

Governance Workgroup – Subgroup #2
Draft Transcript
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Roll Call

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Thank you very much operator. Good afternoon everyone. This is Mary Jo Deering in the Office of the National Coordinator for health IT and this is a meeting of the HIT Policy Committee's Governance Workgroup and it's a Subgroup Called Subgroup #2 of that. It is a public meeting and there will be an opportunity for public comment at the end and I will begin by taking roll. Jonah Frohlich?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

John Blair?

John Blair – Taconic IPA

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Laura Adams?

Laura Adams – President & CEO - Rhode Island Quality Institute

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

John Mattison? Doug Gentile? Are there any other members of the Governance Workgroup on the call?

Jan Root – Utah Health Information Network

Jan Root.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Oh, Jan, good, thank you.

Jan Root – Utah Health Information Network

Hi.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Glad to have you here. Any other members of the Governance Workgroup on the call? Okay, would staff on the line please identify themselves?

MacKenzie Robertson – Office of the National Coordinator

MacKenzie Robertson, ONC.

Adam Aten – Office of the National Coordinator

Adam Aten, ONC.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Okay, over to you Jonah.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Great, thanks everybody, appreciate you all making the time and joining our Subgroup today. We are Subgroup #2 and we actually have 9 questions that we're going to be addressing, we'll get through as many of them as we can today. We have a second call scheduled later in the week in the event that we need it and then we are going to discuss with the larger NwHIN Workgroup, the Governance Workgroup and then receive their feedback and then we have a final follow-up call to discuss their input and then we'll present the final recommendations, which will go to the HIT Policy Committee. So, that is our schedule for the next 8 or 9 days I believe.

So, if we just go to the discussion of the RFI questions, let me go right to...there were 8, there actually are 9 now, but these are the 8 questions originally we just have to focus on, they include sort of 3 areas, so the actors, accreditation validation, bodies of validation, entity eligibility and the first set of questions is around the appropriateness of ONC's role in coordinating governance. The second is around the validation process and so question 9 gets to the validation process and I've put bold and I've talk...that's not actually part of the RFI. So the question is around a voluntary validation process and what other validation processes could be leveraged and we will revisit these questions as we get into some more details here.

The third question is around the validation methodology for CTEs and I'll discuss these terms in a second, but CTEs are Conditions for Trusted Exchange. Question 11 focuses on successful validation models or approaches in other industries to the extent that we are well connected and understand other industries and their ability to validate entities as we're trying to do here or at least to guide ONC. And then we're going to focus on eligibility criteria and these are eligibility criteria for the validated entities themselves, a validated entity could be any participant including, you know, state exchange entities, EHR vendors, local exchanges, RHIOs, they could be hospital systems, etcetera. And so we'll talk a little bit about what those eligibility criteria are, whether they need prior exchange experience, are there other criteria and whether or not they should be tax exempt.

And then there is a 9th question that was added onto our scope and that question is focused on the optimal role of stakeholders and if we get to that, that will be the last question that we focus on as a group. Just so that you are grounded in the RFI there are three domains they call Conditions for Trusted Exchange. The three domains are broadly safeguards so the safeguard is the focus on protecting individually identifiable health information to ensure its confidentiality, integrity and availability and to prevent unauthorized inappropriate access, use of disclosure. So, one example in the RFI that is brought up is that a validated entity, an entity is a Nationwide Health Information Network Validated Entity and an NVE must comply as if it were a covered entity and must treat all implementation specifications as required, that is one example of one of the safeguard conditions.

And then there are interoperability conditions and these are focusing on the technical standards and implementation specs needed for exchanging electronic health information. An example here is that a validated entity must follow required standards for establishing and discovering digital certificates. And then the third condition is around business practices and these are focusing on the operational and financial practices to which these validated entities would need to adhere. And then an example here is that a validated entity must provide open access to the directory services it provides to enable planned electronic exchange. So, that is an example. And we will see some other examples in here because we are going to be asked to make some comment on those.

So, in the first domain we are being asked to comment on the accreditation and validation process, and so just so that we level set here again this is from the RFI, I mean this is paraphrased from the RFI, but this is the general process that is being proposed and some of the main points. So, first of all similar to

the permanent certification program that exist today for health information technology what's being proposed is that the National Coordinator would approve a single body to a credit and oversee validation bodies. So, there would be an accrediting organization much like there is now for the certification process that would oversee bodies that validate entities that would participate.

So, a validation body would evaluate an entities conformance to adopted Conditions for Trusted Exchange or CTEs as opposed to a particular product certification, alignment to certification criteria I should say. So, basically instead of in the current EHR certification process that we understand today in Meaningful Use it wouldn't be a product that would be validated, it would be an entity of conformance to Conditions for Trusted Exchange. I hope that's clear, but it's just really meant to define the differences between the validation body and the accrediting body.

Third that certified HIT could be used by an entity as a way to demonstrate conformance. Fourth is that accreditation body would be expected to conform to internationally accepted standards, they talk about ISO and others in the RFI. Fifth is that validation bodies upon accreditation would subsequently perform the validation of entities conformance to adopted Conditions for Trusted Exchange.

