

**Information Exchange Workgroup**  
**Draft Transcript**  
**June 4, 2012**

**Presentation**

**Operator**

Ms. Robertson, all lines are bridged.

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

Thank you. Hello, everyone, this is MacKenzie Robertson in the Office of the National Coordinator. This is a meeting of the HIT Policy Committee's Information Exchange Workgroup, subgroup number two. This is a public call and there'll be time for public comment at the end. The call is also being transcribed, so please be sure to identify yourself before speaking. I'll quickly go through roll and then ask any staff members to also identify themselves. Cris Ross.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

I'm here.

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

Thanks, Cris. Larry Garber.

**Lawrence Garber – Reliant Medical Group**

Here.

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

Thanks, Larry. Chris Tashjian.

**Christopher Tashjian, MD – River Falls Medical Clinics**

Here.

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

Thanks, Chris. And Deven McGraw, I know, wasn't able to make it, and Arien Malec was not able to make it as well. Are there any workgroup members on the line?

**Carl Dvorak – EPIC Systems Corporation**

Carl Dvorak's on for Judy Faulkner.

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

Thanks, Carl.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

And Micky Tripathi.

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

Thanks, Micky, and is there any staff on the line?

**Tari Owi – Office of the National Coordinator**

Tari Owi.

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

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

**Steven Stack – American Medical Association**

And Steven Stack is here.

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

Oh, thanks, Steven.

**Christopher Tashjian, MD – River Falls Medical Clinics**

So, MacKenzie, just so we're clear, this is a full Information Exchange Workgroup meeting, I believe, correct?

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

I have a subgroup two workgroup meeting.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Oh, is this subgroup two?

**Tari Owi – Office of the National Coordinator**

No, Mickey, this is Tari. This is just final presentation of subgroup two for the full workgroup.

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

Okay, this is subgroup two's presentation.

**Christopher Tashjian, MD – River Falls Medical Clinics**

Yes, so a full workgroup meeting, but subgroup two is presenting.

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

Okay.

**Christopher Tashjian, MD – River Falls Medical Clinics**

Okay, I just wanted to make sure we're clear.

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

Sorry.

**M**

No, this is definitely Micky's meeting.

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

I will turn it over to Micky then.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

No, I'm turning it right back to Cris. So welcome, everyone, now that we've got that established, this is Micky Tripathi of the Information Exchange Workgroup. Today we're going to discuss the recommendations from subgroup two, which was focused on the inland governance RFI and in particular the conditions for trusted exchange related to safeguards and business practices. I know they've got a lot of stuff to discuss that we want to be able to cover in this hour, so let me turn it over to Cris Ross who I want to thank also for helping to lead the subgroup through a set of very challenging and interesting questions.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Thanks, Micky and you're welcome. This team is terrific. Larry and Chris are both on the call, so they can lead this as much as I can, and Deven and Arien have been terrific. So I think we've got on the website, do you we have the document, yes, we do. So I guess what I would do would be to simply walk through comments and relate it back to the RFI and interested in getting your viewpoints.

Tari, I'm assuming that if we have some commentary from this, are you going to be able to take some notes about feedback from the information exchange workgroup as a whole?

**Tari Owi – Office of the National Coordinator**

Yes, and then I'll check back, I'll circle those comments back around again.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Terrific. So Micky, how much time would you like me take to walk through this document, just so we can pace ourselves?

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

We have until 1:30, I think, and so you can take all the way to 1:25 and then we just need a public comment.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Terrific, okay, we'll get going. So we started with question 34, which relates back to the condition S-5 about an NVE making publicly available a notice of its data practices describing why IHA is collected and so on. The question was what is the anticipated cost and administrative burden. You can read our comments.

I think our viewpoint was that the cost is closely related to how clearly the NVE is provided with a model notice or guideline around specific categories of information and types of data practice to be reported. If NVEs have to guess or if the categories are ill defined, there may be significant amount of administrative time simply trying to answer questions that aren't well defined or well understood. Reporting to an unclear target is always hard I think was the bottom line.

If there aren't any questions or comments, let's move on to the next one. Question 37 relates to condition S-6: An NVE must not use or disclose de-identified health information to which it has access for commercial purposes. The question here was around the impact on evolving business models and about whether trust came from the CTE outweighs the potential impact on these models. We had a pretty robust conversation about this. Our conclusion was that as proposed condition S-6 would have a chilling effect on many existing and emerging business models. We cited quality improvement, public health and research in addition to commercial opportunities. We made some suggestions that the NVEs be required to disclose de-identified information only based on the conditions listed below, which mainly align with HIPAA with some exceptions, for example, when the NVE prohibits downstream recipients from re-identifying patient information.

