operator
All lines are bridged.

Deven McGraw – Center for Democracy & Technology
OK, terrific. Welcome, everyone, to the June 16 meeting of the Tiger Team. I have no idea what number meeting this is [laugh] in the lengthy number of meetings that we've held. I'll do a roll call now. I'm here; this is Deven McGraw. Is Paul Egerman on the line yet? [Pause] He's going to try to join us later. Dixie Baker?

Dixie Baker – Science Applications International Corporation
I'm here.

Deven McGraw – Center for Democracy & Technology
Alice Leiter?

Alice Leiter – National Partnership for Women and Families
Here.

Deven McGraw – Center for Democracy & Technology
Neil Calman? Carol Diamond? Carl Dvorak, you're on for duty, right?

Carl Dvorak – Epic Systems
Yes, I am, Deven; thank you.

Deven McGraw – Center for Democracy & Technology
OK, great. Leslie Francis I know couldn't be here. Gayle Harrell? John Houston? David Lansky? David McCallie?

David McCallie – Cerner Corporation
Here.

Deven McGraw – Center for Democracy & Technology
Terrific. Wes Rishel? Latanya Sweeney? Micky Tripathi? Do we have Joy Pritts on the line? How about Deborah Lafky? Anyone else from ONC want to announce themselves?

Erin Poetter – Office of the National Coordinator
Yes. This is Erin Poetter.

Deven McGraw – Center for Democracy & Technology
Hi, Erin. Thanks for joining us. And folks from our MITRE team that helped us? Do we have Linda Koontz or Lisa Tutterow? OK, terrific. Well, with a group this small, we really should be able to make some quick progress today [laugh].

We are going to be ending the meeting a little bit earlier than originally scheduled due to, my apologies, but a schedule constraint on my part. But we are going to spend the call today talking about the amendments and corrections issue that we began to talk about on our last call but didn't really finish. And so, I'm hopeful that we actually will be able to get those recommendations done even in a short call. This is our last scheduled call before the July Policy Committee meeting, where we would hope to present

these recommendations. However, it is only June 16, so it does occur to me that if we run into some snags on this call that we need to resolve before the July meeting, we actually do have some time to do so, whether by email or if we need to schedule another call. But again, it's my hope that we will be able to wrap up these recommendations today.

Before we jump into that, though, I want to start with a little report on the Policy Committee meeting that took place a week ago, where we presented our recommendations for digital certificate authorities in terms of desiring a process that met with a high degree of confidence that the entity is who the entity says they are but that would also enable entities to exchange data with federal agencies. We also presented to the Policy Committee, and they agreed that any process that we chose should make sure that it was affordable and not overly burdensome, particularly for small providers, and would result in a number of certificate issuers so that there would actually be a market. And inevitably, we recommended that the certificates for exchange in the Nationwide Health Information Network be issued by issuers who were directly certified or cross-certified to the Federal Bridge. However, we did acknowledge that there were still some lingering concerns that had been expressed about this approach, based largely on the issues of cost and potential operating burdens. And so, we left room to revisit the recommendation if, in fact, facts are revealed, such as through the S&I Framework, which had a public comment period on this issue, with additional facts that call into question the core facts that led to the Tiger Team being comfortable with the recommendation that we revisit it. And the Policy Committee agreed with that approach and adopted it without reservation or dissent.

So I think a number of you were either present at the Policy Committee meeting or were on the call listening. If there's anything you want to add, I would welcome you to do that now. [Pause] OK, terrific, then let's jump right into the issue of amendments and corrections. And I'm trying to advance the slides, but my computer might be frozen. Altarum, can you give me the first slide, please?

Dixie Baker – Science Applications International Corporation
Deven, I have the scope of today's discussion slide up on the screen.

Deven McGraw – Center for Democracy & Technology
OK. Funny, I don't see it. OK.

Unidentified Man
I think your computer's frozen.

Deven McGraw – Center for Democracy & Technology
Yeah, I think it is. All right, I'm going with paper. I'm going to go Luddite on everyone today.

So I remember, on a previous Tiger Team call (I think it was actually two calls ago), that we had decided that we would not establish any additional policy dictating when providers are to report amendments to health information, either upstream or downstream. And you received in your email, in preparation for this call, a transmittal letter that lays out in a little bit more detail our rationale for deciding that, really, current law and ethical obligations on physicians and other health care providers was enough to motivate them to report corrections, amendments, or updates. But what was really lacking necessarily was the technological capability to do this. And we also acknowledged that, under the HIPAA Privacy Rule, individuals have a right to request amendments to their health information and certainly, or at least ideally, the certified electronic medical records would provide the technology that could support the making of amendments and passing amendments forward or passing on information indicating a dispute about the underlying data—and that, essentially, the same technical functionalities that would be needed to comply with HIPAA are really the same that are going to support the transmission of amendments or updates, even when they're being done not necessarily at the request of the patient but because the physician or provider wants to transmit those amendments forward.

So we're going to focus really—the recommendations really, for the most part, deal with what those certification requirements ought to look like. And we know that the Standards Committee really takes on the bulk of the responsibility of figuring out the details, both in terms of functionalities as well as any

particular standards that need to be adopted, but Dixie can probably underscore this. It's helpful when the Policy Committee sets the priorities for what certification would need to address to give them a little bit of direction and some more information on what our thinking is in order to get that done. And that's essentially what the recommendations really try to cover today.

So with that, let's go to Draft Recommendation 1, and just let me know when it's up on the screen.

Dixie Baker – Science Applications International Corporation
It's up.

Deven McGraw – Center for Democracy & Technology
OK, great, thank you. So this recommendation really deals with the ability of the certified EHR to have the capability to support an amendment. When we get to Draft Recommendation 2, that one's really about the ability to transmit the amendment to other providers—the amendment and any other information.

So this Recommendation 1 was really intended to focus on just the capability of making the amendment to health information either at the request of the patient or something that the provider has identified that he or she needs to do, consistent with other legal or ethical obligations. And in addition to making an amendment, obviously, if there's a need to append data such as information about a dispute or a rebuttal on the part of the covered entity, that would ideally need to be part of the record as well. And we tried to frame this amendment so that it's clear that the way that this needs to be handled in a certified HER needs to be consistent with the entity's obligations with respect to the legal medical record, where it would not be advisable for the information, for example, to be able to be deleted in the circumstance of an amendment. You need to be able to still identify the original data and see what changes were made.

So I'm actually going to see—Dan Rode from AHIMA, do you think we got this right in terms of the issues with respect to the legal medical record?

Dan Rode – American Health Information Management Association
Yes, I do.

Deven McGraw – Center for Democracy & Technology
OK. Oh, good [laugh]. That's always good to hear. Does anybody have any thoughts on this? You'll note that I also raised a question about whether this would be for stage 2 or stage 3.

Dan Rode – American Health Information Management Association
Deven?

Deven McGraw – Center for Democracy & Technology
Yes.

Dan Rode – American Health Information Management Association
I do have one question.

Deven McGraw – Center for Democracy & Technology
Sure.

Dan Rode – American Health Information Management Association
We're talking about certified EHRs here, but the original regulation also mentioned the designated record set. And that may be, at least in your explanation (not what's up on the screen right now), something that you want to make sure people understand: that the EHR is part of the designated record set.

Deven McGraw – Center for Democracy & Technology
Well, so probably, the designated record set, which is a HIPAA term of art, right, is maybe one part of what might be a certified EHR, right?

