

Privacy & Security Tiger Team
Draft Transcript
June 3, 2011

Presentation

Judy Sparrow – Office of the National Coordinator

Good morning, everybody, and welcome to the Policy Committee's Privacy & Security Tiger Team. This is a Federal Advisory call, so there will be opportunity at the end of the call for the public to make comments. And a reminder: Workgroup members, please identify yourselves when speaking. Deven McGraw?

Deven McGraw – Center for Democracy & Technology

Here.

Judy Sparrow – Office of the National Coordinator

Paul Egerman?

Paul Egerman – Software Entrepreneur

Here.

Judy Sparrow – Office of the National Coordinator

Latanya Sweeney? Gayle Harrell? Carol Diamond? Judy Faulkner?

Judy Faulkner – EPIC Systems Corp.

Here.

Judy Sparrow – Office of the National Coordinator

David McCallie?

David McCallie – Cerner Corp.

Here.

Judy Sparrow – Office of the National Coordinator

Neil Calman? David Lansky? Dixie Baker? Micky Tripathi? Alice Brown Leiter?

Alice Leiter – National Partnership for Women and Families

Here.

Judy Sparrow – Office of the National Coordinator

John Houston? Wes Rishel?

Wes Rishel – Gartner, Inc.

Here.

Judy Sparrow – Office of the National Coordinator

Leslie Francis?

Leslie Francis – University of Utah School of Medicine

Here.

Judy Sparrow – Office of the National Coordinator

Verne Rinker?

Verne Rinker – Office for Civil Rights

Here.

Judy Sparrow – Office of the National Coordinator

Lisa Tutterow?

Lisa Tutterow – Kaiser Permanente

Here.

Judy Sparrow – Office of the National Coordinator

Deborah Lafky?

Deborah Lafky – Office of the National Coordinator

Here.

Judy Sparrow – Office of the National Coordinator

And Dan Rode is joining a little bit late. So did I leave anyone off? [Pause] All right, I'll turn it over to Deven and Paul.

Deven McGraw – Center for Democracy & Technology

Go ahead, Paul.

Paul Egerman – Software Entrepreneur

Yes, thank you very much, Judy, and thank you, Deven. It's Paul Egerman. I want to welcome everyone to our Friday afternoon Tiger Team meeting. This is the Friday of a short week, and I know what that means for most people on this call: It means that instead of what you normally do, which is to try to complete 70 or 80 hours of work in 5 days, this week you try to complete 70 or 80 hours a week in 4 days. And so, I appreciate your time on this very hectic Friday.

We are a Tiger Team of the HIT Policy Committee. I want to first quickly remind everybody what that means. HIT Policy Committee was really created as part of ARRA, the American Reinvestment and Reconstruction Act, sometimes called "the Stimulus Bill." And we are related to what is popularly called in the press "meaningful use regulations." And the Tiger Team is really like a subcommittee of the Policy Committee. And really all we do is, we create, in effect, documents or suggested recommendations. We really don't, as a group, make decisions; we draft almost a physician paper, a document that gets submitted to the Policy Committee. The Policy Committee then reviews that material and chooses to either accept it as a recommendation or reject it as a recommendation or may alter it in some way. Once it's approved, if it's approved by the Policy Committee, it is simply a recommendation to the Office of the National Coordinator, ONC. It's not really a decision; this is something that we are recommending to them. So I just want to make sure everyone understands that's what we are trying to do.

Now, what we have teed up for us on our agenda today is really two topics. One is to possibly wrap up our discussion about certificate authorities—and also then to complete or continue our discussion about amendments and corrections. So I want to talk about certificate authorities, but first let me pause and see: Deven, did I say all that correctly? Anything you want to add?

Deven McGraw – Center for Democracy & Technology

No, you did that beautifully, Paul. It's always nice to be reminded where we sit in the broader infrastructure and what our role is.

Paul Egerman – Software Entrepreneur

Yeah, and the reason I did that relates a little bit to what is going on with the certificate authority recommendation, because there's been some discussions that I want to bring everybody up to date with. But first, to refresh everybody's memory about that recommendation [laugh] itself, it's actually a recommendation that's an oldie-but-goodie. It's one we did November of 2010. And it was a

recommendation that we did as part of a topic that we called “provider authentication,” which really relates to providers as entities. And we tried to talk about the environment that was needed to establish a high level of trust so that, in effect, one EHR computer system could talk to another EHR computer system.

So we did these recommendations in November, and those were approved by the Policy Committee. And as the process completed itself, it was submitted to our sister organization, the Standards Committee, and the Standards Committee did some work on it. The Standards Committee came back to us on a very narrow aspect of our original recommendation related to what’s called “the certificate authorities.” The certificate authority, which is abbreviated “CA” (and it’s sort of mandatory that everything get abbreviated), is simply the organizations that are able to issue these digital certificates. And so, we were asked to consider and elaborate on the qualifications of the certificate authority; in other words, “What are the qualifications of an organization that can issue a digital certificate?”

And we set up a task force that met—I think it was three times. It was headed by Dixie Baker and David McCallie and considered a number of issues. We received what I would call expert advice from Deborah Lafky from ONC. And our task force then, at our most recent or previous Tiger Team meeting, came forward with a recommendation that Dixie described in a series of PowerPoint presentations, and that was approved by the Tiger Team. And I sent out an email a few hours ago with basically a write-up of that recommendation, and that email was not intended to change anything at all of what we said; it was actually simply intended to write it all down in a format that we could submit this coming Wednesday, June 8, at the upcoming Policy Committee meeting. And originally, what we thought we would be doing would be simply informing you of that and asking you to wordsmith it and check to make sure that the document was accurate and complete and correct and see if you had any changes or additions.

But in that process—I don’t know if I’d say we ran across an interesting snag, but in that process of doing that, we received a call from David Kibbe, who works on another project called “the Direct Project.” It’s complicated to explain to everybody, but the Direct Project was formerly called “NHIN Direct.” It’s a special project that ONC has and a great deal of effort has been placed into, to try to facilitate and jump-start and do some innovative things with information exchange. And as a result of that phone call, there was a suggestion that David McCallie and I should speak with David Kibbe, which we did last night, and also included in the phone call were Sean Nolan and Arien Malec. Arien Malec is the person who is the coordinator or who basically is facilitating the entire Direct Project. And I think it’s really important that, from both a transparency standpoint—but for a lot of reasons, that the information from the phone call (there’s actually two phone calls from last night) be described to everybody.

As I said, two of the participants were David Kibbe and Sean Nolan. Sean Nolan is, I think, the Amalga product manager at Microsoft. And the two of them express a lot of concern about our recommendation. I always get nervous when I try to summarize what somebody else said, so I hope I’m doing this accurately, but David McCallie was on the call, so hopefully if you think I’m inaccurate, you’ll correct this or elaborate. But I think their first issue was a sense that they felt that the federal government was overreaching in establishing a federal standard or federal policy around digital certificates or actually around anything—was the sense I had. Their concern was broader than digital certificates. They felt that the federal government should not be establishing policies and standards in this way. And there was a feeling that, by establishing these standards (I think Sean Nolan articulated), we were creating a sense of uncertainty that organizations would not know where the federal government might strike next. And as a result, there’d be less activity. There’d be a significant chilling effect on everything that was going on with the Direct Project. These concerns were expressed, I would tell you, with a fair amount of passion, and the reason I would say they were expressed with that passion was, it’s clear to me that these people put a lot of work into the Direct Project, and they were very concerned about the entire process.

I have to say, I responded by saying that I thought the N and the W in NWHIN stood for “nationwide,” and if this was going to be a nationwide information exchange, there had to be some sense of nationwide standards at some level. And I also said, however, if they disagreed, I was the wrong guy to talk to, because I thought our job was to create the policies, and that they were addressing perhaps what I consider a very fundamental issue about whether or not the federal government should be involved in this process. But it was really not the kind of topic that I really had anything to add or to do anything with. And

as I said, the conversation was passionate. Arien Malec was trying his best to say, “Well, let’s look at this more from a factual standpoint,” which I thought was a good way to look at it, because the question that I was trying to raise was, “Well, do you have some new facts or some new evidence or something that we didn’t consider that would cause us to reconsider our recommendation?”

And the two areas that were raised—one was the cost to become a certificate authority and resellers and how all that worked, and the second area was the operational characteristics of the certificates. And on the first one, I said, “Well, you’re raising a concern, but you’re not giving us any new information that”—we looked at this with Deborah Lafky, and we came to the conclusion that there was competition, that these certificates were available at reasonable prices, and that there was a way to install them—that you could have resellers; you could have organizations installed in four small-group practices, and we thought all of that was practical. And on the issue of the operational characteristics, they had a concern that they said that this was unproven technology, that they needed to really test out whether or not the certificates would really work when they were obtained from these sources. And they suggested that there might be operational impacts on this on ongoing expenses to medical groups, and it might take 2 or 3 years to really evaluate. And my response to that was, I thought these certificates were fairly common use in technology and fairly commonly used within health care for exactly these purposes: for information exchange and for EHR systems. So we had some, I’d say, disagreements on where things are, because what they were asking for was additional investigation, I think, of these issues, and I was saying I thought we’d already investigated them.

