

NwHIN Power Team
Draft Transcript
June 12, 2012

Presentation

Operator

Ms. Robertson, all lines are bridged.

MacKenzie Robertson – Office of the National Coordinator

Thank you. Good afternoon, everyone. This is MacKenzie Robertson in the Office of the National Coordinator. This is a meeting of the HIT Standards Committee's Nationwide Health Information Network Power 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 now take roll. Dixie Baker?

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

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Dixie. Tim Cromwell?

MacKenzie Robertson – Office of the National Coordinator

Floyd Eisenberg? Ollie Gray?

Ollie Gray – Department of Defense

Here.

MacKenzie Robertson – Office of the National Coordinator

David Groves?

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks, David. Arien Malec? David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Present.

MacKenzie Robertson – Office of the National Coordinator

All right, thanks, David. Nancy Orvis? Marc Overhage? Wes Rishel? Cris Ross? And are there any staff members on the line?

Matthew Rahn – Office of the National Coordinator

This is Matthew Rahn with ONC.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Matt.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Mary Jo Deering, ONC.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Mary Jo. Okay, Dixie, I'll turn it back over to you.

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

Okay. Thank you all for dialing in today. I wanted to start out, I wasn't able to attend last week's meeting on Tuesday, but Matt sent me some notes from the meeting and especially since I will be presenting this to the Standards Committee I want to make sure I understand what the recommendations are, so I'd like to just start by going through those recommendations captured from last week and make sure that we've articulated them well and also make sure I understand what it is. And then I think we just have a few more questions to address, and then we will have completed all of the RFI comments that were assigned to us. I'll put together the comments after we finish all the questions and comments and our responses, work with Matt on that, and we'll get those out for you to review before I present them in a more condensed, succinct form to the Standards Committee. And then at the end of the meeting we'll have public comment. Any questions?

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Dixie, this is David Groves. I just wanted you to know I was not at the last meeting either so I'm not going to be much help in interpreting our results, but I guess, David, you ran the meeting, McCallie?

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

Yes, David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Hi. I was on mute. Yes, this is David. I was there.

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

Good. Yes, I'm really glad you dialed in here today, David, so that you can help us understand and then we can bring these to closure. The first one here that's shown on the screen, question 64, "Would this approach for classifying technical standards and implementation specifications be effective for updating and refreshing interoperability CTEs?" It seems to me, first of all, that there seems to be not only from last meeting but from meetings leading up to last Tuesday as well, there seems to be a recurring theme that this group thinks that the CTEs that are at the regulated governance level should be very high level CTEs, policy level CTEs, and that really fleshing out the more detailed requirements for the NVEs, which are more likely to change, etc., should be done more by the validating bodies and the NVEs themselves. Is that what I'm hearing?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. Yes, I think we, on our call last Tuesday, which was just a few of us, Chris Ross and Marc Overhage and myself did most of the talking, but I think that a pattern that we've seen in some of the other calls was the belief that the core value of the NVEs is in ensuring a rapidly achievable trust fabric and that the secondary benefit is to ensure that standards for interoperability that work at scale are achieved, but that we would see those as different processes. So the rules for trust are more rigid and slower changing and probably don't really reflect any particular market inputs, they just are the criteria for trust, whereas, the CTEs that might govern interoperability and even conceivably sustainability models and business practices might be more influenced by market evolution. And so I think we've seen a consistent pattern of trying to separate them into core CTEs and less core; I'm not sure we came up with a good way to describe that, but that pattern's come back several times.

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

Yes, it definitely was there at the last meeting I attended. It looks to me like the additional step that you guys took last week was to make that clear distinction between trust fabric at the governance level written into regulations, versus interoperability CTEs. So before that we hadn't really talked about the lower level being interoperability CTEs, is that right, that's kind of the additional –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I think that's the easiest case to make, which is that interoperability standards may emerge that don't exist today in response to new market demands, or current standards that exist today may need to be improved upon as scalability issues emerge or deficits emerge, and that we'd like to avoid a cumbersome process that requires filtering down from the top through the accreditation bodies into the validation bodies and into the NVEs. That might be too slow and cumbersome a process. And then I think you asked a question in one of our other responses about innovation suppression, and that's really what we were trying to get at is that innovation from the bottom up in terms of interoperability capabilities should be preserved while at the same time guaranteeing that the core trust relationships, which would include identify management and the certificate questions and things like that, would be maintained at a more steady pace or with consistency.

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

Okay, that's good. Thank you. Now, with that, this one, the return to this question was Matt put it in here, so I assume that you guys decided that you wanted to return to this question, right?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I think we were struggling with it, and in an attempt to make sure we covered our assigned question for the hour we just said, gee, let's not struggle anymore.

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

Okay, so we said that the Power Team approach is a start for classifying technical standards and implementation specs, but any additional specificity may be added by the certifying bodies that support protocols, which is consistent with what you just said.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, and I think the technical word, maybe those are the validating bodies they use to be consistent.

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

Yes, yes, validating bodies.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

The accrediting body is the one at the very top, then there are these validating bodies that actually validate CTEs. There is no such term as "certifying body," I don't think.

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

But the RFI does talk about certifying solutions, and we do certify EHR technology.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, and that's where it gets really confusing, with these words meaning different things in the different frameworks.

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

Yes, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

There is certification that is done by the validating bodies, is as best I can tell how it's structured.

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

Yes, yes I think they talked about the validating bodies. Yes, certification and accreditation is part of validation. Okay, so we endorsed the framework, endorsed on page 62 the RFI. Now what's 62? That must be the –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is the original governance RFI before it was in the federal register.

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

Yes, so the framework is what?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Page 62 is the page that has Figure 1, which is the graphic that has maturity on one axis and adaptability on the second axis –

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

Oh, okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

... emerging pilots and actual –

M

... On the last page of the federal register, right, David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Say that again.

