

# Governance Workgroup Transcript May 21, 2012

## Presentation

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

Thank you very much operator. Good morning, this is Mary Jo Deering in the Office of the National Coordinator for Health Information Technology and this is a meeting of the HIT Policy Committee's Governance Workgroup. It is a public meeting, a public call and there will be an opportunity at the end for the public to make comments. So, I'll begin by taking the roll. John Lumpkin?

### **John Lumpkin – Robert Wood Johnson Foundation**

I'm 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**

Laura Bailyn? John Blair? Neil Calman? Tim Cromwell? Doug Gentile? 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**

Leslie Harris or Kate Black for Leslie? No? John Houston? Arien Malec?

### **Arien Malec – RelayHealth Clinical Solutions**

I'm here.

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

Mike Matthews?

### **Michael Matthews – CEO – MedVA**

I'm here.

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

John Mattison? Wes Rishel?

### **Wes Rishel – Gartner, Incorporated**

Here.

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

Jan Root? Judy Warren?

**Judith Warren, PhD, RN – University of Kansas Nursing School**

Here.

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

Okay, over to you John.

**John Lumpkin – Robert Wood Johnson Foundation**

Great.

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

Let me just ask staff who are on the line.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay.

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

I do apologize, if staff who are on the line would introduce themselves.

**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, I guess that's it, my apologies.

**John Lumpkin – Robert Wood Johnson Foundation**

Great, so basically what we're doing here today is that we have a very short timeline until the meeting on the 6<sup>th</sup> of the HITPC is that right?

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

That's correct.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay and so we have a meeting today to just sort of check in to see where the Workgroups are, whether there are issues with any of the directions that the Workgroups are going in and then we're going to follow up with another meeting on the 4<sup>th</sup> I believe of June?

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

That's correct.

**John Lumpkin – Robert Wood Johnson Foundation**

And that's when we decide what we're going to be presenting to the HITPC on the 6<sup>th</sup>. So, that's really our agenda to start off with a presentation and we'll go through the Workgroups to see what the status is.

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

Okay Arien, I think you're first.

**Arien Malec – RelayHealth Clinical Solutions**

Excellent, so we walked through all of our 10 questions in the space of a couple of hours. Our 10 questions really dealt with the why of the Governance Workgroup, a set of questions dealing with justification for nationwide governance as well as the structure of governance and then a set of issues at the end so we dealt with the first 7 and the last 3 I believe questions in the RFI, the last 3 dealing with the lifecycle for CTEs, they kind of clustered nicely with the first 7. So, I guess if we can go onto the next slide? Do we have all the...Mary Jo, do we have all those questions?

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

Yeah, Caitlin, can you put up the text that says...

**Caitlin Collins – Altarum Institute**

The Word Document?

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

The Word Document that says Subgroup #1.

**Caitlin Collins – Altarum Institute**

Okay.

**Arien Malec – RelayHealth Clinical Solutions**

All right, so what we did was we took our questions a little bit out of order. We felt that question 3 raised the substantial issues relating to the need and justification for governance and so answering that question helped us answer the rest of the questions I think quite nicely. So, we dealt with question 3 first and what we found was that there actually were a number of efforts that could be called nationwide governance and in fact no lack of governance across the country. So, we didn't see a need for nationwide governance in the sense that there was not adequate governance currently occurring. We didn't find any evidence that there had been significant or egregious efforts that were undertaken because of the lack of nationwide governance and although we didn't discuss this, I was reflecting that the existence of HIPAA helps make sure that bad actors are kept reasonably well in check.

What we did find though is that and I'm sorry at the nationwide level we pointed to obviously the NwHIN exchange but also the CCC, the direct trust work and of course the work from organizations like the Markle Foundation to create policy frameworks for nationwide exchange. What we did find however was in some sense all too much governance, that is that every regional and statewide organization tends to recreate governance as one of its first acts of being and that the kind of private commercial level organizations end up rehashing questions that again are quite predictable and occur in the same form in repeated areas.

There is also a substantial cost to organization to organization forms of exchange, that is if I've got one organization that is providing local or regional exchange and then I need to connect that organization to another organization that is doing the same thing you often find each organization separately contracting with each other organization and again there is a substantial amount of cost associated with that. So, we pointed to the major benefit of nationwide governance as reducing the total cost and complexity out of overall governance and making forms of exchange that are explicitly nationwide, for example Direct, making them more feasible at a nationwide level.

So, again the main purpose of governance in this frame is to reduce the cost of governance and to reduce the cost and complexity of organization to organization issues and that really calls for a governance framework that is lightweight and where the major benefit of governance is the federal government's unique ability to convene and coordinate across multiple stakeholders and basically create

a space for dialog and deliberation and create a space for settling some of the frequently resettled and rehashed questions in one place.

Importantly, that governance framework shouldn't limit the opportunity for innovation in the market particularly in the areas of the interoperability CTEs that is it would be a bad outcome for governance if it froze the kinds of interoperability that were allowed at a nationwide level. So, I'll stop there and see if there are questions. This is really a pretty meaty area and meaty question and the answer and the way that we answer this question really informed the way that we answered the other questions.

**Wes Rishel – Gartner, Incorporated**

This is Wes Rishel, you talk about effectively two conflicting virtues there, one is standard interchange and the other is innovation, how did you reconcile those?

**Arien Malec – RelayHealth Clinical Solutions**

So, actually this is a little bit later down in the document. We noted that the policy level of things that want to happen and particularly the policy level of things that want to happen in information exchange tends to evolve only slowly and that the actual certification criterion and standards that are associated with the certification criteria tend often to move very quickly or in context much more quickly. We didn't note, although again I've been reflecting on this over the weekend, that the accreditation related areas, and again we get into this in the next cluster of questions, tend to be much more broadly applicable than the interoperability CTEs. So, you can imagine that there is broad applicability for some of the accreditation related issues even if there is innovation in the interoperability space. And again, we get at this in the second cluster of questions.

**Wes Rishel – Gartner, Incorporated**

Okay, I'll come back and ask then.

**Arien Malec – RelayHealth Clinical Solutions**

All right.

**Michael Matthews – CEO – MedVA**

Arien?

**Arien Malec – RelayHealth Clinical Solutions**

Yes?

**Michael Matthews – CEO – MedVA**

This is Michael Matthews. Thank you for all of this good hard work and giving us something to react to. In that paragraph you mention leveraging the federal government's coordination function and convening role that seems central to your thoughts and response to the various questions. Did you discuss in any kind of detail what the federal government's coordination function and convening role is on a go forward basis? And what was that defined as?

**Arien Malec – RelayHealth Clinical Solutions**

We did and we actually get to that later in the questions. In particular we pointed out the existing FACA framework as providing a workable and good means for collecting broad public input.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay, let's move...

**Arien Malec – RelayHealth Clinical Solutions**

All right.

**John Lumpkin – Robert Wood Johnson Foundation**

You know, just before you go, because this really is sort of the crux and I think the crux of much of what our comments are going to build on this, so just want to double check there are no further comments on 3? Okay, let's move onto one.

