

# Privacy & Security Tiger Team Transcript May 18, 2012

## Roll Call

### MacKenzie Robertson – Office of the National Coordinator

Good afternoon everyone, this is MacKenzie Robertson in the Office of the National Coordinator. This is a meeting of the HIT Policy Committee's Privacy and Security Tiger Team. This is a public call and there will be time for public comment at the end. The call is also being transcribed so please make sure you identify yourself before speaking. I'll go through roll call and then at the end also ask any staff members on the line to identify themselves. Deven McGraw?

### Deven McGraw – Center for Democracy & Technology – Director

Here.

### MacKenzie Robertson – Office of the National Coordinator

Thanks, Deven. Paul Egerman?

### Deven McGraw – Center for Democracy & Technology – Director

Yeah, he's out today.

### MacKenzie Robertson – Office of the National Coordinator

Okay. Dixie Baker?

### Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I'm here.

### MacKenzie Robertson – Office of the National Coordinator

Thanks, Dixie. Dan Callahan? Neil Calman? Carol Diamond?

### Rebekah Rockwood – Markle Foundation

This is Rebekah Rockwood for Carol.

### MacKenzie Robertson – Office of the National Coordinator

Thanks, Rebekah. Judy Faulkner?

### Judy Faulkner – EPIC Systems Corporation

Here.

### MacKenzie Robertson – Office of the National Coordinator

Thanks, Judy. Leslie Francis? Gayle Harrell? Can someone just be sure to mute their computer speakers so we don't have the echo, thanks? John Houston?

### John Houston – University of Pittsburgh Medical Center – NCVHS

I'm here.

### MacKenzie Robertson – Office of the National Coordinator

Thanks, John. Alice Leiter? David McCallie?

### David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, David. Wes Rishel? Micky Tripathi? Latanya Sweeney? And are there any staff members on the line?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Joy Pritts.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Joy.

**Kathryn Marchesini – Office of the National Coordinator**

Kathryn Marchesini.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Steve Posnack.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Steve and Kathryn?

**Kathryn Marchesini – Office of the National Coordinator**

Yes.

**MacKenzie Robertson – Office of the National Coordinator**

Okay. Thanks, Deven, I'll turn it over to you.

**Deven McGraw – Center for Democracy & Technology – Director**

All right, great, thanks MacKenzie, much appreciated. Paul is not able to join us today but he will be with us for our really first discussion call that we're going to have on these request for information questions which is next Tuesday. What we have before us today is an introduction and a summary of what is in the request for information that the Office of the National Coordinator for Health IT released just about a week ago, maybe a little longer than that on potential governance conditions for the Nationwide Health Information Network and we are fortunate to have Steve Posnack from ONC with us to sort of lead us through a summary of what is in the rule.

So, since we only have an hour for this call really most of what we will be doing on the call today is to have Steve explain the rule for those of you who haven't had a chance to have it explained to you yet, even if you've read it I think it's always helpful to hear from Steve about what kind of feedback the Office of the National Coordinator is looking for and then you also received, in advance of this meeting, a list of the questions that are in the RFI that we have been asked as a Tiger Team to prioritize in terms of giving feedback to ONC. They have done the work to kind of divvy up in terms of priority the questions among the Workgroups of both the Policy and the Standards Committee which is helpful, because there are a number of questions that are asked in this RFI, having said that we have a really pretty healthy stack of questions that we are priority on and it will be a bit of a challenge for us to take them on in a comprehensive way in the short amount of time that we have and so what we'll aim to do on this call again is to make sure everybody has a solid grounding on what's in the RFI and a chance to ask Steve some questions if you have them.

If we have any time left on the call, we'd love to get your feedback on some of the questions that you, as a Tiger Team member, would like to make sure that we address and then on Tuesday we'll just start tackling through some of the issues, probably initially prioritizing unless you all tell me otherwise those issues upon which we've actually given ONC some advise previously and so it's a matter of doing something similar to what we did with the Meaningful Use in certification rules where we're sort of looking at the way that ONC may have taken our advice and potentially incorporated into governance of the Nationwide Health Information Network and it gives us the chance to provide some additional feedback,

but there also are, you know, some issues that we haven't necessarily discussed in detail that they've asked us to prioritize and again, we'll do our best to try to find a way to address ideally all of them, but we may have to do some prioritization given the timing and specifically we have to be done with whatever advice we're going to give before the June Health IT Policy Committee meeting because this request for information has only a 30 day comment period on it.