M

It was on the last page of the federal register –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. Yes, that would be right, because it's at the very end of the other document.

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

Okay. So this is still more of the same, and what's emerging here is this regulated, top level set of CTEs that really have to do with the trust fabric. So the CTEs now have security, interoperability, and business, right?

M

Business process, right.

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

Business process. Did you guys talk about whether those interoperability and business process CTEs that are recommended, should they be in the regulations? Are they still trust fabric?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I don't know that you could necessarily take the list of proposed CTEs and segregate them out cleanly. Some of them might need to be swiveled a little bit because they may overlap between core trust and specific interoperability. The core trust might say that identity has to meet certain levels of assurance and be backed up by certificates that are issued according to Federal Bridge consistent certificate policy, and that would be a trust one, but the specific details of how to use DNS for certificate look up in Direct would certainly not be a core one, even though it's about certificates, it would be an interoperability one. I think we struggle a little bit that these, they didn't design the CTEs to fit that framework of the notion of core and interoperability –

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

Right. They're really saying revisit and if they're not core to trust fabric –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right.

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

Let's see, what are they, interoperability, facilitate secure electronic health exchange, ... required standards for establishing and discovering digital certificates, ability to verify and match the subject of the message – yes, these are all having to do with trust anyway.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, but something like that matched the subject of the message, we decided that that's really very use case specific. There are certain interoperability standards where that doesn't happen at all –

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

Oh yes, that's true. Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That could hardly be a core, because it's not core to everything.

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

So the business ones are that they can't charge for it without imposing financial pre-conditions, "An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial pre-conditions on any other NVE."

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Have we discussed that one in our workgroup?

M

I don't think we have.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think that's been off the table for us.

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

Yes, "open access to directory services and report on users and transaction volumes for validated services."

David McCallie – Cerner Corporation – Vice President of Medical Informatics

We have consistently called out for transparency, rather than establishing of pre-defined SLAs we've instead I think been fairly consistent, saying that actual performance should be transparent and then the market will establish appropriate SLAs.

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

Yes, I'm trying to capture this set of really core ideas that come up in every single response, yes, that the actual performance should be transparent and –

M

I guess it's safe to say that if somebody had this mental model from the get-go they might have constructed these CTEs a little differently.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I think so.

M

And the CTE is conditioned for trusted exchange. And yet, let's just look at the last one, being able to produce a report on volume I don't see that as a condition for trust, or a condition for trusted exchange. It might be a condition that we'd want to impose on a member of the NwHIN, but it's not really a condition of trust and I think if we were to re-craft CTEs around a trust fabric first and interoperability second, we would come up, I think, with a different set of CTEs altogether, some of which need to be established right out of the box and some of which might be implemented over a period of time and not necessarily firm requirements in year one.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I would agree with that. I think most of the right concepts are in the RFI; they just may be organized in a different fashion than what we're coming back to as we think about this over and over again.

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

I think what you're saying is that, and you actually say – Matt, would you move the slide forward? I think it's the next question or maybe two questions. Not that one, the next one after that. The next one after that, where you really talked about – one more – where you really talked about interoperability – this one, where it says "should focus governance mechanisms to ensure trusted exchange and let the private sector, through validating bodies, focus on interoperability." Interoperability CTEs, I think what is being proposed here is they would be really managed, those lower level interoperability CTEs would be managed amongst the validating bodies, collaboratively amongst the validating bodies and the NVEs. Is that right?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, that's where we were headed. I went back and re-read the part of the RFI where they described the ONC's proposed role, and I think what we're saying here is consistent with the open-endedness of the way they describe the ONC proposed role. So they say things like "classify the readiness of technical standards necessary for interoperability."

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

Yes, that's right, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But that's a classification of readiness. That's not actually figuring out the details of how to implement what's the best practice, what's the testing suite, what are the minimum SLAs. There's a ton of details beyond just mere readiness. We were saying that the people closest to the use of the protocols are in the best position to actually make them work and keep them up to date, and that's going to be at the validating level, not at the ONC top level or at the accreditation body.

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

What ONC has really envisioned, how they envisioned it working, which is why our Power Team was put together to begin with, is that the ONC would say the modular exchange specification, we want this body to evaluate its readiness as a national standard. And ONC would decide it's ready to be evaluated and then some other party, and I think in the RFI they suggested it be the Standards Committee, would then actually do the evaluation. But what I think I hear you saying is that it wouldn't be the Standards Committee, it would be a collaboration among the validating bodies.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's what I'm leaning towards. And I like the language in that ONC responsibilities session is they reserve the right for overall, I think they just use the word "oversight" of the validating bodies and an assessment of the readiness of these standards. But that leaves plenty of room for the validating bodies to actually have real work to do. And they asked the question about what should be best done by the private sector, and it seemed to us on our last call that that low level detail work, which is complicated, expensive, and needs a business model to succeed, is probably what the validating bodies would do more or less in the private sector, but with ONC oversight.

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

Yes, that makes sense to me. Now, my question here, as you can see, is that we already have quite a few, and going to be even more in 2014 and 2016, a lot of standards that are interoperability standards that are regulated. So if we would recommend that really moving forward that the interoperability standards setting should be done by the validating bodies, then it wouldn't be codified in regulation anymore either, right?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I think we're all concerned about the slow moving regulatory train.

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

Yes, yes, okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Avoiding that.

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

All right, I just wanted to make sure I understood it. Matt, would you go back to page 9. I just want to make sure I understood the overall message here.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

You're asking the right question because we really struggled with this.

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

No, too far, Matt. I'm sorry, I said 9. No, back one, there, right there, yes.

Matthew Rahn – Office of the National Coordinator

Question 64.