And then finally, validation could use different methodologies, so a validation process could use a self-attesting method, it could use laboratory testing for conformance and that's done to some extent in the certification process we understand today. There could be a certification process that could be here and an accreditation methodology and these could vary depending on the type and potential methodology burden. So, again, these are directly taken out of the RFI and is supposed to give us a sense of what this process looks like, okay.

So, number one, the first question is really around ONC's role and delegation responsibilities to the private sector. In the proposed rule or excuse me in the RFI there are six areas of proposed rule that ONC is proposing that they align with or that they support. One, is in endorsing and adopting conditions for trusted exchange and then publishing guidance on those. So, that is one of the proposed rules that ONC would play here in discovering this process.

The second is to facilitate the receipt of input from the Health IT Policy and Standards Committees and that would include revising conditions of exchange, adding new conditions and retiring conditions as appropriate. A third role would be the selection and oversight process of an accreditation body much like they have overseen that for EHR certification, they would be in a role of selecting the accreditation body. Again, the accreditation body would credit or oversee validated entities; it would validate entities that would be able to participate in an exchange.

Fourth is authorizing and overseeing validation bodies responsible for validating if eligible entities have met adopted CTEs, so this is another oversight function. Fifth is an administrating process to classify the readiness for nationwide adoption and use of technical standards and implementation specifications much the way that this process works through coordination with the HIT Standards Committee and also to an extent the S&I Framework. And the sixth, overall oversight of all entities and processes established as part of the governance mechanism. Okay, any questions before I move onto the question at hand in getting your comments?

Okay, so I'm going to go the actual question now and ask for some feedback here. So, the first question for us to address 8, is in ONC's role and the question here, the nature of the question here is that ONC is soliciting feedback on the appropriateness of ONCs role in coordinating the governance mechanism and whether certain responsibilities maybe better delegated to and/or fulfilled by the private sector. So, that is directly asking and if we go back here, whether or not ONC is sort of the right place and the right body to support these and oversee these responsibilities or if there is an appropriate role for the private sector to do any of the following roles as we see here or any other roles. Any comments from the Workgroup first of all about the role of ONC or private entities? I'm happy to sit back for a moment and just relax.

Jan Root – Utah Health Information Network

This is Jan.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Hi, Jan.

Jan Root – Utah Health Information Network

Is this okay to make comments, I'm not officially part of group 2?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

You absolutely may.

Jan Root – Utah Health Information Network

You know, a lot of my experience comes out of the whole HIPAA piece and looking at what happened with HIPAA where the Feds took a pretty, you know, clear cut role in adopting standards and doing the regulatory thing, but they didn't actually do the creation of standards, they didn't do the creation of the validation entities like foresight at least we called clarity and those sorts of things. And just in sort of just cogitating about this question, you know, certain parts of HIPAA have worked sort of well, you know, HHS's role as a regulatory here's the new standards and here is you must comply, and here's the penalties if you don't, that has been very powerful. And we're going through the whole 5010 transition right now and there is no question that the Feds have everybody's attention.

So, the areas where it has gotten a little more difficult, although I don't really have a good solution, is for example on the validation part of it, the technical validation part of it, you know, does your healthcare claim your 837 comply with the technical reference guide adopted by the federal government. When you look at the different accreditation entities that or validation, I should say validation entities that test transactions, you know, most of their rules agree but there are always places where they disagree with each other and that has created difficulties for the healthcare providers because depending on which validator your clearinghouse uses you get a good claim or a bad claim, and there is no final arbiter about what's a good interpretation of the X12 books.

I mean, you know, it works pretty good most of the time, but it's been a problem on certain key areas, for example Medicare went off and interpreted the ISA03 in '04, which is right at the top of the package, differently than just about anybody else and you're like, oh okay.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right.

Jan Root – Utah Health Information Network

And that created immense problems for providers because they were formatting messages in a way that worked for all the commercial payers but of course from some providers Medicare is their major payer and so they lost a lot income as a result of that because they couldn't get their claims through in a timely manner.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right.

Jan Root – Utah Health Information Network

And also thinking about like the whole sort of CCHIT kind of thing for testing EHRs, I don't want to be unpolitic here, but it hasn't been really very effective, you know, it's done in test environments, it's not a production environment and there is no guarantee that the product is going to be implemented like that, I mean there is just so many technical issues in doing this that it would be nice if you could figure out a way to make it more effective so that the promise of standardization that is being ostensibly sold to providers is actually true, but it's not.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right.

Jan Root – Utah Health Information Network

So, those are just some thoughts to maybe just sort of start the conversation of going where should ONC exist in this enormous spectrum of, you know, oversight all the way down to, you know, is that the right interpretation of a particular element.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So, you brought up a couple of interesting points that I want to come back to, one is that ONC could potentially serve as an arbiter when and if these validation entities may have a difference in interpretation, is that an accurate statement, because I think that could potentially be one role that ONC can play.

Jan Root – Utah Health Information Network

Yeah, again, just looking back at my experience with HL7 and X12 is the best arbiters are the people that wrote the book to begin with, because as soon as you step away from those authors you begin to second guess what they were thinking and I should add that the people that write these technical manuals are not lawyer.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right.