So, we essentially just have a couple of meetings to take some of this stuff on. So, does anybody have any questions about the process or what we're doing here before I turn it over to Steve to walk us through what's in the RFI? All right, terrific. Steve, are you still on the line?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

I am, take it away? Do we have the slides loaded?

**Deven McGraw – Center for Democracy & Technology – Director**

Hang on; it looks like they're loading right now.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Okay. So, why don't I do a little bit of introductory stuff in general?

**Deven McGraw – Center for Democracy & Technology – Director**

Yes.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

And then as the slides load someone just needs to let me know and then I can do the next slide.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Kind of take it from here. So, thanks everyone for joining late on a Friday, I know it's hard, especially with the weather as Deven was mentioning earlier, as Deven eluded to and just in case I find myself doing this as well, we are at the request for information phase so this is not a rule yet, but I'll get to how all this work will help inform the regulatory processes that we'd like to engage in going forward. So, the RFI, Request For Information, is titled the Nationwide Health Information Network Conditions for Trusted Exchange and it is jammed pack with lots of information as I think Deven also eluded to and so there are a few overarching points that I'd like to ground folks in over the course of my kind of summarization of the presentation here and I hope those of you or some of you who have caught some of the other presentations that I've given to either the other Workgroups or to the...So, jumping right in.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

This is really a unique opportunity for those of you that have been engaged in this dialogue for quite a long time I'm sure about the Nationwide Health Information Network, about various aspects of governance to provide us some feedback at this point before we come up with proposals that we would include in the Notice of Proposed Rulemaking. So, we're really coming to you with a little dose of humility saying, you know, that we need your help to get these things right or as right as possible for a proposal to take shape and also recognizing that governance, the concept, is a lot bigger than just ONC and we need as much feedback as possible to help us shape the proposal that we have in mind.

So, again, that's why I'm here today. The RFI is our chance to say it's now your turn to take a swing at what we've been working on and pardon me for a second, just changing locations, I was getting dropped off.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

...as before, were you saying something Deven?

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah, your title slide is up.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Good, okay great. So, I'm still talking off the title slide. So, process-wise we are at a point where we are very much interested in everyone's feedback, they are obviously a lot of questions in there. I wouldn't be too dismayed about the number of questions or scared off by the number of questions that are involved, instead of doing, you know, fewer multipart questions we just broke them up into simpler concepts, but I envision that folks will be able to answer them in batches with respect to, you know, kind of longer response.

So, now that my title slide is up here, after we get the input from the RFI we'll take that, go through everything that we possibly can, use it to inform a proposal that we would shape into a Notice of Proposed Rulemaking and that would again be available for public comment at some time later in the future. So, moving to the next slide please, should say take it from the top.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, you've got it.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

All right, good. Then I'll try to stay in sync with the slides here. We do have authority in the HITECH Act to establish a governance mechanism for the Nationwide Health Information Network and this is the statutory authority that I referenced here. We also have indicated additional statutory authority that we'd be leveraging through the proposed rule that we would subsequently develop. I note here that the statute didn't say the National Coordinator shall govern the Nationwide Health Information Network, rather it charges us to establish a mechanism for governance and as the RFI explains in greater detail we've approached implementing this statutory language by asking where can ONC uniquely add value and in answering this question we framed a multifaceted approach in terms of what we think an effective governance mechanism should include.

So, as I do my fly by here of everything that's in the RFI I'll be addressing some of those points about where ONC thinks we have a unique role in providing governance and establishing this mechanism that the statute calls for. So, what we're looking to do and what was laid out in the RFI is we're looking to create the foundational structures and processes that would be necessary to support Nationwide Electronic Health Information Exchange over the long-term. So, at its core the governance mechanism is not necessarily about one particular form or method of electronic exchange rather it's about putting in place the policy and technical building blocks that the nation would need to have in place an alert to support all forms of electronic health information exchange and enable them to take place. Next, slide please.

So, I'm just going to assume after like 3 seconds that the slides are taken away. So, for those of you who are familiar with ONCs efforts over the past few years, we have described the Nationwide Health Information Network as a set of standards, services and policies that enable secure health information

exchange over the Internet, for those of you, that again have been involved over probably close to a decade now at this point, the Nationwide Health Information Network is not a single national database, it's no longer in the conceptual phase referred to as what it previously was considered more so a network of networks, it's not that, and it's not a single body or specific group of entities.

So, like the Internet where and when there's a right set of standards, services and policies and they're put in place great things can happen and that's really our vision for the governance mechanism and focusing on standards, services and policies so that we can create really a big bang moment for electronic health information exchange. Next slide, please.