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

This is Mary Jo; can I just ask a process question? What I think I'm hearing, John is that as we go through these, to the extent that we can get finality on these we're done with them, is that correct? And we won't necessarily go back and revisit them unless there are issues that the groups are asked to go back and address, but otherwise we'll keep those behind us and keep going next time?

**John Lumpkin – Robert Wood Johnson Foundation**

Correct, you know, to fit the work in, that doesn't mean that if something goes by and then something later comes up someone can't pull something off of what we've agreed on, but we won't come back and revisit them unless that's done.

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

Great, thanks.

**Arien Malec – RelayHealth Clinical Solutions**

Thank you, so we next looked at the categories of governance, the three categories that were proposed were safeguards, interoperability and help me here, the last category was?

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

Business practices?

**Arien Malec – RelayHealth Clinical Solutions**

Business practices, thank you. What we found in our comments were that the categories were appropriate but that consistently across the RFI there was a missing level of CTEs and what I mean by that is this was particularly obvious in the interoperability CTEs but was also applicable to the certification related or accreditation related CTEs. What we found in the RFI were a set of CTEs that were at vastly different levels ranging from policy outcomes and desiderata all the way down to specific certification or accreditation criteria.

And what we've proposed is that the CTEs should first be expressed at the level of a policy outcome or policy goal and then be mapped to specific accreditation or certification criteria and in particular for interoperability CTEs should also be mapped to specific implementation guidance and standards in much the same way that the Policy Committee recommends areas of clinical outcome for Meaningful Use and then the Standards Committee maps those policy goals to enabling standards and implementation specifications or guidance and certification criteria.

So, we gave one example here related to the Direct Project. We also noted and discussed that the Markle Foundation created a policy framework for record locator services, those would be the kinds of things in the interoperability CTEs that would be identified at the policy level and then they would be mapped to specific standards and implementation guidance and those would be turned into specific certification criteria and we felt this approach would help make the CTEs much more robust, that is that the policy requirements for a record locator service tend not to change rapidly over time, because the basic business need and policy need for a record locator service is a generalized need whereas the implementation guidance might actually change quite rapidly.

We also found that although the RFI in what I've now mentally referred to as the famous footnote 26 on page 23, but it may be famous only to myself, the RFI defines the term validation and under a broad way and we felt that actually being explicit in terms of accreditation and certification criteria that are linked to policy goals or linked to policy level CTEs would be a much less confusing way of describing the role of

accreditation and certification in regard to the RFI and again the split in levels helps address the brittleness of an RFI or of a rulemaking structure and then the associated rule for certification.

And with response to Wes's question, although we didn't discuss this at the Workgroup, as I said I note that the safeguards and business practices tend to be more broadly applicable and interoperability CTEs tend to be applicable to specific interoperability use cases. And so the split in levels would also make it, I think, a little more obvious which CTEs are broadly applicable and which CTEs are much more modular in scope and to answer Wes's question I don't believe that the governance mechanism should seek to lock down all of the interoperability CTEs, but seek to at least standardize those that have been...for which there is an overriding policy goal. I'll pause there.

**Wes Rishel – Gartner, Incorporated**

This is Wes. I clearly, you know, agree with what you're saying, I'm just trying to think through it to see if it goes far enough. We have had in the past an interlocking set of standards that purported to achieve very tight interoperability for very specific use cases but really offered no ability for two academic medical centers for example to modify what they were doing in order to account for proteomic results or didn't allow for a state that has a particular business case around tribes that use federal funding a little differently than other tribes to create a place where some use of a...communication...specific business case can be tried before it becomes the law of the land, if you will, and my concern is to see that the governance follows the principles that you and I both agree on which are that there are principles that apply to virtually all communications and principles such as the mechanics of how we communicate trust and the mechanics of how we identify trustful entities. And there are those that apply to broad swaps of communications and there are those that are more narrow and that there is a place for all of them in the governance processes associated with this RFI.

**Arien Malec – RelayHealth Clinical Solutions**

So, it occurs to me, Wes, you're raising a really excellent point and obviously we discussed this point of a bunch. It occurs to me that what we should do as the group 1 group is go back, probably via e-mail and formulate some language that we'll then review back with the full Workgroup and Wes, if you don't mind I'll include you in that e-mail chain to make sure that we're crafting language that gets at this point, the point being that the business practices and safeguard CTEs have broad applicability whereas interoperability CTEs ought and should be much more modular and focused in scope.

**Wes Rishel – Gartner, Incorporated**

Yeah, I think that's really important. Probably define some...to set up my soapbox and talk about my other issue too.

**Arien Malec – RelayHealth Clinical Solutions**

And, then I think we addressed the lifecycle issues much more explicitly.

**Wes Rishel – Gartner, Incorporated**

All right. Okay, good. Thank you.

**Arien Malec – RelayHealth Clinical Solutions**

All right, so should we go onto the second cluster or the third cluster?

**John Lumpkin – Robert Wood Johnson Foundation**

It sounds like "yes" unless there are other comments.

**Arien Malec – RelayHealth Clinical Solutions**

All right.

**John Lumpkin – Robert Wood Johnson Foundation**

Forge ahead.

**Arien Malec – RelayHealth Clinical Solutions**

The third cluster really deals with the form of governance and we noted here and there's a whole set of questions relating to the proposed voluntary nature of governance to more general questions as to what form of governance should be undertaken and again, here we pointed back to the answer to our first question, which is question number 3, given that the primary benefit of governance is to reduce the total cost of governance nationwide but that we didn't find that there had been a preponderance of bad actors who were ungoverned.

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

Excuse me Arien, could I just ask a quick question for one minute? I think that we're on the wrong text on-line. I think you're on 2 perhaps?

**Arien Malec – RelayHealth Clinical Solutions**

Yeah, I'm on 2, 4 and 7.

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

There you go.

**Arien Malec – RelayHealth Clinical Solutions**

Yes, that's right.

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

No, that's the answer, if you just scroll up a bit please, there you go, there you can see the question.

**Arien Malec – RelayHealth Clinical Solutions**

Those are the questions. We addressed 3 questions relating to what kind of governance approach would a voluntary governance approach or voluntary validation approach achieve the goal and what other approaches should be considered? Again, back to our answer to question 3, where the main benefit of governance is to reduce the total cost of governance nationwide in particular by addressing questions, so that they can be addressed once and for all, as well as by reducing the cost of exchange to exchange forms of governance.

We first outlined and I thank Stefaan for bringing up this point, we first outlined the need for success criteria for governance and we noted a number of success criteria that were mapped back to our answer to question 3, first of all the cost effective nature of the governance, the participative and nature of governance, the outcome of the governance being accepted by a broad range of stakeholders and the note that governance be flexible and allow for change in the market, and finally that it helps states fulfill their local governance to their citizens without having to recreate governance. And again, all of those success criteria get mapped back to the justification for governance in the first place in our response to question 3. If you go down just a little bit more.