Jan Root – Utah Health Information Network

Okay, but often the people that interpret the technical manuals are lawyers and so you end up with a language problem there. Anyway, my suggestion is that is what has largely happened on the X12 world anyway is when the two interpretations of some, you know, one minor in the book some place conflicts with each other they have gone back to X12 and X12 or HL7, and those people are the ones that really know these books because knowing the rules, the syntax and semantic rules and all the code rules is a body of knowledge that takes years to acquire. So, my suggestion is that ONC would not get into that level of detail, not that they don't have bright competent people, but the people that have, you know, gone to X12 and HL7 for 20 years they know their stuff, so they would probably be the best arbiters of something that detailed.

Laura Adams – President & CEO - Rhode Island Quality Institute

But, Jonah, this is Laura, I agree that there is a nugget there in that sense of if there is a role for ONC to play an arbiter role here it would be about the interpretation of the CTEs, is that what I think we're looking at that particular level of what it is that they might get in the middle of helping reconcile and would that be between say an eligible entity has an issue with a validation body and their interpretation of the CTEs, it seems to me that is a distinct possibility that this might come about and then therefore, you know, what mechanism do we have to reconcile that? Is that more along the lines of what we were talking about?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes, yes, I think that's exactly right and we could definitely imagine a scenario whereby an NVE, the validation entity has an issue with the CTE if there's one that really is available to validate it and there needs to be somebody to reconcile that difference, so I think that's...

Laura Adams – President & CEO - Rhode Island Quality Institute

Right, right, yeah.

Jan Root – Utah Health Information Network

Yeah, that would be good. I worry about the proliferation of again we're suffering from this on the X12 side, of a proliferation of validation entities which, you know, is great from a market perspective and I'm not saying no to it but I'm just saying that it does create inevitably people take the same sentence because it's just human nature and interpret it differently. So, that does create some problems, not necessarily fatal ones, but just problems and maybe, you know, if you're going to go in that direction you would give ONC that ability to mediate those kinds of questions.

Laura Adams – President & CEO - Rhode Island Quality Institute

We would also then add a responsibility, to the extent that it can, ONC comes out with descriptions of the CTEs that operationally define it as clearly as possible. So, that is some added element here that these CTEs have some additional information or content that helps with the interpretation and then there is this, as obviously we'll never be able to anticipate all of the ways in which it could be misinterpreted or interpreted differently than in some way be able to catalog and understand that and periodically review the different interpretations and come out with more refined descriptors of this so that those interpretations don't persist into the future but that we are able to improve the clarity.

Jan Root – Utah Health Information Network

That's a great idea, because right now under HIPAA there isn't really anybody that officially has that role and so these differences in interpretation has persisted and it continues to be problematic.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes, okay.

John Blair – Taconic IPA

Okay, so this is John Blair, I've got a couple of questions and a comment on whether ONC being appropriate here. On accreditation, I'm trying to understand how the standards, the standards and implementation specs fall under accreditation. Is the thinking that, that that will go through a testing process the way EHR vendors do currently?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

I think the way that it's described in the RFI is that it could be done that way. It could be an accreditation or certification process like done today for EHRs or it could be self-attestation or it could be lab testing, i.e., you test a non-production system. It could be any of those, it could be a combination of them depending on the CTE, in fact that is one of the issues we need to address. That is one of the questions we need to address.

John Blair – Taconic IPA

Yeah, see, because I kind of...I mean I break down the testing as we have today where you would have your HIE or direct, or whatever sending and receiving to the cloud under certain specs to test that it can actually send and receive those messages and I see that as strictly around testing. Accreditation I think of in terms of how you handle PKI or how you handle your certificate authorities or registration authorities, what the, you know, authentication requirements are going to be and some of that. I mean, are they breaking those two apart or are they saying accreditation would handle both of those things?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

This is Mary Jo and I'll jump in and I think as Jonah indicated earlier, we make the same distinction you do and we recognize that accreditation is often more around processes and policies and that the standards and implementation specs themselves do lend themselves more to the certification, and testing would certainly squarely fall under certification and that is where the standards and specs themselves would be validated.

John Blair – Taconic IPA

Right, so right now it's not really determined whether the accreditation and certification would be separate or that's not clear yet, right?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes, that's actually an area that they want input on.

John Blair – Taconic IPA

Right. Are you asking for input on that now or do you want just to answer the question?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

If we could go to finishing this question because we're actually going to get to that very soon.

John Blair – Taconic IPA

Okay, so my view is, it is appropriate for ONC to be doing this.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, is there anything John or Laura, Jan or others that you see on the webinar here, there are six proposed rules, are there any roles that you see here that may be more appropriate to either be led by another entity outside of ONC or co-lead or somehow managed?

John Blair – Taconic IPA

I mean, I would say number five, but, you know, I don't feel strongly about that.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yeah, I would agree with number five. I wonder a bit about number four as well, the authorization I think needs to be separate from the oversight and the processes of oversight I think are within the realm of ONC but the actual going through the process of doing the overseeing might be something that could be done outside of ONC as long as the process is established and those doing the overseeing are following a prescribed protocol for that.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So, it's almost as if, if I get your meaning, I think this is what you're saying is that the overseeing sort of the NVEs on a day-to-day basis could be overseen by another body like a private entity but it is a creation of sort of the process itself ONC would retain.