So, I'm not going to cover these bullets in great detail with respect to why we feel it's necessary to act now to establish a governance mechanism, we include a lot of discussion in the RFI, but just touching on the fact that, you know, we believe and I think everyone shares this belief, that electronic health information exchange addresses a critical need in our healthcare system to improve care coordination and quality of care, that trust and I'm speaking to the choir here with respect to this Workgroup, and I think you've probably heard Farzad mention this as well, do we think and expect that the speed of trust is really going to be the rate at which electronic health information will be exchanged and again, another preaching to the choir aspect here, how long has it been discussed that we need a common and consistent kind of base to align for electronic health information exchange, some rules of the road and that's really what we're trying to help people wrap their heads around with respect to this RFI and where we think we can go in establishing a governance mechanism. Next slide please.

So, overall objectives for the governance mechanism would be to establish a more competitive and open market for electronic health information exchange. The last bullet on the prior slide identified that in cases and we've watched and monitored the industry and the maturity of electronic health information exchange that there could be unmet needs from stakeholders with respect to privacy and security policies, other exchange, electronically exchange policies in general and technical standards, and if those needs go unmet that those stakeholders would be in a position that they'll need to fill the void and we see ONC, again from a unique role in which we can play, is to use our coordination, to use our national viewpoint to help facilitate the discussion nation-wide on what those baseline consistent common rules of the road should be for electronic health information exchange upon which different stakeholders could build, but really to jump start where people can begin. So, trying to take things off the table that we can get everyone to agree to where there are particular instances that different stakeholders would need based on the level of assurance that they would seek for a particular form of electronic health information exchange though governance in its early stages may not get to those, but would hopefully create a baseline upon which a more efficient dialogue could take place in order to make electronic health information exchange possible. Next slide, please.

So, I'm going to dwell on this one for a little bit, this should be the bird's eye view slide. So, the first thing I'd call to your attention is that the RFI focuses on entities to facilitate electronic health information exchange and that's really a good bit of the body of the RFI and so the next one I guess I'd emphasize is that what we discussed is a voluntary framework. So, we're not considering proposing some type of mandatory governance paradigm that would require people to follow these conditions for trusted exchange, rather we would like to construct the governance mechanism in such a way that its value to all stakeholders in the market is what drives compliance with the conditions for trusted exchange that we'd establish. So, really enforcing the value proposition and really making being part of the governance mechanism, following the conditions for trusted exchange, a value added component to the marketplace at large. So, the RFI comments...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Steve, could I...

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Sure, go ahead.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

If I could add something. This RFI is about establishing what the conditions would be in becoming a nationally validated entity. Somewhat different from that is the issue of whether and to what extent policy leaders could be brought to bear to make that designation desirable, you know, incentivize, even in some context required. So, I just want to say, you know, how it's used and what it means is something that could be, in a sense, leveraged separate from this.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Right, yeah, that's a great point that Farzad folded in here and we do mention that at the onset of the RFI that the governance mechanism that we would establish, the structures and processes that we would establish, the ultimate identification and designation of these Nationwide Health Information Network Validated Entities could then subsequently be leveraged through other policy informatics approaches and so that's where another aspect of the value of this approach that we're discussing could fit in.

So, as I mentioned with respect to the areas of the RFI and what you all will probably be focusing on most directly, I'll get to you in a second, there is a large portion of the RFI focuses on the conditions for trusted exchange, the rules of the road. Then subsequently, a discussion about how entities that facilitate electronic health information exchange would be validated to those conditions for trusted exchange and those entities that would become validated you would call, so this is you're keeping in mind acronyms, an NVE, which again stands for Nationwide Health Information Network Validated Entity. There's also a process for updating, retiring, including new conditions for trusted exchange and how we would go about doing that in an open and transparent process as well as, for those of you that have been engaged in the standards community, a process to classify the readiness and maturity, and adoptability of technical standards, interoperability standards, implementation specifications and then finally we discussed potential approaches to monitoring and transparent oversight. I think I will continue on here. Next slide, please.

So, we have three categories of conditions for trusted exchange, the first being the safeguards, CTEs and I'm not going to read the language associated with them, those for this group will be probably right in your wheelhouse and the ones that you will focus on the most and I think the questions that you have divvied up are most appropriately assigned to them. We also have interoperability conditions of trusted exchange that some of your other compadres in the other Workgroups are going to be focusing on and then business practice conditions for trusted exchange as well.

