



## Collaboration of the Health IT Policy and Standards Committees

Final Transcript

July 27, 2016

### Presentation

#### **Operator**

All lines are now bridged.

#### **Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a joint meeting between the Health IT Policy and the Health IT Standards Committee. This is a public meeting and there will be time for public comment at the end of today's meeting. As a reminder please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll; bear with me because it's a lot of folks. Arien Malec?

#### **Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Good morning.

#### **Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Arien. Kathy Blake?

#### **Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association**

Here.

#### **Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kathy. Lisa Gallagher?

#### **Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Here.

#### **Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Lisa. And Paul Tang?

#### **Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Paul. Aaron Miri?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata**

I am here, good morning.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Aaron. Andy Wiesenthal?

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)**

Good morning.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Andy. Andrey Ostrovsky?

**Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Andrey. Angela Kennedy?

**Angela Kennedy, EdD, MBA, RHIA – Head of Department & Professor Health information Management – Louisiana Tech University**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Angela. Anjum Khurshid?

**Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Anjum. Anne LaMaistre? Aury Nagy? Brent Snyder? Carolyn Peterson?

**Carolyn Peterson, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions**

I'm here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Carolyn. Chesley Richards? Chris Lehmann? Dale Nordenberg? David Kotz?

**David F. Kotz, MS, PhD – Champion International Professor, Department of Computer Science – Dartmouth College**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, David. Devin Mann? Donna Cryer?

**Donna R. Cryer, JD – Founder and President – Global Liver Institute**

Good morning.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Donna. Eric Rose?

**Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Eric. Floyd Eisenberg?

**Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Floyd. Gayle Harrell?

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Good morning from Southern...from South Florida.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Gayle. Jamie Ferguson?

**Jamie Ferguson – President, Health Information Technology Strategy & Policy, Fellow, Institute for Health Policy – Kaiser Permanente Institute for Health Policy**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Jamie. Jitin Asnaani?

**Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance**

Good morning.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Jitin. John Scott? Jon White?

**W**

He's not here today.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you. Josh Mandel? Karen van Caulil? Kay Eron?

**Kay Eron, MBA – General Manager Health IT & Medical Device – Intel Corporation**

Hi, good morning; this is Kay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kay. Kevin Johnson? Kim Nolen?

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

Hey Michelle, I'm here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kim. Kim Schoefield? Kyle Meadors?

**Kyle Meadors – President, Director of EHR Testing – Drummond Group, Inc., LLC**

Hi, here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kyle. Larry Wolf?

**Larry Wolf, MS – Principal – Strategic Health Network**

Good morning; I'm on.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Larry. Leslie Kelly Hall? Lorraine Doo?

**Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services – Health & Human Services**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Lorraine.

**Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services – Health & Human Services**

Hello.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Nancy Orvis?

**Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Neal Patterson? Patty Sengstack? Paul Egerman? Peter Johnson?

**Peter Johnson, MBA – Senior Vice President & Chief Information Officer – Dartmouth Hitchcock Health Care System**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Peter.

**Peter Johnson, MBA – Senior Vice President & Chief Information Officer – Dartmouth Hitchcock Health Care System**

Hi.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Raj Dash?

**Rajesh C. Dash, MD, FCAP – Director of Laboratory Informatics Strategy, Office of CIO – Duke University Health System**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Raj. Ram Srirami or Sriram, I'm sorry. Rich Elmore?

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Hi, Michelle.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Rich. Scott Gottlieb?

**Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hey, Scott. Steven Brown...Steve Brown, I'm sorry?

**Steven H. Brown, MD, MS – Director, Compensation and Pension Exam Program (CPEP) – Veterans Health Administration**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi. Terry O'Malley?

**Terrence "Terry" O'Malley, MD – Medical Director for Non-Acute Care Services, Partners HealthCare System – Massachusetts General Hospital**

Good morning.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Good morning. Troy Seagondollar?

**Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Troy. Wanmei Ou?

**Wanmei Ou, PhD – Director, Product Strategy in Precision Medicine - Oracle**

Here; good morning.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Wanmei. And that was a long list; has anybody joined us since we started roll?

**Kevin Brady, MS – Group Leader, ITL Interoperability Group – National Institute of Standards and Technology**

Kevin Bra...

**Karen van Caulil, PhD – President and Chief Executive Officer – Florida Health Care Coalition**

Hi it's Karen van Caulil, I might have missed my name.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yes, hi, Karen. And I heard a male voice as well.

**Kevin Brady, MS – Group Leader, ITL Interoperability Group – National Institute of Standards and Technology**

Kevin Brady for Dr. Charles Romine.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kevin. Anyone else join us? Okay so that was a long list of folks; thank you all for your patience. As you all know, at the last in-person meeting we announced a number of new members; there's a few new members who weren't able to join us at that meeting and they're here today; so I just want to thank them for joining and welcome them. And with that I'm going to turn it over to Paul to review the agenda today.

I'm sorry, but before I do that, Vindell, I'm not sure; I'm sorry to put you on the spot, do you want to make any opening remarks or should we just turn it over to Paul?