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

Yes, question 64. I think we have returned to this and I think, let's see, the approach, the classifying technical standards will be effective for updates, so what we're saying here is that we believe that interoperability CTEs, the updating and refreshing of interoperability CTEs should not be a regulatory function but should be accomplished by a collaboration among the validating bodies, right?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I'm comfortable with that.

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

Okay, Matt, let's capture that.

M

And the question's really referring to the Power Team's classification of technical readiness, right?

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

Yes.

Matthew Rahn – Office of the National Coordinator

Can you repeat that, please?

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

Yes, I can fix the rest of the language, that, “We do not believe that updating and refreshing interoperability CTEs should be a regulatory question under the regulatory process, but rather should be accomplished through collaboration among the validating bodies.”

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And we could put “with oversight by ONC,” or something like that.

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

“... with oversight by ONC.” Excellent, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Because one of the other roles that ONC reserved, which I think makes a lot of sense, is to be the channel for the FACA input, so if the FACAs have strong feelings about something that should change in these interoperability CTEs, ONC would be the channel to get that to the validating bodies.

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

Yes, good. Okay, I think that sentence right there is our response to this one. I think I can clean up the language in the other ones. Let’s go to the next one, Matt. Okay, question 65, “... criteria to be used for categorizing standards and implementation specifications ... CTEs, we would prefer criteria ...” – okay. And then Matt has put in there “using the...” – there were no criteria set forth in the RFI.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, they have those broad categories there.

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

Well, those aren’t criteria.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I know, but that’s what they call criteria. I think this is the one where we get a free pass, because this is what we’ve been doing for the last “x” meetings.

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

I think we just say, “The Power Team recommends using the following criteria.”

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, the work that we’re not quite finished with, that is what we think the criteria should look like.

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

Yes, and I think we should just stop there.

Matthew Rahn – Office of the National Coordinator

Those are criteria?

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

Those are our criteria, and then we have attributes under each of them.

Matthew Rahn – Office of the National Coordinator

Yes.

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

Maybe we'll put in the attributes there too and then just delete the rest. Yes, thank you, Matt. Good. Okay, and then the next one. Is this one "How urgent is the need for a nationwide governance approach for electronic health information exchange? Please indicate if you believe that it is untimely for a nationwide approach to be developed and why. Why is it important for ONC to ..." – okay. "The NPRM for Stage 2, great emphasis on the importance of ..." – now I understand, okay, yes, this is consistent with what you said before. Okay.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Yes, and this is the first time I've seen this, Dixie – this is David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center – but it definitely matches my concern. I think initially this ... needs to be fairly light handed. This is a very immature exchange marketplace, and we certainly don't want to be doing things that make it prohibitively costly and unwieldy, difficult for an exchange to get stood up.

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

Yes.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

I think the whole notion of getting a trust fabric laid out and some direction established as to where the CTEs may be going over time would be important, but I don't think you can impose a whole lot of regulation on this industry in the next few years.

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

Yes. Well, I don't think it ever should be heavy handed. Okay.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Some of this was heavy handed.

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

Yes. Okay, next one, "Would a voluntary validation approach as described above sufficiently achieve this goal? If not, why not?" And our answer is, we agree with the voluntary approach, however we note that this may be a moot point if federal entities require NVE certification for business partners. "If NVE validation becomes a de facto requirement, ONC should be mindful of the comprehensive nature of some of the proposed regulations in this RFI." Yes, I don't understand that.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, it's careful language to reiterate the heavy handed issue. The thought is, it's one thing to say something is voluntary, but if the payor of record for 50+% of healthcare requires that you adopt that voluntary standard, then it's really not voluntary.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Exactly.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And therefore, the tail is wagging the dog and ONC, if that's what they expect to happen, should be mindful that these regulations shouldn't put these undue burdens and barriers and inflexibility into the system. So being voluntary doesn't get you off the hook of making sure that this is a responsible set of requirements because practically speaking we expect most people will in fact want to become NVEs. That was a really redundant way of saying it, but that's what we were trying to capture in language that wasn't too coarse.

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

You're not trying to discourage the federal agencies from requiring use of the NVEs. It's just that the governance around the NVEs shouldn't be heavy handed, it shouldn't be burdensome.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right, because even though it's voluntary it may become essentially a requirement for business.

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

I do understand.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

For some business.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

For some business.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

So the requirement should not be such that you can't be an exchange without being an NVE, because if that's true then it's not voluntary.

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

I think you're saying it's not a bad thing for the federal agencies to require that they use NVEs, but it would be a bad thing if becoming an NVE was so burdensome that nobody wanted to do it. Is that right, David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I –

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

I would go one step further. I think it's a bad thing if being an NVE is really a requirement to have a sustainable business. Taking our business as an example, we should have the opportunity to choose whether or not we want to be an NVE while not impacting anything we do in our local market. We obviously might be constrained from doing work with the federal government, but in our local market –

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

It shouldn't matter.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

... it shouldn't matter.

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

Yes, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is the other David. You can imagine some of these business practice proposed CTEs could be incompatible with certain businesses that do exchange health information with the government, and you wouldn't want to have a voluntary program that they had to achieve and that therefore really disrupted existing business models. I don't know if I have a good one to use as an example so I probably won't even try, but you're trying to capture the notion that just because it's voluntary doesn't mean that it has no impact. It could have profound impact on business, even though it's voluntary.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

So being a patient-centered medical home is a voluntary objective, but if Medicare decided it wasn't going to pay a provider who was not a primary care provider in a patient-centered medical home, it's no longer voluntary.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

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

Yes, I see.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

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

Yes, I do understand what you're saying. Okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But by all means we like the notion that it's voluntary. We just don't want them to drift into the notion that that means it can set unachievable goals just because it's voluntary, and if you don't like the goals just don't do it, because in fact you may not really have the choice.