There's a reference here to a recent FTC report protecting consumer privacy in an era of rapid change, which dealt with issues like re-identification. So I think in our conversation, we came down pretty four square on the side of de-identified health information has substantial value, and we would not want to prohibit the opportunity for NVE to support that value, but instead to make sure that the controls on it were clear.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Chris, this is Micky, just one thing, I assume on the second bullet under comment, it says instead of prohibiting the use, blah, blah, blah, the workgroup recommends that NVEs be required to disclose. I assume that means be allowed to disclose.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

The idea was to say that they could manage de-identified data, but when they do, that they would be required to disclose it, how does the grammar work?

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Then they're not required to disclose de-identified data. It's only it's the opportunity that they can have to do that, right?

**M**

I think you're right, providing that all four of those bullets or conditions are met.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Right.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

A fair point, so you would change the language to say—

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Recommend that NVEs be allowed to disclose.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Yes, thank you, yes, good point. Any other comments or questions? If not, question 38 was on what other entities would this have an effect, and we listed a substantial number of other ones in our conversation. But it fell into the categories of things like EHR and PHR vendors, the NVEs themselves and the covered entities they serve and other third party affiliates. So we thought about all the examples of where, for example, discussion around the use of de-identified data for public health management purposes for accountable care, for the opportunity for one organization to benchmark themselves against another from a clinical performance perspective by knowing how does another organization or group of organizations manage against a public health goal using de-identified data.

Question 52 relates to condition BP-1: an NVE must send and receive any final electronic exchange message from another NVE without imposing financial preconditions on any other NVE. We probably had the most robust conversation on this and the previous question, 37. So the question 52 specifically said should the CTE be limited to only preventing one NVE from imposing a financial precondition on another, or should it be broader.

I think the consensus of the group frankly was that it should be neither. That the CTE should not in general prevent NVEs from imposing financial preconditions, except for under certain circumstances. So to be specific our first bullet point was that we recommended using a net neutrality type framework to encourage an open network and level playing field. That if providers use one NVE, they ought to be able to connect to another NVE, generally speaking.

Probably we might want to reverse the bullet points here. The third bullet point I would go to is that we recommended that NVEs should not be permitted to impose fees or requirements on other NVEs for basic services, such as transporting messages and discovering digital certificates. But we did believe in bullet four that there's an expectation that NVEs will develop the capacity to develop other valued services, in which case these should be reasonable and nondiscriminatory in some language we borrowed from some other settings specifically around ATCB expense and some ISO precedence.

We did not think that it made sense for ONC or federal regulatory agencies to regulate such fees, but that the marketplace subject to normal legal protections and competitive protections should be held to a reasonable and nondiscriminatory standard. I go back up to bullet point two where we believe that fees might be permitted in some cases as I just described, the framework should in general first prohibit NVEs with large market shares from using their influence to impose accepted fees, and second avoid the need for NVEs to negotiate business agreements with each other in order for the customers to exchange basic information and that the focus of the NVE business agreements may be around evaluated services only.

So lots and lots of discussion that led to this, I think, Cris or Larry can please weight in as well. But I think our conclusion was that the NVEs are going to be building business models themselves, need to find a way to cover the costs of the operation of their business. But that we didn't want to have those economics get in the way of basic net neutrality kinds of communication in the same way that net vendors connect to each other in the same way that cell phones companies connect to each other in the same way that other networks connect to each other and things like that, other telecommunications, power transmission, railways, all those kinds of things you get rights to adjacent networks. We did not want to limit the ability for entities, whether they are for-profit or not-for-profit, to cover the costs of their operations by imposing reasonable and nondiscriminatory fees for evaluated services.

**Christopher Tashjian, MD – River Falls Medical Clinics**

Yes, it's Chris Tashjian, and I'd agree with that, but we did give them the opportunity if they want to create some value adds, that they could do that and that was reasonable to provide extra value, then they could charge for that.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

This is Amy and I joined the call a little bit late, but a question I have related to that is that the definition of NVE I think encompasses a lot of different types of entities. So I'm trying to think about how this, what the implication is for the different types of entities; whether it's an IDN versus a nonprofit, versus a state run. Like I'm trying to think about how this fits in and sort of the net neutrality and fairness across the various—did you have any discussion about the different types of NVEs and how this impacts them? I'm not sure I have an answer for that. I'm just trying to think it through and to see if you had any discussion about that.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Yes, that's fair, this is Cris Ross, and we did. We also included in that category the belief that there would be independent networks that would enter this space of the type that exist today in things like labs, e-prescribing and clinical exchange. It might also include EHR vendors, where they act as a network in certain purposes. So I think we tried to keep in mind as we talked about it, mindful of both not-for-profit sort of public purpose entities, as well as commercial entities. I think in general our model was to say in order to make messages move cleanly and easily, they all ought to play by a no-cost level playing field with respect to each other for that basic message exchange. But I guess we anticipated and guessed that NVEs are going to do more than, for example, simple directed exchange and they're going to offer a variety of other services. We started to talk about what some examples of what some of those services may be.