Dan Rode – American Health Information Management Association
It'd be the other way around, but yes.

Deven McGraw – Center for Democracy & Technology
OK. Yeah, I mean, keeping in mind that we're not changing the obligation under HIPAA with respect to amendments, which applies to a designated record set. And given that the designated record set—and Dan, you can correct me if I'm wrong about this; we also have Verne Rinker from OCR on the phone, but it's—the designated record set is essentially the information that is used to make a treatment decision about a patient. So if the patient asks for an amendment to an item in the designated record set, then I think it's a pretty safe assumption that the certified EHR would ideally have the capability to accommodate that, right?

Dan Rode – American Health Information Management Association
Correct.

Deven McGraw – Center for Democracy & Technology
OK.

Dixie Baker – Science Applications International Corporation
So—Dixie—Deven, would you go over that definition? I'm not familiar with that term.

Deven McGraw – Center for Democracy & Technology
The designated record set?

Dixie Baker – Science Applications International Corporation
Yeah.

Deven McGraw – Center for Democracy & Technology
OK [laugh]. Well, at the risk of getting it wrong, Verne, can you help me out here?

Verne Rinker – Office for Civil Rights
Sure.

Deven McGraw – Center for Democracy & Technology
[Laugh] Actually, I have to say: I thought that some of the explanation of what a designated record set is that's in the recently proposed accounting of disclosure rule was about the clearest explanation I think I've ever seen.

Dixie Baker – Science Applications International Corporation
Oh, OK, I should go to that. [Laugh]

Verne Rinker – Office for Civil Rights
Yeah, I mean, that probably is a better way. I mean, it's one of those terms, once you start delving into something like individually identifiable health information, that, unless you know where it comes from, kind of gets short-cut, similar to "provided bills electronically" as opposed to "uses a PHI in standard transactions." So the designated record set is another way of just saying "PHI" such that "entity" is holding its—gets into a little bit more of a technical term of where it actually sits in their information, such that if there is data that they have, for example, for quality insurances that they don't include in a designated record set, then that information would not be something that, for example, a patient would be able to request access to. So the designated record set makes a little bit of a distinction, but still the obligations are going to go to the PHI. Is that—?

Joy Pritts – Office of the National Coordinator
Verne, can I jump in? This is Joy Pritts. Is that OK?

Verne Rinker – Office for Civil Rights

Sure.

Joy Pritts – Office of the National Coordinator
OK. So Verne's very right: It gets very complicated very quickly. But as a general rule, the designated record set, at least as it pertains to the covered health care provider, expressly includes medical records and billing records about individuals. And the area where it gets really, I think, complicated is that it also has a catch-all provision, which means any record that's used in whole or in part by the covered entity to make decisions about individuals. So that's why, if you're talking about something that's in a peer-reviewed quality of care—the provider isn't necessarily using those to make decisions about that particular patient; they're more likely to be using that information to make decisions about the doctor and the doctor's behavior.

Dan Rode – American Health Information Management Association
This is Dan Rode again. Joy brings up a point. And because of that, in #1, where the sentence starts out "EHRs," I think since we're looking at making a recommendation related to certification, you might want to put "certified EHRs or modules." Some organizations that are working on a modular basis might have the amendment in a record that's not EHR but should be covered, because we're certifying modules as well as full EHRs.

Dixie Baker – Science Applications International Corporation
We could just use "EHR technology," which is what the regulation—

Deven McGraw – Center for Democracy & Technology
Oh, yeah.

Dan Rode – American Health Information Management Association
OK, great idea.

Deven McGraw – Center for Democracy & Technology
Good point, Dixie. Excellent. Thank you. OK.

David McCallie – Cerner Corporation
This is David. I have a question.

Deven McGraw – Center for Democracy & Technology
Yes, David.

David McCallie – Cerner Corporation
I'm not sure how to formulate it; I'm not even really quite sure what it is, but I'm thinking that the capability to do this exists. Does that mean that the lack of the capability to do it doesn't exist? In other words, does it require that every EHR function has to support this technical capacity to accept an amendment?

Deven McGraw – Center for Democracy & Technology
I don't think so, David. So when you say the capability exists, I'm assuming that you mean that, in fact, the EHR technology sold on the market typically does have an ability to do this?

David McCallie – Cerner Corporation
Right.

Deven McGraw – Center for Democracy & Technology
But unless I miss something in the certification rule, there certainly wasn't any requirement that this be part of the certification or testing process. Nor is it necessarily subject to any particular standards. Now, I'm not sure it needs to be, and that's the Standards Committee determination, but I think that the reason for including it here was, I guess, to make sure that, in fact, the technology does have the capability to support what providers would need to do in order to comply with the HIPAA rule with respect to patient

requests for amendments and then, ideally, any amendments/updates/corrections that they might want to make unprompted by an individual request.

David McCallie – Cerner Corporation
So I think I know the way out of it, but where I'm coming from is, I'm thinking about the use case that we targeted Direct at, which was the small provider. And we structured Direct so that it could, for example, send a simple text message. Now, a simple text message doesn't possess the technical capacity to be amended in the way that a CDA document does. On the other hand, if he's sending simple text messages, he's probably not using a certified EHR. But I'm worried about the implications on the low end, I guess. I mean, totally, I agree this is a standard capability on the full-spectrum EHR space, but are we going to create a burden on the low end by requiring, in some way, a more sophisticated technology than is maybe necessary—maybe that's just not certified if you're less sophisticated? I'm not sure I can articulate it yet, but that just popped into my head—is to worry about the implication on the low end.

Deven McGraw – Center for Democracy & Technology
Do you think that's something that could be addressed through—I'm not trying to punt this down the road; I'm just trying to think of what's the right venue to tease out what level of technical functionality might be required for certified EHR technology, acknowledging that we do want systems to be out there and eligible for purchase with financial incentives that small providers can afford.

David McCallie – Cerner Corporation
Right, and presumably they would have this amendment capability, although I can't say for certainty that they all would have it; I haven't surveyed the market. I was thinking, in a paper world, you meet the HIPAA obligations by—scratch through; write a note on the bottom of the page; send out a notice that says, "Disregard what I sent yesterday; here's a better version of it." There's a variety of manual processes, but you couldn't find a standard to cover that. If you give it to the Standards Committee and say, "Define a standard that covers this," you're going to get back something like CDA or HL7 v2 and a variety of standards that have well-defined mechanisms for sending and supporting amendments. I'm just worried that we eliminate use of simple, textual capture and forwarding. And maybe that's what we want to do, but anyway, it's worth some thought.

Deven McGraw – Center for Democracy & Technology
OK.

John Houston – National Committee on Vital and Health Statistics
Hey, Deven?

Deven McGraw – Center for Democracy & Technology
Yes.

John Houston – National Committee on Vital and Health Statistics
This is John Houston.

Deven McGraw – Center for Democracy & Technology
Hi, John.

John Houston – National Committee on Vital and Health Statistics
Sorry I'm a little bit late.

Deven McGraw – Center for Democracy & Technology
No worries.

John Houston – National Committee on Vital and Health Statistics
So I change the tone of things for a sec: I have a side question to this. I understand we're talking about EHRs, but as we've won HIEs and HIOs that might be retaining data and aggregating data from multiple sources and then passing it forward to some recipient organization, I guess the question I have relates to

what happens if it's not the covered entity that's provoking the error in the information, but rather it's the HIE of the intermediary that's doing it. And how do we try to address that data that might exist within that—I'm going to call it the cloud, but—within that environment? And is that within the scope of what we should be talking about?