Laura Adams – President & CEO - Rhode Island Quality Institute

That's right and those private entities might be operating within a very prescribed framework for doing that actual oversight.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay.

John Blair – Taconic IPA

You know, I didn't read any of this as actually day-to-day oversight by ONC, where was that?

Laura Adams – President & CEO - Rhode Island Quality Institute

Oh, that's just authorizing and overseeing validation bodies, number four.

John Blair – Taconic IPA

Okay, okay.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yeah, and then it's overseeing validation bodies responsible for validating that eligible entities have met adopted CTEs, so I think what we're just saying here is that the day to day management and oversight of those CTEs once they've been validated would really fall likely to another entity, to a private entity.

John Blair – Taconic IPA

Right, right.

Laura Adams – President & CEO - Rhode Island Quality Institute

Right.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, all right, I think we have successfully...before I move on, any other comments on this question? Excellent, we have successfully completed question eight. Let's talk about question nine; this is in two parts essentially. First would a voluntary validation process be effective for ensuring that entities engaged in facilitating electronic exchange continue to comply with adopted CTEs and then the second part is what other validation processes could be leveraged for validating conformance with adopted CTEs?

Laura Adams – President & CEO - Rhode Island Quality Institute

This is Laura, just a clarification question here. When we're talking about voluntary validation we don't mean I might decide to validate, I might not, we mean everybody here must validate and I'm a little confused about voluntary validation, voluntary seems to imply that you can opt out of validating, but I don't think that's the intent here, is that correct?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

That's my interpretation is that you are not being coerced into participating and to be validating, but if you want to participate then you would have to.

Jan Root – Utah Health Information Network

That's a good clarification, because I noted that, this is Jan, I noted that when I was reading this too, I'm like what does this mean it's voluntary, but if you're going to participate in this its mandatory.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

This is Mary Jo and just to...not to put too fine a point on it, no one needs to submit to governance, but if they choose to then they must undergo validation.

Laura Adams – President & CEO - Rhode Island Quality Institute

So, I think that statement is confusing to put voluntary in front of validation. I think what we're talking about here is more along the lines of self validation versus I mean, I think we're talking about them performing activities that would validate their own performance versus volunteering or not, because if you're in, you're in and then we're now talking about a self validation process, is that correct?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

This is Mary Jo again, I think the gist of this question perhaps is back to the very initial concept of should there be a voluntary governance mechanism. I think they would welcome your feedback on that and we'll get to validation then secondarily, because I think I hear the direction you're going with your decision, but I think that higher-level question is really should governance be voluntary? Is there any aspect of these activities that should be mandatory?

John Blair – Taconic IPA

It should be mandatory if you're a validated entity?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

No, I think before we even get to that point. I think it's the question of we are setting up governance as a voluntary approach.

John Blair – Taconic IPA

Well, if they're not going to be a validated entity how would you have any say over it?

Jan Root – Utah Health Information Network

Yeah, you've lost me, Mary Jo. I don't understand what you mean by what you're saying.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Okay, well then if I've only muddled the waters then I'll certainly just step back and let you carry on, that's okay.

Jan Root – Utah Health Information Network

Well, just like are you asking the question of should there be a governing body over this exchange, is that your question?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

I think the question could be is, should entities who wish to exchange information be required to participate and submit to validation.

Jan Root – Utah Health Information Network

Yeah, those are two separate questions.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Exactly.

Jan Root – Utah Health Information Network

And I don't know, if everybody is required to participate in the governance you're going to get this huge body and I don't know how effective that could be, but I would say that they must participate in the validation process. So, I think those are two separate questions.

Laura Adams – President & CEO - Rhode Island Quality Institute

By participation, Mary Jo, do you mean allow themselves to be governed?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Yes, yes, yes, in other words should it be required that any entity that seeks to exchange information should submit to governance? Not participate in the activities and the management of the governance process, but should they be required to submit to governance?

Jan Root – Utah Health Information Network

So, for example the DURSA right now says that you will follow the rules set up by the governance.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

That's right. So, in other words if it's a totally voluntary governance structure than there could be many key entities who choose not to participate in...not to submit to governance and not to seek validation.

Jan Root – Utah Health Information Network

I think you're going to have total chaos.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Well that would be...I think that is...

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

I mean this is the status quo, isn't it? I mean, this is basically what we have to do.

Jan Root – Utah Health Information Network

Well, it's worse than the status quo, Jonah, because, you know, like when I hook up with clearinghouses to do claims we all have rules. I mean, there are rules when you exchange data and you agree to comply with HIPAA and you agree to...I mean and there's liability, I mean, I'm not sure I would want to...I mean, what I'm going to end up with is thousands of versions of the DURSA, what a mess.

Laura Adams – President & CEO - Rhode Island Quality Institute

The truth of the matter is that is probably going on in spades right now.

Jan Root – Utah Health Information Network

Yes.