So I would say that that was the first conversation, and I have to say, it was contentious. There was a lot of emotion in the conversation. There was a second conversation afterwards that was with Arien Malec and me. Arien did say in the second conversation that he thought our recommendation was fine; he didn’t see anything wrong with it. He did say, however, there was some information that was additional that hadn’t been discussed in the first conversation, which—he said that some of the members of this group—and he didn’t identify who it was, so it wasn’t necessarily people involved in the prior conversation. Some of the members of the group were really trying to create a business model for their HIE organizations or their organizations called “HISPs.” And part of their business model, part of the way they were going to make money, was going to be by selling these digital certificates. And they were concerned that our recommendation was going to somehow damage their financial model and that they needed more time to really look through the financial model to understand that and understand the financial impact on them. That was really a fundamental issue, though, that he was facing.

So those were the two phone calls, and then after those calls, we engaged in what I would call an American business ritual, which means we sent 200 emails to each other and [laugh] cc’ed a bunch of people. So that went on for several hours, but I think that was all done according to normal business practices, and it’s fairly incomprehensible. And then after that, I also did receive an email from Arien saying that ONC, through its S&I Framework, had a website, which is actually something I already knew about, that was gathering public comment on our recommendation and that he had had, I guess, some contact with somebody at ONC, and he thought it was probably OK for us to go ahead with our recommendation, but we needed to know that ONC was rechecking the previous evaluation that had already occurred on some of these issues. And depending on how that turned out, that information might eventually be submitted to the Standards Committee.

So that’s a fairly long-winded description that probably makes no sense to anybody at all. But let me first ask you, David McCallie, since you were on the first of the calls: I don’t know if I captured it correctly or if you want to add anything.

David McCallie – Cerner Corp.

Yeah, I think you captured it pretty well. I will make a couple of comments. One is from the “federal government overreaching” notion. I think the context there is that the Direct group was a voluntary, self-assembled, self-governing process for more than 18 months and had managed across 30 or so vendors and many stakeholders to do a pretty good job of self-governing. And I think it was a surprise to some of the members of the group to find out that they are considered to be under the rubric of the Nationwide

Health Information Network. So that didn't really come into our call, but I think that's kind of the backdrop context. That may be where some of the angst came from.

But that's neither here nor there. The question is what to do about it, and I think you captured their practical concerns, with one—I would make one addition. I think in addition to the unknown operational complexity—and I think it's not so much that they fear that certificates don't work; I think they fear that the cost of meeting federal requirements, the FISMA requirements—I'm sorry—the FICAM requirements might turn out to be expensive and unanticipated. So there's an operational complexity concern.

And then the third concern, which was just barely touched on but I think is a real one, is that the rules might change significantly between now and, say, 2 years from now, when the governance rule has been issued and gone through the various refinements that regulations go through, and that there was a fear that HISPs might say, "Well, if it's going to be regulated by the government and they're not going to settle on this stuff in detail for 2 more years, let's just sit this out and wait on the sidelines," in which case Direct, which I think is a critical part of the strategy for Health Information Exchange, which is, of course, a critical part of stage 2—I assume it will be—could be inhibited. So I'm just adding that fear of the unknown and change that might occur over the next 18 months to the list of their concerns.

Arien Malec – The Direct Project

And Paul, this is Arien. I just want to add, I totally agree with what David just said. And I want to add one more brief factual correction, which is that the Standards Committee, I think, punted one issue back to you and then punted one issue to the S&I Framework. And as it happens, we are ending up covering very similar ground, where the Standards Committee asks the S&I Framework explicitly to evaluate cost complexity and market dynamics for Federal Bridge-compliant certification authorities. And I think, as part of your evaluation and your due diligence for the federal requirements that you were asked to evaluate from the Standards Committee, that you ended up covering the same ground. So that's why—I'm trying not to characterize—it's actually incorrect to characterize the S&I work essentially as a second check. We were both handed, as it turns out, more or less the same task and are trying to faithfully execute it.

Paul Egerman – Software Entrepreneur

OK, that's helpful. So I don't know if this makes any sense to anybody at all on the call, if they have any comments or questions.

Wes Rishel – Gartner, Inc.

Paul?

Paul Egerman – Software Entrepreneur

Yes.

Wes Rishel – Gartner, Inc.

This is Wes Rishel. I want to ask a couple of questions that might help clarify, at least for me, some of these issues around complexity. We know in general that one requirement that we've taken on as a set of requirements is the ability to communicate with federal agencies. We have taken as a fact one of two positions with regards to that. One is that federal agencies can only establish secure links with other entities that are certified through this series of cross-certifications back to the Federal Bridge. The other is, that's simply the most convenient way for the federal government to do that. I don't know which is true, but whichever is true, what seems, I think, to have been a surprise to some people is that communications from Dr. Jones to Dr. Smith that really have nothing to do with the federal agency are suddenly under this aegis of requiring certificates that are issued to the Federal Bridge. So I think it's important to be clear on what it means to say this is an NWHIN standard. Does it mean that there's some law or practical issue that precludes any communications about health care and private commerce unless the certificates are issued through this complex process, not necessarily complex to do but complex to describe?

So I think that's one important issue to consider. The other one, I think, is to understand who in this process, if anyone, is actually verifying the assertion that the holder of one of these certificates is in fact a

qualified member of the health care system. I don't believe that the multiple-sided authorities that are already cross-certified with the Federal Bridge categorically offer that as a service; I think perhaps one of them does, or one of the major phone companies. But if we're concerned about how these are issued, the question would come up: "Does the combination of cross-certified with the Federal Bridge and validating that this is a legitimate participant in health care information communications—does that create a new level of complexity or level of cost that we haven't thought about so far?" Thanks.

Paul Egerman – Software Entrepreneur

So let me do my best to respond to both those questions, Wes. On the first question, "What is the impact of the recommendation?", the recommendation's impact is one of two possibilities. One possibility would be that this concept is part of EHR certification for stage 2. The other possibility would be that it would be part of NWHIN governance. So in either case, if you participated in NWHIN, then you would have to have one of these certificates. So that would be the impact of it. Did I get that right Deven?

Deven McGraw – Center for Democracy & Technology

Yeah, no, I think you did. I mean, it's a condition of using the NWHIN brand. It's what the governance is supposed to set out.

Paul Egerman – Software Entrepreneur

Yeah, and there's a number of reasons why we came up with this proposal, which again relates to your second question, Wes, that we did not want to have a situation where we thought the group should have two certificates: one when they deal with CMS and another one when they deal with Dr. Smith across the street, which—makes more sense to have just a single certificate. And we did think that it was important for these groups to be able to communicate with the federal government or federal agencies like the VA or Indian Health Service—be able to do that themselves directly—or CDC. But we also came to the belief that the rules to participate in the Federal Bridge were such that the certificate authorities would have to validate the identity of the groups requesting the certificate. It was one of the benefits that the task force saw with this approach as compared to the other approaches: The other approaches seemed like anybody who wanted a certificate could just get one. This approach did include validation that the entity was really who they said they were—that they were really a group practice or a DME supplier, that they really existed—

Wes Rishel – Gartner, Inc.

Paul, I just don't hear that in anything that's been said. I hear that a person has been identified by a process such as taking a government-issued ID to a post office, while it only appears that a business has been identified. Is Joe's Endoscopy Shack a legitimate health care provider or not? I mean, there's a business license issued to it, but it's not necessarily...

Paul Egerman – Software Entrepreneur

Well, Deborah Lafky, did I get it right on the phone? Are you on the call still?

Deborah Lafky – Office of the National Coordinator

I'm here. I'm listening intently. The recommendation—we may not be entirely explicit on that point that Wes raised. There certainly is a requirement the identity of the entity applying for the certificate is validated by reliable registration authorities. And it is possible, within a set of government rules, to specify what types of entities are permissible. I'm not entirely sure that that has been clarified in the recommendation.

Paul Egerman – Software Entrepreneur

OK, but it is the case that this type—making this recommendation, we are requiring that, at a minimum, the entities be accurately identified. In other words, I could not apply for one of these and claim to be Mass General Hospital. You'd somehow check and find out that I'm not Mass General Hospital.

Deborah Lafky – Office of the National Coordinator

That's correct.

Deven McGraw – Center for Democracy & Technology

Yeah, this is Deven. I do think that part of our goal here was to almost kill two birds with one stone. One was to say that, because certification to the Federal Bridge or cross-certification does necessitate some vetting of the entity, that would take care of our desire to create a high level of assurance that an entity with a digital certificate through this process is reliable, is involved in health care, and can be trusted. The second bird that we were looking to strike out was “Well, most providers are, in fact, going to have to exchange, even if just occasionally, with federal entities.” And so you get both of those goals met in one set of recommendations, and then the remaining question that we had was, “Well, is this going to be too costly for people?” And that, I thought, was the issue that we thought was resolved but for which there remain some questions. Is that an accurate statement?

Paul Egerman – Software Entrepreneur

Yeah.

David McCallie – Cerner Corp.

This is David. That’s accurate, but I think Wes has introduced another concern, which I think is completely different, but it’s an important one, which is, the way the model is written now, NASA astronauts could participate in Direct. There’s nothing in the process—

Paul Egerman – Software Entrepreneur

As long as they correctly said, “I’m NASA,” [indiscernible] not quite right, because it has to be a server. I mean, it’s a different issue. One of the problems I had with what the S&I Framework at ONC is doing is, they’re also talking about individual certificates. But that’s not what our recommendation is—

Wes Rishel – Gartner, Inc.

Paul, a NASA astronaut would be using a server that was cross-certified. So [indiscernible].