Is that helpful?

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Yes, I'm trying to think of it more from the government side, like public health, like would they have added value service they could charge for, would they always get hit for costs from others, but not be able to charge, because I'm thinking of it more from where government, where if there are any sort of NVEs coming through government, how that's affected under the definition of NVE.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

This is Micky. It sounds like that would be more determined by government policy itself rather than NVE policy.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Yes.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

I was able to participate in some of these conversations. I thought it was really thoughtful, and as Cris said, that there was a lot of conversation around it. I personally like the net neutrality framework because I think it's something that's relatively familiar now as we think about networks and appropriately frame this in the context of those other industries and in those other areas where they've been grappling with the same exact issues.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Yes, and I think our big compromise to some degree was saying we were going to apply strong net neutrality to those instances that related to basic services like transporting messages and discovering digital certificates. I think we didn't say it explicitly, we said it implicitly, and we could say it explicitly that we would hope that a final rule would be clear about what those basic services are, as opposed to value added services. But once we got to the point of saying well, look, let's use net neutrality for basic services and expect the market to manage itself with respect to value added, it became a much easier conversation I think.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Yes, the trick will be in defining a dial tone.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Exactly.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

That's where we push that off to others.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Exactly, exactly, smarter brains than ours. So question 53 was related to this of addressing the fees that an NVE should charge its customers. We just didn't believe that there should be a determination of what the fees should be for charging it, based on our conclusion before, which is if it really is free for purposes of basic message exchange, that the market ought to determine pricing for other services.

Question 54 was related: Under what circumstances should an NVE be permitted to impose requirements on other NVEs? We believe that they should be allowed to impose requirements on other NVEs only when it pertained to valued added services beyond basic services essential of the function of nationwide health information network activities. So the examples of that would be things like requirements for exchanges and other types of higher value added data, probably issues related to certification for participation on a network for purposes of safety and integrity, those kinds of things were the clearest examples.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Cris, this is Micky. I think one interesting thing, and I know we'll get to it later, as I recall in the conversation, the subgroup conversation, we didn't think of it sort of in this context, but later we're going to talk about the level of assurance and authentication.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Correct.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

It does seem like it's related somewhat to this about the question of can one NVE impose requirements on another, you can imagine people having a different view of what the appropriate level of assurance ought to be and is that considered an unfair trade practice if one says that they have a higher level than another one and won't allow exchange to happen, based on that.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Yes, fantastic point, Micky and a good general one. I think for those of us who are participating on multiple of these workgroups or even people who are just on one, there's a degree to which it's hard to answer any of the questions in isolation. But there's some questions in particular that are strongly triggered by how you answer a whole bunch other questions, and the idea of net neutrality all makes sense, but it presumes that the answers to a bunch of others questions fall a particular way in the way that you just described, Micky. So some of these I think are, we didn't try to do the work of saying let's go mine the rest of the RFI to look for all related questions in order to say, well, we would answer this way, but only if the answer to question 22 was X. Someone clearly is going to need to do that and if our teams don't have time to do it, it's going to be ONC.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Right.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

So maybe moving to our last primary question 55, which relates to condition BP-3, an NVE must report on users and transaction volume for validated services, and the question is what data should be collected, how should it be made available and so on and so forth. The flavor of our conversation here was that you know it certainly makes sense to know what's happening across the network for purposes of regulatory purposes, policy making, and so on. So our first bullet point was you know reporting of transaction volumes to federal agencies and state regulatory agencies is appropriate.

We then had a lot of conversation about you know disclosing of users and transaction volume may be an issue for NVEs that are competitive or commercial entities in particular. There are not similar requirements today that require that vendors and networks say who their customers are or how much are they using the network and that would create a potentially competitive advantage or disadvantage.

So because of that, we suggested that the reporting standards should be transparent to both the public and the NVEs to ensure participation; but we believe that public reporting should be in de-identified aggregate form to evaluate the progress of national and statewide exchange, but to not reveal transaction volume or type of transactions that were facilitated for specific NVEs.

We believe that operational and adoption or use rates would be likely to be the most useful for reporting and that reporting requirements may vary, depending on what services that NVE offers. In other places, and we'll get to this in some secondary questions, we believe that not every NVE, actually I'm blurring two workgroups. In a separate workgroup the ... team we had a discussion about beliefs that not every NVE is necessarily going to support absolutely every form of exchange and there are different forms of exchange identified. I think we brought a little bit of that conversation into this discussion and said, well, if this was the case that NVEs are not all identical, but they may have more particular purpose for one thing or another, that may impose a reporting requirement on that NVE, depending on what they're doing. They may do simple directed exchange and other direct protocols, for example, or they may support a wider set of protocols like XDR or ... or N-1 exchange based.