Deven McGraw – Center for Democracy & Technology
Well, Neil Calman offline asked a similar question of Paul Egerman and me. And so, there is actually a Draft Recommendation #4, which was not in previous materials, regarding requiring health information organizations to establish policies and procedures related to amendments. On the other hand, keep in mind that they are business associates of the entities that are members or participants. And so, they certainly can be required to be part of the process of making sure that amendments get discovered, particularly in response to patient requests. But otherwise, I mean, I think it's fairly complicated, particularly since what's in the business associate agreement in terms of the obligations that are passed forward is really going to be up to the participating entities. And in many respects, the HIO might have more bargaining power to set the terms of participation than any of the individual participants. But we do, in Draft Recommendation #4, ask for HIOs to adopt policies and procedures that would deal with this issue. In previous recommendations, when we've been eager for HIOs to play an affirmative role, that's typically how we've done it.

John Houston – National Committee on Vital and Health Statistics
Yeah, I understand that they are business associates. I just think that certain contexts that they may—as a business associate of many providers, the compiling and aggregating information—and so the problem itself occurs within a black box, so the providers that are contributing the information may not even know that there is some error or issue that's arriving, because it's fundamentally not something that they're contributing to directly. It's the HIE that's actually causing the problem. So I'm just a little concerned that, yeah, they are business associates, but it's an incomplete way to address the problem.

Deven McGraw – Center for Democracy & Technology
Yeah, so if you can just hold onto that thread of discussion until we get to Draft Recommendation #4, that would be terrific. Thanks.

John Houston – National Committee on Vital and Health Statistics
Sure. Sorry about that.

Deven McGraw – Center for Democracy & Technology
That's all right.

So David, back to the recommendation at hand, which is #1, what would you suggest that we might do to the text that we drafted here in order to provide some direction to the Standards Committee to make sure that the interests of small providers are acknowledged?

David McCallie – Cerner Corporation
So I've been thinking about this. I think if Wes was on the call, he would probably remind us—and maybe I just need to channel my inner Wes—that what you're certified for is not the same as what you're required to actually use. In other words, actual use is a meaningful use measure, but certification is to demonstrate the capability. So I think the way this reads now, it's fine if we believe that every certified EHR should have this capability. That doesn't mean you have to use this capability in every circumstance. That's a use question.

Deven McGraw – Center for Democracy & Technology
That's right.

David McCallie – Cerner Corporation
And so, under that clarification of my own question [laugh], I think I'm OK with it, because I think we would want every EHR to be able to demonstrate that they have a mechanism whereby they can capture and persist amendments, finalize documents, and do the other things that we talk about here.

Carl, do you agree? Are you comfortable with that?

Carl Dvorak – Epic Systems
I do. I was waiting to see what comes next. I was thinking that one thing that would be nice is if we foresaw standardizing the communication of those amendments across entities.

David McCallie – Cerner Corporation
Yeah. That's a harder question. I agree.

Carl Dvorak – Epic Systems
Yeah, and it would be nice, if we saw that coming, to try to nail that down quickly so that as people program for this, they could program it in that paradigm and do it once rather than have to then pull the rug out, change all the workflows for users, etc.

David McCallie – Cerner Corporation
And that one scares me, but I've been holding off on that till a bit later. It may be premature in the standards world to do that yet [indiscernible].

Carl Dvorak – Epic Systems
And yeah, I do agree with what you had said previously with that small addition.

Deven McGraw – Center for Democracy & Technology
OK. That's terrific. So the only other question that I had raised on this recommendation is whether this would be for stage 2 or stage 3. And in many respects, there certainly are a lot of technical issues in the pipeline for stage 2 that are directly tied to new meaningful use objectives. On the other hand, the HIPAA rule, one could argue, predated anything in meaningful use, and so this is an ongoing obligation of providers. And so, the question is, do we specify a stage at all? And if so, what would we say about that? Or should we maybe leave that up to Standards to try to set some priorities? We're the ones that are supposed to set priorities, so let me know what [indiscernible].

Dixie Baker – Science Applications International Corporation
Yes, this is Dixie. I think, for exactly the reason that you articulated, because it's been HIPAA law and, in fact, it's been in health care practice forever, I think that we should specify it for stage 2, because that's a core function for an EHR.

David McCallie – Cerner Corporation
This is David. I'm comfortable with that, but the only caveat is Carl's point, where we talked in the next recommendation about standardizing a way to propagate that change.

Deven McGraw – Center for Democracy & Technology
That's other recommendations.

David McCallie – Cerner Corporation
That's not as easy, right?

Deven McGraw – Center for Democracy & Technology
Right.

David McCallie – Cerner Corporation
So we may need to split those apart [indiscernible].

Deven McGraw – Center for Democracy & Technology
All right, well, let's say stage 2 for now, and then when we get to that recommendation on specifics and standards, which I think is draft 3, let's try to dive into that in a little bit more detail.

Dixie Baker – Science Applications International Corporation
With the understanding that we don't have to make both recording and propagation the same stage, either.

Deven McGraw – Center for Democracy & Technology
That's right. OK, so let's move to the next slide. And you'll be pleased to know that I have actually refueled the hamster that runs in my computer and can now see the slide [laugh]. Thank you for your patience.

So this second recommendation deals with the ability to transmit amendments to other providers, and that's exactly the way it's phrased: "Certified EHR"—let's just say "technology." "Certified EHR technology should have the ability to transmit amendments, updates, or appended information to other providers whom the entity knows have received prior data." Yeah, I was wondering if the punctuation was right there; I think it is.

And then there's a question, because initially, when we had crafted this recommendation for an earlier Tiger Team discussion, we didn't quite get to it. We wondered whether we would want to limit this to existing standard exchange transactions. I think that came from Paul Egerman; it was his impression that our earlier discussion was looking more specifically at standard exchanges and to what extent can we make sure that those have the ability to transmit amendments versus having this recommendation be, in some way, interpreted to be requiring additional exchange transactions than those that are already required by meaningful use and supported by certified EHR technology.

And inevitably, I trip off the limitation on standard exchange transactions, because certainly there will be amendments that will likely take place to nonstandardized data. And until we reach the holy grail of complete data standardization across the board in EHRs, there is going to be a time when we're going to have the ability to amend and transmit amendments to data that isn't standardized. So inevitably, I took this off, but I wanted to keep it up on the slide as a question in case there was a technical issue that I was missing, which frequently happens.

So what does everyone think about this amendment? Again, we will change it to "certified EHR technology," but the idea that we were intending to capture here is the ability to transmit an amendment or updates or information that's appended to data to be able to transmit it to other providers.

David McCallie – Cerner Corporation
So this is David. There's a couple of words that are missing from that that—we have to be careful whether we want them to be missing or make sure that somebody doesn't stick them in. So one would be "automatically transmit." That ups the ante quite a bit, right? And to automatically transmit amendments "in a standard manner" would up it even more, because it might imply that there is one right way to do that. And at the moment, that's not certainly state-of-the-art. I mean, many of the health care protocols allow for this, but there's not a single right way to do it. You can do it with DICOM, with HL7 v2, with HL7 v3. I'm sure there's many, many custom protocols that propagate. So I would be uncomfortable if we tried to say there was a standard way to do it at this level.