We did believe that a voluntary approach would be sufficient. The success of that voluntary approach of course would be predicated on the actual utility of governance related to the success criteria. We also noted that that federal government has a wide range of tools at its power and then more broadly again if the governance mechanisms are in fact useful we would expect that many private organizations would include those criteria and the need for certification or accreditation in their RFIs and RFPs and other kinds of mechanisms, contractual mechanisms and that that would be again sufficient in the private market for driving use of the governance mechanisms. So, I'll pause there.

**Laura Adams – President & CEO - Rhode Island Quality Institute**

Hi, it's Laura, you may have said this when you were describing sort of the criteria for success and was there a particular discussion around does this actually produce the sort of interoperability and trusted exchange that it was meant too?

**Arien Malec – RelayHealth Clinical Solutions**

That's a great point, and again, I think with regard to the point that Wes brought up what I'd suggest is we go back and probably by e-mail draft some language and see if we can get local agreement and then propose that back to the group. I think it's an absolutely essential outcome.

**Laura Adams – President & CEO - Rhode Island Quality Institute**

Thanks.

**Arien Malec – RelayHealth Clinical Solutions**

For the interoperability CTEs governance isn't worth much if you don't actually get interoperability. So thanks for that point.

**John Lumpkin – Robert Wood Johnson Foundation**

Arien and since we're on a such a tight timeframe, if you get agreement in the Workgroup on these modifications, if you could send it to the entire Workgroup after that?

**Arien Malec – RelayHealth Clinical Solutions**

Absolutely.

**John Lumpkin – Robert Wood Johnson Foundation**

Then perhaps we can do some e-mail exchange and not have to come back to it on next Monday.

**Arien Malec – RelayHealth Clinical Solutions**

Perfect. All right. So, I think we're on a roll now. We found that once we got through these questions we ended up going much more quickly through the remaining questions. So, question 5 and 6 relate to the role that governance would play in terms of relieving burden on the states and creating alignment between the governance mechanisms and state governance approaches and again, because our success criteria were explicitly predicated on our answer to question 3 that is the major role of governance in reducing the overall cost of nationwide governance. If the success criteria were in fact met we would expect that it would aid and assist the states by providing a nationwide framework, that it would aid and assist exchange entities by reducing variability state-by-state, and that the main role that governance has is the moral authority of governance, particularly governance at the nationwide level and the utility and acceptances that that governance would have for a success criteria.

We also did note that the federal government has a wide range of tools in its granting powers to create alignment between the states but again, we didn't explicitly discuss this but implied nor answered a question 3, as well as the cluster of 2, 4 and 7. We believed that the main rule should actually be for governance to be useful and in being so useful to create alignment with the states because the states actually believe in the governance and believe in the goal of nationwide governance. So, we didn't see any need to explicitly create alignment mechanisms.

All right, the next cluster relates to the lifecycle, its question 60, 61, and 62 with related to 60, which was the big one, and I believe for 61 and 62 we mostly just point back at our answer to 60. The question was asked what process should we use to update the CTEs and it pointed back at a proposed process for bringing CTEs through an emergence pilot and nationwide. We had a little bit of confusion in the Workgroup because pilot is often used to describe the emergence level and so we clarified within the Workgroup that emergence is used for truly innovative efforts but pilot is used for efforts that have some kind of need to go nationwide and that nationwide of course is nationwide.

So, first of all we believed that by adding a policy level into the CTEs that the policy outcomes tended to change much more slowly than the associated certification criteria and accreditation criteria, that is that with regard, for example to a safeguard CTE, the need to protect individual identifiable health information isn't likely to change much at a policy level, we may find in practice that there are specific accreditation criteria that better meet the policy goals or maybe accreditation criteria that end up being onerous in practice and aren't actually associated with meeting the policy goal, but the policy goal itself isn't likely to change over time.

We note that there are lifecycles and a set of predictable changes that tend to change the policy level goals. There may be real new challenges, there may be developments in law and there might be new requirements. The first two would tend to be broad in their applicability, that is would change the safeguard and the business practice CTEs as well as interoperability CTEs. And the third one primarily relates to the need for new interoperability CTEs. We noted that each of the types of ways of updating or needs for updating policy level CTEs require different kinds of processes mostly participatory of course legal changes require legal input and that changes to new uses require a really good framework for identifying what those uses are.

We also noted that there needs to be another process for evaluating how the association between the CTEs and the accreditation certification criteria are performing to make sure that we're reaching the policy goal in the most cost effective way. We noted that the interoperability CTEs are likely to evolve faster than the safeguard and business process CTEs and that the implementation guidance and certification criteria tied to the interoperability CTEs are likely to evolve fastest at all evolve, and that accreditation criteria types, safeguards and business practice process CTEs will likely change again but in a much more different and much more predictable way than the interoperability CTEs and their associated standards and implementation guidance.

So, we noted that the governance process needs to be thoughtful and recognize and accommodate the different rates of change. Again, we would imagine that safeguard and business process CTEs at a policy level would tend to change very, very slowly, that the associated accreditation criteria would then tend to get hashed out through use to be cost-effective but then would change quite slowly, whereas we're likely to find new justifications for interoperability policy goals and we're likely to see rapid change for standards and implementation guidance.

We also noted that the governance mechanism only looked at a CTE lifecycle up through nationwide acceptance. We noted the need for a process for retiring CTEs and the association accreditation standards implementation guidance and certification criteria, and we noted in particular that when you retire interoperability CTEs you need to note that you're likely to have a crossover period which sometimes can be quite lengthy where you have multiple entities that speak different interoperability languages at the same time, that's in particular when you change you have the same policy outcome but you change standards and implementation guidance you're likely to have different actors that respond to the different versions of the implementation guidance or different versions of the standard at the same time. So you need to actually explicitly accommodate bilaterally asynchronous, what's

the term Wes?

#### **Wes Rishel – Gartner, Incorporated**

Cutover.

#### **Arien Malec – RelayHealth Clinical Solutions**

Bilateral asynchronous cutover and Wes actually on the Standards Committee comments to the NPRM had a really good description of bilateral asynchronous cutover that really makes the point that successful standards have been designed for upgrade and that the best kind of standards allow for different versions of the standard to be in use at the same time with actors that understand the later version implementing more functionality than actors that understand the earlier version. So, that's our big answer for question 60. And I'll pause there.

#### **John Lumpkin – Robert Wood Johnson Foundation**

So, John Lumpkin here, I think looking at these I'm struck by an assumption it seems that when the CTEs are published that they're going to get it right. And it would seem to me that there should be some sort of metrics or mechanism to say whether or not the initial CTEs are actually achieving the goals as outlined earlier. And that a fourth criteria for changing is that there is demonstration that these CTEs aren't working.

#### **Arien Malec – RelayHealth Clinical Solutions**

I think that's an excellent point and again following the same process we proposed let's go back and hash up some text via e-mail and see if we can get that to a local state of readiness and then post it to the full

group. We did note that cost-effective criteria in particular relating to the accreditation certification criteria should be an explicit measure. We didn't note the same thing at the policy level, our assumption is that the policy goals if they're well-written don't change that much, but I agree with you that we shouldn't make that assumption at least for the first draft.