Paul Egerman – Software Entrepreneur

[Indiscernible] That’s right. They’re already cross-certified. But a better example might be if I’m Acme Hardware Store. I think what you’re saying is, as long as I accurately say, “I’m Acme Hardware Store,” I can [indiscernible] get one of these certificates, because it doesn’t necessarily say that it has to be a health care organization. So that’s a better way of saying it, because NASA is part of the government.

Wes Rishel – Gartner, Inc.

But still, I mean, so is a bunch of agencies that people get very concerned about poking around in their health care data. So that’s not a trivial issue to say that anyone who’s cross-certified with the government exchange has access as if they were a health care provider. I’d just like to say, however, that what I hear that the actual impact of the recommendations we’ve made be is that you can’t communicate with a government agency using the Direct protocols, unless you have such a certificate, and you can’t use the NWHIN trademark without having a special certificate. Whatever else may be the case in terms of the effect on industry and so forth, I don’t see either one of those things as a sudden increase in the use of the authority of the government. NWHIN’s trademark was created by the government, and by definition, communicating with a federal agency involves government actions.

Paul Egerman – Software Entrepreneur

That’s a good comment, Wes. I also wanted to make a comment—I can’t remember if you, Wes, or David made some comment about the complexity involved. I just wanted a reminder: When the task force considered the complexity issue—and one of the things we pointed is that there are resellers, so that means an EHR vendor or perhaps one of these HIE organizations could obtain a certificate for somebody for—

Wes Rishel – Gartner, Inc.

What we don’t know, I think, is what is the likely cost of getting and maintaining [indiscernible] to be a reseller.

David McCallie – Cerner Corp.

And then there are quite a number of volumes of FICAM regulations on how you have to handle these certificates, who can touch them, who can installed them, how many machines they can be installed on, and so forth. And until we get a full reading of how you actually use them, it's not that they don't work, but what's the overhead of actually using this and treating it properly? That's the operational complexity that I was referring to, not the complexity of obtaining one but of actually using it in a HISP that's, say, serving—let's say they have 5,000 organizations that they're serving. What's the overhead of managing to federal standards these very secure, precious certificates?

Wes Rishel – Gartner, Inc.

Can you just tell us what FICAM is?

David McCallie – Cerner Corp.

Oh, that's the—boy, Arien or one of you guys could probably tell me what the acronym is. It's essentially the rules of the road for operationalizing many of these things in federal systems. Arien?

Deven McGraw – Center for Democracy & Technology

The Federal Identity, Credential, and Access Management Plan or Roadmap.

David McCallie – Cerner Corp.

And it's regulations on using them. Ah, "regulations" may be not the right word.

Paul Egerman – Software Entrepreneur

So this is the issue—again, what you're saying, David, is the same as Sean saying that we need 2 or 3 years of evaluation before we—

David McCallie – Cerner Corp.

Well, no. I honestly think that this can be settled fairly quickly. And I think that Arien's description of what the S&I Framework is already under way trying to do will, in fact, settle it fairly quickly.

Paul Egerman – Software Entrepreneur

But Deborah, is there an operational cost for, say, a small medical group that just spent money every month or every day or every—do they have to do things all the time to make these certificates? Is it just a certificate?

Deborah Lafky – Office of the National Coordinator

A certificate is at most an annual cost, and they're also available for 3 years. And it's a one-time fee. There is a cost associated with becoming identity proof, which is whatever a notary would charge to do this, usually \$10–\$15. There's no fee; there's no maintenance required; you get the certificate; it's installed; you're done.

Paul Egerman – Software Entrepreneur

And I'm using the word "complexity," not "cost." You elaborated the cost, Deborah, correctly. It's the FICAM rules and whether that requires, for example, a different configuration of your server firewalls than is commonly used or a different configuration of physical security of the device on which the certificate sits.

Deborah Lafky – Office of the National Coordinator

Not for the end user. Simply, there's no visible difference to the end user. It's the certificate's issuers who are held to a higher standard of integrity.

Wes Rishel – Gartner, Inc.

Paul, I think the concern is more for a chilling effect on HISPs than it is for a chilling effect on the end user. One of the whole underlying users' Direct is that we can take the operational complexity away from the end user by making it a reasonable business proposition toward various empathies to be HISPs, including hospitals, including vendors of EHR products, including companies that just want to be HISPs. (This is Wes.) If we don't know what they have to do, how much cost they have to pass along, how much

volume they have to get in order to justify the investment, I think it's reasonable to say that we may slow down the development of the HISP market.

Paul Egerman – Software Entrepreneur

I thought we already answered those.

Deven McGraw – Center for Democracy & Technology

Yeah, but Wes, can you also explain to folks on the phone who might not be aware what the concept of a HISP is? I think folks who deal with Direct pretty regularly understand it, but I'm not sure that everyone does.

Wes Rishel – Gartner, Inc.

Sure. So the acronym is "Health Care ISP" or "Health Care Information Service Provider," assuming that everyone understands that their ISP is—my ISP from my home is my cable TV vendor. Other people use their phone system vendor. Other people might use Harris Corporation. But fundamentally, it's a firm that offers me the Internet service. The Health Care ISP was felt to be one that could operate its servers and generally maintain its operation in a way that's met the requirements of Direct in order to ensure the integrity and privacy of the information passing through. And the feeling was that any reasonably large organization with a presence in health care was already fulfilling the requirements of an HISP so that, for example, if a hospital wanted to help local practices [indiscernible] the HISP, that was fine. If a vendor of electronic health record products wanted to do it, that was within what would be an acceptable additional cost and complexity for them. And if vendors of communication services wanted to do that, the supporting Direct would be a reasonable business proposition for them.

Paul Egerman – Software Entrepreneur

OK. So I thought, though, we'd already looked at that issue in our task force and that resellers' requirements were reasonable and [indiscernible].

Wes Rishel – Gartner, Inc.

I don't think that we looked at the issue [indiscernible]. Paul, I'd like to finish my statement.

Paul Egerman – Software Entrepreneur

Go ahead.

Wes Rishel – Gartner, Inc.

I don't think we looked at the issue of operational complexity imposed by FICAM.

David McCallie – Cerner Corp.

This is David. I don't want my comments and concerns to be interpreted that I think there will, in fact, be significant, important operational complexity. I'm just saying that we don't know yet and that some of the fear of the folks working on Direct is that we're not only introducing the need to get the certificate from them through a slightly more rigorous process; we are also possibly introducing unknown regulatory impact on the data center. And until we can make sure that that's not a problem, they're going to be concerned. And I think we will, in fact, confirm that it's not a problem, but I'm just passing on the concern. And I think—

Deven McGraw – Center for Democracy & Technology

David, this is—I'm sorry; go ahead.

David McCallie – Cerner Corp.

No, I was just going to say, "And I think Arien's got a process under way to chase this down." So I think we're in good shape.

Deven McGraw – Center for Democracy & Technology

Well, that's what I wanted to ask. (This is Deven again.) You said you thought it could be relatively easily, and maybe Arien should speak to this, but what are you envisioning?

David McCallie – Cerner Corp.

Well, what I have suggested back to the rules-of-the-road group, the Direct group, is, if they think there's an easier way to do this, line up the steps and the costs and the operational issues to do it the quote-unquote "easier" way, and then we'll compare that side by side with what we're recommending and let people make a straightforward decision that this is hopefully not a tremendous incremental cost, and yet it is a huge gain in the creation of a nationwide addressability world, which is what I think we all would like to see the final outcome be—is that you can talk to anybody securely without worrying about these trust issues. So I'm anxious to just compare the two choices—

Wes Rishel – Gartner, Inc.

But there are no two choices.

Deven McGraw – Center for Democracy & Technology

Yeah. Well, and the other thing is, actually, what concerns me about that is, I think, fundamentally, the foundation to the recommendations that we initially adopted was a level of assurance that an entity is who they say they are and some ability to exchange data with a federal agency. And so, it's not just "Is one methodology cheaper or easier than another?" I think we actually need some standards here, which is what attracted us to this set of recommendations in the first place. And so, really, the outstanding issue is whether, given that set of criteria, which I don't think we should waver on—is the set of recommendations that we have set forth, in fact, doable as we believed it was when we adopted it.

David McCallie – Cerner Corp.

And Deven, this is David again. That's a great point, and I should add one more context for my concern. It's not so much the question of whether we should retract our recommendation; I don't think we should. I think it is reasonable, and the federal communication issues are as you just described. What's happening, however, is, the direct group is essentially creating a second tier of users of Direct, which would fragment the network in half or in some fraction; I don't know if it's going to be half or not. And I'd like to avoid that happening. I'd like to convince the rest of the people that this federal requirement that we have introduced in the Tiger Team is not a burden and it is game. It's a win, so don't go fork, don't go split, don't go fragment the Direct network before we even get started. So I'm trying to strengthen our recommendation and eliminate the need for a quote-unquote "simpler" approach, because I don't think it is any simpler.

Paul Egerman – Software Entrepreneur

Well, this is Paul. I have a couple of comments. First I want to talk about this issue of complexity. And I'd simply say, we're talking about information exchange, and we're talking about how you validate a server when a server says who they say they are. We're also somewhere in this mix talking about encryption. Those are complicated issues. But at the same time, there's a lot of complexity in a lot of other things we do. I mean, I look at the Direct standards, and you have a standard on SMTP. But since you're running a mail server, there's a lot of complexity around a mail server. And when you start dealing with mail servers and federal communications, there's a lot of federal communications regulations also. And that's just an observation. I don't see that we're introducing with this recommendation any level of complexity that is any different at all from what these organizations already have to deal with.