Any other comments or questions about that?

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

This is Amy. I have one question and that has to go with the type of service. So I fully agree that de-identified aggregate information and reporting makes sense and that NVEs shouldn't have to give report by specific participant. I'm not sure I fully understand the rationale why you would be opposed to reporting to say lab transaction versus e-prescribing versus whatever, because I think from a policy perspective understanding the uptake and the services that different NVEs are providing versus not and how that's going might have some value. So I agree not revealing at the individual participant level this lab versus that lab, but I'm not sure I understand the rationale for not saying these are the number of lab transactions or e-prescribing transactions or direct transactions or in those categories and I got the sense that's what you were saying.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

It's a great point, Amy, and I think, and my fellow committee members can also answer to it, it may very well be the case that lots of people report things that just say NA, because they didn't happen to carry a certain type of transaction. I think that was maybe kind of our intent. I don't think the intent here was to create some sort of a blindness. I think we would assume that you would want to report types of transactions and if it would be helpful to make that explicit, we probably should list type of transaction, as well as aggregate volume.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Yes, because you have a statement in your second bullet that says reporting should not reveal transaction volume or type of transactions, so I read that as saying you shouldn't reveal that and I'm saying that's what I was questioning; why not.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Yes, that's a fair point. Chris or Larry, I'm going to ask you guys as well. I know we're going through this pretty fast and I don't have recollection of exactly why we would call out not reporting type.

**Lawrence Garber – Reliant Medical Group**

This is Larry. I think what we were trying and probably not doing a great job of it, but what we're trying to do is that for public reporting, we didn't want to do things that would make ... like a particular NVE could be identifiable, but that certainly for the reporting to the federal agencies this was all fine.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Yes, I think the intent was to say if you had two NVEs operating in some area, for example, you wouldn't necessarily want to have the data reveal the fact that one NVE was really going gangbusters and gaining a lion's share of the lab business, for example, and the other NVE was not in a way to create competitive intelligence.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

So it's a distinction between what's publicly reported versus what's reported to the federal agency.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Correct.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Yes, I'm trying to think, but from a public transparency point of view, I understand the competitive edge, but you're saying because then one NVE could say, oh look, the counterpart in my community has got all this lab business and I'm going to go after it now or something.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Or that he go to their customers and say, you know, we've locked up the lab business and see this public report says that the other guys are really lousy at labs, so you should connect to us.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Or it could impact their stock price.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Right.

**M**

If it's de-identified where I think de-identified means the NVE isn't identified as in the previous sentence, does that matter?

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Well, it wouldn't if the report were to say that within this particular state, X percentage of lab transactions are carried by NVEs compared to this other state where they're at a different level.

**M**

Yes, it has to be appropriately aggregated, yes.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Yes, I understand what you're saying. I think it's a little bit of a fine line. I'm trying to think of instances where it would be important in a de-identified way at the NVE level, but still important to share, so.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

It's a fair point. We wrestled with a lot of these things looking at the potential kind of commercial implications. I think there's as well as policy, of course, but I think part of our concern was these NVEs don't exist, there are things that look like NVEs today, we think, or things that will be that are operating today that will have a tag of NVE put on them under this regulation eventually. But we also believe that there was the need for NVEs to emerge, evolve, change, compete, meet new market needs and all the rest. I think we were cautious of having a regulatory environment in place that would impede with innovation and market development. It was part of our concern. We believed that there was a sufficient number of requirements in the RFI that required that NVEs would act in the public good, so we wanted to balance that in some instances with making sure we had innovation and success.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Yes, I guess I was also just trying to think about it, I don't want to belabor this. I was trying to think about it from a funding point of view, so to the extent that the NVEs have whatever their business model is or if they have particular funding entities like insurers or others that wouldn't necessarily be state government that might want this information to make decisions about funding. So I don't know if that was considered at all and how that would weigh into it. I'm probably thinking more from a slightly different perspective than a strictly private NVE that has a fully sustainable business model based on direct fees and thinking about some other kinds of funding models where it's more sort of pieced together from a variety of stakeholders for public good.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Sure, I think we observe the fact that this doesn't prohibit an NVE from using their own data to try to report to other stakeholders or so on. I can imagine easily an NVE would say here's our data of performance compared to the markets in which we operate, so therefore saying to a health plan or some other customer or some other stakeholder, look, we have 10% of the market, or we have 90% of the market, or something along those lines, too. They're not prohibited from using their own data for their own purposes if they so choose.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Okay.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

This just got to the issue of for what purpose should we have public agencies or mandatory public reporting around what was going on within a NVE opening up that data. It's good discussion. It matches what we slogged through in a couple of meetings.