Laura Adams – President & CEO - Rhode Island Quality Institute

People are exchanging all kinds of data using varying degrees, wildly varying degrees of sophistication around their validation processes and their governance processes.

Jan Root – Utah Health Information Network

Yes.

Laura Adams – President & CEO - Rhode Island Quality Institute

So, we kind of have that now so the question might be, do we ever have a hope of what compliance mechanism would we have if we were going to make something mandatory? So, is this more like a stamp of approval meaning I'm more likely to do business with you if I understand that you voluntarily submitted to governance, I might be more worried if I find that you haven't...I not sure how we would enforce that.

John Blair – Taconic IPA

Yeah, I'm not sure we're talking about what's on this, on 9A, because they're talking about to comply with adopted CTEs. So, they're talking about validated entities here. So, they're already in that piece I think, right?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

No, this is pre...this is should they submit to validation.

John Blair – Taconic IPA

Yeah, but should they do...would it be voluntary validation process be effective for ensuring that entities engage in facilitating electronic exchange comply with CTEs, those that are compliant with CTEs would be that falls under validated entities. I mean, there is a doctor doing a lab order out of the EHR is not going to be doing a CTE.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So, why don't we take this, because this is very challenging, why don't we take this...why don't we take an example here. One example may be that you have two entities; you have a hospital and a provider organization and in order to...and in some sort of a NwHIN governance structure being proposed there are a set of CTEs and let's say that there is a voluntary process for validation and that the hospital has submitted to this voluntary governance process and the provider organization has not.

John Blair – Taconic IPA

Right.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

And they want to exchange data, should that be allowed to happen?

John Blair – Taconic IPA

Yeah, I think that is the question. So, it wasn't everything out there on electronic exchange, it was electronic exchange where the CTE would be applicable and I think your example is right and I would say that this would not be...a voluntary validation would not be good enough.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yeah.

Jan Root – Utah Health Information Network

Yes, I would agree.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Does anyone disagree with the analogy I just made because I think that's kind of where we need to go, but I want to make sure that others agree?

John Blair – Taconic IPA

No, I think you're right; I think that analogy was...that example was correct.

Laura Adams – President & CEO - Rhode Island Quality Institute

I thought it was very helpful.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So, if we're saying a voluntary process is not sufficient, are we then suggesting that it needs to be some sort of...in order to participate in the Nationwide Health Information Network Exchange activity there needs to be mandatory validation, that's what we're saying.

John Blair – Taconic IPA

Yes.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yeah.

Jan Root – Utah Health Information Network

Yeah.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

And the rationale is that we have...without it you have...

John Blair – Taconic IPA

Well, I think, I mean, this is about trust and I think that it degenerates or deteriorates at that level. I think you just need to have a higher-level.

Jan Root – Utah Health Information Network

Well, it's also about cost, you know, if everybody does a different CCD and I have to write to 500 different CCDs, that's nuts. The cost gets crazy. So, if we have standards that are fairly, fairly, I mean there has to be some flexibility obviously, but if there a fair amount of rigidity in the testing and the implementation and the fact that these entities are certified to comply with HIPAA or accredited or whatever term you want to use, so I have some trust, yes, trust, but also cost.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes.

Jan Root – Utah Health Information Network

I mean, that's what HIPAA was all about, you know, so we're not all supporting 800 versions of the

CCD.

John Blair – Taconic IPA

Yeah, I'm seeing this more on the trust side and the private security side and I'm thinking more about users at the edge and authentication and registration authorities and stuff and having different standards and voluntarily saying you're doing it, I think that's a problem.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yeah.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yes.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, so in terms of the second question, whether validation processes could be leveraged for validating conformance with adopted CTEs, I think the question here is are there other validation processes, we're talking non-voluntary.

John Blair – Taconic IPA

Right.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

And I think this leads into the next question that there is some sort of a certification or accreditation of these entities conformance with CTEs.

John Blair – Taconic IPA

Right.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

I think we all agree that that's appropriate.

John Blair – Taconic IPA

Yes.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yes.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

From the conversation we just had.

Jan Root – Utah Health Information Network

Yes.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, so I think we just answered 9B. Did you get that Mary Jo?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

No, actually you lost me there.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Oh, so 9B is what other validation processes could be leveraged?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Right.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

And, I think what the group suggested is that the other validation processes would be...the validation process would be non-voluntary and it could be a combination of certification, accreditation or other that we'll get to in the next question, which is exactly the next question, but there needs to be some process to validate conformance to CTEs by participating entities by these entities.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Good.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Non-voluntary.

Jan Root – Utah Health Information Network

Yeah, so Jonah, does that include...I'm just trying to understand here, does that include Mary Jo's question about conformance with, you know, agreeing to conform to being governed by somebody who is setting these rules?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Some body? I would think that it would have to and I don't know that...I mean, how can you...if...

Jan Root – Utah Health Information Network

Yeah, that's what I thought; I just...Mary Jo teased that out and I thought that was a good question, because I'm not a social scientist major.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Well, I mean actually this brings up an interesting point about whether there is just simply a self-policing mechanism.