**Vindell Washington, MD – Principal Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

I just had three things, thanks for the opportunity. I wanted to share one anecdote before we got started today. We had had a couple of trips, more on the introductory phase with the...a couple the committees on the Hill and one of the things that struck me is just how often we, in describing our work and our collaboration with the community, that this particular set of committees came up.

And so I wanted to start the comments with just a word of thanks for all of you who have chosen to give your time in the service of this work. We know whether it's a day like today where you're spending your time virtually, or the more onerous part where you have to sort of have to travel and be with us in-person. I think it's really integral to the work that we do at the Office of the National Coordinator, so I do want to both welcome our new members and thank you all, in particular thanks to our chairs who have even additional time that they spend with us in helping us shape our policy and to inform the work that we do here. I really appreciate that.

The second couple of things I wanted to comment on is, we have a couple presentations today that have been a little bit of a while in coming, so we're particularly excited to have discussion today about the non-covered entities report that Lucia will lead for us. It's, we think, an important report for both informing as well as sort of being a nidus for discussion; and so we're looking forward to that.

And we had had some interoperability request for information from this committee, tis joint committee that we hope to be able to respond to later on in the meeting when we talk about some of our, what's going on in some of our rural hospitals and some of the follow-up answers to some of the questions that were posed when some of this data was initially presented. So we look forward to that, in addition to the work that was already mentioned that we're going to have from our Interoperability Standards Advisory and the vote is to follow.

I think the whole point on that, and Michelle has outlined it well, I believe, is we think that some of the value and some of the joint committee work is that very often some of the discussions around policy affects standards and vice versa. So the idea of us being able to have those discussions in such a way that both of those committees that are so important to our work are able to participate, hear the dialogue and sort of ruminate and help us work on policy and direction from there I think is important.

So again, thanks everyone, and particularly for your participation and your support. Thanks for the time, Michelle.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you Vindell. Now I'll turn it over to you, Paul.

**Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health**

Okay. Thank you Michelle and thanks everyone for participating on this call. We have had a change in our agenda at the last minute, just want to explain that a little bit.

We had a pre-conference call with the Co-Chairs of the committee and Co-Chairs of the Interoperability Experience Workforce...Task Force and discussed some of our interest in making sure we focus on the federal role. We've had a number of task forces directly related to interoperability and the things

related to that, such as usability, but we want to make sure we minimize the overlap with the previous task force findings and recommendations and emphasize the federal role for their recommendations.

So as we reviewed the recommendations, we asked them to look with the perspective in mind, so they've agreed to do that and they'll be returning instead of today, returning in September with their

final draft recommendations for our consideration. You know that we sort of talked some about their initial draft last time and so we'll just postpone their final draft recommendations for September, since we have a bye in August.

So anyone who might have their...the slides...the preliminary slides were posted for about an hour and in case anybody's downloaded those we have not presented, discussed or acted upon those, so, please treat that as non-official and will come back next time to talk about those.

So as Vindell just mentioned, we have a very important update from the Office of National Coordinator, the Office of the Chief Privacy Officer, having to deal with the non-covered entities, and that's the HIPAA term for, HIPAA does cover all of the providers, the payers clearinghouses, but all else, and in this world 20 years later from HIPAA, the world has changed a lot so there are a lot of non-covered entities that now will have access to PHI, what we consider PHI in the HIPAA world. How do we deal with that and do we have the right policies in place or are there gaps that we need to fill? And Lucia's going to talk about their work in that area.

Then we have the Interoperability Standards Advisory Task Force, which is a task force of the Standards Committee presenting their final draft recommendations for the Standards Committee to take action on, followed by a data update, and Vindell referred to some of that data as well, in terms of what's happening in the rural communities of the country and some other data. We'll close with...

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hey Paul, it's Michelle; I'm sorry to interrupt. We wanted to make today especially confusing so we had a last minute change and so the Interoperability Standards Advisory is going to go before Lucia's update; so my apologies.

**Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health**

Okay. That happened at the last minute then; okay. So yeah, so we'll just have a shift in that...the order. We'll close with the public comment and then we'll wish people a happy summer, give you a little time off before we come back, reconvene in September.

Any other additions to that and if now I could turn to of the summary of the last meeting and ask for a motion to approve those. I submitted some updates, some of the way it's recorded...the recording of...

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

So moved.

**Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health**

Thank you.

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)**

Second.

**Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health**

Second, thank you. Any other further discussions or edits? If not, all those who approve, please say aye.

**Multiple speakers**

Aye.

**Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health**

And is there any...are there any abstentions or disapprove? Thank you so much, and we'll turn it now over to I think Arien, you're going to be leading or facilitating the discussion from the Interoperability Standards Advisory Task Force.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Excellent. Good morning. This task force has been looking at the periodic revisions of the

Interoperability Standards Advisory. The standards advisory as I think many people know, is a non-regulatory set of guidance that ONC puts out that lists for a variety of needs and purposes, the best available or most appropriate standards at play for that need.