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

This is Mary Jo and I may ask Adam to fill me here, but it has specifically to do with language in the RFI that mentions publishing CTEs, you know, through the rulemaking process and so, it might be worthwhile for this group to go into a little more in detail about the use of the rulemaking process and any timing issues for, especially the interoperability CTEs in light of this conversation that they need to be very nimble. Again, I think Arien you've got some of that language in either here or at the next two answers, but I'm not sure, you also do strongly endorse the role of the FACAs. So, perhaps as you look through this answer and the answers to the next two questions be sure that you're comfortable that you've expressed your thoughts about exactly how rulemaking should be used for these.

**Arien Malec – RelayHealth Clinical Solutions**

That's an excellent point and I think we did actually point to the FACAs as being a really good place to collect the learning that I think Mary Jo raises from personal and painful experience the point that if you've then got to go back through the rulemaking process to fix something you have a substantial amount of limitation in your ability to do so and I think there is some...that's how the government works aspect of that, but we should definitely address it.

Let's go onto question 61. We were asked explicitly should we expressly permit validation bodies to provide for validation for pilot to pilot CTEs and again I'd remind everybody that the pilot phase is not the same as the emergence phase. The pilot phase in the language of the RFI is reserved for CTEs that have achieved some measure of goodness that makes them applicable nationwide or makes them potentially applicable nationwide and the pilot phase is used explicitly to test those CTEs for their applicability for nationwide use. And in the context of that understanding of pilot we believe that having validation bodies, accreditation and certification bodies and in particular certification bodies available to facilitate pilots seemed like a very helpful thing to do.

With regard to question 62, we were asked what the role of the advisory committees should be and whether we should consider a process outside of advisory committees for identification development of new CTEs. And we noted that the FACAs are the most appropriate mechanism for the pilot national and retired steps and updating policy level CTEs and critically they're associated accreditations and certification criteria. We noted that we'd profiled different kinds of updates that were anticipated and described and that the FACA should have an appropriate mechanism for addressing those types of changes.

We noted that the emergence process should explicitly allow for innovation and should not require formal FACA oversight and in particular for interoperability CTEs and their associated certification criteria, that is we should have a governance mechanism that makes it explicit that local actors are free to develop different mechanisms of interoperability to account for, as Wes notes, changes in medicine, changes in practice, dissatisfaction with current levels of exchange and the like. And that the FACAs can then be a mechanism for collecting public participation and feedback relating to the use of the CTEs and their utility, to items that require national discussion, to showcase what's going on, the ability to recommend pilots and innovations and they also provide a single place for stakeholders to go learn what the state-of-the-art and developments are. So with regard to, again the pilot national and retired levels we did find that the FACAs were the appropriate mechanisms. So I'll pause there.

And I think we've got a little bit of homework to do, so we will get through that homework this week and get back to the full Workgroup hopefully later this week with the output of our three items that we're considering.

**John Lumpkin – Robert Wood Johnson Foundation**

Great, any last questions or comments? Okay, let's move onto Workgroup 2. Jonah?

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Hey, I'm sorry, it's me, I'm about to make a trip on the train could we possibly do 3 while I get settled, I should be at a desk pretty soon.

**John Lumpkin – Robert Wood Johnson Foundation**

Sure, Jan is that okay with you?

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

I don't know if we have Jan or John Blair on the line right now do we?

**Caitlin Collins – Altarum Institute**

No, we do not have them on the phone.

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

I don't know, John, if you would like to read through what's there?

**John Lumpkin – Robert Wood Johnson Foundation**

Okay.

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

And have some discussion since Jonah isn't available?

**John Lumpkin – Robert Wood Johnson Foundation**

Okay, let's walk our way then through recommendations from Workgroup 3. There is a PDF that you can download from the meeting space that does list the comments from group number 3, they went through questions 18, 19, 20 and 21, and it looks like they had some comments on there. So, the first one is question 18. What are the most appropriate monitoring and oversight methods to include as part of the governance mechanism for the nationwide health information network and why. So, the comment there is that...

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

Caitlin, could you please find the text that says...

**Caitlin Collins – Altarum Institute**

Yes, we're getting it up right now.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay, so I will read it, question 18 comment, appropriate monitoring and enforcement methods would rest on robust validation both accreditation and certification in addition to the duties a regulating agency such as OCR and FTC. Accreditation should include monitoring of self attestation and might accept accreditation by other bodies such as the Joint or ONC. ONC should retain overall oversight. And then just a comment that the subgroup doesn't fully understand what accreditation means yet, so some clarification on that. Any questions?

**Arien Malec – RelayHealth Clinical Solutions**

This is Arien; I have a follow-up question to that, if that's appropriate?

**John Lumpkin – Robert Wood Johnson Foundation**

Sure.

**Arien Malec – RelayHealth Clinical Solutions**

So, I'm just wondering whether the subgroup feels that self-accreditation, they're explicitly recommending self-accreditation or they're recommending that as one of the options? I was a little confused by the language there?

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

Michael are you on the line, because I think you had given an example of that, I think that may have been part of your discussion?

**Michael Matthews – CEO – MedVA**

Yeah, I am on the line, Mary Jo. I don't think we had gotten that specific with it Arien. I think at this point we were exploring dimensions of what could be but it was not to the point of recommending self-attestation or self-accreditation. The self-attestation had more to do with just recognizing that there is not going to be an NWHIN governance police force out there to be able to monitor and there has to be some role for self-attestation and self-reporting in an overall governance framework and I think that was about as far as the conversation went.

**Arien Malec – RelayHealth Clinical Solutions**

Okay, that's helpful, thank you.

**Michael Matthews – CEO – MedVA**

Good.

**John Lumpkin – Robert Wood Johnson Foundation**

Mary Jo do you know if the intent is to revisit that or at the next meeting with the Workgroup?

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

Yes, when I sent back the notes I was hoping that they would, you know, be able to do some e-mail exchange.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay.

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

I don't think that that has happened. So, they do have another call this week and I will certainly flag the items that they need to revisit from these questions as well as the questions that they haven't gotten to yet.

**John Lumpkin – Robert Wood Johnson Foundation**

So, I think what I'm hearing is, my thought would be too is a little bit more fleshing out of this concept of self-attestation.

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

Okay.

**Wes Rishel – Gartner, Incorporated**

I've been on a couple of calls with different players on the calls, this is Wes, and I've heard two different stories on the term accreditation. And to be frank, I haven't gone back and looked at the language of the RFI. One view is that there is one accreditor and that an accreditor accredits certifying bodies much the same as it's done now for Meaningful Use or as planned for in process for Meaningful Use. The other is that the entities that are certified to provide the health information exchange in being validated have to go through two separate processes one of which is accreditation and the other of which is certification,

accreditation focusing more on business issues and policy issues, and certification issues being closer to what certification means from electronic health record in terms of demonstrating operational capabilities. Do we actually know which of those two interpretations is correct?