Jan Root – Utah Health Information Network

Oh, no.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yeah, and so why don't we just very quickly take a poll, is there a sense from the group that a self-policing mechanism is in any way more advantageous or better than having some sort of a body and might be ONCs, you know, as the arbiter, some sort of body that is overseeing governance. Is the silence I'm hearing suggestions that self-policing will not be an effective mechanism here?

Laura Adams – President & CEO - Rhode Island Quality Institute

That's my sense.

Jan Root – Utah Health Information Network

Yeah, I would find it very ineffective.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, all right, good then let's move on.

Jan Root – Utah Health Information Network

Basically the 800 pound gorilla rules when you self-police.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes, okay, all right let's move on then, because we have a few more to get through today. We've listed the Conditions for Trusted Exchange here and again there are these three domains, I don't think we should walk through them all but I want to pull a couple of examples just to give you a sense of what we're talking about, so one is around safeguards and safeguards are really around things like privacy and security, but just to give you an example, a validated entity must only facilitate electronic health information exchange, I mean it has to, for parties it is authenticated and authorized either directly or indirectly.

Number four, a validated entity must only exchange encrypted information, health information, identifiable health information, and there are others. Let's see of another one, here an NVE must have means to verify that a provider requesting an individual's health information through a query and response model has or is in the process of establishing a treatment relationship with that individual, okay?

Jan Root – Utah Health Information Network

That one is...

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

That one is interesting isn't it?

Jan Root – Utah Health Information Network

That one is really hard. I mean, it's a great idea, but oh my gosh, it's pretty tough to actually do.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes, let's move on and lets, Jan if you could keep a note on that because we will be asking about these individual conditions.

Jan Root – Utah Health Information Network

Yes.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So, let's note that when we get back to that question. Then there is the interoperability domain, let me just take one here, interoperability one, Conditions for Trusted Exchange is that an NVE must be able to facilitate secure electronic information exchange in two circumstances, one when the sender and receiver are known and two when the exchange occurs at the patient's direction. Okay, so that's patient mediated exchange.

And then, third are the business practices, CTEs and there are three that were listed and the three you can read here, the second here that I'm reading, an NVE must provide open access to the directory services it provides to enable planned electronic exchange. So, it must basically expose its directory to other NVEs that can then use it to search for, you know, a digital certificate or a directory of certificates or if providers have certificates for example.

Jan Root – Utah Health Information Network

Hey, Jonah, can you go back one slide? I didn't quite finish reading the slide before this one.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

I'm sorry, this one?

Jan Root – Utah Health Information Network

Yeah, that one. Ability to verify and match the subject of a message including the ability to locate a potential source of information available for a specific subject. I don't understand I-3 at all. I'm sorry. I don't know what that means when it is held.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yeah, it is a little convoluted. Okay, I'm going to move on.

Jan Root – Utah Health Information Network

Sure.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

That one is a little strange and we might need to get back to that. So, question 10, there are two parts again, first part is should the validation method vary by CTE and then just again, the examples that they pull in the RFI of validation methods are self-attestation, laboratory testing for conformance, certification and accreditation and I don't think this is necessarily the universe, but these are the four methods they mention. So, one should the validation method vary by CTE and two, which method would be most effective for ensuring compliance with CTEs. And, Mary Jo this kind of goes back to your clarification earlier around certification for standards and accreditation for policies.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Right.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

I think the question for us is do we sort of want to...do we suggest to apply sort of that model which is I think broadly the model we're using for the EHR process, do we want to apply it here?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Well, with the added domains if the EHR process is purely certification of technology, it does not seek to validate any policies or processes.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

And, so one of the ways you might approach this since you've seen the three categories is ask yourself, it might be your first a priori decision since it may be the most straightforward is which are the technologically oriented CTEs, obviously the interoperability ones, but, you know, there could be some others that you think are squarely in the certification camp and then if you want to make comments about whether you think it should be self-attestation or laboratory testing that you could do that and then secondly, you could say, okay for everything else that's more policy or process do we think that it should have accreditation and if so should it have, you know, attestation, is that enough, should it have a full accreditation which obviously can sometimes include the submission of different documents and even site visits there is a variety of degrees of strengths of accreditation itself and to get your feel for how those conditions would fall into those buckets.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes.

Jan Root – Utah Health Information Network

Can I ask one quick question, this is Jan, was there a reason why this laboratory testing for conformance with pulled out as opposed to all the other...kinds of messages that one can exchange?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

No, no I think they're trying to provide people with a sense that we appreciate that there is a range.

Jan Root – Utah Health Information Network

Okay. I was just wondering does that translate into message testing for conformance? Is that what...?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

It could.

Jan Root – Utah Health Information Network

What is trying to be suggested here? I just...

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

It certainly would include that, right.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yeah, I think it could.

Jan Root – Utah Health Information Network

Okay.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So, let's start with the first one, does the group believe that there should be different methods for CTE, so if you look at for example safeguards around things like protected health information. Are some of these more conducive to an accreditation process?

John Blair – Taconic IPA

I think the answer is yes.