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

The second part of the first sentence is kind of bothersome to me. It almost sounds like you're saying it's a bad thing that federal entities require NVE certification for their business partners. I don't hear David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center saying that that's necessarily a bad thing, as long as it didn't disrupt their local business practices.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. Certainly we're not saying that. We're just using that as an example that if, for example, take the federal bridge issues that we've been wrestling with, our federal partners believe that they require federal bridge certificates. That actually turns out to have a pretty profound impact on the private exchange market. That's where a federal requirement has unexpected side effects and percolating back into private business. So the notion of a voluntary NVE sounds like a low impact approach, but if, for example, the federal partners and payers, CMS and the states, decided to require that you be an NVE, essentially you've made something that was voluntary into something that becomes, practically speaking, mandatory.

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

Yes, but I think two things. I think they have a right to say if you're CMS or VA or MHS you have a right to say I require that if you're going to exchange information with me you must use an NVE to do that. I think they have a right to also say you must use a digital certificate that I send you, that's their purview, and I don't think that's a bad thing either. And I'm also saying that if this governance is going to be nothing but trust fabric, it had better be pretty good at providing trust.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right. And I totally agree. I fully expect that federal partners will in fact require that their exchange partners be NVEs. And the only point is that if they do require that then that will percolate through the whole system and effectively make NVE not a voluntary standard, but in fact a de facto required standard.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

It would be a business imperative.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It would be a business imperative, and therefore, the CTEs should keep them in mind.

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

That's what I thought you were saying, ... RFIs recognize that they're relying on their business partners to require the use of NVEs and therefore people will be encouraged to use NVEs. But I thought your second sentence was really the main point here, is that if NVE validation becomes the de facto requirement, that we need to be doubly sensitive –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

... about ONC –

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

... about how heavy handed the CTEs are.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Exactly.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

How about if it said something like “ONC should be mindful of the profound impact of some of the proposed CTEs on the private sector?”

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Right, those impacts are a combination of technical challenges as well as cost, implementation costs and operating costs.

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

And they only add after sector “especially those that go beyond trust fabric.”

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, although even the trust fabric ones can be, as we know from our federal bridge discussions, can be actually fairly –

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

I don't ... all agree on the federal bridge thing.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, it just has a big impact.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So it –

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

Oh, I know what you're saying, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It's a big change from the way private companies currently do business.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And they do business in a secure fashion today, but this would require that they all change, and that's a big impact simply to meet a federal requirement.

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

Yes. Okay, I think we got it. Next one, okay this one, “We solicit feedback on the appropriateness of ONC’s role in coordinating the governance mechanism and whether certain responsibilities might be better delegated to or fulfilled by the private sector.” Now, we said that we captured that pretty well earlier. “ONC should focus on governance mechanisms to ensure trusted exchange and that the private sector, through the validating bodies, focus on interoperability.” Okay, delete my comment there, please, Matt. I understand.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I think that the way the RFI is written, it actually seems pretty consistent with that in that ONC would appoint an accrediting body but not actually be the accrediting body, so that’s appointing a private sector entity to do that, and then the accrediting body would accredit various validating bodies that ONC would have oversight over. But ONC wouldn’t actually be the validating body, so that’s private sector as well.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It seems like what they’re proposing is very consistent with what we’ve suggested back.

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

Matt, why don’t we add a sentence and say that, “We believe that this is consistent with what is proposed in the RFI.”

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I went back and read it to try and tease out where would they think there’s something that could become private that they haven’t named as private, and I really couldn’t find it.

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

Yes. I want to just put this right after the first sentence, yes, because we think that first sentence is consistent. “We believe that some CTEs should apply to all NVEs and the degree that they are related to the core trust framework could be ONC’s responsibility, but the CTEs that are focused on the interoperability should be delegated to the validating bodies of private entities in order to foster innovation and efficiency.” Okay. “We anticipate that validated entities create additional CTEs as needed for the efficient operation of NwHINs and we suggest that it may be possible that ONC should focus on those CTEs that establish the trust framework and should avoid those CTEs that might inhibit innovation. CTEs that have to do with core trust should be the responsibility of ONC where additional certification processes from private companies would be necessary to guarantee interoperability.” Okay, I think you can delete my last sentence and I think that I understand what that means.

Okay. All right, the next question. These are our next three, 9, 10, and 11, the accreditation body and validation bodies. “Would a voluntary validation process be effective for ensuring the entities engaged in facilitating electronic exchange continue to comply with the adopted CTEs?” It’s not, “What other validation processes should be leveraged for validating conformance with adopted CTEs if you identify existing processes ... exchange.” I think our answer here is yes, right?

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

I don’t think there’s another answer.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I wasn't clear; when they say "voluntary validation" I assume they mean voluntary decision to become an NVE?

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

That's what I'm assuming too, David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Voluntary participation.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

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

Yes, to become an NVE, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, and it seems like we've answered that question before. That's essentially the same question we just finished discussing.

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

Exactly. I think so too. "Should the validation methods vary by CTE? What methods would be most effective for ensuring compliance with the CTEs? Before answering this question it may be useful to first review the CTEs you're considering to adopt." Okay.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

So –

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

Of course.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Dixie, this is David. I would say yes, it's probably true that some CTEs would have to be validated in different ways. But the thing that came to my mind is the way a medical practice goes through its PCMH accreditation. A lot of it is self-assessment with documentation and it's submitted in an application with the documentation. If, for example, one of the business practices was being evaluated, you'd have to submit with the documentation a copy of your business process or policy that establishes that that is the way you do business. Some of the more technical ones may have to actually be tested and validated by a validation entity. I don't know. But many of these I think would be in the form of an attestation with documentation submitted for review.