**Arien Malec – RelayHealth Clinical Solutions**

Wes, this is Arien and I'd add, I think, in amplification to your second definition, group 1 explicitly defined accreditation as the validation oversight for business practices and policies.

**Wes Rishel – Gartner, Incorporated**

Right.

**Arien Malec – RelayHealth Clinical Solutions**

And certification as associated with standards and how mechanisms actually function. And we tied accreditation to generally...we tied accreditation to safeguard and business practice CTEs and certifications generally to interoperability CTEs under that definition the role of the master accreditation body is to accredit the business practices, both of the accreditors and of the certification bodies.

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

Well, this is Mary Jo and I think to pull it all together, you're all right. So, and I'll start out with Wes's first statement, yes they're in the RFI as its laid out, there is intended to be one overarching accreditation body that does indeed accredit other sub entities and you are correct that one of the categories of sub entities that it will accredit are the certification bodies exactly like in the EHR. However, picking up on what you said and then Arien was correct too, there will be also at the same sublevel sub accreditation bodies who would indeed look at more of the policy process things that would in fact tend to be more associated with the safeguard and business practice CTEs. So, in a way...

**Wes Rishel – Gartner, Incorporated**

Yeah, so everybody is right.

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

Everybody's right.

**Wes Rishel – Gartner, Incorporated**

Yeah, okay. We just didn't know that the other guy wasn't wrong.

**Arien Malec – RelayHealth Clinical Solutions**

Hopefully, we can be right with more specificity next time though.

**Wes Rishel – Gartner, Incorporated**

Yeah, right, yeah. So, what would be the anticipated mechanism if there were a dispute between two validated entities on policy or even standards issues? How is there is a quirk in this governance here?

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

I think that per se, and again, Adam is on the line, I don't believe that there is a formal court of appeals for resolving disputes between the parties. I think what is mentioned is certainly ONC among its other activities of general oversight and monitoring can certainly hear complaints and so while I don't recall that that is ever referenced as dispute resolution, it certainly is a channel for issues to be raised to ONC.

**Adam Aten – Office of the National Coordinator**

This is Adam, just to confirm, Mary Jo, yes we don't have any specific proposals outlined in the RFI and are soliciting comments on how monitoring and enforcement should be generally framed for the governance mechanism.

**Wes Rishel – Gartner, Incorporated**

Okay, so those questions have been parceled out to one of the three subworkgroups?

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

I don't think there is a question and it occurs to me that if this group feels it's important to address the need for dispute resolution between entities just exactly as you've stated it, then you should make a comment to that effect that you see it as a gap in the process or not, I mean, whatever you choose.

**Wes Rishel – Gartner, Incorporated**

Yeah, I don't know what I think, it's just...

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

But it is missing that's the...

**Arien Malec – RelayHealth Clinical Solutions**

This is Arien, I can actually offer an anecdote here in that we, RelayHealth, makes an electronic prescribing web-based software that is modularly certified and we have been certified both through two of the certification agencies at different times and found...or to the certification bodies at different times, and found that there were divergences in the way that the certification bodies operated, and found a couple of cases where we were asked to do one thing through a certification Body A and another thing through certification Body B, so it's not a theoretical challenge.

**Wes Rishel – Gartner, Incorporated**

So, what you have to do is have three modes, the mode for A, the mode for B, and the mode for the real world.

**Arien Malec – RelayHealth Clinical Solutions**

We did, we were able to convince B that since A had passed it, it should be okay, but, yeah.

**Wes Rishel – Gartner, Incorporated**

All right. Okay, well that's at a level of certification and I also think there are going to be cases where a doctor in Columbus can't see data from the doctor in Painesville, Ohio and each of the health information exchanges that are moderating the exchange could say the other guy's wrong. But, it's just...you know, that's life.

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

Well, it would be helpful if the group would be clear on whether...you can be silent on it, if you would either state an opinion or be consciously silent on whether something like that should be addressed in the mechanism.

**John Lumpkin – Robert Wood Johnson Foundation**

This is John; I guess I'm still struggling with how this is, you know, how this is an issue of governance as opposed to a technical issue.

**Arien Malec – RelayHealth Clinical Solutions**

It's an issue of governance when you have two different accreditation bodies for example or certification bodies who are accrediting or certifying the exact same CTE and do so in different ways that cause different requirements on one of the NVEs.

**John Lumpkin – Robert Wood Johnson Foundation**

So, that would be more of an issue on the CTEs related to interoperability than...

**Arien Malec – RelayHealth Clinical Solutions**

I don't think so. I think you could have the same thing related to accreditation where at the accreditation level the safeguards are interpreted in two different ways by each accrediting body.

**Wes Rishel – Gartner, Incorporated**

So, the effective policy is that an employee gets fired unless he's a doctor, you know, in one and not in the other. You know, I guess I'm not the best one to fully understand the technical definition of governance but just speaking as an intuitive person here, it seems that governance that sets rules but has no mechanism for resolving disputes in the rules in effect creates governance by the largest entities without much recourse for the smaller entities except to play ball, which, you know, that's not always bad, but it may be an unintended consequence of the current approach.

**Stefaan Verhulst – Chief of Research – Markle Foundation**

This is Stefaan here from Markle Foundation, I would agree with Wes that dispute resolution mechanisms are a key element of governance especially as to insure a certain level of accountability, which I think as we tried to do in the first working group, which we mentioned as a critical success factor behind any governance effort, so I would raise it here and the question is of course to what extent do you want to provide for granularity and how that will happen, but I think it's definitely an element that should be embedded.

**John Lumpkin – Robert Wood Johnson Foundation**

So, this is John Lumpkin again, so I think what we need to do Mary Jo is I don't see how this actually fits with the questions that we're dealing with right now but it seems to me to be more of an overarching issue and we may want to just place it in a lot so we can come back to it when we meet in two weeks and if we can't find a place for it within the questions then we ought to raise it as an overarching issue, because I think that there are some very clear arguments that are being made by the Workgroup members about the importance of adjudicating these differences/conflict resolutions.

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

Okay.

**John Lumpkin – Robert Wood Johnson Foundation**

Any other questions on 18? Okay, so let's move on to 19. What other approaches might ONC consider for addressing violations of compliance with CTEs and where Workgroup 3 is at is that the validation body should have the power to impose remediation. OCR and FTC should have authority in their own domains and should consider examples from other sectors such as finance. Any other thoughts on those?

Okay, number 20, what limits, if any, would need to be in place in order to ensure that services or activities performed by NVEs for which no validation is available are not misrepresented as being part of an NVE validation. Should NVEs be required to make some type of public disclosure or associate some type of labeling with the validated services or activities they support? Subworkgroup 3's draft comment is that the validation sticker in whatever form should clearly but simply indicate what the entity is validated for, possibly stated as a functional capacity rather than more granular elements which could be incorporated into the validation criteria. NVEs should be required to clearly and publically display their validation status perhaps with expiration date prominently featured. Any comments on that?