Jan Root – Utah Health Information Network

Yeah, I would agree. When you're looking at compliance around safeguards I'm assuming that that, sort of anyway, translates into HIPAA and HITECH and do you have and follow the appropriate policies and procedures, all your logs, all your, you know, monitoring of sites and blah, blah, blah, blah that you do to comply with HIPAA and sort of, you know, HIPAA is not the be all and end all sort of best industry practices.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yeah.

John Blair – Taconic IPA

Yeah, I mean, you run the range here from standards and messaging specs, etcetera that do need to be certified and tested, you know, NIST test or whatever to policies that could be handled with attestation and going further with site visits or audits or whatever. So, I think this is much broader than just an EHR certification, but it has some of those kind of components. So I think the answer is yes there is going to be different approaches and various levels of intensity depending on which aspect of this, particularly as these progress because these CTEs I kind of see as steps up to a higher level and some are retired and other more stringent come into play there is going to need to be different approaches.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yes, I agree.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes. Okay.

Jan Root – Utah Health Information Network

Yeah, I think as far as the like the security and privacy compliance piece goes though is that kind of, more or less a single package deal. We spent 10 years here trying to figure out if there is a way you could persuade small providers, right to comply with HIPAA and just comply with a piece of it rather than the whole 9 yards and we haven't figured it out, it doesn't mean there isn't an answer, but, you know, if you're

going to comply with HIPAA then you have to comply with HIPAA it doesn't matter if you're a one doctor shop or you're Kaiser Permanente.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yeah, so you must comply with all.

Jan Root – Utah Health Information Network

Yeah, I mean, part of it is scalable, but the requirements, you know, the list of things you need to do, that is not scalable.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes, okay, so what I heard is that the standards and implementation guides, the technical issues or conditions should be...we're recommending that they should fall under a certification process, a technology certification process that they conform to the CTEs, but for all others that are non sort of technology related and let's just give an example of this business process for example, or maybe it's actually back into the first one, for safeguards that there is either an accreditation or a self-attestation process.

John Blair – Taconic IPA

Sure, yeah, I mean do your CAs have to be federal bridged that kind of thing, you attest and, you know, that kind of...

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

And would a self-attestation...does anyone have a preference or a suggestion about self-attestation over an accreditation process? Accreditation can be, you know, it can be very extensive and costly or an accreditation process is designed specifically for this, it could be lighter, but...

John Blair – Taconic IPA

I think it will evolve, it depends, I mean early days on the CTEs probably not necessarily, but as this evolves and particularly if there is a coalescence of these NVEs and they get larger and larger you may be able to impose a higher standard and you may be able to move from accreditation to, I mean from self-attestation to accreditation.

Jan Root – Utah Health Information Network

Well you might also be able to accept, like if you're a hospital and you've been through Joint Commission, guess what you do HIPAA, so, you know, if you're a clearinghouse and you do eNet, you know, if you're accredited that way, if you're a payer and you're accredited by NAAC, you know, all of those entities will all have a HIPAA component to them, that's very stringent. So, it might be also an option might be to accept the accreditation of some other entity.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yes.

Jan Root – Utah Health Information Network

Rather than forcing people to do the same thing twice.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay. Any other questions on this because I think we have our answer and I like John the suggestion about sort of this progression from a self-attestation to an accreditation model over time so this evolutionary process I think is important.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yeah, especially keeping in mind and balancing that, you know, this whole thing is only as solid as its weakest link in the sense that, you know, just that whole idea...I mean think of it sometimes as sort of like airport security or something, you know, there are so many standards.

Jan Root – Utah Health Information Network

We just had a huge breach here Utah Medicaid 800,000 records, I'll tell you we're into trust and it's a big, big topic.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay.

Jan Root – Utah Health Information Network

Yeah, it wasn't trivial.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Must avoid the weakest link, I like that.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Could I ask just to verify, first I heard that you thought that under the general rubric of accreditation self-attestation could be the preferred approach early on but now I'm hearing a little bit of more fine tuning there. So, do you or do you not wish to say that at the beginning self-attestation is fine for everything that's not certification or do you want to make some gradations within that?

John Blair – Taconic IPA

I think you have to see how these CTEs play out. I think, what I was saying is as this moves along it'll be easier to raise the bar, but it depends on what some of these CTEs are, some of them may need to have something more robust than just self-attestation.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yeah, this is Laura, I think part of the issue here and where the comparison to HIPAA falls apart is that there are really stiff legal penalties with HIPAA, there are no stiff legal penalties associated with this except for obvious, you know, those things that would fall under HIPAA, but a breach of a CTE for example that doesn't have the same corollary in HIPAA or doesn't follow or align with that wouldn't have the same sort of a penalty. So, that is where my hesitation comes in on really sort of loosey goosey kind of voluntary self...that's where I worry about it.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So, is there a principle that we can specify here about where...and maybe instead of getting specific and getting into every one of the CTEs, because that would probably take us too long, but is there a principle that we can state where we may recommend a more formal accreditation non-self-attestation process or some sort of validation process?

John Blair – Taconic IPA

Well, I think you have to have some kind of feasibility lens with what the market can consume.

Laura Adams – President & CEO - Rhode Island Quality Institute

Right.