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

Yes. I think, just like when you build a system and you're validating the system, you do some with tests, you do some with analytics, you do some with documentation, inspection, I think, yes, they're just different methods for validating. But what I wish you had asked is, and I think we should maybe address, is should the same methods for validating a given CTE be used across all NVEs? Should you be able to go to one NVE and be validated against CTE "x" by attestation and another one requires testing?

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

That's a great question. My first reaction would be of course it should be standard across all validating entities, but ... standard across all business types, so I may be an NVE at a certain type and maybe that changes up how that particular CTE's evaluated. I don't know.

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

Yes, you might have these NVEs that specialize in particular types of data exchanged. I think the methods should be consistent across the NVEs, but I think that the scenarios that they run might be different, like the test scenarios.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

It seems an opportunity for somebody to noodle –

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

Yes.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

... as the CTEs get nailed down.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, and there are so many different kinds of validation at different levels based on the risk issues, the importance of the principle being validated, so certificate authorities, the way they handle the private ... is rigorously audited and inspected and the like, whereas, a statement of how you proof your level of assurance, how you establish your identify proofing may be attestation, because you can't audit it. It goes on all the time.

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

Yes, but if you're really a validated NwHIN exchange node, which is basically what these things are, right, and maybe this is the answer, maybe the trust CTEs, the one that's regulated – how do you like this one? "The CTEs that are regulated, the trust fabric CTEs, the validation method should be consistent across all validating bodies, but the validation methods for CTEs that are lower level CTEs might be different."

David McCallie – Cerner Corporation – Vice President of Medical Informatics

The one's focused on interoperability. It could be different.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think that's a good way to frame it. That's consistent with our other –

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I like that, whatever you said.

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

"... for interoperability CTEs." That's better than lower level, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, yes. And some of the interoperability stuff is going to be a simple test rig, you can validate yourself in five minutes by attaching to a well-known Web address, and others may require something in the form of attestation around how you handle your audit logs or whatever else, and then some may require actual inspection.

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

Yes. "... may vary among validating bodies."

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, wouldn't it be more likely to be "... vary based on the CTE being tested."

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

Well, that's the question, though. That's the question. If you have the same CTE, a single CTE, is that CTE always validated the same way –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So let's say it was an interoperability standard like, I'll just pick Direct for funsies because it's fresh in everybody's mind, maybe there's some NVEs that are standalone HISPs that don't do anything other than Direct, but there are some NVEs that do a combination of Direct and Exchange and SureScripts or whatever else emerges, and I think you would assume that validating for compliance with the CTE that describes Direct would be consistent regardless of how the NVE has packaged its services. For interoperability it almost has to be consistent, otherwise it's going to not be interoperable.

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

It's not going to be interoperable, that's right. I think that for a given CTE, regardless of what it is, the validation method should be consistent.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I think so.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But they may not be the same across CTEs, so validating –

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

Right, they may vary between CTEs, but for a given CTE the validation method should be consistent.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

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

Yes. So we just changed our mind on that one, Matt. "For a given CTE the validation method should be consistent ... validating bodies."

Matthew Rahn – Office of the National Coordinator

I'm sorry, some people walked by. Validating bodies, is that good?

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

Yes, just delete the first sentence. Okay, what successful validation models or approaches exist in other industries that could be used as a model for our purposes in this context? My goodness. Testing, what are the methods that they commonly specify? There's testing, observations, inspections, and attestations, right, aren't those the four? Oh, and formal proof of correctness. Those are the only validation models I know of.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. I don't have any expertise in this. I thought maybe they were looking for organizations that do validations successfully, or industries that have internal validation processes, like the certificate authority industry has their CT and CTS statements and mechanisms to go through an audit and –

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

It's not methods; it's models or approaches, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is outside my knowledge.

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

Yes, that's a good example of what they use. Certificate authority, how do you become a validated certificate authority like VeriSign –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And then what is the banking industry, the PCI framework, they must have an approach for their members.

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

Yes, because they have PCI validation, right?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. That, to me, is even closer in a way because that's a mass scale, whereas, certificate authorities is limited to a very small number.

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

Right, yes. Let me see, is there a PCI –

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

What is PCI, David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It's the –

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

The credit card standards.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It's the standards for credit card identity and Web sites that banks host with consumer facing access to accounts. I forget what it stands for.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

This is Mary Jo. It's Payment Card Industry.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Payment Card Industry, there you go.

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

Yes, you can get PCI validation, so that might be something they could look at.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. There's another one that Arien brought up a number of times when we were discussing DirectTrust.org, and I always forget the name of it, but it's the –

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

Oh, I know who you're talking about. It's the one that's equivalent to the federal bridge but –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, if you want to get an extra validation, extended valuation certificate, yes.

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

Yes, extended valuation certificate, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

EV certificate. There's a process you can go through if you're a business and you want to voluntarily have that little green symbol on your Web browser bar, you can get an EV certificate. That one has a lot of similarities to what we've talked about here.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

You just might want to make the comment that both of these have a lot of similarities to our focus.

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

The PCI validation. Oh, you already have the PCI, I see, okay. And just put "... have similarities that may be drawn upon, or something."

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I'm not aware of this, but is there any certification in the X12 industry for claims clearinghouses and claims submitters, or has the claim clearinghouse effectively just become its own certification –

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

They just declare themselves.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

They just declare themselves –

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

There's a common criteria. You can get the common criteria evaluations that NIST – NIST has a whole structure for validating labs, what do they call that, the NVLAP, I think, if I remember correctly. I'm not sure what that stands for, but NVLAP for NIST laboratory, and actually that's National Voluntary Laboratory Accreditation Program. And NIST uses that program to validate labs for all sorts of things.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

These are the technology labs, Dixie?

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

Yes, yes. And they have one, like one of them they use that NVLAP program to accredit these labs that evaluate security technology, for example, against a common criteria. The NVLAP operates an accreditation system that is compliant with ISO-17011 conformity assessment. They should look at these.