I mean, I don't know. Carl, you're the one who was edging toward this concern. Does that fit what you were thinking?

Carl Dvorak – Epic Systems
In that neighborhood [laugh; indiscernible] a little bit. And here I think we want to go extremely straightforward in terms of being able to transmit that there is an issue with the record, and keep it as simple as possible to start with, and see how it evolves. I think simply being able to flag a chart as "in dispute," be able to articulate what the dispute is, and then what vendors could do is to post that appropriately to the headers. And I think we'd have to evolve over time very, very carefully what the paradigms of the mechanisms were that actually fired, automatically updating a chart. What I think people just grossly underestimate is how you have to tear a chart apart piece by piece with the forensic team to figure out what's come after this information and how to make appropriate adjustments for this patient,

notifying all the appropriate caregivers. The notion you can automatically fix it through an EDI transaction is fundamentally flawed. But I think we want to respect that and keep the notification of a problem as simple a notification as possible and then evolve over time as we get a better way to deal with trying to fix the chart.

David McCallie – Cerner Corporation
Yeah, and that's consistent with what I'm thinking. (This is David again.) I don't think we can make this automatic yet.

Carl Dvorak – Epic Systems
I think somewhere down the road, after we perfect EDI or [indiscernible] information exchange (it's going to be 5 or 10 years, I bet), I think then, once those structures are just religiously in place and uniform across the country, then you can start to do surgery on a chart after the fact. But I think it's going to take a lot longer than people think to get to that level.

Deven McGraw – Center for Democracy & Technology
So given that, do you think it's worth—again, we have these transmittal letters that provide us with the opportunity to provide some—I'll call it interpretive guidance on recommendations. Do you think it's worth me trying to draft up and sending around for your approval a sentence or two or a short paragraph on what not in this recommendation [laugh]—i.e., that we advise keeping it as simple as possible at the start, with the expectation that down the road, we may be able to move to transmission that occurs more automatically and in a standard manner? Or does it speak for itself? I mean, I'm completely aware of the ways in which our recommendations are often misinterpreted by people when they read them, and I want to try to avoid that [laugh].

Carl Dvorak – Epic Systems
I think that's very wise, Deven, and particularly the position of how to keep this one simple and to think about evolving it after the fact. The other forms of exchange of it could be really, really good things for us to do.

Dixie Baker – Science Applications International Corporation
Deven, this is Dixie. I've been sitting here having trouble with "the entity knows." It's pretty hard to quantify and model what an entity knows. So it occurred to me that we might want to change that to read "to whom the record has been disclosed," because there is a legal requirement to account for disclosures, and that would clearly point to that record of disclosures rather than what the entity knows. The entity might know something from reading the newspaper, and what we really are talking about is that that entity has a record of having disclosed it before.

David McCallie – Cerner Corporation
I like the spirit of that (it's David again), but I'd be careful not to equate the same set of disclosures tracked in accounting for "disclosure" as in the sense that we might mean it here, because those disclosures—some of them may not need to know about a change. They've been disclosures that have [indiscernible].

Dixie Baker – Science Applications International Corporation
Well, that's true, but just state it differently so that it says "to other providers to whom the record has previously been disclosed."

David McCallie – Cerner Corporation
Did it say something to appropriate providers?

Dixie Baker – Science Applications International Corporation
Well, it just said that it has the ability. I like that part: "…should have the ability." So that leaves out the judgment of exactly when you do it and when you don't. It says that EHR technology must have the ability to do this. And if you change it to "to whom the record has been disclosed," that means that the EHR must have the ability to look at a record of other people to whom the record has been disclosed.

Deven McGraw – Center for Democracy & Technology
I think that's fair, Dixie. And this is another one where we can make sure that there's an explanation in the letter that makes it clear that the provider must make a judgment based on his or her legal and ethical obligations about who needs to receive an amendment. And so, that would cover what they legally have to do under HIPAA and then other providers that they just think should get it, in their best judgment.

Dixie Baker – Science Applications International Corporation
Yeah, and from a certification perspective, it leaves you with the ability to transmit it, given that, in their judgment, it needs to be transmitted.

Dan Rode – American Health Information Management Association
Deven?

Deven McGraw – Center for Democracy & Technology
Yes.

Dan Rode – American Health Information Management Association
Dan Rode.

Deven McGraw – Center for Democracy & Technology
Yes, Dan.

Dan Rode – American Health Information Management Association
I think you might want to at least add "prior affected data" so only you're notifying those people who received the data that was under question by the individual, not just anybody that's received prior data.

Deven McGraw – Center for Democracy & Technology
OK, so what was the adjective you put before—?

Dan Rode – American Health Information Management Association
I said "affected data." There may be a better term: "the prior data" or [indiscernible] or whatever it'd be, or "the prior data being amended."

Deven McGraw – Center for Democracy & Technology
[Laugh] Well, try not to legalese it too much, but I guess what you're saying. [Laugh]

David McCallie – Cerner Corporation
And I agree with that point. It's not everybody; it's just people that have gotten the data in question.

Deven McGraw – Center for Democracy & Technology
That's right. OK, that's wordsmithable, I think. Is there anything anybody wants to add to this one before we move on to #3? I think we have a lot to talk about on #3, maybe not. All right, I'm still going to have Altarum help me out and take us to #3. I don't trust myself on my computer. [Laugh]

All right, this is where we are formally asking the Health IT Standards Committee to fill in the details here. And the way we currently have it worded is that the Health IT Standards Committee should recommend standards implementation specifications and certification criteria for providing the capability for EHRs to report amendments to health information, including the context in which those amendments are made. And Dixie, you did help me to frame this a little bit; but I recognize now, even as I read it, that it sounds like we are asking for standardization here. And based on some of the discussion that we just had, we may need to change the wording a little bit, consistent with our "keep it simple" discussion. But what do folks think about this?

Carl Dvorak – Epic Systems

I think even if we kept it simple, standardization is still a good thing, so that'll be where we have to help draw a very fuzzy line, because I would like to see a standard defined for how to do that simple exchange at the notification that a record has a dispute or an inaccuracy that's significant. That should be standardized even though kept simple.

David McCallie – Cerner Corporation
Yeah, this is David. I think it's interesting that Carl is focusing on one aspect of this and I'm, in my mind, thinking of different aspects of it, and we might want to be careful to either include both or keep them apart. I'm thinking of actually propagating the change, and Carl was propagating the notice that it is contested. Is that a fair distinction?

Carl Dvorak – Epic Systems
It's contested or contaminated.

David McCallie – Cerner Corporation
Yeah, or it needs to be changed. I mean, how do you get an amendment out to somebody such that it preserves the original but also makes clear what has been changed? I mean, you need standards to specify how to do that.

Carl Dvorak – Epic Systems
And I guess what I was actually thinking is, in my mind, the amendment is going to be the topic of standardization discussion. What I was thinking is that the amendment to start with would be a document that expresses the type of problem that could be standardized and codified against a category, could contain a description of the problem or description of the contested information, who to contact for further information or follow-up, and any instructions on who else has been notified or if the place that got it should also proceed to notify other—I'm just making things up there. But the amendment itself might start off as a simple body of content, maybe in a CCD document that's defined to start with a simple description of what's wrong, which could eventually grow into standardizing other information that could then be disassembled and placed into charged and appropriate manner down the road.

David McCallie – Cerner Corporation
But are you thinking of metadata about the change, or is the change itself?