That's one comment. The second is, I don't [indiscernible] the fact that the people have fears, but that's always gone so far as fears and concerns. I mean, so far, there hasn't been anybody who's pointing to something that says, "Here's a problem." And that's why we can't go forward, but the door's always open for people to do that. In other words, we don't make our recommendation to the Policy Committee till Wednesday; even after Wednesday, if the Policy Committee accepts the recommendation, still a whole boatload of stuff has to happen: The Standards Committee's got to do some things—there's a whole series of things, and if somewhere along the way, if we come up with something that says, "Hold everything; here's a problem that we haven't understood," then we can adjust to it.

Arien Malec – The Direct Project

Paul, this is Ari, and I have a proposal. I want to point out that in the same transmittal letter where the Standards Committee essentially handed back to the Policy Committee this issue around evaluation of policy and government certification authorities. The Standards Committee also handed to ONC the charge to examine special benefits and implications in cost market dynamics and complexity for use of the Federal Bridge Certification Authority. And that's the work that I think we've been doing in parallel; that is, Paul, you and the Tiger Team, in your due diligence to adjust your issues, have explored some of the same ground that—what ONC decided to do was spin up a standards and operability framework initiative on the cost complexity and market dynamics issue for Federal Bridge.

What I would propose is that on the policy grounds and on the factual grounds with the great input and advice of Deborah Lafky, the policy recommendations that you have in front of you are reasonably founded. The factual—there's more, I think, that needs to be done from a factual exploration that the S&I Framework Initiative collaborating with Deborah Lafky is engaged in. And so, my proposal, regardless of whether this recommendation goes through the Policy Committee or not, would be to continue the S&I Framework Initiative and essentially hand back, either to the Policy Committee or the Standards Committee, those additional findings of fact that are relevant to cost complexity and market dynamics, which I think are the issues involved.

Paul Egerman – Software Entrepreneur

It's a great proposal, Ari, but is it a proposal to us? Because I don't think we have any [indiscernible] S&I Framework has nothing to do with us.

Wes Rishel – Gartner, Inc.

Paul, this is Wes. I want to say that I think you mischaracterized this issue in several ways in your summary, which seemed to be designed just to avoid any changes to the work products, and that I would support a change to our transmittal letter along the lines of what Ari said. Or we can have a discussion on what those mischaracterizations were.

Paul Egerman – Software Entrepreneur

I'm open to either one. If you think I mischaracterized it, I think we should correct it.

Wes Rishel – Gartner, Inc.

Paul, the mischaracterization was in spoken information that's not necessary if we simply agree that there are issues important to the dynamic of Direct that are not yet reconciled, that we recognize that, and that we suggest essentially the process that Ari described.

Deven McGraw – Center for Democracy & Technology

So what that would mean would be that we would present our recommendations to the Policy Committee and ask them to endorse them with the recognition that there is some ongoing work on operational complexity and potentially cost issues that the Standards Committee asked the S&I Framework to engage in that is still ongoing and that if there, in fact, is a change in circumstances that would cause us to reassess those recommendations, either we would do it as a Policy Committee or perhaps ask the Standards Committee to do it. Is that what you're suggesting?

Wes Rishel – Gartner, Inc.

Yeah. The only thing I would, at all, amend in the way you summarize it would be that if new information comes to life through S&I evaluation...

Deven McGraw – Center for Democracy & Technology

OK—that we would reassess. But otherwise, based on what we know of the facts on our exploration, we would ask the Policy Committee to accept the recommendations with the caveat that, again, if new information comes to light, we would reassess.

Wes Rishel – Gartner, Inc.

Yeah, no, we have to recognize that they may decide to table it at that point.

Deven McGraw – Center for Democracy & Technology

Well, I mean, it's entirely possible; you never know.

Wes Rishel – Gartner, Inc.

Yeah, but in my opinion, that accurately describes the situation of what we should be responsibly doing.

Deven McGraw – Center for Democracy & Technology

And I think it could also potentially have the Policy Committee endorsing what was really the foundation for our recommendation in the first place, which was, again, the idea that we wanted a high level of assurance that entities who get digital certificates are who they say they are and that we want there to be connectivity with the federal government, because that is such a frequent occurrence in health care and likely to increase.

Paul Egerman – Software Entrepreneur

I like that. I like what Wes said, and I like how you put it, Deven.

David McCallie – Cerner Corp.

This is David again. There's another possible outcome that there might be operational complexities that could be addressed in and of themselves. And our recommendation stands, but we find ways to simplify out-of-the-box operational procedures and say, "For the use case of the NWHIN, these are sufficient," and create some clarity where there might be a boilerplate federal policy that just needs some clarity.

Paul Egerman – Software Entrepreneur

Yeah, and David, this is Paul. So I wanted to be clear: Our recommendation is only for NWHIN. I wanted to be clear. It's only intended to be for NWHIN.

David McCallie – Cerner Corp.

That's what I said: for NWHIN. Our recommendation could stand; there could be operational complexity if you just take a face-value assessment of FICAM, which we could lead maybe through S&I work and intergovernmental work to a simplified set of those operational constraints so that it works well for NWHIN.

Wes Rishel – Gartner, Inc.

Yeah, I just want to emphasize what David described earlier, which is that there's a potential schism developing that could, depending how all of the information develops, leave physicians the choice of saying, "Well, for this much, you can communicate with all the doctors in your community, and for this much more, you can communicate with the VA." And I don't think we should have to put them in that position.

David McCallie – Cerner Corp.

And I can tell you: What would have to happen is, essentially, everyone would have to certify twice, because if Direct's going to work at all, every doc is going to have to certify twice, which is just silly.

Deven McGraw – Center for Democracy & Technology

Well, right. I mean that—this is Deven—I thought that's what we were ultimately trying to avoid. We want one policy for NWHIN, and ideally the Direct Project would ultimately follow that.

David McCallie – Cerner Corp.

Yes, that's the desirable goal. And we've got a schism under way now based on what I think is a lot of uncertainty; it's FUD right now. And I think the proposal is, "Stick to our guns on our policy. Acknowledge that there's a process under way to address the FUD. If there's a surprise, we go back and readdress things; otherwise, we are done."

Paul Egerman – Software Entrepreneur

I think that's reasonable. The only—well, first of all, I want to find out: Is there anybody who...?

Deven McGraw – Center for Democracy & Technology

No, it's true, Paul (thank you), that conversation's been taking place with a small number of people.

Paul Egerman – Software Entrepreneur

[Indiscernible] Is there anybody who dislikes what is being said, who disagrees or has a different approach? [Pause] So the question, though, is, how do we draft this [indiscernible; laugh]? I'm just a little bit nervous, because first of all, we've got an entire document here that's four pages long. And what I tried to do was write up an explanation for all this stuff. I want to make sure that the document itself is correct. And sensitive to what Wes's comment is, I'm not trying to misrepresent or construe this inaccurately, so if there's something wrong here, please correct it.

That's one thing, but the second is, how do we write up this other concept? We had this section of the document called "Recommendation." I mean, Deven, maybe, can you write one or two sentences that will...?

Deven McGraw – Center for Democracy & Technology

Yeah, I think I can, again, focusing on the core of our recommendations, acknowledging the existence of this other process that the Standards Committee asked for to pin down some of the issues that we thought were resolved, but questions have been raised. And so, I think it's quite possible to characterize that and commit to a reassessment if, in fact, it turns out that there are facts that diminish the conclusions that we were so confident of when we initially approved the recommendations; we would move forward with it. And I'm much more articulate of a writer than I am a speaker, so I promise it'll turn out better. But I'd certainly be happy [laugh; indiscernible].

Paul Egerman – Software Entrepreneur

Well, the basic issue here that I think is important is, we need to separate out facts from fears.

Deven McGraw – Center for Democracy & Technology

Right, but there's nothing that some more factual exploration (assuming that it is in fact a factual exploration) can do to ease people's fears.

Paul Egerman – Software Entrepreneur

Well, that's right, but that's what I've been trying to say all along. If somebody has something specific that they point out that somehow we didn't know, then that's important, and we need to fix it.

Wes Rishel – Gartner, Inc.

Yeah, I think it's important not to accidentally imply by saying "fears" that we're thinking unfounded fears. I think we just need to find out whether they're founded or not, whatever the [indiscernible].

Judy Sparrow – Office of the National Coordinator

Paul, this is Judy. When you say "that four-page document," you mean the one that starts off with "Draft for Policy Committee Review"?

Paul Egerman – Software Entrepreneur

Yes.

Judy Sparrow – Office of the National Coordinator

The "Dear Dr." whatever?

Paul Egerman – Software Entrepreneur

"Dear Dr. Mostashari."

Judy Sparrow – Office of the National Coordinator

Yeah. It's signed "Paul Tang."

Paul Egerman – Software Entrepreneur

Yes, I think—

Deven McGraw – Center for Democracy & Technology

Oh, it's a transmittal letter, Judy. They all—

Paul Egerman – Software Entrepreneur

—transmittal letter. What I did explain that is—I took our original transmittal letter of November 19, and I used that as my template for using this letter. And then that letter happened to be signed by Paul Tang. I think that's how these things work.

Deven McGraw – Center for Democracy & Technology

It is.

Paul Egerman – Software Entrepreneur

And so the first page of it is boilerplate. It's the charge of the Privacy & Security Team. And there's something that's background I suspect Deven wrote, but it's really very well written—that talks about the importance of having a high level of trust. So I put this document together, and I saw that thing, and I said, "Well, that looks good," and so I just tossed it in here. [Laugh] And anyway, that's why it's signed by Paul Tang. I think that's the correct administrative way you do these things.