Last question 21, how long should validation status be effective? The draft comment is status should be maintained for two years to start, the accreditation rule should specify circumstances requiring either a notification from the entity, i.e., major changes like Chapter 11 or acquisition or other trigger to revalidation, in other words changes to elements which the governance mechanism like CTEs and standards timeline could change as the validation criteria stabilize. Any comments on that? Okay, I think that takes us as far as group 3 has gone and perhaps at this point Jonah, are you back in communication range? I know the train sometimes can be a bit tricky.

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

Caitlin are we able to see whether Jonah has dialed in through the operator?

**Caitlin Collins – Altarum Institute**

We do have him in but he maybe on mute.

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

Jonah, are you on mute?

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Can you all hear me? Hello?

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

Yes.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

I'm sorry, I'm not sure you are going to be able to hear this. Can you hear me?

**John Lumpkin – Robert Wood Johnson Foundation**

Yes, yes, we can hear you, there is a little background noise but I think we can hear you reasonably well.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Okay, let's give this a shot then. I sent you over some slides, Mary Jo I'm not sure if you had a chance to put them up, but I sent them over a few minutes before this meeting started.

**John Lumpkin – Robert Wood Johnson Foundation**

Yes, yes, we do have them up.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Okay. I'm sorry; I can't see the screen right now but if I can go from number 8 the voluntary nature of the process. So, this is the first question that we were asked to respond to and specifically with the appropriateness of ONC's rule in coordinating...sorry, the appropriateness of ONC's rule and coordinating the governance mechanism and whether certain responsibilities might be better delegated to and or fulfilled by the private sector. So, there are a few preliminary recommendations that the Workgroup 2 felt were important here, one is that the Workgroup agreed that ONC does have a critical role to play in coordinating NwHIN governance and specifically in the following areas, one was in endorsing and adopting CTEs and publishing further guidance on those CTEs in detail. The second was...

**John Lumpkin – Robert Wood Johnson Foundation**

Just a second, that should be slide number 5 I believe?

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

I'm sorry, we should be on number 8, I'm not sure what slide you're looking at.

**John Lumpkin – Robert Wood Johnson Foundation**

Yes.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

I think its slide 6.

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

Slide 6.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Is that okay?

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

That's right, that's got your recommendations on it.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Okay. So, in terms of ONCs role, as I mentioned one is in endorsing and adopting, clarifying CTEs and publishing further guidance on those. The second is facilitating input from and to the HIT Policy and Standards Committee and its various Workgroups, specifically on the revision the CTEs creating and adopting new CTEs and in retiring previous CTEs. So, the third is in the selection oversight of the accreditation body, and the fourth would be overall oversight of all entities and processes established as part of the governance mechanism. What we meant by that was not that ONC should have sort of day-to-day responsibility but ensuring for example that the accreditation body is not just selected but it is appropriately overseeing validation bodies that ultimately will validate entities to participate in NwHIN exchange. Let me finish this and then open it up for questions.

The Workgroup further recommended that ONC should ultimately oversee the process for selecting and overseeing the accreditation body but that the day-to-day as I mentioned validation should and overseeing the NVE should fall to the private sector entity overseen by that accreditation body much like I think the certification process happens with EHR technology today with the Meaningful Use Program. The third overall recommendation is that the Workgroup recommends that ONC play an arbiter role and this was discussed previously in one of the previous groups we just heard from, that the ONC should play an arbiter role for any disputes that may arise between actors, accreditation body, foundation body or NVEs to reconcile disputes and ensure that the intent of the CTEs are followed and in practice. So, I think that really does speak to a discussion we just had about this dispute resolution issue.

The fourth recommendation, preliminary recommendation is that the Workgroup recommends that ONC produce operationally defined descriptions of CTEs that are more defined than what we've seen today and be responsible for updating and clarifying those definitions over time and specifically to do that through the Policy and Standards Committee where appropriate. And then finally, the Workgroup recommends that other private entities may have a significant role to play in adoption and use of standards and implementation specifications to support interoperability related to CTEs. So, I'm going to stop there and see if anyone has any questions.

**John Lumpkin – Robert Wood Johnson Foundation**

This is John Lumpkin again, I think on the issue about dispute resolution would it be...could we flesh that out a little bit and just say that any proposed rule should clarify that process?

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Yes, I think that's how other members of the Workgroup feel otherwise and that makes sense.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay, any other questions on this?

**Wes Rishel – Gartner, Incorporated**

Yes, this is Wes again. As I look at both the actual question from the RFI and the responses I'm still confused about the title of this section, a voluntary nature of process. Does that mean to imply that an underlying principle is that no one has to do any of this in order to participate and that there are no privileges or anything associated with it, it is simply the value of the community itself is enough that it will drive people into being accredited and certified and so forth?

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

So, this is, I mean, I think that's actually a good point for ONC because this is the way that this section is defined I believe in the RFI and it actually ended up being a point of discussion that we spent 10 or 15 minutes on trying to really get to the bottom of what does voluntary mean in this case? What does it mean to have a voluntary process?

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

Jonah, I only want to break in, this is Mary Jo, actually this is in the section called actors and associated responsibilities. So, this section broadly covers the roles of actors and responsibilities and I think the voluntary question came up earlier on in group 1. So, this is an actors and responsibilities section.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Okay, I think then the second question, question 9 is where the voluntary issue came up. So, Wes the answer to your question is it shouldn't say voluntary if there is a process.

**Wes Rishel – Gartner, Incorporated**

Well, I'm just interested in seeing the either assumption or question about the voluntary nature of the process to be called out explicitly somewhere and there be a chance for the group to come to a consensus on it, you know, as I read it, so far, it's pretty...it could be anywhere from just right baby bear to being too cool mama bear, to being too strong papa bear and I just don't know.

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

I apologize, Jonah, you're quite right; you do address the voluntary question on the very next slide if you think that this is a good way if you want to wait until your very next question? My apologies.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Well, I think getting back to Wes's point; it was a point that we also agreed was one that was important to clarify. I mean, if you want to go to slide 7 before we start to talk about the voluntary nature of the program or the process. I mean, the first thing we recommend is that there be more definition and to clarify what the intent of the question or the issue is or is the entire process being voluntary. I mean, Wes, I think we'll ultimately...it was hard for us to sort of reconcile what this really meant and we essentially took an example, we said, if for example we have a hospital and a provider group who decide they want to engage in a form of information exchange...voluntary process and another that the hospital does, the provider group does not what does that mean? What are the implications of that? And is voluntary really have any meaning in that case?

**Wes Rishel – Gartner, Incorporated**

Well, I think there is a yin and yang about enabling innovation versus ensuring interoperability and depending on the meaning of the word voluntary, I mean, there is sort of a compromise in the Meaningful Use Program where there are several cases, lab results being the most notable, where we certify EHR products to a certain standard but the Meaningful Use language clearly pays for the result whether or not it was accomplished using the given standard, for example, for lab test results you can achieve the standard of structured data by retyping the data into the system if you want to. That's an excellent compromise because it says that if the standard is well-chosen and the economics are there that time will become...when it becomes the easy choice because all or most of the software out there will have been certified to use it, but it doesn't take that standard and force it on the nation all at once before we've had enough experience with it to ensure that it meets the requirements.