Carl Dvorak – Epic Systems
Both. So if, for example, somebody realizes that they have placed the wrong allergy on a patient, phase 1 might be to notify others who've received an electronic copy of the record that we've discovered that an allergy has been entered in there and describe it. Let the receiver of that then go update their chart appropriately. And then, down the road, we might actually create a CCD section or a CDA section that says, "Here's how we'll adjust an allergy," if we can standardize that. And then, 5 years down the road, you've got parts of that document that carry the discrete data that could be used to automatically update if appropriate or to update with review and approval by a physician—a staging kind of process.

David McCallie – Cerner Corporation
I mean, those things don't exist yet, so that's asking a lot.

Carl Dvorak – Epic Systems
I think we'd ask the Standards Committee to start with a container and within that container, for the first phase, simply describe the problem and make sure that we can get notice out to people that there is a problem.

Deven McGraw – Center for Democracy & Technology
Yeah, but even something that's that specific—we have never, as a Policy Committee, been that directive to the Standards Committee. That'll show up as "establish a container." What I want to do is to give the Standards Committee enough of a recommendation to get started on addressing the other two recommendations that we've just come to agreement on, but without tying their hands, because they have a different body of expertise there, including much more vendor and informaticist representation that

can help suss out the details. It's not something that the Policy Committee does typically well, and so therefore, we tend not to do that.

Carl Dvorak – Epic Systems
Yeah, I wouldn't disagree with you, Deven. What I'm thinking is offering it up as "You could start as simple as…" and let them try to take it from there. I agree: I don't think we have to get prescriptive about specific stuff. I was more offering it up as an example where you could just request that they start, and you could start simple and then grow it over time.

Deven McGraw – Center for Democracy & Technology
Yeah. Well, definitely, I think we want an acknowledgement that starting simple is the right way to begin.

Dixie Baker – Science Applications International Corporation
I have a question, Deven.

Deven McGraw – Center for Democracy & Technology
Yes, Dixie.

Dixie Baker – Science Applications International Corporation
Are we saying that any kind of amendment to the record needs to be—and this isn't the propagation one, actually, but we're talking about propagation. Let's say somebody changes their address. Are we saying that you have to propagate that to every—

Deven McGraw – Center for Democracy & Technology
We are not. In fact, the transmittal letter is very clear that we're not making any substantive policy recommendation about when amendments either need to be made or, more importantly, need to be transmitted either forwards or backwards—say you're not the source and you discover it. Instead, we're just making sure that there's the technical mechanism to support a decision to transmit an amendment, either based on legal obligation to comply with a patient's request under HIPAA or because the provider thinks it's the right thing to do. But we are definitely not placing any significant, substantive, additional policy recommendations with respect to when providers are expected to amend and/or transmit forward.

Dixie Baker – Science Applications International Corporation
Well, it seems like, in some cases, we should, like if there's a change to drug allergies. [Indiscernible] would want that to be propagated. You know what I mean? It seems [indiscernible] Policy Tiger Team, after all.

Deven McGraw – Center for Democracy & Technology
Well, I get that, Dixie. But two calls ago, we had a pretty exhaustive discussion about that and decided that the circumstances under which amendments would need to be moved forward; that it was very difficult in one policy sentence to determine that; and that we had providers with different obligations already under professional liability statutes and common law, that that was sufficient motivation for them to make the right judgment call with respect to making sure that amendments get pushed forward, and we determined not to do that.

Carl Dvorak – Epic Systems
[Indiscernible] the case that, I mean, technically, charts are amended continuously. It's a process of updating medical information about a patient. So I think somewhere in the spectrum of grayness, straight-up HIE is in large part just continuously amending charts and broadcasting information. I think the thing that was a little bit special about this discussion was also that you wanted to capture the patient's ability to contest and to communicate that information was contested. That was almost one special case. And then where there was a significant error in a chart that got transmitted out to notify people that there was an error, in theory, the chart might actually get updated through standard HIE in terms of bringing it back into synchronization with other people's [indiscernible]. It does exist on a spectrum, so it gets fuzzy where you call it straight HIE versus where you call it an amendment to a chart.

Dixie Baker – Science Applications International Corporation
Yeah, I think I missed that discussion, but I can see exactly what you're saying, so that's fine. Thank you.

Deven McGraw – Center for Democracy & Technology
OK. Yeah, I mean, I'm going to go back and look at the language of the transmittal letter and make sure that it's absolutely clear that we don't think that passing on an opportunity to say more from a substantive standpoint on when amendments should be transmitted means that we think providers should take a pass on that. We just decided that we thought there was sufficient other motivations as well as infrastructure that would likely take care of that, but the technical piece to support it was the missing component. But I think that it's still worth underscoring that if we didn't think this was an important issue from a substantive standpoint, we certainly wouldn't be having these conversations. So if you want to take a look, Dixie, at the text in the transmittal letter where that explanation is laid out and see what you think and let me know if you have any suggestions on how to strengthen it, I'd greatly appreciate it.

OK. So with respect to this Draft Recommendation 3, I actually noticed something that I didn't see the first time around, and that is that we do specify that it's about recording amendments. And I think we want this recommendation to direct the Standards Committee to recommend any necessary standards implementation specs and certification criteria for the capability of EHRs to both record and transmit, right? It just says "record." I just noticed it.

David McCallie – Cerner Corporation
Yeah, as long as we're not specifying when. And what it really boils down to is, we're saying it's time to take these HIPAA provisions which already exist and reflect them into the standardization certification process.

Deven McGraw – Center for Democracy & Technology
Exactly, yeah, that's a good shorthand way of saying what we're doing. And we do actually have, in an appendix to the transmittal letter, the summary of what is actually in the HIPAA rule so that it's all in one place.

Dixie Baker – Science Applications International Corporation
This is Dixie. I was just looking at the whole thing. Draft Recommendation 2 relates to transmittal. I think we should leave this as just "recording" and leave them separate, because it implies what David brought up earlier: If you say "record and transmit," it almost implies an automatic, and we don't want that.

Deven McGraw – Center for Democracy & Technology
Well, right, but then we're missing a direction to the Standards Committee on #2. I mean, maybe we don't need one, and then I would argue we don't need this at all, because #1 is about the technical capability with respect to amendments and appended information in an EHR or in EHR technology; #2's about transmitting that, whether it's an amendment or a package of information about a dispute; and then #3 was really intended to be "Standards, please take care of #1 and #2."

Dixie Baker – Science Applications International Corporation
I don't think we need #3, because that's what ARRA tasked the Standards Committee to do.

Deven McGraw – Center for Democracy & Technology
OK. I'm fine with removing it, and we could make a note in the transmittal letter, not in the recommendation, but that the Health IT Standards Committee would develop any necessary standards implementation specs and certification criteria to implement 1 and 2.

Dixie Baker – Science Applications International Corporation
Yeah, that's what I would do.

Deven McGraw – Center for Democracy & Technology

And I'm fine with that, especially if we run the risk by calling it out in a recommendation of people misinterpreting it and thinking that we mean automatic and all of the concerns that were raised earlier. I'm fine with that.

Dixie Baker – Science Applications International Corporation
Yeah, I think that I would just stick with #1 and #2, make #1 stage 2 and #2 stage 3, and let it go at that.

Deven McGraw – Center for Democracy & Technology
What do folks think about Dixie's staging recommendation?