Deven McGraw – Center for Democracy & Technology

Yeah, once recommendations get through the Policy Committee, the ultimate transmittal letter that gets sent to ONC, which is the official passing along of the recommendations, they're always signed by Paul Tang, since he's the vice chair of the Policy Committee.

Judy Sparrow – Office of the National Coordinator

OK. I just thought you got confused; that's it. [Laugh]

Deven McGraw – Center for Democracy & Technology

Getting Pauls confused?

Judy Sparrow – Office of the National Coordinator

Yes, exactly.

Paul Egerman – Software Entrepreneur

The hard part was replacing "Blumenthal" with "Mostashari" and spelling that correctly. I checked it six times to get it right.

So is this discussion wrapped up? Is everybody comfortable with where we are on this? Are you comfortable, Wes, that this is correct and accurate and everything?

Wes Rishel – Gartner, Inc.

Yes sir.

Paul Egerman – Software Entrepreneur

OK, so here's what we're going to do: When do you think, Deven, you could draft the two or three sentences or whatever it's going to be?

Deven McGraw – Center for Democracy & Technology

I'll try to do it today. Yes, I have a crazy weekend, so I probably should do it today, since we need to do slides by Monday.

Paul Egerman – Software Entrepreneur

Yeah, so we'll try to get that to you today as a revision of this document. But we would like everybody to do their best, as soon as they could, to read through the document carefully and make sure we got it right. In other words, I just want to make absolutely certain that this is correct and that we're not describing something inaccurately. So if you have time to start doing that even without Deven's sentences, that's great, but hopefully we'll get them by the end of the day.

And when do you think we should ask for revisions back? Because I know we've got to post this for the Policy Committee to review also. I mean, can we ask people to get it back by, say, noon on Monday? Is that too little time? Is that enough time for Judy Sparrow?

Deven McGraw – Center for Democracy & Technology

Well, Judy gave us a noon deadline for slides. So do we have her on the phone? Can you give us a little wiggle room? [Laugh]

Judy Sparrow – Office of the National Coordinator

Yeah, no, that's fine, no problem.

Deven McGraw – Center for Democracy & Technology

OK.

Paul Egerman – Software Entrepreneur

OK, but if you have comments before noon on Monday...

Deven McGraw – Center for Democracy & Technology

Yes, don't hesitate to send them.

Paul Egerman – Software Entrepreneur

Yeah, that's what we need. And we've got to be clear: We're trying to get it right. That is what we're trying to do.

So I think we're completed with this topic. Are you ready to move on to [laugh] corrections and amendments? I don't know that it ought to be something funny to say as we correct and amend our document here.

Deven McGraw – Center for Democracy & Technology

Our documents, right [laugh]. We have to live by our own policies [laugh]. I think we're ready.

Paul Egerman – Software Entrepreneur

OK. Were you going to introduce this one, Deven?

Deven McGraw – Center for Democracy & Technology

Sure. So in light of the conversation that we had on our last Tiger Team call about amendments and corrections, of which the overarching conclusion was not to have additional policy requirements beyond those that are already in HIPAA that would [inaudible; indiscernible] to persist corrections forward, that we would not pursue that track because of a lot of complexity, but instead focus on making sure that technical aspects of the systems were in place in order to allow corrections to be made and moved forward, regardless of whether they were being done in response to a patient's request or whether, in fact, a provider had made a decision in his or her professional judgment that there needed to be an amendment that moved forward. And so, there was a draft letter that Judy sent out yesterday, where we tried to encompass what we thought was the consensus of our last meeting on the technical issues, and explaining briefly why we decided that it was not prudent to put a specific requirement on providers to propagate amendments forward that they might find on their own.

And so, we didn't actually have a lot of time on our Tiger Team call, because we spent so much time on the substantive issue of whether or not providers should be required to move corrections either forward or

backward that they discover themselves. Since we spent so much time on that, we didn't have as much time to deal with some of the technical issues. So much of the language in this letter may have been something that you saw for the first time, but we did use some of the material that MIDR had provided us from the initial materials from last week's call as well as thinking through what might be needed to, at a minimum, comply with the HIPAA requirements and to set those up for your discussion.

So essentially, what we've got is one recommendation with budget components, again, with the idea that what we're trying to do is make it technically possible for providers to communicate information about potential corrections, such as through a special icon or a button, to make amendments in a way that is consistent with the entities' obligations with respect to their legal medical record to be able to append information from the patient and any rebuttal from the entity regarding disputed data—again, this is a requirement with respect to HIPAA—and then, with respect to existing standard exchange transactions, to be able to transmit amendments, updates, or appended information to other providers whom the entity knows have received the disputed data. And then, of course, as always, with respect to the development of certification criteria, the details on that, and any necessary standards, we try to look to the Standards Committee to do that.

So, I'm not the technical expert on the call. We have many more. And so, we wanted to use the time we have on this call to get feedback. And if we're reasonably close and we can come to consensus, then we would be able to present essentially two sets of recommendations to the Policy Committee next Wednesday. If we're not able to do that given the short amount of time left that we have on this call, we might have to use a little bit of time on a subsequent Tiger Team call to wrap it up. So I'm going to stop and, Paul, ask you to...

Paul Egerman – Software Entrepreneur

OK, so what I think I'll do is see if we can walk through this letter. Is it possible to ask Altarum to put it up on the screen for everybody? It's the last document: "Tiger team Recommendations on Amendment."

Deven McGraw – Center for Democracy & Technology

Yeah. It's funny: It shows up as the first document on my screen. [Laugh] Thanks, Caitlin.

Paul Egerman – Software Entrepreneur

Caitlin, also, I probably will need some screen controls.

Caitlin Collins – Altarum Institute

Not a problem, Paul; I'll set that up for you right now.

Carol Diamond – Markle Foundation

Deven?

Deven McGraw – Center for Democracy & Technology

Yes?

Carol Diamond – Markle Foundation

It's Carol. I have a question just for context. And I know we had some discussion on the last call about this requirement in terms of how it could or might get implemented. I'm wondering, since certification has really been something that's been reserved for the requirement of meaningful use—in other words, there's a clear policy requirement—on this issue, is there a clear policy requirement that we're trying to help implement through certification of technology that I'm missing? Because I'm worried that this is a little bit of one of those issues where, yes, it would be good to do these things, but getting to certifications has really been reserved for the things that are required.

Deven McGraw – Center for Democracy & Technology

So I think the answer to your question, Carol (this is Deven), is that the required nexus between meaningful use and certification—there's an exception to that—is my understanding. And Paul, since this

came from the Certification and Adoption Workgroup, I'll ask you to make sure that I have articulated this right. But with respect to privacy and security requirements, the certification requirements for EHRs are not necessarily tied just to meaningful use criteria. And in fact, when we drafted these recommendations, we looked specifically at what obligations providers would already have under HIPAA with respect to patient-requested amendments to get the systems to be able to comply with that. That was the basis for how we structured this. And then, of course, having those technical capabilities in place to honor what the patient might request and the various components that exist in the HIPAA rules provide the technical pathway for providers if they discover errors on their own and believe that it's important to propagate those amendments forward—that they would have the technical capability to do so. So that's my answer.

Carol Diamond – Markle Foundation

So in this case, then, you believe HIPAA creates the policy amendments?

Deven McGraw – Center for Democracy & Technology

Yes.

Carol Diamond – Markle Foundation

OK.

Paul Egerman – Software Entrepreneur

This is Paul. Carol, I think it's a good comment, but this also relates to our framework issues of data integrity and quality, in my opinion.

Carol Diamond – Markle Foundation

There's no doubt that an important—that's not what I'm questioning. I was just questioning whether this is one of those issues that's a good thing to do because of [indiscernible] integrity. And if it's a good thing to do, that's great; but if it's not required, how do we get to [inaudible; indiscernible]?

Deven McGraw – Center for Democracy & Technology

Right. It is required through other policy vehicles, which would be HIPAA.

Carol Diamond – Markle Foundation

OK, that's good.

Paul Egerman – Software Entrepreneur

OK. So the way I was going to propose to go about this is to just walk through the actual recommendations that are in bold. The introductory material is very important. I think people should read and make sure that we've got it right. But part of this is referring to HIPAA, and what I want to find out is, "Do we have agreement, consensus, or alterations to the material that's written here?"

So there's really, I think, four or five comments here. One says certified EHRs should have a capability support and provider's compliance with HIPAA obligations to respond to patient requests for amendments. It says the system shouldn't make it technically possible for providers to do—I mean, there's some question about whether it's stage 2 or 3—but there's two bullet points. First one is "Make amendments to a patient's health information in a way that's consistent with the entity's obligations with respect to a legal medical record," and then it's an interesting—it says, "For example, certified EHR systems should have the capability to finalize progress notes so that any changes are shown as amendments." So that's tossed in, because in stage 2 progress notes, it's been discussed as possibly also being a stage 2 meaningful use requirement. And then there's the letter B: "Append information from the patient and any rebuttal from the entity regarding disputed data."

So the question is, what do people think about this? Is this good, bad, all right? What do we think?
[Pause]

Wes Rishel – Gartner, Inc.

This is Wes. I'm trying to let someone else go first this time. [Laugh]

Paul Egerman – Software Entrepreneur

I think everyone was hoping you would go first, because you actually capture it very well. So why don't you go ahead, Wes?