Okay, next question, is that our last question? No, I think we have one more. Okay, "What is the optimum role for stakeholders, including consumers, in governance of the Nationwide Health Information Network? What mechanisms would most effectively implement that role?" Oh, are you guys familiar with the ISEC that the banking industry uses? The ISEC, I don't know what that stands for either, but they use it for the banking industry if they have a security intrusion of any sort they can anonymously report it to the ISEC, so that's how they self-govern kind of.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I wonder if what they're getting at here might be something more along the lines of saying, for example, that any validating entity that gets approved would have to have representative membership in its governance structure from stakeholders that are affected by the work.

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

Like an individual NVE?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

No, the validating entities that will certify the NVEs.

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

Oh yes, oh.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

You could say that the governance of the validating entity had to have stakeholder representation in its internal governance.

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

Yes, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So, for example, if DirectTrust.org became a validating entity for HISPs, then it should have some physicians and some HIE administrators on its internal board just to be representative. That's a place where the stakeholder representation could feed back into this process. There's obviously other places, like the FACAs and the like, that they already exist.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Matt, you might want to just switch the placement of the word "internal" and "stakeholder."

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

"Stakeholder representation," yes, good. And I think we're saying the governance of each validating body.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

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

Not overall.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, and I would say something like "should have" instead of "must" or something, or "has to." It may not always be possible, but "should seek to have," there's language that would give a little bit of wiggle room. Some of them may not make sense to have every single stakeholder involved.

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

But what about the "overall governance at the ONC or national level"?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

The FACAs is one route where stakeholders have input, and if ONC is the channel between the FACAs and accrediting agency, that's somewhat covered. They're talking about –

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

David, is the consumer part of that well covered in that model?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Maybe not as well as it could be. There are consumer representatives on both the Standards and the Policy Committee, but they don't always have a loud voice because it's outside their scope of expertise. What I wonder about is in the RFI they describe that ONC would appoint an accrediting body, and they even used ANSI as their example, Steven did in one of his presentations, and I don't think they're in a position to go tell someone like ANSI to change their governance model to add consumers.

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

No, but I think that if you're talking about ONC at that level. And also who's a consumer? As an NVE a consumer is a healthcare provider, right?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, although there may be patients. Some of these NVEs may in fact be personal health records, health banks, consumer decision aids for finding the best physician for their maladies and the like. I think there might be actual consumer consumers.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

One of the questions maybe is, and the way you asked it implicitly a second ago, Dixie, and I let it slip by, but maybe the NVEs themselves should have stakeholder representation in addition to the validating bodies. I'm not so sure about that, but maybe that's what they're looking for here, is that's the question.

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

Oh.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

I didn't interpret it that way, David. It seemed to me more a question as to how the stakeholders get representatives creating the CTEs and establishing NVE requirements.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, that's how I read it as well, but it occurred to me that maybe they were really –

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

This is Mary Jo. I think you're free to interpret it any way you want. I think however you feel is the best way to address it is fine.

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

I think we should, at the very least, address how the NVEs and validating bodies, what roles they should have in the overall NWHIN governance, because the trust fabric level governance, the regulated governance, is it just the FACAs, is that it?

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Dixie, to rephrase your question, if there were 100 NVEs recognized, how would they, as a group, be represented?

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

Yes. And the overall changes, you know, the CTEs at the trust fabric type CTEs, that very top level CTEs, right now we've said that that's appropriate to be regulated. Well, how are these NVEs, and validating bodies, how are they going to exert influence on what CTEs might become regulations?

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

I think that's a great question. I definitely think that the NVE should have a voice. Maybe there's an industry group that represents them and is part of FACA or not, I don't know.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

I guess I would say also for the record, this is Mary Jo, that in the Policy Committee it did come up, a recommendation about stakeholder representation within the NVEs, including consumers. So, as I say, you're certainly free to address that question if you feel like it.

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

Well, the NVEs themselves probably could have, they probably on their own maybe even have community interest, user groups, but I think that – well, both the NVEs and the validating bodies, I think should have a voice in what becomes a regulated CTE.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

And I think that's all we need to say at this point. I think that's true how it looks, ... matter of discussion.

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

Yes, why don't we just put that, Matt? Why don't we put, "We believe that both the NVEs and the validating bodies should have input into what becomes input into ..." –

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

"... conditions or changes to CTEs."

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

Yes, "... into overall NWHIN governance and changes to the CTEs." Okay, is that our last question, or do we still have one more? Ah, I lied, we have one more. "Which CTEs would you revise or delete and why? Are there other CTEs not listed here that we should also consider?" They're all at the beginning of this, at the beginning of this document.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This seems to me such an open-ended question. This is what all these other questions were about.

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

Yes.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Although, David, I would like to offer a couple for deletion.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. But I mean in a way we've discussed the ones we didn't like and suggested changes to them, although there's no harm in calling out ones that we think deserve special attention –

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

I think for this question right here we should say that we think the regulatory CTEs should be limited to those that –

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

... that establish the –

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

... trust framework.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

... the trust framework, right, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, and that interoperability CTEs should be the purview of the validating bodies and the ones that are left are those business practice ones, which are, I think, the most controversial, right?

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Yes, I agree, I think.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Of the ones that you probably want to strike down, I bet some of them are the business ones.

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

Matt, go to the beginning of this document, that's where we have the CTEs. Yes. Okay, that first one has to do with the HIPAA security rules. David's already been through this because we went through it in the Privacy and Security Workgroup. "All of the implementation specifications that are labeled addressable would be required for an NVE." And I can tell you that the Privacy and Security Workgroup went through them one by one and we decided this was a reasonable requirement. None of them are all that tough. "An NVE must only facilitate electronic exchange for ... it has authenticated and authorized, either directly or indirectly." Of those in front of you, read through those and see if you want to discuss any of them.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Item three - I have a bit of a concern with the use of the term "meaningful choice," because I'm afraid it creates a platform for a lot of additional regulations later. If we're going to be specific about how consumers need to have control over their records, let's be specific here. But I don't want to see another meaningful use term created that creates endless new regulations and requirements over time.