David McCallie – Cerner Corporation
Which one was stage 3?

Dixie Baker – Science Applications International Corporation
One is record, 2 is transmit, and 3 is the Standards Committee to develop standards. And all I'm saying is, because ARRA HITECH already says that the Standards Committee will recommend standards to support the policies that the Policy Committee recommends, there's no need for 3.

David McCallie – Cerner Corporation
No, I agree with that part, but I thought it sounded like you said stage 2 was transmit.

Dixie Baker – Science Applications International Corporation
Yeah, leave stage 2 as record, stage 3 as transmit.

David McCallie – Cerner Corporation
OK. I think you said it backwards the first time.

Dixie Baker – Science Applications International Corporation
Oh, I'm sorry.

David McCallie – Cerner Corporation
Yeah, a standardized way to transmit it is going to be harder than a standard way to record it.

Dixie Baker – Science Applications International Corporation
Yeah, absolutely.

Deven McGraw – Center for Democracy & Technology
OK, I got it.

David McCallie – Cerner Corporation
And it will affect the #4 recommendation a lot, too. So we may have to revisit all this once we get to that one [laugh].

Deven McGraw – Center for Democracy & Technology
All right, well, does anyone else have anything they want to add? Otherwise, we should move to #4. [Pause] All right, let's move to #4. Altarum, if you can help me move the slides, that would be great.

So this is rather simply stated, and that is that health information exchange organizations should have policies and procedures in place regarding notification to relevant providers of amendments to health information. And we did not have this on previous drafts of our amendment and corrections recommendations that we had begun to discuss in prior calls. But this arose primarily out of an email that Paul Egerman and I received from Neil Calman, where he talked about how, if he uses an HIO (and it sounded like an HIO where the data might be centralized) and there is an update to information about one of his patients that—another provider participates in the exchange—makes the update, it's not clear to him, or maybe in fact it's not the practice currently, that he would necessarily receive that update, even

if the HIO did. And I think that this is also maybe a recommendation in response to the issue that John Houston raised earlier on this call. Now, it's not terribly specific.

David McCallie – Cerner Corporation
Deven, can you just remind us what the HIPAA obligations are with respect to this kind of question? Is HIPAA silent on this?

Deven McGraw – Center for Democracy & Technology
HIPAA doesn't speak to this, so the only HIPAA provisions with respect to amendment and corrections are the ones that are triggered when an individual requests a change to data. And of course, we know that "health information exchanges" as a noun, which—we have tended to call them HIOs to distinguish them from the verb form of "exchange"—that HIOs are business associates under the HIPAA rule. But of course, business associates get their marching orders about what they can and cannot do with protected health information from the covered entities that they serve. And I looked at the DURSA, which is the Data Use and Reciprocal Support Agreement, used by the participants in the Nationwide Health Information Network exchange project. And in fact, the DURSA doesn't actually have any provisions related to obligations to transmit updates to information or to transmit amendments if they are surfaced either by a patient, which might not be likely but is not necessarily unimaginable given that patients will become increasingly familiar with HIOs the longer they exist; or the error is discovered through some other means; or it's not an error but just a need to update, say, a progress note or the interpretation of an x-ray, which was Neil's particular use case from his emails.

David McCallie – Cerner Corporation
So the spirit of this is clear, and it sure sounds good, but the implementation of it would be pretty challenging, right? I mean, the spirit is that anybody who might have looked at this data indirectly through the exchange should be notified if, at some future point, the data is known to be incorrect; the data is amended.

Deven McGraw – Center for Democracy & Technology
Well, I mean, I think I used the term "relevant providers" on purpose to make some room for judgment calls about who should get an update or a correction or notice of an amendment without trying to be overly specific.

David McCallie – Cerner Corporation
As long as it's more than zero, it's still a challenge. In other words, you have to track who's seen it, and you have to somehow decide who ought to be notified, and then you have to somehow notify them. And I totally agree that that's the right thing to do. I'm just really nervous about jumping into that too fast.

John Houston – National Committee on Vital and Health Statistics
Hey, Deven? [Cross-talk]

Deven McGraw – Center for Democracy & Technology
OK, hold on; let John go.

John Houston – National Committee on Vital and Health Statistics
Yeah, I actually have to go to a meeting (I apologize), so I have to drop off quickly. You understand my perspectives on this. I think that, again, there's two separate scenarios, one where a provider knows that their data that they've submitted is in error and one where the HIE actually creates data in error. And so, I think we need to make sure that whatever we put in place adequately addresses both of those. And so, however we do this, I do believe that we do need to make a combination for it, but just recognize that it's often the HIE that'll be in the best position or the only position to know that data was sent in error.

David McCallie – Cerner Corporation
John Houston, before you go, could you give your example of when the HIE is creating the error?

John Houston – National Committee on Vital and Health Statistics

Yeah. Well, HIEs will often, I think, by design, put a request out for information from all the other providers that are in the HIE, for information about a patient, such that they can provide information to respond to a request for information from another provider that's part of the HIE. So they may be aggregating information across providers up on a specific patient. They can either get incorrect information from multiple patients that would result in an error; or they potentially, because of a programmatic error in the HIE system, could cause the data to be wrong, because it's just translated wrong, or for some reason there's an error in the data as it's passed. So that's my concern.

David McCallie – Cerner Corporation
So it would be a side effect of some error in aggregation, probably.

John Houston – National Committee on Vital and Health Statistics
Or in math, and you can [cross-talk] math lab results and get something wrong. Or often these things will run some sort of MPI that might actually merge a person with someone where they shouldn't have been.

David McCallie – Cerner Corporation
Right. And I mean, that would include aggregation in what I'm saying, as opposed to a strictly passive pass-through. But I agree: Even then, you could screw something up. I got you. So it's an error that's introduced in the processing that happens in the HIE.

John Houston – National Committee on Vital and Health Statistics
Right, the HIE creates the error itself.

David McCallie – Cerner Corporation
Yeah. OK, in that case, it seems the HIE is obligated at least under the same spirit as the original provider. And if they've discovered that they've made an error, they have to propagate the fix.

Deven McGraw – Center for Democracy & Technology
Right, although I think the concern is that, while we may have some confidence in providers' ethical obligations to fix self-discovered errors and notify people who received the data in question appropriately, I don't know that people necessarily would place the same degree of confidence in some of these brand-new entities. But maybe I'm wrong with that. I mean, what do folks think?

John Houston – National Committee on Vital and Health Statistics
Well, I think the confidence would still be there, but I think the issue is that, as [indiscernible] brought up, you have an EMPI, and what happens if—now, it is likely to occur that patients could get mismatched. And even though it's a very low percentage, it's still going to occur. So we have to be prepared for the reality of this.

Deven McGraw – Center for Democracy & Technology
Well, right, but—I know you're trying to run, John, but keep in mind that in our matching recommendations, we did say that HIOs should have processes in place to—I mean, I wish I could rattle it off off the top of my head, but we did make a recommendation that would place an obligation on HIOs to have a policy about matching accuracy and procedures for achieving it.

John Houston – National Committee on Vital and Health Statistics
Oh, absolutely. I don't disagree, and I think it's important to maybe cross-reference here. But you know that even the most dedicated and sophisticated HIE will sooner or later mismatch a patient.