Should I move on to the secondary questions?

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Yes, I think so.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

So we got through some of these, but not all of these and some of these were handled by email communication when we got to the end, so we'll launch into them.

The first one was question 24, which relates to condition S-2, an NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized either directly or indirectly. We had a lot of conversation about appropriate level of assurances. A lot of our conversation here related to the role of an NVE as opposed to the roles of those who connect to NVEs, so we really answered questions 24, 25 and 26 in the same context.

A big part of our determination or our discussion was about you know in many instances, in many very important instances, the job of authentication and authorization would be related to the entities that they connect, as opposed to individuals and so on that where an NVE would take direct responsibility. We believed most likely the role of authentication and authorization will be the job, for example, of certified electronic health record technology vendors, which was important to deal with question 26, which dealt with you know flow-down and delegated roles for authentication and authorization. So the text is similar across some of these sentences that we believe that NVEs should be responsible for authenticating and authorizing entities they serve at an organizational level, which would allow organizations to authorize and authenticate their own users.

There's a lot of practical reasons why that was the case. We didn't explicitly discuss it, but I know that in some other conversations that I've been involved in in some other workgroups and so on, part of this was alignment to HIPAA where HIPAA assigns liability at the organizational level rather than at the individual level, so there's some ways in which this is both a practical recommendation and one that also aligns nicely with HIPAA.

Our second comment was in regards in NVE to NVE communication, which was different than authenticating an end point user that might be originated by an NVE. We wanted to recognize that NVEs may have different standards for authentication, due to the nature of services that are provided, and that we wanted to make sure that those standards for authentication and authorization would be transparent and wouldn't provide undue burdens on other NVEs. We wanted to observe that robust exchange and sustainability of N-1 is dependent on minimizing differences in authentication requirements among NVEs. So the result of that is probably some belief that there would be some minimum core set of standards that hopefully will be in our final rule, but there may be some specific ones.

We had a long conversation about things like an example that was given in a privacy and security Tiger Team hearing quite some time ago about the need, for example, in an operating room setting that you wouldn't want to have to have a surgeon or supporting staff stop and have to log into a system to get data. So in some of those sorts of settings where there's a high level of physical security, sometimes applications are simply left open in the appropriate setting, so that data can be retrieved very quickly. There are probably a number of other settings that are examples that we could talk about in the same sort of thing. But in general we focused on two things, one of which is we believe that authentication and authorization ought to be on a delegated basis through entities that the NVE served, and then we focused it on NVE to NVE communication trying to create a level playing field between them.

I'll pause there. We can get into the nuances on questions 25 and 26 as well, too, but that's really the core of our comments unless Larry or Chris, you guys want to clarify and correct what I just said.

**Lawrence Garber – Reliant Medical Group**

No, I'm pretty comfortable with it.

**Christopher Tashjian, MD – River Falls Medical Clinics**

Yes, me, too.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

So any questions or comments from the workgroup as a whole about that? Are we making sense here?

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

This is Micky. I think that makes sense.

**Steven Stack – American Medical Association**

Yes, this is Steve Stack, and I think it makes sense.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

I think the only interesting for us, which was I was alluding to before, the interesting sort of subtlety here that I guess will just be borne out in practice is this question of whether you have two NVEs who have different level of assurance and is that going to violate sort of the network neutrality concept above that is seen as a restraint of trade or something where they may have very legitimate reasons for having differences. One entity may have a very legitimate reason from their perspective to have a higher level of assurance requirements for everything that goes into or out of their NVE, but it's voluntary, so they could choose not to participate at all if they thought that was a—

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Yes, absolutely and I think we had some passing comments about particularly sensitive areas like perhaps behavioral health or, you know, some STD communication, those kinds of things that typically have higher levels of standard and protection on them. Anyway, we wrestled with it a fair amount and it won't be simple, but it seems like it's pretty straightforward how to handle it. So I think our answers to question 24, 25, and 26 are essentially the same and in the interest of time, I'd probably just move on from that.

So question 27 related to condition S-3, an NVE must ensure that individuals are provided with a meaningful choice regarding whether their IHI may be exchanged with the NVE. There's a question 27 was you know we've talked about opt in, opt out, or a combination of the two, what are the operational challenges, what criteria would be used and what are the ways that we could get consistency relative to the variation between states.

I hope we weren't simply ducking the question, but our answer basically started with the viewpoint that an NVE is not likely to act itself as a provider or otherwise be tasked with obtaining and monitoring meaningful choice directly from patients. We talked about some exceptions like when an NVE operated, for example, a patient portal, for example, would have that task, but in other instances, likely would not. So unless NVEs or providers who are already required to obtain consent, we believe that NVEs working to facilitate directed exchange should not be required to obtain consent. We believe that requiring the NVE to ensure that consent was obtained it would create some significant operational barriers for most NVEs.