Wes Rishel – Gartner, Inc.

All right. Well, I hate to be the goody two-shoes standing in front of the class here, but what I don't quite understand is whether there's implied a requirement to—here's the scenario I'm worried about: A patient requests an amendment to their record, and the physician reviews the amendment and says, "Yeah, that's correct," right? Is there an obligation now for the physician to go through and review document that's been created to make sure that it's an amendment, or does this apply to a specific—I'm going to say "document," but obviously we understand that means an object that could be structured or text or whatever; it's not necessarily a pure text document. Does it apply to one thing, or does it apply to a whole raft of things?

Deven McGraw – Center for Democracy & Technology

Oh, that's a good question, Wes. This is Deven. We were not trying to either constrict or enlarge the existing HIPAA right for patients to request an amendment and what providers have to do in response. So if phrasing it as "Make amendments to a patient's health information" makes it sound like we're enlarging the right so the patient says, "Hey, I got discharge instructions, and it says that I'm on X prescription when in fact I'm not," then the provider makes a judgment call about making the amendment and fixes whatever needs to be fixed in the record based on their judgment call. But what we're trying to do is say, "In an electronic medical record, there ought to be a technical capability to do that in a way that is, again, consistent with an entity's obligations with respect to the legal medical records," which means—and Dan Rode's on the phone, hopefully, by now, and he can correct me if I'm wrong—you can't erase the previous data. There's a way that you likely need to go about this so that the previous entry can still be viewed but the correction is also visible.

Judy Sparrow – Office of the National Coordinator

This is Judy, and I'm wondering whether we should be a little bit more careful with the wording (and I don't know what the wording would be), just because, in fact, people take it that the correction is an amendment. I think that the way to do it is more like the chart does it, which is, you change what people see, and then they can look to see what previously had been rather than—they have to go to an amendment to see that it's the right eye, not the left eye, that's in danger.

Paul Egerman – Software Entrepreneur

Yeah, and this is Paul. If I understand you correctly, it's a good point. Our intention was not to say anything about how the data was displayed but simply that the information was [indiscernible] consistent with what—you would keep some track record or history or something.

Judy Sparrow – Office of the National Coordinator

Yeah, and so my concern is, it says, "Any changes are shown as amendments." That's very definitive, and that's not the way to do it. You don't want to show those amendments; you want to actually change what people say.

Paul Egerman – Software Entrepreneur

Where does it say, "Any change is shown as amendments"?

Deven McGraw – Center for Democracy & Technology

It's the example for the finalization of progress notes, Paul.

Judy Sparrow – Office of the National Coordinator

Yeah. It says the word "amendments" all over the place, and if that's what people think they have to develop to, that's not the right word.

Paul Egerman – Software Entrepreneur

Oh, for certified EHR systems [indiscernible], you would finalize programs [indiscernible] so any changes are handled as amendments/corrections/updates.

Deven McGraw – Center for Democracy & Technology

Or actually, it can be—oh, I'm sorry; who did I interrupt?

Wes Rishel – Gartner, Inc.

No, this is Wes, and I interrupted you. But I was going to suggest that there might be a wording that is consistent—“these changes are made consistent with other changes to the records” or whatever the right term is. I think “handle those amendments”—I read it as, “Well, if there's another amendment to the record”—no, I guess Judy's right, so I'm going to just shut up and babble with mute on for a while.

Paul Egerman – Software Entrepreneur

[Indiscernible] The way I'm understanding Judy, [indiscernible]. It's almost two issues. One is the word “amendment,” and the other one is where it says “shown as amendments.” [Indiscernible]

Judy Sparrow – Office of the National Coordinator

Yeah, and I'm afraid that someone will follow too religiously, or that's what it's going to be interpreted as. And I think that's the wrong way to do it, and it's not a safe way.

Wes Rishel – Gartner, Inc.

And so, can we get clarified—does the term “amendment,” in terms of the legal record, imply anything about how it's shown? For example, I mean, I know that in the paper record, it's normal to line out something that's been changed and mark the change. And I think that meets Judy's requirement for left eye versus right eye. I don't know to what extent, currently, the display of this information is being certified by NIST, but I'm just wondering: Is there anything we can say that should be done consistent with how something else is done in the EHR and make it not a special but treated like any other correction, amendment—whatever the right word is here?

Judy Sparrow – Office of the National Coordinator

Right, you could do that or just simply avoid it. Instead of saying that changes are shown as amendments, it should say that any changes are obvious or something like that.

David McCallie – Cerner Corp.

This is David. How about something like “capture the correction while preserving access to the original”—just a functional statement?

Judy Sparrow – Office of the National Coordinator

Yeah, any of those. I just want to stay away from something that implies a certain way to do it.

Paul Egerman – Software Entrepreneur

OK. So we won't hold everyone while we try to wordsmith it. The basic concept—if I hear you right, Judy, you gave it correctly—is that concept that you could capture a correction and preserve access to the original.

Judy Sparrow – Office of the National Coordinator

Correct. That's the right way to do it.

Paul Egerman – Software Entrepreneur

OK.

Neil Calman – Institute for Family Health

This is Neil; I have a question. Does this mean that anything that the patient wants to put in the record as a correction has to be accepted? Is that what the [indiscernible] is?

Deven McGraw – Center for Democracy & Technology

No.

Neil Calman – Institute for Family Health

How does it work?

Deven McGraw – Center for Democracy & Technology

So the way that it works is that what we're trying to achieve here, Neil, is to have the technical capability to support a provider's obligations under HIPAA, and the provider is not obligated to accept every correction. The provider makes a judgment call about whether or not to accept a patient's request. And if they deny it, I mean, that's why, in the appendix, there's that summary of the HIPAA rules so people are clear. And we made it clear here that we're talking about having certified EHRs supporting a provider's compliance with their HIPAA obligations, so no, not expanding the patient's right to amendment to be something that the patient gets all the time or restricting it in any way but saying, "The technical capability to support compliance with HIPAA ought to be there." And in some cases, that will mean that the provider makes the amendment based on his or her judgment call; and in some cases, that might mean that appended information, because there's a dispute about the data, has to be able to be, again, appended to the data so that, when it's subsequently disclosed, all that information can be viewed.

Neil Calman – Institute for Family Health

Thanks.

Dan Rode – American Health Information Management Association

Neil, this is Dan Rode. I just want to concur that I think the explanation is correct, and I think that change that was suggested is certainly workable.

Deven McGraw – Center for Democracy & Technology

Oh, good. [Laugh]

David McCallie – Cerner Corp.

This is David, and I want to backtrack on my suggested change that we've all agreed was acceptable.

Deven McGraw – Center for Democracy & Technology

[Laugh] You're not allowed to do that, David.

David McCallie – Cerner Corp.

Well, only to the degree that what you've just said, Deven, made me wonder: When I used the word "correction," that might not be the right word; in other words, instead of "capture the correction," "capture the changes." You know what I'm saying?

Deven McGraw – Center for Democracy & Technology

OK.

David McCallie – Cerner Corp.

Because you pointed out that it might just be a dispute, and it's not a correction.

Wes Rishel – Gartner, Inc.

It also might be an omission that the patient wants to add into the record.

Paul Egerman – Software Entrepreneur

There's a lot of things it could be.

David McCallie – Cerner Corp.

But "capture the new information and preserve access to the original version"—something like that.

Deven McGraw – Center for Democracy & Technology

Right. Well, and we've tripped over what makes something a correction, what makes something an amendment, what makes something an update. We maybe can rely on the way that HIPAA characterizes it, which is the right to request an amendment.

Dan Rode – American Health Information Management Association

This is Dan, and I think you almost have to, because we're going to get down the road into a question of how to handle a patient's additions to records, and if we were to use the other language, I think it would just complicate things. So I'd keep it attached to the HIPAA.

Deven McGraw – Center for Democracy & Technology

OK, right, although the example of the finalization of progress notes is, in fact, not actually tied to the HIPAA obligations—I mean, I guess, unless a patient calls the doctor and says, "Please finalize my progress notes" [laugh], but I don't really see that happening.

Paul Egerman – Software Entrepreneur

The reason that was there (this is Paul) was twofold. One was that progress notes is in meaningful use stage 2, so it seems like it was a good example. But the second was in the discussion of corrections. I forget what was the source of the comment, but somebody made a comment that some EHR systems aren't handling this correctly, that they just let changes occur without doing it right. And so, I thought it might be helpful to shine a little bit of a spotlight on the area of progress notes as a result of both those two things together. [Indiscernible] to do it, but that's why it's there.

Dan Rode – American Health Information Management Association

This is Dan Rode, and the issue is that the capacity to finalize a progress note—I think what you're trying to recognize is post-discharge or post-release. The finalization of progress notes could occur during the admission, so it's probably not the best example [indiscernible].

Paul Egerman – Software Entrepreneur

Would it be simpler? I mean, the previous sentence says what we want to say?

Dan Rode – American Health Information Management Association

I think it does.

Wes Rishel – Gartner, Inc.

Well, to me (this is Wes), this almost goes back to the issue of what do we mean. I mean, I always thought that most patient-requested amendments would come post-finalization, because until they're finalized, they're probably not accessible to the patient anyway. So, is that, in fact, Dan, the definition of an amendment—is something that's added post-finalization or change that's made post-finalization?

Dan Rode – American Health Information Management Association

Yes, I think you're absolutely right, Wes. That's why it's not a good example.