All together we have included in the RFI 16 conditions for trusted exchange, 10 out of those 16 happen to be safeguards, CTEs, but again this list of CTEs isn't meant to be exhaustive, it represents really our best first effort at giving folks a glimpse, a first look at what conditions for trusted exchange would look like, understand the concepts, ground folks in the areas in which we think that some consistent rules of the road could be established and then make it a little bit easier for folks to give us some better informed comments. So, I think I will move on.

Conditions for trusted exchange, so, the next few slides list in a tabular format the conditions for trusted exchange. I'm not going to dwell on these two in too much detail, but where we try to leverage, and you'll notice in some of these and I'll do one programming announcement here, because I know folks have gotten caught up in prior presentations that I've given, in front of each of the conditions for trusted exchange we include a little bit of an abbreviation and a numbering system for us to keep track of them to make it easier for you to keep track of them and so you'll see either the first letter or two letters followed by a number that's assigned to each condition for trusted exchange. So, at the top you'll see S-1 that stands for Safeguard-1.

So, getting back to the paid program here, we do everything we can to leverage and acknowledge existing regulatory framework. So, you'll see a lot of interplay, especially for your Workgroup relative to the HIPAA Privacy and Security rules. The first safeguard is an example where we've looked at this environment and what we think from a policy perspective would be advantageous again from a rules of the road consistent requirements considering that where the scope of the conditions for trusted exchange

would be applicable to entities that facilitate electronic health information exchange which we believe in most cases, if not all, would be business associates or covered entities, or covered entities themselves that we think that it would be appropriate to apply the...that they would need to follow the HIPAA security rule and from a consistency perspective, given that they're going to be performing similar responsibilities and services, that all of those implementation specifications that are currently designated as addressable would be required and so there is a much more eloquent discussion in the request for information about our thinking behind this, but that's just to kind of play things out for you in a little bit more detail. I would also encourage folks not to take these out of context, again, they're just listed here as the actual conditions for trusted exchange language, there are a lot more discussion under each one of these in the RFI that gets to different facets.

Another that I would just call out to give you an example of how we've tried to leverage different regulatory paradigms would be the S-5 Safeguard CTE at the bottom. This has an interplay with the notice of privacy practices or kind of a contrast to the notice of privacy practices that you may be familiar with in the HIPAA Privacy Rule, with this we took a look and said, you know, this environment is a little bit different here, there are deltas, there are gaps and we thought that it would be, from a policy perspective, and especially keeping in mind the scope of the RFI, entities again that it would be helpful for them to make publically available a notice of the data practices describing what they do, the notice of privacy practices paradigm and on the HIPAA Privacy Rule side it discusses how a covered entity is permitted to use and disclose protected health information, this is a little bit...turns it on its head a little bit and requires the Nationwide Health Information Network Validated Entity to describe what it does with the data. Next slide, please.

So, there are other rounding out the ten, these are the other five conditions for trusted exchange, on the safeguard side, I'm not going to touch on any of these directly right now, many of them I think encompass a lot of the work that you all have done as a Workgroup and recommendations that you've provided to the Policy Committee that they've transmitted to us. So, I hope you'll find a lot of your work referenced in here and hopefully we've done it some justice in applying it to the different policy objectives that we hope to achieve. I'm going to fly through the interoperability conditions for trusted exchange and the business practice ones. So, hopefully we're on...if you haven't gone to the next slide that says interoperability at the top, please do that and then continue on to the business practice one.

Stopping here at the business practice one, these are really about the Nationwide Health Information Network Validated Entities being trusted not only by the healthcare providers for whom they would facilitate electronic health information exchange, but also the other NVEs that they would engage with and so essentially being a stand-up health information exchange...Next slide please.

So, we have discussed in the RFI some eligibility criteria which would essentially would be preconditioned that an entity would need to meet in order to continue down the pathway towards becoming a Nationwide Health Information Network Validated Entity some of which I think are probably on your list of questions to take a look at and if the entity meets those preconditions they continue down their pathway they would be able to become an entity. The list that we include in the RFI is out there for feedback. I don't think that we've made any determination whether we would keep all of those preconditions, that's why we're seeking your feedback at the present time. Just a short list here, including, but not limited to, these are all of the types of the entities that we think could be eligible that would potentially be in a position to facilitate electronic health information exchange and may also see some value in becoming a Nationwide Health Information Network Validated Entity. Next slide, please.