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

This term "meaningful choice," it's a term created by the –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Tiger Team.

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

No, Carol Diamond's organization, the Markle Foundation, and they documented the definition of meaningful choice and then the Tiger Team just picked that up. But it has to do with especially if you have opt in and opt out, either one's fine so long as the choice happens before any information is exchanged. So it has been laid out, but I –

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

But it's not laid out here, and I think it needs to be laid out here.

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

I think that that's our comment, that meaningful choice needs to be defined. Just stick it in the table there, Matt. You don't have to be moving back and forth. Just put a comment there.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

My other question on this one, Dixie, was just the extent to which the states and the federal government need to cooperate on this particular requirement. How much should the federal government leave to the states to define?

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

... echo with question three?

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Yes, this whole notion of consumer choice.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I'm not following what you're saying.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Well, I just think that, not knowing exactly how meaningful choice was defined in the first place, but I would hate to see the federal government go overboard on prescribing exactly what NVEs have to do here when states have different ideas.

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

Yes, the meaningful choice, if they use the Markle Foundation definition, and David and I and the Tiger Team have spent hours in discussions about this, the opt in and opt out thing, that's what really varies among the states the most, and the meaningful choice as defined by the Markle Foundation would allow either one. It doesn't constrain, it more defines how you have to package what the choices are.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And there's nothing that we can do that changes the constitutional separation of powers here, so it is what it is. I think the NVEs, the federal government doesn't have the right to trump the states in the definition of consumer consent.

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

I have more of a technical concern here. I think it's impossible to ensure that individuals are given a meaningful choice regarding whether their IHI may be exchanged by the NVE, because an NVE, somebody might say that's fine, if my information is sent to another doctor using this exchange over here, you know, David's exchange. But then how does that get propagated farther and how do you know what all the links are between you and the NVE and the other hops it might take to where it's ultimately being shared. You lose control pretty quickly. First of all, I think that the NVE, and this is what the Privacy and Security Workgroup concluded, is that the NVE is not the one that gives the consumer any choice. It really should be the provider that says is it okay if I send your information through this NVE. But if you have an NVE that actually persists data in its own data repository, I think you've –

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

That's exactly right. That's where it comes into play, Dixie, where the NVE has the data persisted and allows it to be queried, at that point the consumer –

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

Oh –

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

... over.

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

Okay, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And then there are other NVEs that will accumulate data as side effects of other business processes that the provider doesn't have control over. Something like Surescripts, for example, builds a prescription record as a side effect of an ePrescription, so the consumer should have say-so over how and where that information is shared.

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

That's right. That's right. Yes, I think we even made a comment about that, something like if the NVE persists the data that they have to provide their choice.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, but it's just if the NVE makes the data available, because "persists" is an almost meaningless word in an Internet age. If it's at the other end of an HTTP link that you can chain down, then it's available.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

The old notion of central and distributed, I think kind of becomes moot.

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

Yes, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It's really is it available or not. I'm just leery of going through and revisiting each one of these. We've just spent dozens of meetings on this.

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

Yes, we have. Both the Tiger Team and the workgroup

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And the Policy Team and the Governance Team and the –

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

Well, why don't we –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

... and Cerner. I'm so tired of this stuff. Are there ones that we would wholesale strike? We've said we would reorganize them, and I think we've been fairly consistent about how we would approach separating trust from interoperability.

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

Well, but all of their safeguards are trust ones.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right, right.

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

Go down to the interoperability ones, Matt. We briefly visited them a while ago. "An NVE must be able to facilitate secure electronic" – oh yes, I remember discussing this one too.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

See, I would say that's not an interoperability one. Really, that's a trust one.

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

Yes, it is, yes. The i2 is trust as well.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I think if it was up to us to write this, we'd twizzle some of that and say digital certificates will be the basis for all identity and trust via Direct or Indirect, and that would apply across the board.

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

Is that under the security one, safeguards one?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

No, I think it's here under interoperability. There's something else I think, a lower interoperability one, about DNS and LDAP, or Directory Services. But that's one I would put down in a –

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

... in an interoperability one.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

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

Yes, I agree. Yes. So we would say i2, it should be rephrased as digital certificates should be the mechanism used for establishing trust.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's kind of what they're getting at. I think we're just rewording it.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

We're not implying, necessarily, full PKI as in individual ownership of digital certificates, because some of these protocols use organizational certificates, in fact, all of them at the moment.

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

If we make a recommendation that only the trust fabric should be under the governance CTEs, then it is important that there be a safeguard that says digital certificates must be used to –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I agree with that. I'm just saying that some people might read that to mean individual –

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

Yes, between organizations.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And we're saying it's organizational digital certificates.

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

Okay, put that, Matt. "Digital certificates must be used to authenticate the identity of organizations on the NwHIN." Are you there?

Matthew Rahn – Office of the National Coordinator

Yes, sorry. Is that good?

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

I don't –

Matthew Rahn – Office of the National Coordinator

Is it not showing up? I might have it in the wrong spot.

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

No, that's fine. That's good. The next one I think we made a comment a while ago that ... the subject of a message, including the ability to locate a potential source if available. The comment was that that might not be possible. I don't remember, don't write anything yet, Matt, I don't know what the comment was. Did you guys have a comment about this one?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Which one?

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

Capturing the subject of the message.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think that's an interoperability one, because some of the protocols require patient matching and some of them don't.