With that general statement, we believe that NVEs should be transparent and provide notice about how data access would be used and therefore, patients could offer meaningful opt in or opt out their consent to providers based on the provider that the NVE uses, which means in effect that the provider would need to describe essentially these are the ways that the data can be used, which is informed by the activity of the entity at which the provider is employed, as well as relationships that they have with other covered entities and business associates that could be facilitated by an NVE.

We observed some examples of places where existing entities have these kinds of things, so we had a long discussion about e-prescribing, about how patient consent is gained or not, what is the burden on providers and vendors to provide evidence that they have practices for opt in and opt out and access to data in order to get access to a network and that the NVE would reasonably need to provide reasonable assurance that those that connect to it have in place a policy that supports meaningful choice.

So this is a somewhat tricky one, but in essence, we believe that this is one that was delegated to others on the network, as opposed to the NVE themselves.

Any questions, comments, critiques?

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

This is Amy, and again, I think this is an area where it is very tricky, because depending on what the NVE is, I think they may be doing it on behalf of providers and not necessarily—I just think the stakes are higher—if it's directed exchange, that's one thing. If it's a more centralized type of exchange or HIE, I think it's a potentially different thing at least in the public's eye. I'm not saying they should require one or the other. It'll be interesting to see if there's pushback from others on this.

**W**

Coming from a state that it's very strictly opt-in, where we have lots of community discussion and trust me, where we've landed is not where I initially thought we were going to land or even where we in terms of the developers were starting. And so all those complexities you talked about are correct, but my general understanding is that there's been much more move overall towards at least less on point to point and directed exchange more on centralized type of NVE type of exchange or lookup and retrieve, where people just view it as a different—while it is your individual provider, the providers do not want to have to track this kind of stuff and did want to have to be—the implication of this then puts a lot of burden on the providers at an extra level, which we got huge pushback on locally. So I point that out just as a consideration. Requiring one or the other I don't think is an option either, because I think that that gets confusing.

The other thing is when it comes to behavioral health; there are big implications on just meaningful choice and not active consent. I understand we're not saying places can't do that. We're saying they're not required to do that, so I'm okay with it. I'm just raising a couple of issues, based on our experience.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

That's totally fair, so I think the nature of our conversation would say that in a state that had an opt in model, that the NVE operating in that state would impose on the providers the role of explaining to a patient that data will be used for these purposes, and you have the option to opt into it, and that the NVE would depend on that decision of the patient as communicated to the NVE by the provider, because the NVE does not itself have the ability to interrogate the patient directly, right?

So I think our viewpoint was if you look at the ecosystem as a whole that included NVEs plus providers plus the vendors that serve the providers, should there be a meaningful choice regarding whether their IHI may be exchanged, absolutely. I think the question was where is that recorded and enforced.

**Carl Dvorak – EPIC Systems Corporation**

This is Carl. We should also in our thinking about this, think through how the use of it might change through time and having the re-notification and re-permission steps might work in order to make it practical.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

That's a fair point.

**W**

I just think if what you're saying is it's really up to the provider to track all of this, because I just think that we need to have ... providers about the reality and practicality of that.

**Christopher Tashjian, MD – River Falls Medical Clinics**

Yes, this is Chris Tashjian. There's no way we can keep track of it. My question is unlike the e-prescribing, don't the pharmacies and such play with that information now as it is, whether it's e-prescribed or hand prescribed?

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

What do you mean play with that?

**Christopher Tashjian, MD – River Falls Medical Clinics**

I mean they sell it to the pharmaceutical companies.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

That's a good point, so there's oftentimes some confusion about that and I'm going to put on my Surescripts hat right now. When data is sold to pharmaceutical companies and so on, that may be sold by a pharmacy or by a PBM or others. It is absolutely not sold by Surescripts on behalf of any of those parties.

**Christopher Tashjian, MD – River Falls Medical Clinics**

But that's what I'm saying, even the paper scripts, not counting the electronic ones, they've been, the pharmacies or PBMs have been selling that information to pharmacies for as long as I've been a doc.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

They do, in fact sell de-identified data for different purposes. A lot of clinical data is sold in that fashion. I don't think whatever our answer is to this would not change that practice, right?

**Christopher Tashjian, MD – River Falls Medical Clinics**

No, I don't think so, but to make the docs be responsible for keeping track of it, I just don't see it happening.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Yes, so let's put a clarification on it, and I think that's a fair point. I think in our conversation, and Chris, correct me where I get this wrong, I think we were looking at a combination of the provider's vendor and the NVE, believing that that place where consent would be recorded is in the patient record that will be managed within the CEHRT technology as opposed to—that's where it would be originated and it will be stored. So a practice would say this is what I understand we're on the history of my patient Jane Doe around what forms of consent have been offered at what point, and that that consent would then be passed on to any NVE that would manage that data on behalf of that provider and patient.