John Blair – Taconic IPA

On the other hand if you're too light you will...you'll undermine the trust too much for this to ultimately get off the ground with patients, etcetera.

Laura Adams – President & CEO - Rhode Island Quality Institute

Well and with legal counsel within a large organization.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, so in this case, for example, and I think Laura you were sort of suggesting this, but I may have misinterpreted, but if we're talking about areas of legal implication for breaches that may violate state or federal law then in that case we may want to suggest something that is more rigid than a self-attestation. Do we go that far?

Laura Adams – President & CEO - Rhode Island Quality Institute

You know, Jonah, you just raised a really interesting point that...answer your first question then I got another comment. Can you say that again Jonah, just to be sure?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Well, so, you know, I'm responding to the issue that you brought up about feeling concerned about us being wary of being too loose with our recommendations or we said that there is no...other than a self-attestation process, there may be some real concerns about a validated entity's ability to protect information and that we may want to suggest that there is a principle by which if there are CTEs that potentially if broken have real legal implications, legal implications like violations of HIPAA, then do we want to suggest that a validation process is more than just self-attestation to try to avoid what Jan is experiencing in Utah or just made reference to.

Laura Adams – President & CEO - Rhode Island Quality Institute

Well, that's actually maybe the flip of what I was suggesting. I was suggesting that people are less likely to violate those things that align with stiff penalties than they would be with something for which they see no consequences necessarily so they are not a significant legal consequence. So, I was more worried about those that don't have some sort of deterrent connected to them rather than those that do have the deterrent.

John Blair – Taconic IPA

Well, but the NVEs are going to be covered entities or treated as covered entities so HIPAA will apply and the force of law will apply already.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yes.

Jan Root – Utah Health Information Network

Yes, that's right, that's right. So we don't have to reproduce HIPAA. The penalties are already in place.

Laura Adams – President & CEO - Rhode Island Quality Institute

Yeah, so I guess that's what begs the question then do we do lesser validation on those types of things that are already covered or have a relationship with HIPAA than we do with the things that don't have such a connection?

Jan Root – Utah Health Information Network

Like operating rules you mean?

Laura Adams – President & CEO - Rhode Island Quality Institute

Exactly.

Jan Root – Utah Health Information Network

Yes. I think there needs to be something beyond self-attestation as far as HIPAA compliance goes, because I can tell you if that doesn't work, we've been through that, but in terms of like operating rules, those are things that the NwHIN governance whatever could actually create those rules kind of like, again

what's going on with admin side with core and such and all those operating rules that coming into play and there is some piece in those kinds of rules because there can be a body that could turn you off of the network if you don't comply with the operating rules.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes, okay.

Laura Adams – President & CEO - Rhode Island Quality Institute

Right, right.

Jan Root – Utah Health Information Network

So, not necessarily a monetary fine or legal fine, but an operational fine in a sense that you no longer have access to the network.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Can I make just a point clarification here though for the record that this is not a separate network. So there is no such thing as taking them off the network, it would simply be to remove their recognition, you know, their seal of approval, their...status.

Jan Root – Utah Health Information Network

Well, you know, Mary Jo, that raises an interesting thing...food for thought is perhaps in the future, you know, ONC could think about some kind of liability relief or something, so if you are a member of the network, not a physical network but of its governing body, maybe that a better way to say it, is that you have some kind of protection against certain kinds of things and I have no idea what that would be, but that would imply, that would give people a reason to want to comply with the rules. It's not necessarily a stick; it's more like a carrot.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yeah, you know, I know we're at the hour and we need to give at least a moment for public comment, but I think what I heard is that for those areas and I think this maybe a principle that we can propose is that for those areas where there is not a formal deterrent like HIPAA and penalties imposed by them that there may need to be a more rigorous validation process than self-attestation and I think that sounds like a general rule that can be applied so that we're not hamstrung if the CTEs change over time. Does that sound appropriate?

Laura Adams – President & CEO - Rhode Island Quality Institute

That is sort of where I was going with it.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, and Laura, does that make sense?

Laura Adams – President & CEO - Rhode Island Quality Institute

That was me.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Oh, that was you, okay, great. All right, so I'm going to stop us now and I guess turn it back you Mary Jo for public comment.

Public Comment

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Yes and thank you very much for a very good call. Operator, would you open the lines, please?

Caitlin Collins – Altarum Institute

Yes. If you are on the phone and would like to make a public comment please press *1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. We do not have any comments at this time.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Terrific, well thanks everybody, appreciate you making the time. We have another meeting, Mary Jo?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

I was just looking for it, I don't think it is this week somehow, but I will look. MacKenzie are you on the line, do you know when the next governance group 2 call is? I thought I had it, but...

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Maybe next Tuesday or is that our community governance committee meeting?

W

Our governance committee meeting is on the 21st Monday at 10:00 o'clock.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Right, but then there is another...but you have at least...you have two more one hour calls mapped out but I think they're both after the 21st Jonah is my recollection, but I will find that and I will send it out to you.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, terrific. Thanks everybody.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Thank you.

John Blair – Taconic IPA

Great, nice job, Jonah.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Thanks.

W

Yes, good job Jonah.