If that's what they're looking for in the validation process that's fine, if in fact it's less than that it says, well, you know, you can get certified if you want but, you know, if there is no penalty for anyone for dealing with a noncertified, non-validated thing then I think it becomes the way most standards become truly national standards which is to say a few big players say this is how we'll do this and soon that becomes the rule. So, if you look at X12 being used for logistics it was DoD, for light manufacturing it was Walmart and you can argue whether their interpretation was right or wrong, but if you want to do business with Walmart

you're going to do it their way. And, I'm not at this point advocating a position as much as advocating that we have some discussion on the issue.

**John Lumpkin – Robert Wood Johnson Foundation**

Well, we have about another 28 minutes or 38 minutes for discussion. The question I think, as I'm looking at this, is are we comfortable with saying that what the subworkgroup recommended, which says that we're not comfortable with a voluntary system because it doesn't adequately support the framework. So, that's what's on the table. Are there comments about that recommendation?

**Wes Rishel – Gartner, Incorporated**

So, that is page 7?

**John Lumpkin – Robert Wood Johnson Foundation**

Yes, it's on slide 7 under 9(a), the second bullet.

**Wes Rishel – Gartner, Incorporated**

Yeah, I see.

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

John, this is Mary Jo again, and again bumping it up a level, it's my belief that what ONC meant by voluntary is it's just like Meaningful Use, you don't need to become a Meaningful User, you just won't get the incentives, but no one is forcing people to enter the Meaningful Use Incentive Program and I think it's at that level that the question of being voluntary comes in.

**Wes Rishel – Gartner, Incorporated**

Yeah, I think that is understanding what they mean by voluntary is a critical part of this discussion. Mary Jo, in the context is there an incentive for this that corresponds to Meaningful Use Incentives?

**Arien Malec – RelayHealth Clinical Solutions**

This is Arien and I'd note that RFI explicitly notes a number of incentives that one might have in order to become accredited or certified including sort of the reputational stickery notion, the branded notion, the notion that somebody might add criteria to an RFP or a contract or that government agencies such as DoD or VA might require it as a precondition for exchange.

**Wes Rishel – Gartner, Incorporated**

Chunk, chunk, chunk, chunk. There is nothing that corresponds to the direct dollars associated with Meaningful Use or the ability to achieve a safe harbor and avoid losing a nonprofit tax status that were associating with prior certification criteria.

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

They did add that there is a question 59, which our groups are not looking at, that says it's question 59, which is on page 57 of the RFI, which says should we consider including safe harbors for certain CTEs, if so, which CTEs and what should the safe harbors be? So, that's a question in the RFI.

**Wes Rishel – Gartner, Incorporated**

Okay.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

And I think, this is Jonah, I'm sorry, I dropped and I'm back on so I missed some of the conversation, but I think to your point, Wes, about incentives, I mean we could theoretically see that if there were to be a Stage 3 set of criteria that one of the criteria menu or core would be that you are, you know, accredited, certified and such or you are an NVE. So, while it's a way it stands now there is no sort of direct link to

the Meaningful Use program in terms of incentives, there could be and I think that would have significant implications on the kind of recommendations that we may want to make.

**Wes Rishel – Gartner, Incorporated**

Well, there's no...the Meaningful Use Program is for Meaningful Use of electronic health records systems, it doesn't have a legislative authority to regulate HIEs.

**Arien Malec – RelayHealth Clinical Solutions**

One could imagine that for achievement of a transition of care or other associated Meaningful Use criterion that the Policy Committee could recommend only the use of a governed NVE for that purpose.

**Wes Rishel – Gartner, Incorporated**

Yeah, okay. Well, I know John Lumpkin is properly pushing us to make some progress here and I'm feeling uncertain about the meaning of voluntary validation and therefore unwilling to agree or disagree with the comments, but I'm just one person here, so.

**John Lumpkin – Robert Wood Johnson Foundation**

Well, John Lumpkin here, and I think what I'm hearing is that in this scheme and let's toss out the word "voluntary" there are it seems to me three options. Completely voluntary, do what you want, we think it would be good for you to follow...to become an NVE but whatever. Option number...on the other end of the spectrum is if you've got data and you're going to be exchanging it that you have to be an NVE and, you know, you've got to have a license and if you don't have a license then the NwHIN police will be knocking at your door and then the in between option is that ONC will provide a number of incentives which may include safe harbor, may include financial incentives for those organizations that are NVEs to have access that others will not. Is that a fair description of the three options and maybe we can see where people lie in one of those three directions?

**Wes Rishel – Gartner, Incorporated**

I would say it's a great description, John, but my concern stems from my experience with CCHIT and the likelihood that anyone would have gone through the substantial trauma to get certified if they didn't have their marketing department saying we can't sell the product unless you do it. And when I hear about your middle thing where the incentive is, well maybe some healthcare organizations will require this seal of approval, in those situations speaking as a recovering vendor, the vendors job, the salesman's job is to talk the client out of requiring that and they're pretty good at it. So, I would somehow like to maybe even have two middle ones, one is token incentives and the other is meaningful incentives, pardon the expression, but that's my concern with the three options that you proposed.

**Arien Malec – RelayHealth Clinical Solutions**

So, this is Arien, I would just go back to group 1's note that we didn't find that the lack of formalized nationwide governance had caused harm, what we found was that it had raised the overall cost of exchange and so we recommended that the mechanism of governance should be appropriately lightweight and focused on achieving defined value through a set of success criteria primarily focused on reducing the cost of exchange and reducing the cost of governance and I think if you believe that it would be hard to recommend a governance mechanism with sharper teeth unless you believe that the cost of governance is to the extent that it constitutes market failure for information exchange broadly.

**Wes Rishel – Gartner, Incorporated**

So, then that would lead you to favor a purely voluntary.

**Arien Malec – RelayHealth Clinical Solutions**

Voluntary with, for example, it may not be voluntary if you're doing business with the federal government, it may not be voluntary if you're doing business with states that have adopted the governance mechanism, it may not be voluntary if you are doing business with a large institution like a Kaiser that is a member of a CCC that has itself adopted the governance mechanism. So, my experience as a vendor in the information exchange space is that there are indeed actually relatively good ways

through which governance mechanisms filter their way down to the various actors who are providing exchange services.

**John Lumpkin – Robert Wood Johnson Foundation**

So, if I'm hearing this correctly, I think what we're recommending and we just need to figure out how to get the language into 9(a) is that a voluntary mechanism can work as long as there is strong enough incentives for participation. These incentives include requirement of validation for doing business with government agencies, could include safe harbors, could include financial incentives, but they need to be strong enough to ensure widespread participation.

**Wes Rishel – Gartner, Incorporated**

Arien, is that comfortable for you?