**Lawrence Garber – Reliant Medical Group**

This is Larry, which is the case right now we'd be prescribing in Surescripts is that ... that technology that yes I have obtained the appropriate consent.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

And the job of Surescripts in that particular instance is that we have certification requirements that we impose on the EHR vendor that says we're not going to provide medication history data to you unless you certify that your technology has the provision the manage a box that says I'm checking the box that my patient has offered consent. Then the same requirement is also imposed on the other side on the pharmacy and PBM.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

So let me try this. In an example where, as I'm thinking now about a Rhode Island case, my understanding is our HIE is able to get med history data from Surescripts, and because as an HIE to make it available when people are looking up information on query retrieve basis, because the HIE has consent. So we're able to actually, providers can access the data in addition to labs and whatever else they can access and that our HIE will be able to actually store it, but that is because we actually have consent, so—

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Right, so in that instance—

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

So again, and our providers, some providers are choosing—I mean I'm not pushing back, I'm just thinking this through.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Yes, yes.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Some of our providers choose to or want to incorporate in this EHR, but many of them did not want to have to change their systems. Now this is going back a while ago, which was in part why somewhat why the model when we chose to go opt in, that the management of that was centrally and not on the providers. I just think we want to be careful that we don't—I think we have to think about forcing that while I agree, but I think that's maybe a good place to go. I think we just have to be practical about the ability to actually do that. We're still testing different enrollment models. We actually, in our case, have a state law that says the HIE has to enroll and has to be voluntary, so I know we'd be going above and beyond this; but the part that wouldn't fit, let's say, in a Rhode Island type model and maybe we're unique, and I'm just putting it out there as we think this through, is that it doesn't say that the providers have to do it. So to the extent that we got any enrollment from places other than providers, they may or may not be able to track that.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Can I stop, this is Micky. Amy, I just wanted to touch on a word that you used, actually, which was force. It seems to me that the nice part about the way this has been approached is that all this is saying is that an NVE should not be required to maintain the consent status of individual patients. It doesn't mean that they can't and it may be that in many situations, that ends up being operationally the best way that they do it. So to Cris' point, there may be places where physicians say I really don't want to deal with this and then the NVE chooses to do this. All this is saying is that they shouldn't be required to do it.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Okay, yes, I agree with that and I have no problem with that. I thought, though, in the conversation it put the onus actually on the providers, and that's what I was objecting to.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Well, I guess the way I would read it is doesn't put the onus on the providers. It just says that that would happen flexibly in each market. If you require that the NVE does it, then it seems to me you've put the onus on one side.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Right. I wanted to make sure that while we weren't requiring the NVEs, and I agree. If it works in that community, then you can go above and beyond, which is what I'm saying. When we were verbally talking, I got the sense that the requirement and onus was on the providers and I was concerned about that, so I think we're good.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

I think Chris raised the concern about, Chris Tashjian, around it would be difficult for the provider to do, agreed. I think we were trying to observe that within a particular jurisdiction, you've got HIPAA regulation, you've got local regulation. You've got business associate agreements between entities around what data they want to share or not. You have a NVE. You have EHR technology and other technologies used by providers and you're got the providers themselves.

And so our question was across that whole ecosystem, who should ensure that individuals are provided with a meaningful choice regarding whether their IAHA may be exchanged by the NVE. I think our observation was out of that whole cast of characters it's not obvious why the NVE should be the one who is the trust holder on behalf of the patient. They're probably further removed than the combination of the provider and the technology system that they use, for example, and that if you could act in a god-like way to say, okay, where are we going to put that control, you probably wouldn't start with the NVE. You start with the provider and CEHRT. That I think is the core of our conversation and the NVE would play a part, but they would not be the ensuring party.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Right, so then it goes back to are we requiring the actual provider to be the ensuring party and I just—I'll let it go. It's fine. I'm just raising a couple of—that's where I think where I was sort of thinking where you were coming from.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

It's a great conversation, yes, absolutely, we wrestled with exactly the same thing.

If I can continue here, I'm sorry.

**Lawrence Garber – Reliant Medical Group**

I would just going to say on the next condition, there's a type, that S-5 is actually S-4, and it should say an NVE must only exchange encrypted IIHI ... answers a different question ...

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

You're absolutely right, so what is question 31? Question 31 is relating to what, Larry?

**Lawrence Garber – Reliant Medical Group**

An NVE must only exchange encrypted—

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Encrypted in IIHI. Thank you.