Paul Egerman – Software Entrepreneur

OK, so let's respond to the question that I hear you saying, Wes. Maybe we dug in a little too deep, and we were talking about where we were worrying. What we're trying to say with section #1 is that certified EHRs (so suggesting that this is going to be part of the certification criteria) are going to have these two capabilities. The first one is to make changes to data in such a way that you preserve accessibility to the prior information. And the second thing that we're saying is that there needs to be some capability to append or enter information from the patient and possibly any rebuttal concerning some disputed information. But that also would be part of the certification process. So what I'm saying is, are we comfortable with this as a recommendation?—or asking that.

Wes Rishel – Gartner, Inc.

I think just dropping the search for examples and preserving, based on what Dan has said—but just making sure we haven't gone away from using the word "amendment"—seems to do what we need to do, right?

Deven McGraw – Center for Democracy & Technology

Right.

Paul Egerman – Software Entrepreneur

OK. Are there any other comments about #1 before we move on to #2? [Pause]

Deven McGraw – Center for Democracy & Technology

OK.

Neil Calman – Institute for Family Health

Neil again; I'm sorry. Is there an assumption that all of these entries are time and date stamped and everything? Are there any other specifications about these amended entries that need to be put in our recommendations, or is that just assumed?

Deven McGraw – Center for Democracy & Technology

I don't think it's assumed, Neil. I think we left those details to the Standards Committee to work out.

Neil Calman – Institute for Family Health

Oh, joy. [Laugh]

Wes Rishel – Gartner, Inc.

Well, my problem is, I don't know what's in the NIST certification requirements, but as a general assumption, in all medical records programs, everything is dated and attributed. I wouldn't assume it was necessary to explicitly refine them here, but—

Neil Calman – Institute for Family Health

Well, the reason I ask is, there's two things that are taking place here. There's a patient request. Actually, what's going to get time and date stamped is when the provider actually puts it in there. But my question is, do we need to say something about the request—that the provider's basically documenting something that happened? "The patient called last week to request such-and-such be changed." And when you get

to the next section about the exchange and retroactively doing things, the time and the date of this stuff might be relevant. That's all. I just didn't know whether that was important to specify and document that.

David McCallie – Cerner Corp.

That's a really good point.

Deven McGraw – Center for Democracy & Technology

Yeah, it is the case that providers have a deadline for responding to patient requests. So having some way to record when the request comes in—I don't know whether that has to be within the EHR itself, but the clock is ticking from the receipt of the request to the point that they have to decide what they're going to do with it, one way or the other.

Neil Calman – Institute for Family Health

Well, if it's not in the EHR, then it doesn't exist, because we don't have any other records. So that was my only point.

Wes Rishel – Gartner, Inc.

I think the question here is, there is no action in the medical record until someone (a physician's assistant or the physician) puts it in the medical record, except for those EHRs that might have the ability to let patients directly enter these requests online. And are we recommending that the EHR record, if you will, the putative date and time of the request—that is, whenever it came in on a fax or whenever the phone call message was taken or something like that? Or is that not important enough to raise here?

Dan Rode – American Health Information Management Association

This is Dan Rode. The date and time when it's actually corrected or when they put in the patient request because it's been denied and the patient [indiscernible] in there would need to be in there. And essentially anything now entered into an electronic medical record's going to have to be time stamped with date and time. With regard to the request, right now those are usually kept in logs in the privacy officer's filing system; it's not part of the record until such time as it's accepted. If it's denied, again, the patient rebuttal would be put in at the patient's own request and, at that time, would be dated and stamped whether it's paper or electronic, quite frankly. But I think, from an electronic standpoint, just about everything now entering the record has to be time stamped.

Wes Rishel – Gartner, Inc.

So Dan, I think that we all understand that it's a general requirement that every entry is time stamped at the time of entry. What we might want to do or not do is say that the information content in that entry includes the putative date—in other words, the date that the first request came in or something like that. From what I'm hearing you say, I think maybe we don't want to do it.

Dan Rode – American Health Information Management Association

I think you ought to do it, because you're going to add another administrative area that's going to have to have software built into the electronic record itself. And it's not a record at that point; it's an administrative request. On the other hand, one thing you may want to include would be who authorizes [inaudible].

Wes Rishel – Gartner, Inc.

I assume that everything that goes in an electronic health record is time stamped and attributed.

Deven McGraw – Center for Democracy & Technology

Yeah, I would think so, too, unless people are sharing their IDs and passwords.

Paul Egerman – Software Entrepreneur

So we have this great question. What I'm trying to understand is—

Wes Rishel – Gartner, Inc.

I'm withdrawing my question, Paul. I don't think we need to worry about it.

Paul Egerman – Software Entrepreneur

We don't need to worry about it?

Wes Rishel – Gartner, Inc.

Yeah. In other words, pretend I never asked, OK? [Laugh]

Deven McGraw – Center for Democracy & Technology

We have it on the record, Wes [laugh], and it's date and time stamped [laugh].

Paul Egerman – Software Entrepreneur

So my question is, are we ready to move on to item #2?

Deven McGraw – Center for Democracy & Technology

I think we are.

Paul Egerman – Software Entrepreneur

OK. So item #2 is interesting. There was some back-and-forth between Deven and me to make sure we understood this correctly. I think this actually came from you, David McCallie, in the last meeting. But here's what we said: We said, "With respect to existing standard exchange transactions, certified EHR systems should have the ability to transmit amendments, updates, or appended information to other providers whom the entity knows have received prior data." So this is my interpretation of a prior meeting, where I thought we said, "Well, the exchange transactions had already standardized. You need to be able to somehow formally transmit changes if you want to." So it doesn't have any requirement or statement about when you want to do it—just says there needs to be some standards and some capability to actually transmit changes. So I don't know—I'll ask you, David: I get this right, or...?

Deven McGraw – Center for Democracy & Technology

Well, before we move to David, I just want to say, again, in keeping with the goal of trying to have the certified EHR system support the physicians or other providers' obligations under HIPAA, in fact, if they do accept an amendment from a patient or there is a dispute about date and some appended information and a rebuttal, it is the requirement when subsequent disclosures of that data happen for that all to be transmitted going forward, whether it's a transaction for which we have standards or not.

Paul Egerman – Software Entrepreneur

But you're talking about subsequent transmissions.

Deven McGraw – Center for Democracy & Technology

Yes.

Paul Egerman – Software Entrepreneur

That's not quite the same as this. This is, you've already transmitted something, and now you've made a change. It's up to you, but if you've made the change, it says, "We want to make it technically possible if you want to transmit a change."

Judy Sparrow – Office of the National Coordinator

This is Judy. This is interesting, because let's say I go to the doctors, and 2 years ago, my information went over to someplace or other for my broken wrist. And then it's 2 years later, and now I have stuff in the record that maybe hasn't—don't need to go over anymore; I don't want it to go over. But I have a new allergy, so that is an amendment; it's an update: "Here's my new allergy."

Deven McGraw – Center for Democracy & Technology

Right, so I actually did not—I think that, Paul, now that you've clarified what you thought we meant by this, I actually think there's a missing recommendation, because essentially, what I thought we were trying to do was, at a minimum, to provide through the certification process for EHRs to have the capability to support a provider's compliance with HIPAA. And they are required, in subsequent disclosures of data, to be able to move a package of information forward if, in fact, they've either accepted the amendment from the patient—the amendment has to be reflected in the data that is subsequently disclosed. Similarly, if there's a dispute and there's a rebuttal or there's appended information from the patient, that requirement to, in any subsequent disclosure of any particular data that is subject to a dispute or is an amendment—ideally, there's a technical capability to move all of that forward. So it's not just in circumstances of the option where the provider chooses to move additional data forward. There actually is, in some circumstances, a legal requirement to move a package forward, and that's what I thought we were doing in #2. And I thought we were probably—

Paul Egerman – Software Entrepreneur

Well, I think that's a separate phase. What I thought we were doing in #2—and maybe we have to break this into two pieces, if you don't mind doing that. So the first piece is really not quite the same as what you're saying, Deven, or what you're saying, Judy. It's more a case of—you transmit (I don't know) a lab result or a radiology interpretation or a CCD. And then, 10 minutes later, you have some additional piece of information that you didn't have before, or you have some correction. And you transmitted it from a physician group to, say, a hospital. So what #2 says is, if you want to transmit the correction, there ought to be a way in the exchange specifications for you to do that. So 10 minutes later, if you want to, you say, "Before, I said the patient wasn't allergic to anything; now I want to say the patient's allergic to penicillin. This is an updated CCD; throw away the old one."

Judy Sparrow – Office of the National Coordinator

So you're really talking about a retransmission of a recent transmission, not a—

Paul Egerman – Software Entrepreneur

Yes, it's a retransmission, probably recent, that indicates that there was some alteration. That is correct.

Judy Sparrow – Office of the National Coordinator

And I'm assuming, because of how you positioned that when you said it, Paul, that you're saying that the two of you, you and the other health care provider that you're transmitting it to, are simultaneously caring for this patient, whereas it doesn't say that here; it just says they've received prior data. So I understand what you're saying, and that makes sense; I just don't read it in what you wrote.

Deven McGraw – Center for Democracy & Technology

Ah, OK. Well, we can [indiscernible]—all right.