Matthew Rahn – Office of the National Coordinator

... write?

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

Interoperability, just write "interoperability one," it's fine.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And we had long discussions about whether or not to set a floor threshold for true positives and false positives, and decided that, no, that the market's not ready for that. But I think that's very protocol specific.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

One of the problems with this one is, this is David Groves, the NVE must have the ability to verify. This statement implies that the NVE is in the business and provides a service of querying for a record.

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

Yes.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Not all NVEs will be in that business or have that service. And if the NVE is in the business of directed exchange only, pushing data from a provider to another provider, this doesn't apply, so it has to be reworded at the least.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, and that's what I meant by saying that this is a specific interoperability requirement. If you're going to run a query style exchange where you have to support demographic matching, and that's a protocol CTE, it wouldn't apply if your protocol didn't do demographic matching.

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

It also implies that the NVE has access to the content that passes through it, which may not be the case.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Which may not be the case for many of them, right.

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

So just write, Matt, that it doesn't apply to all NVEs.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Or, "it will not apply to all NVEs."

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

Or not, good, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, it belongs at the level of specific interoperability.

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

Yes, it certainly doesn't belong at this top level. Let's go down to the BP ones, Matt. So these are the ones we want to talk about. "Must send and receive any planned electronic exchange message from another NVE without imposing financial pre-conditions on any other NVE." Is this something that should be established at the regulatory level?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I'm very leery of this. I think this is a market solution.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Well, my thinking on this was that if this is really relating to nothing more than transporting across the network a piece of content and that the NVE that was handed this piece of information has no responsibility other than final delivery, maybe this is reasonable. But if there's any other service involved in order to satisfy the intended request in the form of a transformation or a message validation or anything else, I think the NVE has to have the ability to have the business relationships with other NVEs that allow for any kind of fee-for-service to occur that's reasonable for that activity.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think that the legitimate concern here of a monopoly NVE that sets such a high bar for cost of participation that it inhibits exchange, that's a legitimate fear. You can even argue that there are some parts of our market that work that way today. On the other hand, precluding any kind of business arrangement would really limit the market's ability to develop a robust NVE infrastructure.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

I completely agree with you, David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's why we have rules like the Sherman Antitrust Act, we recognize that in the capitalistic society it's possible to get monopoly power that disrupts the benefits of a capitalist approach and we have safeguards in place to prevent that from happening. Maybe this should be worded that "The oversight of the NVEs should seek to address any monopolistic practices that inhibit exchange" –

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

Excellent. Matt, write that down.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

"... seek to address any monopolistic pricing practices that inhibit free flowing data exchange, but without imposing an absolute requirement that ... involved."

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

Yes, I think that second part, "without imposing," I think that we should just reiterate that we think that this type of CTE is more suitable for an NVE for a validating body level, CTE, than a regulatory.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. Well, it's an oversight function maybe, although under what authority would the oversight entity –

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

Oh, you're saying the ONC as the NVE oversight. I see.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I'm trying to say who would determine when monopolistic behavior is occurring and under what authority could they do anything about it? That's a tough question.

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

And is it part of the trust fabric?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I don't know if it's part of trust. I think it really is a business practice one. It's really a part of what are the rules for oversight. If ONC's going to oversee, what's it going to measure against? And one of the things it could oversee, one of its measurements could be is information flowing appropriately freely. And if it detects monopolistic behavior it ideally should do something about it. I'm not sure under what authority, though.

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

Matt, delete that second bullet. Yes. I do think that that's part of trust, that you can't have –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, either way.

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

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It's core, however I think it's one of those that sits up at the ... level.

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

Yes, so an NVE must provide open access to the directory services it provides. This, to me, is clearly a lower level requirement.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I think that's protocol specific. There are some protocols that don't even have directory services.

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

Yes, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's an interoperability CTE or something like that.

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

Yes, yes. And the third one we just believe that ... said that in a good way –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

We said ... transparency.

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

Yes, actual performance should be transparent.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

I'm just inclined to think this ought to be a voluntary thing.

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

Yes, and we said we should leave it up to the market.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

I think there's a lot of good reasons to have data from each of the NVEs, but I don't think there's a strong case that that be a requirement.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, don't you think transparency is in general a really good thing, as opposed to trying to regulate actual SLA-like constraints?

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

I think as a trust CTE that they should say that "Transparency of business practices and performance on services should be transparent."

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, then how about saying, "It's up to the validating bodies to determine the reportable measures."

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

Yes.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

I would be fine with that.

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

Yes, good. Okay, I think we've just finished it all. Is there anything else we want to say? I'll put together our slides for next week and run them by you. Matt will clean this up and get it to me.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Matt, even if you don't get it all cleaned up, could you at least get a copy of our work out to us?

Matthew Rahn – Office of the National Coordinator

Yes, yes, I'll send that today.

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

Yes, that will be good. All right, are there other comments before we open this to the public comments? I think we've done a wonderful job here. I think we've got some good recommendations to give. I'm proud of our work, so thank you all.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

You did a great job organizing it, Dixie. That's really hard work.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I can speak from experience.

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

Thank you. I appreciate that. Okay, MacKenzie, I think we're ready to open it for public comment.

MacKenzie Robertson – Office of the National Coordinator

Great. Operator, please open the line for public comment.

Public Comment

Operator

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. We have no comments at this time.

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

Okay, well thank you all again for dialing in, and we'll get something out to you to look at. When I do send you something to look at for, this will be the draft for next week, I'd appreciate you looking at it as quickly as you can because it will be a quick turnaround I'm sure.

M

(Inaudible.)

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

Thank you.

David Groves – HealthBridge – Executive Director, Tri-State Regional Extension Center

Thanks, Dixie.

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

Bye.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Bye.

MacKenzie Robertson – Office of the National Coordinator

Thanks, everybody.