**Lawrence Garber – Reliant Medical Group**

Sure.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Our comment there was that we believe there should be, that they should exchange in an encrypted manner or through an encrypted channel, then the exception being where IIHI is being exchanged within a physically secure setting, so within an entity, the data may move from one system to another environment. But if it moves outside the boundaries of that organization, it should be encrypted or through an encrypted channel.

**M**

We envision the case where there could be two NVEs sharing the same data center or an organizations that runs two NVEs, and it didn't make sense to have two computers sitting next to each other in a physically secure data center, they have to go through encryption.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Exactly.

**M**

Okay.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Question 32 relates to S-5, an NVE must make publicly available a notice of its data practices describing why IHI is collected and so on. The question was: Are there specific uses or actions that we should consider explicitly requiring an NVE to be transparent? Some of this goes back to the question we had answered previously that we believe that NVEs should be transparent and provide notice about how data, whether it's identifiable or de-identifiable would be used, and we made comments previously about adherence to HIPAA regulations and be transparent with regard to data exchange outside the purview of HIPAA.

We've called out that in particular NVEs that were not directly using a facilitating data exchange for treatment and health care services, i.e., HIPAA activities, the patient should have well defined categories of their uses of data to be exchanged. So this dealt with an NVE that, for instance, may have de-identified data that, let's say, wanted to use for some commercial purpose, the idea here was that those areas in particular should be required to have well defined categories and a high level of notice.

Question 33 relates to the same condition, would an NVE be able to accurately disclose all the activities it may need to include in a notice and should some type of summarization be permitted. We just believe that all NVEs should be transparent and provide notice as to how access data would be used. We had suggested that they'd be permitted to provide categorical use case descriptions to entities that it served. There were some other instances where we talked about category of notice and category of data. We believe that if there was a specific use case set of descriptions, that those could be repurposed from one NVE to another.

Micky, I'm sorry; I'm just looking at the time. Do you want me to go through the remaining questions here? Do you want to do public comment?

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Yes, do you think that, I'm just looking down, is there one question in particular? Which of these do you think can be sort of read offline easily versus ones that might need a little bit of conversation?

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Thirty-five and thirty-six I think related to previous comments.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Right.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

And there were additional clarification and by the time we got to question 43, frankly we have run out of time, so a lot of this was developed by email communication only, so I would say our conclusions here are not terribly robust. But condition S-10 around verifying that a provider requesting individual health information's recurring response has or is in the process of establishing a treatment relationship, our answer there was it would be very, very difficult for an NVE to know how in the world do I know that that provider is establishing a treatment relationship. We just didn't know practically how that could happen and that the meaningful choice should relied on as a primary mechanism to determine whether a provider or the user can query a patient's information.

So we were stumped to know how an NVE would know that when Dr. X says I am an authorized participant on this network. I'm a recognized provider. I'm acting under HIPAA rules of treatment and payment operations and I need to get data on patient Jane Doe, how we would we know, what would be the proof that Jane Doe had an appointment, a letter from Jane Doe? We just didn't know what would be sufficient in that instance.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Right, right. There are certainly networks that are doing different things for that, but again, it's pretty highly varied and highly dependent on what modes of exchange they've already got built in.

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

Hey, Micky, this is MacKenzie. We can go about five minutes over, but other than that, we won't be able to extend the call much longer because we do have another call at two.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Okay. I was actually just thinking, unless anyone has any further comments on this, it seems like we're probably in a position for the public comment, but let me just pause here and see if anyone has any questions or comments on this last, on question 43.

**Carl Dvorak – EPIC Systems Corporation**

This is Carl again; I think we think it's a pretty solid job at this point.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Okay. Great, well, let me pause here and just thank Cris and the entire subgroup for terrific work. I think this strikes a really good and appropriate balance on a bunch of very complicated issues, so thank you very much for that.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

It was a great group, thank you.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Great, best group and best leader ever. Okay, great, I think we're ready for public comment, MacKenzie.

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

Okay, operator, can you please open the line for public comment?

## **Public Comment**

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Don't we usually hear them when they're opening the line?

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

Yes, operator, are you there?

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

We can give them Cris' cell phone number.

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

Could someone please open the line for public comment?

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

There's someone out there probably just desperate to speak up.

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

I know.

**Operator**

(Instructions given.) One moment.

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

Thank you.

**Operator**

There are no public comments at this time.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Micky, this is Amy. I just want to confirm there's no 4 o'clock team one meeting today.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

That's right, yes; we'll be doing it all offline, Amy.

**Amy Zimmerman – Rhode Island Department of Health & Human Services**

Okay.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & Chief Executive Officer**

Great. All right thank you, everyone.

**Cris Ross – Surescripts – Executive Vice President and General Manager of Clinical Interoperability**

Thank you.

**M**

Thanks.

**M**

Bye bye.