Paul Egerman – Software Entrepreneur

But it's actually something that I think happens [indiscernible] not frequently, but it happens, right? I mean, the example I've seen is, a radiologist does an interpretation, signs off on it, transmits it, and then somehow thinks about it some more, and 4 or 5 minutes later says, "I want to say one more thing about this thing." And that's just something that happens, but by the time the radiologist says, "I want to say one more thing," the first one's already, believe it or not, gone its path to somebody. So you need to make sure that there's a capability to go send and receive the one more thing that the radiologist wants to say.

Neil Calman – Institute for Family Health

So, Paul, this is Neil. So we participated in exchange in New York City, and I get a notification that there's information in the exchange. But when I go to that exchange, there's reams of data in 12 different tabs: medication lists, radiology things, and whatever. I'm getting to the issue of "At what level of granularity is this going to take place?" So I may have never looked at the labs; I may have only looked at—I went in there to look at a radiology report, and that's not changed. Are we going to get down to that level where only the piece that's been looked at or transmitted is what's going to get updated? And I'm not even sure how the EHRs interact with the exchange in that regard, because my electronic health record doesn't really know what part of that data was looked at from the exchange. The exchange has that information, but my electronic health record may not.

Wes Rishel – Gartner, Inc.

This is Wes. [Indiscernible] Go ahead, David.

David McCallie – Cerner Corp.

David. Just back to the original intent here, Paul, I think the way you expressed it a few minutes ago what I was trying to get at when I raised this, which is that it's not uncommon for data to leave a system across an interface that then subsequently needs to be corrected, amended, or changed in some way. It could be as simple as a lab result that was discovered to be wrong, or it could be a preliminary microbiology culture that needs to be finalized; it could be a surgical out-note where the surgeon realizes just after he hit the send button that he got left and right mixed and he wants to send out an amendment to fix it. We need to make sure—I mean, I think, commonly, systems do this today; it's in the standards—that it's possible to do that without creating on the receiving system two copies of the note with no way to tell that they're related to each other.

Paul Egerman – Software Entrepreneur

Yes, and that's correct. That is the very narrow case that this item is intended to address. And it's a situation where—I mean, the reality is, people are very busy, and they sometimes—all of us have had this, where you send out an email, and you say, "Oops, [laugh] I forgot the attachment or forgot to send something." So then you send the email out again, right? So then that's what this is: This is—

Neil Calman – Institute for Family Health

That works in those direct model-type transactions, but what I'm asking is, if my data's been accessed through an exchange, I don't know necessarily what pieces of that record have been looked at [indiscernible] through the exchange.

Paul Egerman – Software Entrepreneur

My response is, I don't think you need to worry about that as it relates to this recommendation. This recommendation simply says, "For the places where there's existing information exchange standards, there needs to also be a standard that says how that information will be corrected or updated." That's really what we're trying to say here. [Indiscernible] How that translates to your example is, that information gets into that exchange somehow, hopefully through some of these information exchange standards; and

if there's any corrections, the corrections will get there; but it should not necessarily be visible to you that that's what's going on.

Neil Calman – Institute for Family Health

[Indiscernible] really accomplished anything from a clinical point of view. So, I mean, maybe it needs the letter of #2, but it doesn't accomplish anything from a clinical point of view, because it doesn't get the information back to the person who accessed the information through the exchange that's now being corrected. So—

David McCallie – Cerner Corp.

Neil, it does accomplish—it happens all the time. It accomplishes a lot. It keeps you from seeing out-of-date data. Now, it can't accomplish everything.

Neil Calman – Institute for Family Health

So it doesn't correct the data that somebody's already looked at. That's all [indiscernible] look at it again, you're not going to see the change.

David McCallie – Cerner Corp.

Right, that would require clairvoyance. But it does say “propagate changes to dependent systems.”

Wes Rishel – Gartner, Inc.

I think we're looking at, jointly, the requirements on two different systems here: One is the EHR, and one is the HIE. Unfortunately, we don't have much ability to regulate what HIEs do. I would certainly hope, if I was a physician using an HIE, that my HIE had a rational means for dealing with amendments. And it's certainly not a new issue to them. I mean, every standard that's been out there for transmitting lab data since we were doing it with drums has had a method for doing updates. And the CDA as conceived has a very extensive attention to updates and amendments and things like that so that, when you get a document and your computer is comparing it to another document, it's very easy to understand whether this new document is, in fact, an amended version of the prior document or not.

I would say that we have the following concerns: One is that the basic capabilities of the standards haven't been lost in the creation of specifications for certification or for the NWHIN or whatever. I doubt that they have, but it's certainly worth validating. The second is that an EHR has certain functionality that allows a correction of a document to be forwarded at the discretion of the person who's assigning the updates to the documents and that there, I think, we need to do some clarification with respect to “Are we also expecting the EHR to have recorded all previous transmissions? Or are we simply saying that if the user at the EHR wants to send this to someone, they can?”

So that's kind of a long statement for a short question.

Paul Egerman – Software Entrepreneur

Wes, you've raised a number of issues. Again, what is in item #2 is intended very narrow. It's supposed to be where there's existing exchange transactions. For example, we have an HL7 transaction related to lab results in the standards already, in the meaningful use standards. We're saying, “When that occurs, there needs to also be a standard for how you can make changes if you want to make the change,” and that that's—

Wes Rishel – Gartner, Inc.

I agree: It's worth verifying that that's there. It probably is, but it's worth verifying.

Paul Egerman – Software Entrepreneur

And the reason—this is suggested by David McCallie, but I thought it was a very good idea, because different systems handle that differently, and that causes a fair amount of at least implementation confusion in terms of [indiscernible] overwrite data or duplicate data accidentally and to have a single way of doing it is—

Wes Rishel – Gartner, Inc.

Well, I mean, I think it is the case right now that some EHRs handle amendments very badly. For example, some of them effectively retransmit entire transmissions; others just retransmit the corrected information, and there's no uniformity with respect to that. So I think it's worthy of being examined, but I read the words of #2 as implying more functionality than simply an examination of the standards. I read it that the EHR systems should have the ability—that means it has some function to do something—to transmit yadda-yadda-yadda to other provider whom the entity—and I don't even—

Paul Egerman – Software Entrepreneur

Maybe it should be put more narrowly. It should say, "The exchange transactions should include a specification for the"—

Wes Rishel – Gartner, Inc.

I don't know what the intent was, but right now, I could support either intent. I just don't even know which it is. But I'm very concerned about the term, "The entity notes have received prior data." I don't know what "entity" refers to, and is it a system or is it a person? And I don't know whether, as Judy has often pointed out, there is the potential for interpreting this to mean—so if we took your proposal, Paul, which is to just modify it to speak to the standards, then there wouldn't be any ambiguity. If we want to make a stronger statement, then I think it needs to be clarified.

Paul Egerman – Software Entrepreneur

So, that's helpful. So I hear that, and I'm also looking at the clock, and I'm wondering if probably what we need to do is stop. We also want to see if there's any public comment. So what I think we'll be doing—tell me if this works OK, Deven—is, in our next meeting, we will pick up this discussion. In the interim, what we will do is, we'll try to wordsmith item #1 and #2, and we'll try to capture some of these other comments that you said, Deven, and you said, Judy, and perhaps some additional points here and put that forward for continued discussion—pick it up at our next meeting. Does that sound right?

Deven McGraw – Center for Democracy & Technology

Yeah, I think it makes sense. It's hard to do a hard stop in the middle of a conversation, but it is now 10 of 4, and—

Paul Egerman – Software Entrepreneur

Yeah, I agree, and I don't mean to cut you off, Wes, or anybody, but I also...

Wes Rishel – Gartner, Inc.

Please, please, please, cut me off.

Paul Egerman – Software Entrepreneur

OK. [Laugh] I intended to cut you off, Wes.

Deven McGraw – Center for Democracy & Technology

So clearly, this set of issues, we're going to chew on.

Paul Egerman – Software Entrepreneur

Yes. We're not finalized here yet. This is helpful feedback. We will try to do our best to redraft something based on these comments and pick up this discussion at our next call. Is that acceptable to everybody? Does anybody have anything else they want to say before we go to public comments? [Pause]

I just wanted to say, before we do public comments, "Excellent call; interesting, spirited discussion on a number of topics." Judy, why don't you see if we have any members of the public who want to make some comments about some of these issues?

Judy Sparrow – Office of the National Coordinator

Right, thank you, Paul. Operator, can you see if anybody does wish to make a public comment?

Caitlin Collins – Altarum Institute

Yes. If you are on the phone and would like to make a public comment, please press *1 at this time. If you are listening via your computer speakers, you may dial 1-877-705-2976 and press *1 to be placed in the comment queue.

Judy Sparrow – Office of the National Coordinator

And while we're waiting, just a reminder: The next call is June 16.

Deven McGraw – Center for Democracy & Technology

My, how time flies.

Judy Sparrow – Office of the National Coordinator

I know. [Laugh]

Caitlin Collins – Altarum Institute

We do not have any comments at this time.

Paul Egerman – Software Entrepreneur

So the next call's June 16 at 2 o'clock Eastern time.

Judy Sparrow – Office of the National Coordinator

That's correct.

Paul Egerman – Software Entrepreneur

OK. So we do not have any calls. Let me first say "Thank you" to the ONC people: Judy Sparrow—I don't know if Deborah Lafky and Arien are still on the call, but thank you very much. I really appreciate your participation. And thanks also to all the Tiger Team members and any members of the public who may be listening. See you on June 16. Have a good weekend.

Judy Sparrow – Office of the National Coordinator

Thank you. Bye-bye.

Deven McGraw – Center for Democracy & Technology

Bye-bye.