Validation is the title of the slide here that I'm on. I won't go into this in too much detail. You'll notice, if you've read through the RFI or have read through some of the conditions for trusted exchange they focus on a number of different aspects kind of going across the spectrum from being kind of people process organizationally driven to more technically specific and so we think picking up on a construct that the Governance Workgroup had used when it initially issued its recommendations, more of right now an umbrella term to describe what it would mean to demonstrate compliance with the conditions for trusted exchange and so we called that being validated or demonstrating that you may be validated to the CTEs and so we think underneath this validation construct there could be different approaches for demonstrating or validating compliance whether it be through technical testing and certification or whether

it be through accreditation of services and looking at the people and processes involved at the potential Nationwide Health Information Network Validated Entity and so that's an area where we are seeking comment.

From a process and structure stand-point we envision and discussed in the RFI that we would follow the kind of processes and structures that we've instituted in the permanent certification program where ONC would approve an accreditor that would then be able to assess the competency of multiple validation bodies who would be the one that would be out there in the field actually validating potential NVEs or eligible entities to their conformance to the conditions for trusted exchange and indicating when some organization has met those conditions for trusted exchange. Next slide, please.

So, I'm going to go through these processes pretty quickly the first being a process to update and kind of mature conditions for trusted exchange over time, the second being the process to classify technical standards and implementation specifications and so both really focus on having an inclusive and transparent process for the industry to be involved in tracking these, really road mapping them out into the future and making a path forward that everyone can keep track of and so we have three classifications that we use in both of these processes, emerging, pilot, and national and once either a CTE or the technical standards and implementation specifications have reached that national classification that would be where we would consider including them in rulemaking, where we would encourage their use nationwide among a variety of other factors. Next slide, please.

So we have the technical standard classification process, this would be something that we heard and we thought would be useful from a standards development perspective, from an industry maturity perspective, establishing a pathway for standards to get classified along this emerging pilot and national steps and we think that this will provide, as part of the governance mechanism at large, another vehicle in which stakeholders can have a role to play in governance. Next slide, please. I think this might be my last one. All right.

The monitoring transparent oversight. We've laid out a discussion as well here about what we really think is a shared responsibility among all the stakeholders that could be part of the governance mechanism. There would be, we expect, some type of process for either ONC and others to receive complaints and other types of concerns related to a Nationwide Health Information Network Validated Entities as well as, you know, keeping in mind what happens if something really untoward happens, what would we do and, you know, relationships or revoking the status, or suspending the status of a Nationwide Health Information Network Validated Entity until certain corrective actions had taken place, etcetera.

So, those are some of the things that we're thinking about as being part of our monitoring and oversight as well as the other actors that could be involved whether it be ONC, a potential accreditation or validation bodies that we would authorize in addition, keeping in mind that we're talking about health information, multiple organizations have regulatory Venn Diagrams that overlap with this regulatory paradigm and that there could be other involvement through different channels with the Office of Civil Rights for example or the FDC depending on what the type of monitoring and the oversight would be involved. And, I think I'm going to stop doing the talking head here and open it up for any questions that folks may have. I hope that the quick and dirty presentation here was of some help to you and guide your way through the questions.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, thank you very much, Steve. I'm going to throw it open to Tiger Team Members for questions.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I have a question and I'm hopping in because it has to do with this last slide.

**Deven McGraw – Center for Democracy & Technology – Director**

Oh, okay, go ahead, Dixie.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

This is Dixie, Steve you get better and better every time I hear this. A question was brought up actually in one of the...I think in the NwHIN Power Team meeting, about the oversight...we read about the oversight of the NVEs, but is there intended to be an oversight of the validation authority?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Yes.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

About the body, the validation body?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Yeah, yeah, correct. So, like today, given kind of our structure with the certification program I can give you an example, so in the permanent certification program ONC would authorize an accreditation body, the accreditation body then has a subsequent responsibility delegated to it to assess the competency of the different certification bodies. Those certification bodies come to ONC to get authorized and so we would...

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Oops are you there?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Sorry a motorcycle, I'm not riding on a motorcycle there was a motorcycle passing by. So, the ONC would have an oversight and responsibility for both of those actors and if a validation body was, you know, not performing its duties or was not, you know, assessing according to whatever rules we come up with in the future ONC could take some corrective action with respect to the validation bodies themselves. Does that help?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

So, ONC would oversee the accreditation body which would oversee the validation body is that the way it would work?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

We would also have oversight over the validation bodies as well.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Okay, okay, that helps immensely, thank you.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Yes.

**Deven McGraw – Center for Democracy & Technology – Director**

Other questions?