Deven McGraw – Center for Democracy & Technology
Yeah, no, absolutely. And I'm also acknowledging that matching errors are not the sole issue that we're dealing with in this conversation, that HIOs would have a role in providing some assistance and being helpful. And so, I guess I'm maybe pointing to it, because this recommendation was intended to be similarly more—I used that recommendation as a model for this one—that HIOs have a role to play in this, they have a role to play in potentially being forces of error, and they have a role to play in transmitting

corrections and updates and amendments, and they ought to be specifically tasked with having policies and procedures to address it.

John Houston – National Committee on Vital and Health Statistics
I agree. [Indiscernible] offline.

Deven McGraw – Center for Democracy & Technology
OK, thanks, John. Go ahead, Dixie.

Dixie Baker – Science Applications International Corporation
One of our very strong statements we made early on is that the provider is ultimately responsible for protecting the patient's information. And an HIO is, after all, a business associate of a covered entity. And if it's not, then we're in an entirely different ballgame, and a whole different set of rules apply, because they shouldn't have the patients' information to begin with. But they are a business associate of a covered entity. I think, as a business associate of a covered entity, whether it's an HIO or any other BA, they have an obligation to notify the covered entity of any errors that they may be responsible for. And then, if the covered entity has shared the information with anybody else, it's the covered entity's responsibility to notify them that the error was made. But I think we run a strong risk of overly empowering HIOs if we say, "Oh, you're responsible for looking at all these errors and notifying everybody of everything you find." They're even going to run up against different patient policies across entities. So I think all that we should possibly say is, "As a business associate, the HIO has a responsibility of notifying the covered entities of any errors that have occurred." And I think that's all they should be responsible for: their business associate.

David McCallie – Cerner Corporation
But they're the only ones who know who's actually seen the data. The original physician—

Dixie Baker – Science Applications International Corporation
No, no, no. When entity A shares information with entity B, even if an HIO or an intermediary is in between, the disclosure is not between entity A and the HIO; it's been entity A and entity B. [Indiscernible] the disclosure is the responsibility of entity A, not the HIO.

David McCallie – Cerner Corporation
No, that's not how most of them work, Dixie.

Dixie Baker – Science Applications International Corporation
That's how, theoretically, they—I mean, I think you're confusing technically how they work and how policy-wise they work.

David McCallie – Cerner Corporation
Well, it's an unimplementable policy. I mean, they're not built that way. That's why we created this whole distinction of directed exchange and whatever the other one is that I call indirect exchange, because the original provider doesn't necessarily know who the ultimate consumer of the data is. That's why consent is so important.

Dixie Baker – Science Applications International Corporation
But that's why, at the very outset, we stated that the provider is ultimately responsible for the data. And we've said this over and over again: Even if the provider uses an intermediary, the provider is the one that ultimately makes the decision who to share the data with, even if they do use an HIO.

David McCallie – Cerner Corporation
I don't think that's the way it works in the real world. Sometimes it does, but I think that would be the exception.

Deven McGraw – Center for Democracy & Technology

Yeah, Dixie, I'm not sure that you're taking into account some of the different models of HIO that are out there that are centralized data repositories or that pull data from edge servers, where the edge server has a copy and isn't necessarily part of the EMR.

David McCallie – Cerner Corporation
Or even if it's fully federated, it doesn't go back and ask the original provider, "Is this OK?" It just doesn't.

Dixie Baker – Science Applications International Corporation
Well, but the provider has given them authorization ahead of time to do that, and the provider is who keeps the accounting of disclosures. By law, they have to.

David McCallie – Cerner Corporation
No.

Dixie Baker – Science Applications International Corporation
Well, that's the way the law is stated. They need to revise the law, then, because the law requires that disclosures be accounted for. [Cross-talk]

Deven McGraw – Center for Democracy & Technology
I mean, so we have a change in the law on accounting of disclosures that now will pick up some routine access to information. But even under the proposed rule, which is far from being finalized, the disclosures that have to be accounted for are actually an even smaller number than is under current law. So I think we have to be careful not to over-rely on that provision as a legal mechanism for determining when data has necessarily been disclosed.

Dixie Baker – Science Applications International Corporation
Well, I think we run a heavy risk of overly empowering HIOs. Already there's some abuse going on, and I think that the model of an HIO having this grand clinical information repository in the sky and the HIO making decision—going back to our triggers, in order for an HIO to have this grand repository and the HIO to make decisions on where information goes, that's going to require the consent of every single individual. Is that what these people were doing?

David McCallie – Cerner Corporation
Well, that's why consent is such an issue, and I think that's what they think they're doing. They've got the patients' consent.

Dixie Baker – Science Applications International Corporation
[Indiscernible] the consent of every individual?

David McCallie – Cerner Corporation
They've got the patients' consent to enable this sharing on the behalf of the patients' medical future treatments.

Dixie Baker – Science Applications International Corporation
OK, so that's not a business associate; they're just an entity.

Deven McGraw – Center for Democracy & Technology
Well, but by law, regardless of the model, they were made business associates by virtue of HITECH. And I get, Dixie, that they start to look less and less like business associates under certain models, but that's the reality of what we're dealing with. And I think that, if I interpreted John Houston right before he got off the call (and certainly I would agree with this concern), I have a little bit less faith in business associate agreements as decent tools of limitations on data use. And this is actually consistent with some things that we said in our August recommendations about intermediaries and wanting them to be limited to the data that they need in order to perform the function they've been hired to do. And we expressly acknowledge that the business associate agreement was one tool for doing this stuff, but that we weren't sure that it always worked, because of sometimes the difference in economic power between the

business associate and one single provider, who might be trying to dictate the terms and conditions of participation. So having said all that, I do get what you're saying about not wanting to necessarily overly empower an entity that, at least by law, is supposed to be in a subordinate relationship to the providers.

David McCallie – Cerner Corporation
But you're getting consent of the patient for these downstream things to happen. One big debate is whether it's meaningful consent or not, but let's assume for a second that it is. There's a whole host of things that that patient could consent to that a data aggregator could then turn around and do. And the only thing on our agenda right now is their duties with respect to propagation of discovered errors. I don't know if we're going to go and revisit the whole "What is an HIO allowed to do?"

Deven McGraw – Center for Democracy & Technology
Yeah, I definitely do not want to do that.

David McCallie – Cerner Corporation
Yeah, "Are they required to propagate corrections?" seems the question on the table. And I'm saying, "In theory, yes; in practice, that's challenging, particularly when you consider secondary propagation." You live on one side of the country; you got treated on the other side of the country; the data gets fetched out of the HIO on the other side of the country, comes to your side of the country; and somebody looks at it on your side of the country from your HIO, and now you've got two links in the chain. And maybe the original West Coast discovers and error and propagates it. Does the East Coast propagate it also? It gets pretty complicated. I mean, it ought to happen. I don't think we're quite there yet with understanding how to do that. I think the long-range model is, the data ought to be self-healing (like our digital certificates, they can validate themselves), but we're not there yet.

Deven McGraw – Center for Democracy & Technology
Self-healing [laugh]!

David McCallie – Cerner Corporation
Well, it's actually kind of doable, technically, but nobody's doing it that way.

Deven McGraw – Center for Democracy & Technology
Right. Well, I have a suggestion that we do the first two recommendations that we were able to reach consensus on on our call today. And I'll definitely circulate revised language based on the conversation that we had on the call today so that people can take a look at it. But with respect to this fourth one that is now #3, since we got rid of #3, I suggest actually, since we don't have another intervening call, that we take an opportunity to get some Policy Committee feedback on this issue and then finalize it on our next call.