**Arien Malec – RelayHealth Clinical Solutions**

Strong enough to encourage widespread.

**Wes Rishel – Gartner, Incorporated**

Yeah.

**Arien Malec – RelayHealth Clinical Solutions**

Would be the...

**Wes Rishel – Gartner, Incorporated**

Strong enough to encourage as opposed to ensure, yeah. Okay, I can live with that. There are a number of words there that are extremely closely chosen whether on purpose or just luck, but for example, do business with the state is a lot different than do business within a state and I would jump over to my concerns about stifling innovation if it got too strong. It's a balance.

**John Lumpkin – Robert Wood Johnson Foundation**

So, I think what we need to do is if we can follow-up with the same sort of mechanism of perhaps using some straw person language to beef that section up and then share that with the Workgroup before our next meeting.

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

Jonah, are you still on the line? I know we were going to lose him some of the time.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Yeah, I'm here.

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

Okay, so would you like me or would you like to take a stab at adding this new language to your response here? Would you like to or would like me to?

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

It's been a little hard for me to track this given where I am. So, if you wouldn't mind I would appreciate that.

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

I'll take that as an action item.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Thank you.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay, that takes us to 9(b).

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Okay, so the question in 9(b) is what other validation processes could be leveraged for validating conformance with adopted CTEs? And our Workgroup recommends that the validation process likely would be a combination of certification accreditation and likely some sort of simple and self-attestation early on and this does...our own...again the definitions that we were...or the assumption that we're using in terms of the definition certification and accreditation were along the lines of, Arien, what you described earlier around certification being more on standards and compliance or alignment with implementation specifications and accreditation more around business practices. So, we did recommend that there be a combination of those two and we discussed the notion of some self-attestation and considered that earlier on there may be more self-attestations and as more CTEs became a part of governance and became more sophisticated that this self-attestation might be minimized or go away, but at least up front that there likely would need to be, depending on what the CTEs ultimately were that begin that were required, there would some form of self-attestation for business processes like this.

We also suggested that, as mentioned, that a self-policing mechanism is likely to be insufficient...Any questions then? No? Okay, well why don't we move on them? On slide 8, 9 and 10 we listed the CTEs that were described in the RFI just for your own information, the context to the next questions. So there are these three domains, one was CTEs around safeguards, another on interoperability and a third around business practices.

And question 10, in two parts, the first 10(a) is on slide 11 is should the validation methods vary by CTE? And we did not go through each CTE and try to parse them, but we did suggest that the Workgroup...the Workgroup did recommend that the validation process or method should vary by CTE and again it is along the lines of a previous recommendation, which was just from the technical...so CTEs are a little more technical in nature, that were technical in nature or around the use of standards and implementation guides that maybe certification based and those business processes. Those CTEs were more based on business process, the accreditation rates. So, the Workgroup for this was suggesting the validation methods would be useable over time but they would change and that there needs to be some flexibility for defining or deciding what validation method is more appropriate so that there would be flexibility in the validation or certification process. Any questions on 10(a)?

Okay, and then which method for 10(b) the question was which methods would be most effective for ensuring compliance with CTEs and we suggested that as a principle that the Workgroup recommended that a certification process would be most appropriate for CTEs, again focus on standards and specifications, we called these technical CTEs and as I've probably stated a couple of times the accreditation process should be adopted for policy and process CTEs.

We recommended that as a first pass that accreditation policy and processes should be initially done through self-attestation, however, ONC should consider a more formal accreditation process including audits and site visits, especially with respect to CTEs that don't carry with them similar monetary penalty implications for which there are no other formal compliant processes, and the reason, we brought up the example of HIPAA, that there is enough of a potential monetary civil penalty associated with violating HIPAA in CTEs that based on sort of the privacy and security policies around HIPAA specifically and if there are CTEs that do not carry those sort of monetary penalties then it's going to be more important to have a more formal variation process if there were fewer penalties outside of this process that it would apply to them or not. And that was the final question that we got to. So, we have about 4 more to go. Any comments on this?

**John Lumpkin – Robert Wood Johnson Foundation**

This is John Lumpkin, I think that in the section where it says a formal accreditation process, I think that what we're looking for is a...and I don't want to use the word "validation" but a more formal verification process.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

I'm sorry, are you asking for that as an amendment to the statement?

**John Lumpkin – Robert Wood Johnson Foundation**

Right, because overall thing is an accreditation process, what you're talking about is verifying that what they attest that they have is actually in place.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Yes, that makes sense.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

I don't hear any more questions. That's it.

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

Could I ask just a clarification there, because I think I heard two different things? So, on one hand you can have a more formal verification of self-attestation, on the other hand you can mostly do away with self-attestation and have a more formal accreditation process and I think they're related but slightly different and I just want to understand which the group is pointing too?

**John Lumpkin – Robert Wood Johnson Foundation**

Well, as I see it, and Jonah can correct me, it says that this should be initially done through self-attestation and then subsequently should consider a more formal verification process.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

That's right.

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

And, so it's just a formal verification process of the self-attestation?

**John Lumpkin – Robert Wood Johnson Foundation**

Correct.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

That's right.

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

Okay, gotcha.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay, moving on.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

I think we're done in terms of group 2 that's as far as we got.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay, great. So, I'd like to thank all the Workgroups, I think we're making progress and getting to a point of making our comments that we have scheduled for the 6<sup>th</sup>. While we're perhaps at this point, unless we have other items, Mary Jo, while I'm going to do some summary and remind people of the timeline, we might want to see if there is any public comment?

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

We certainly can. Operator would you open the lines for public comment?

## **Public Comment**

**Alan Merritt– Altarum Institute**

If you'd like to make a public comment and you're listening via your computer speakers please dial 1-877-705-2976 and press \*1 or if you're listening via your telephone you may press \*1 at this time to be entered into the queue.

**John Lumpkin – Robert Wood Johnson Foundation**

Okay, while people are doing that I just want to remind everyone that we are scheduled to meet again by phone on Monday the 4<sup>th</sup>, which is two weeks from today. The subworkgroups have already done substantial work and thank you so much for those who participated and then we will be presenting our recommendations to the HITPC on the 6<sup>th</sup>. Are there any public comments?

**Alan Merritt– Altarum Institute**

We have no questions at this time.

**John Lumpkin – Robert Wood Johnson Foundation**

Mary Jo, I think our work here is done.

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

I think it is; now I know that group 3 is supposed to be meeting tomorrow from 2:30 to 3:30 to continue its work. Group 1 under Arien has completed its work. And Jonah, I'm just trying to remember when we have your group on the 25<sup>th</sup>, yes and you are on Friday from 1:30 to 2:30 for your next call. So, each of those groups has one more one hour call to wrap up.

**John Lumpkin – Robert Wood Johnson Foundation**

Great, thank you much everyone and I think we're done.

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

Thank you.

**Jonah Frohlich – Manatt, Phelps & Phillips, LLP**

Thank you.

**Arien Malec – RelayHealth Clinical Solutions**

Thanks.

**W**

Thank you.