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

This is David, I've got a question.

**Deven McGraw – Center for Democracy & Technology – Director**

Go ahead, David.

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

Steve, I like the fact that the CTEs are broken into those three categories, safeguards, business practice and interoperability. One of the things that's come up in a couple of the discussions that have already gotten underway in various other Workgroups is whether or not the interoperability CTEs could be in a sense decoupled from the overall certification or approval of an NVE with the thought towards the notion that the standards that we use for interoperability will probably continue to evolve.

The questions that are in the current RFI are written in the context of today's standards, in particular the ones that in the NPRM Stage 2 Proposal, but, you know, clearly that is going to change over the course of the next, you know, 5-10 years and is it feasible to think of those as being sort of decoupled, that you could certify against sort of being a trusted entity meeting the safeguard and business practice CTEs, but that the interoperability things could vary over time and be maybe recertified or have additional testing to validate that you adhere to the standard even though you're already an NVE?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Sure, yeah, I mean so I think you guys are having the right level and depth of discussion about the same things that we have struggled with and coming and putting together all of the contents for folks to react to in the request for information and so that would be a valuable, you know, response to the questions suggesting about how we could decouple them in a way. I think from the NEV perspective, as we were drafting and putting together the RFI we were considering that not only would they need to provide some assurances that they could be trusted, for lack of a better word, to be good stewards of patient data and protect it and secure it accordingly, but that they could also...they were fluent in particular, you know, interoperability requirements and if there is a way I think the kind of...my question back to you all or to you David to bring back to the others, would be if there is a way to...in envisioning that decoupling still get at some of that organizations competency and ability to exchange electronic health information, recognizing that there may be a desire to try not to lock down the actual standards that they would need to show their fluency in. Does that make sense?

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

Yeah, it does, absolutely and that is kind of what we hit on as being an ideal, I think we owe you some thoughts about how to do that.

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

If I may jump in, this is Farzad, I think we would expect and be asked about maybe both evolving over time. So, the standards clearly we would expect there to be maturation and broadening of the kinds of standards and the kinds of exchange that could be supported and could be tested and validated for, but too depending on the architecture of the exchange there may be a need to have a couple set of safeguards that are then matured alongside that exchange architecture and standards. Does that make sense?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Yes.

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

Yes, it does, it does.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I would say that they are coupled but that they may both evolve over time and we need to have mechanisms for layering on additional both interoperability and exchange architecture as well as safeguards in a couple of ways.

**Deven McGraw – Center for Democracy & Technology – Director**

Right, but they might, this is Deven, so it sounds like you're saying, they might evolve on a different pace?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Well, I don't know, I just want to...but to have trusted exchange it strikes as unique, you always need to have, you know, policy and technology co-evolve.

**Deven McGraw – Center for Democracy & Technology – Director**

Right.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

And this is Steve, I mean to pick up on a point that Farzad made and this is an area that we solicit comment as well, right now, you know, we have this list of 16 conditions for trusted exchange and we ask because they focus on a variety of different methods, different aspects of trust, interoperability business practices, if there would be more logical packaging of or bundling of certain conditions for trusted exchange that would be representative of a particular method or approach and whether the Nationwide Health Information Network Validated Entities could be validated to that particular bundle. Some of the CTEs discussed or the safeguards related to more comprehensive forms of exchange like query and response, others more focused on kind of planned directed exchange. And so, as we think through the governance mechanism being able to accommodate multiple forms of electronic exchange how we could best pair the right conditions for trusted exchange together to help accelerate things.

**Deven McGraw – Center for Democracy & Technology – Director**

Other questions? Wow.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

...Friday.

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah, no kidding. I'll ask you one question Steve and then I think we'll use what time we have remaining to get some early feedback from the group on some of the conditions. Can you just clarify for us the types of entities that we would seek to have come in as NVEs? You mentioned MTs that facilitate exchange, but what would be some common examples? I see people getting maybe easily confused about who would be asked to sort of voluntarily sign up for this versus, you know, things globally.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Sure, so...someone speaking?

**Deven McGraw – Center for Democracy & Technology – Director**

Steve?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Yeah.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, go ahead.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

All right, I thought I had some feedback from someone else jumping in, I mean in essence we're looking at instances where there would be a trusted third party that...you know, two providers or two hospitals or whomever would use to facilitate...that would provide services to them to facilitate electronic health information exchange. So, there would be some entity in the middle that would be providing services, it could be the health information exchanges that exist today, innovative delivery network, it could be an EHR technology developer that provides services for all of its customers and allows them to exchange electronic health information. So, really ranging across the board, but it would be in a situation where there would be a trusted third-party. I don't know, Joy or others? Any other? Does that help, Deven?