Dixie Baker – Science Applications International Corporation
Yeah, and in terms of asking the Policy Committee, I think it would be worthwhile to make it more general on what business models an HIO can actually get by with.

Deven McGraw – Center for Democracy & Technology
Well, that's a much bigger question, though, Dixie.

David McCallie – Cerner Corporation
Stage 3, stage 3.

Deven McGraw – Center for Democracy & Technology
Yeah, [laugh] I think we can acknowledge that the differences in models that are out there today raise issues for some and make addressing this question much more of a challenge.

Dixie Baker – Science Applications International Corporation
Yeah, are those models that are out there today necessarily the right models? I mean, in truth, if a patient gives their consent for their information to be sent to this grand clinical repository in the sky, that HIO is

not only not a business associate; it's not a covered entity either. So there are some real questions that I think need to be considered.

Deven McGraw – Center for Democracy & Technology
Well, also keep in mind that we have teed up, for future discussion on our call, issues that arise with different HIE models. So we've just gotten a narrow slice of some of the complications by looking at it through this lens of "What role do we want these entities to play with respect to amendments and corrections, which is really such a narrow but important slice of the pie?" I think there are many other questions that arise that we actually did carve out some time this summer to consider, but in a much broader way than this one.

Dixie Baker – Science Applications International Corporation
Why don't we put this question in that pile and consider it along with those other questions?

David McCallie – Cerner Corporation
Because it's a lot harder, I think.

Dixie Baker – Science Applications International Corporation
It might be easier after we've made those other decisions, though, David.

Deven McGraw – Center for Democracy & Technology
Well, either way, I want to be able to flag for the Policy Committee that this issue of the role of HIOs in this process came up; that we had a robust but far-from-complete discussion about it; that we have the plans to take on issues with certain HIO models or an examination of HIO models and with issues that they might raise, and this clearly is one of them; but that we begin to get a little bit of feedback from the Policy Committee. We won't be able to have an extensive discussion on it, because we never have enough time for that, but we'll at least get some initial feedback from them and then feed it into a grand plan of discussing some of these other issues that have been raised. [Cross-talk] David?

David McCallie – Cerner Corporation
Yeah, this is David. It would be nice, although our timetable probably doesn't allow for it, to get some feedback from some of the successful up-and-running HIOs that are out there today in terms of how they handle it [indiscernible].

Deven McGraw – Center for Democracy & Technology
You know what? We do have time to do that, and that's a really good idea.

David McCallie – Cerner Corporation
OK.

Deven McGraw – Center for Democracy & Technology
Yeah, that's a really good idea, because we're running out of time on this call. We have another one scheduled before July; I think we can't finalize this before July 8 (it's an early-July Policy Committee meeting), so we actually do have a little bit of time to get on the phone and talk to some operating models and find out how they deal with this.

David McCallie – Cerner Corporation
Yeah, I'm sure that they've thought about it, so it'd be worth learning what they have encountered.

Deven McGraw – Center for Democracy & Technology
Absolutely. It's a great idea.

All right, along those lines, we're reaching my bewitching hour here. So before we open the call up to public comment, I just wanted to let folks know that we had originally scheduled to talk about on this call, which was a HIPAA security rule gap analysis that ONC has been working on. We obviously didn't have time to get to that today, and we are teeing it up for our next call, although we might have to talk about

how that's going to work with this additional discussion that we need to have on HIOs and whether we take that up with some other HIO issues, as Dixie has suggested, and instead move on to the gap analysis on our next call or switch some things around. We'll make some decisions along those lines, but I just wanted to make sure that people knew that we weren't throwing the schedule out willy-nilly, that we have not indefinitely postponed the gap analysis; we will take that up either on the next call, ideally, or the one shortly thereafter.

Joy Pritts – Office of the National Coordinator
Deven, this is Joy. I don't want to volunteer Verne to do anything, but having listened to this conversation and prior ones about health information exchange organizations, I do think it would be good to have a little briefing before you get too far in the discussion about how these organizations are treated under HIPAA as amended by HITECH.

Deven McGraw – Center for Democracy & Technology
Right, yep. I agree. We can chat offline about the scheduling of that discussion and when we're going to need some good background on that. But I think that'll be really helpful.

Verne Rinker – Office for Civil Rights
Sure, and this is Verne. We're happy to help where we can.

Deven McGraw – Center for Democracy & Technology
Thanks, Verne. Much appreciated. All right, and without further ado, let's move into the public comment period. Thanks to everybody for a terrific discussion today. Alison or Caitlin, do we have an Altarum person on the phone? OK.

Caitlin Collins – Altarum Institute
For those who are on the phone, you may press *1 at this time to be placed into the comment queue. For those who are listening over the computer, please dial 1-877-705-2976 and press *1 to be placed into the queue.

Operator
We have one public comment from Ernie Silver. Please receive.

Ernie Silver
Ah, thank you for inviting me. I've got a question, and this is more, I guess, for general information. I'm interested in understanding the organization or group of individuals that would potentially have the responsibility for the validation, identification, and authentication of those individuals who have been granted authority, if you will, to perform the actual exchange of electronic medical records, both within HIOs and from outside HIOs, in terms of making requests, having access to information via clinical, financial, claims, etc. Is that a question that's appropriate for this call or group of individuals? This, again, goes back to "What's the process or procedure for establishing ground truth validating that the person who's making the request is authorized and/or entitled and to assure that they are who they say they are?"

Deven McGraw – Center for Democracy & Technology
Right. The best I can do for you, sir, is to direct you to some previous recommendations of the Policy Committee on the very topic of the issuance of digital certificates to health care providers and what requirements they ought to meet. There's a Health IT Policy Committee website where you can find that.

Ernie Silver
That's actually addressing issues regarding exchange of the records between the providers, but that doesn't address authenticating the individuals who are making those requests.

Deven McGraw – Center for Democracy & Technology
Actually, our recommendations do get to the issue of how people are to be authenticated and what those processes are.

Ernie Silver
Oh, OK. I haven't seen that.

Deven McGraw – Center for Democracy & Technology
OK. I would take a look at those in more detail. And then, beyond that, your questions might be better directed to the agency, since we're just a recommending body. And also, there are active electronic health record holders today; you might want to inquire about what their processes were. Largely, it's done in the private sector.

Ernie Silver
Right, but I guess my point is that somehow, even internally to the—I'll call it the health care ecosystem—Nurse Nancy, if you will, has to have—somebody has to make certain that that's really her when she—

Deven McGraw – Center for Democracy & Technology
Well, that's right, sir, and institutions already have legal obligations under HIPAA to identify and properly authenticate their staff.

Ernie Silver
OK. Thank you.

Deven McGraw – Center for Democracy & Technology
Thank you. Thanks, everybody. [Multiple thanks and farewells]

Public Comment Received During the Meeting

1. How can this question of whether an HIO is a "business associate" reasonably be forwarded.

2. Consent is a ground floor concept of the sharing of medical record in every exchange of medical information currently. AND covered by HIPAA clearly.

3. In a patient centered eHR, corrections and new information in an HIO should correct/update per a clock cycle

4. Are there protections in place to code information that is transmitted as confidential, i.e. reproductive services to adolescents?

5. Is this committee charged with prescribing the business model?

6. Given the HIO is not a "clinical partner", but how con it not be a "business associate? It clearly is a needed service and you are discussing its liability framework.