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah, no it does, it very much does, it certainly is consistent with the way I read it and I just wanted to make sure I was reading it correctly.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

And of course it might evolve over time, this is Joy.

**Deven McGraw – Center for Democracy & Technology – Director**

Right, right, as the marketplace evolves, yeah.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Well, I think it's not only just as the marketplace evolves but also as the technology evolves.

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

This is David; I have another question if nobody else wants to jump in?

**Deven McGraw – Center for Democracy & Technology – Director**

Go ahead, David.

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

And this may be getting too detailed, but we have such an incredible cast of characters from ONC on this call I can't resist.

**Deven McGraw – Center for Democracy & Technology – Director**

Go ahead.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

I'm not sure if we should be complimented by that comment or not?

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

No, you absolutely should be, but I'm curious as to what the thinking is in a little more depth behind safeguard number six an NVE must not use or disclose de-identified health information to which it has access for any commercial purpose? You know, my question I guess is, you know, what is a commercial purpose, obviously is, you know, supporting a research enterprise a commercial purpose, but maybe more importantly, whatever is legal under HIPAA today with respect to properly de-identified data meeting the HIPAA definitions, are you trying to put a higher barrier to that data and if so, you know, that could have profound impact on who could become an NVE.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

So, David, this is Joy, I'd almost like throw one back right in the Tiger Team's lap because this recommendation really kind of came from the work you guys did.

**Deven McGraw – Center for Democracy & Technology – Director**

Well, although we never recommended this particular action specifically, but we did and I remember this, in that long August or actually it was September recommendation letter that dealt with fair information practices and intermediaries, and consent, we did say that we thought that intermediaries must disclose to their participants or their customers what they do with de-identified data and we may have even included patients in there, that I can't remember, I'd have to go back and look.

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

Yeah, there is obviously a big difference between disclose what you do and be prohibited from doing it, so I mean, I agree we need to discuss that. I just want to make sure I wasn't missing an angle as to, you know, how that got in there.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay. We'll put that one on the list, David.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

This is Steve, I mean there is a...if you haven't gotten a chance to read it David; we do have a pretty substantive discussion, you know, about our thinking behind that safeguard, CTE.

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

Yeah, it's good. I just wanted to see if anything else came out.

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah, you know, for folks who haven't read the RFI in full yet, I agree there is explanatory material that you should definitely read in advance of any discussions we would have on that topic, as well as any others.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

So, Deven, would it be useful to maybe work with our support for you to try to pull some of that language out and send it to people?

**Deven McGraw – Center for Democracy & Technology – Director**

It would, thank you, Joy.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Okay.

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah, you know, given the timing sensitivities and that a number of people are involved in a number of these working groups and, you know, other people just would appreciate being directed to the right place to go.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Okay. So, do you think having the question and then with preamble language right underneath it would help?

**Deven McGraw – Center for Democracy & Technology – Director**

Oh, yeah.

**David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics**

Yeah, that would be useful; it's really hard to read that federal register print.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Especially when you're my age.

**Deven McGraw – Center for Democracy & Technology – Director**

That's why I always do the prepublication version.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Yeah, that's way easier.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Okay.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Deven, I have a question related to that but really it's to you.

**Deven McGraw – Center for Democracy & Technology – Director**

Oh, okay.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

This is Dixie. I recognize that a lot of what is in there came right out of the Tiger Team recommendations; in fact in most cases it does say this came out of the Tiger Team recommendations. We have something like...I don't even know how many, but this Tiger Team has a lot of questions on our plate to address.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I think it might be useful for us to somehow tag those that came directly out of our previous recommendations, is there any intent to do that?

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, Dixie, absolutely we will do that and in fact that maybe one of the thoughts that I have about how to schedule the...how to proceed with the call that we have on Tuesday is to maybe be able to knock off several of the questions, you know, to prioritize first the questions that are related to recommendations that we made and see if we, you know, have additional things to say or to reinforce based on the questions that are asked. Is that what you're talking about?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Exactly. I can see that, great.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I mean, I could see us getting sucked up into a whole new discussion of something we've been previously been sucked up in discussing.

**John Houston – University of Pittsburgh Medical Center – NCVHS**

This is John Houston, can I suggest to add to what Dixie said that where that has occurred that maybe that we put together a strong end recommendation or a response that the Tiger Team can then, hopefully very quickly, agree to so that we can then have some type of response that is already, you know, drafted, we can then concentrate on the ones that we don't have consensus on.

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah, that is a really great idea, John and it's actually one that the folks from MITRE, who help us out in preparing for these meetings, have already started to do for us.

**John Houston – University of Pittsburgh Medical Center – NCVHS**

Good.

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah.

**Judy Faulkner – EPIC Systems Corporation**

This is Judy; could I ask a different question?

**Deven McGraw – Center for Democracy & Technology – Director**

Of course.

**Judy Faulkner – EPIC Systems Corporation**

Okay, thanks. Asking about the electronic health record vendors part in this, if the vendor has software that can allow the healthcare organization to send and receive data, but they don't touch the information at all, are they an NVE or not?

**Deven McGraw – Center for Democracy & Technology – Director**

Steve or Farzad, or Joy want to answer that?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Well, so it would be voluntary. So, they wouldn't need to seek the NVE status if they didn't think that this would be appropriate or applicable to what they would do, but I think it would also be an analysis of the role in which they are providing in terms of the information that's being exchanged and how it's being done. I think...I don't know if I can pass judgment on a particular scenario right now yet.

**Judy Faulkner – EPIC Systems Corporation**

If you could help with that a little bit, I think there are a couple of things, voluntary, what are the plus's and minus's of being in it or not being in it.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Yes.

**Deven McGraw – Center for Democracy & Technology – Director**

Right.

**Judy Faulkner – EPIC Systems Corporation**

And, then what about the role that they're providing? Because, I think all the vendors are going to be very interested in an answer to that.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Sure and I mean that is an area for maybe not this group, but for others as well, as to how that plays out and what clarity we can provide and how we can shape, you know, more formal proposals that would keep in mind the different dynamics that you brought up.

**Judy Faulkner – EPIC Systems Corporation**

Okay, do you have any idea when that will happen or how that will happen?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Well, I think we're hoping that we get input from the people who may be interested in this as to what they would find attractive versus unattractive.

**Deven McGraw – Center for Democracy & Technology – Director**

Right, so like here's an RFI this is the opportunity to shape the conversation, right?

**Judy Faulkner – EPIC Systems Corporation**

Okay.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Yeah, like what would make you want to participate in this program?

**Judy Faulkner – EPIC Systems Corporation**

Okay.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

What benefits do you see?

**Judy Faulkner – EPIC Systems Corporation**

Are you asking me now or that was just a question?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

No, no, no I mean this is just...these are the kind of comments we're looking for is whether...you know, from the outside, is there something about...hopefully there is something about this that would attract people to want...organizations to want to have this designation and what would that be? And, if there are things that would be unattractive or disincentives we need to know those as well.

**Judy Faulkner – EPIC Systems Corporation**

Yes, I've heard of a few disincentives and I think it would be worthwhile to hear what are some of the disincentives, what are some of the incentives and how does that balance out?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

That's what we're hoping to get.

**Judy Faulkner – EPIC Systems Corporation**

Okay. Thank you.

**Deven McGraw – Center for Democracy & Technology – Director**

Thanks, Judy. Anybody else have any questions? We are nearing the end of our hour and we still need to open up for public comment. All right, hearing none, MacKenzie, why don't you open us for public

comment, although hold on, before you do that, just reminding folks that our call is on Tuesday, May 22<sup>nd</sup> at 4:00 p.m. Eastern, we have 90 minutes slotted, so, all right, MacKenzie open us up, please.

**MacKenzie Robertson – Office of the National Coordinator**

Operator, can you please open the lines for public comment?

## **Public Comment**

**Alan Merritt – Altarum Institute**

If you'd like to make a comment and you're listening via your computer speakers, please dial 1-877-705-2976 and press \*1 or if you're listening via your telephone you may press \*1 at this time to be entered into the queue. We have no questions at this time.

**Deven McGraw – Center for Democracy & Technology – Director**

All right, terrific. Thanks everybody for jumping on the call, in particular if this late in your day and it's really nice outside and you'd prefer to be there, many thanks to ONC, to Joy, to Farzad and particularly Steve for walking all us through this it's really extremely helpful and will help us jump right into our discussion of the questions next Tuesday. Happy weekend, all and look forward to talking to you in a few days.

**John Houston – University of Pittsburgh Medical Center – NCVHS**

Thank you. Bye-bye.

**Deven McGraw – Center for Democracy & Technology – Director**

Bye.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, everyone.