It's a rather lengthy document. I think anybody who believes that the problem in healthcare interoperability is the lack of standards would be well served by looking at the ISA and looking at, you know the rather lengthy set of standards, terminologies and the like that are listed in the ISA. The task force was also asked to look at the process by which the ISA is updated, to make sure and the purpose that the ISA serves, to make sure that it's appropriately situation relative to the interoperability needs of this country. It's been a great task force, ably led by Rich Elmore and Kim Nolen, so I am going to turn it over to them to take us through their recommendations.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

Thanks Arien; this is Kim.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Oh sorry, just before we begin. A reminder, as Michelle said, that we are going to vote on these recommendations. So I'm going to ask if we can complete the presentation and discussion by 10:40 and we'll reserve the time between 10:40 and 10:50 for the voting process and for anything concluding. So just a recommendation...a reminder after we go through the recommendations and go through our Q&A that we're going to reserve time for voting. Kim, sorry for the interruption.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

That's okay, thank you. So everybody can hear me okay?

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Yes, I can hear.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

We hear you, thank you.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

So Rich and I would like to thank everybody and if you all could just back up to the task force members, because I think it's important to recognize everybody who participated in the group. And I was sitting

here this morning reflecting on all of our meetings and conversations and I was trying to find a term that would describe what we've been through the past couple of months.

And I found this term crucial conversation, where it means the stakes are high, opinions vary and emotions run strong and I feel like with our group we definitely had that. Because what the ISA document means and having some misunderstandings about what the intentions of the documents are, and so we really had a lot to work through just to clear up that point of the conversation with the group. And I think when things are not always straightforward, it leads to lively discussions and I would say we've had a lot of lively discussions on our group.

But really what Rich and I wanted to do with the group as the Co-Chairs is listen to those conversations, and then try to take them and put them into actionable comments that could add and augment to the current ISA document so that as a move forward with our interoperability needs that we have document that people can go to and use as they see fit, wherever they are in the continuum of health IT, whether they're new to the industry or have been in the industry for a really long time.

So with that, I want to thank all of the committee members that have participated and as you will see in a little bit, we're not quite done yet, but we have a lot that we wanted to share today and get into a transmittal for the next phase of the ISA document and then we're going to continue to finish all...what we had started. So if we could move forward and Rich, I'll just pause real quick if you have anything to add to the introduction.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Good summary Kim, thanks.

\*\*\*During Kim Nolan's presentation on the recommendations of the 2017 Interoperability Standards Advisory Task Force, Altarum experience an audio disruption that required all participants to re-dial into the conference call\*\*\*

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

Okay, thanks Rich. So when our task force charge we put into two phases, and our hope was for Phase 1 to have gone completely through the document with all of its subsections, I, II and III mainly and then on IV we were going to focus in the second phase. We did not get that far, we got through most of Section I, so that's what we're going to present and then we're going to pick up with Section II.

We did ask for any critical comments from Section II and III that needed to be brought forward today and so we will share those. But we will be continuing to finish off our discussions with the document after today's presentation and our recommendation for the transmittal letter. If we could move forward, please.

So some of these slides we have gone through, so the ones that we went through in June, we'll go through fairly quickly. The ones that are new additions, I will spend a little more time on. For the ISA scope and recommendations, what the committee came up with is that you know the ISA document should really focus on the data, the standards and the interoperability needs in the certified health IT domain. And when appropriate, it could include appendixes or references for other authoritative sources for standards.

So last year we did that with the security standards, because there are other bodies that already take care of that and update it in a much more timely fashion than the ISA document. So anything that is not within the domain of a certified health IT technology, we thought it's important for people to

understand it, but let's reference it to that authoritative source, so with administrative standards, research standards, etcetera. And then we just defined secondary data, because that was a big conversation that came up for us. To be the reuse of the same data that is collected for clinical care.

We also recommended that for interoperability we needed to be there to connect to technologies outside of the EHR, because the EHR is not the only component that collects clinical care data. So if there are portals or any other technologies that are used by the patient or clinician, we need to be able to connect all those into a single source. And that when data is put in, no matter which technology it is, that it's put in once, but could be used many times for those secondary uses.

We also talked about that there were some industry gaps in areas where it would be valuable to know more about, but there wasn't a lot known or existed. And one was with data quality and patient matching, and we touched on that in June, and we have those slides at the end of this document for reference. The ISA task force also recommended that a standard...as newer standards came about and older standards aren't used any more, that the list should clear itself of those older standards so that people focus on the newer standards.

And next slide, please. For the ISA structure, one...you know these beginning slides were a lot of our conversation and we felt that it was really important that if we didn't have the foundation of the document settled, it would be difficult to go into the subsections, so we did spend a lot of time on this.

So for the structure, right now we have the ISA document as a PDF document, so you can look at it, it's updated once a year. So one of the things that the committee felt would be helpful for users is for it to be more dynamic and have links to different organizations that could help the user understand the standards and information around the standards.

So the ONC has already started an Interoperability Proving Ground, so we thought as people are putting in information there and demonstrating how they're using different standards for successful interoperability, maybe that could be linked to the ISA document so that people can link from one to the other to say, okay they're recommending this standard, but how have people actually used it and then they could link over to the Interoperability Proving Ground to see that. Also they're...I think once a year, and you all can correct me if I was...I'm wrong on that, they solicit comments for public comment and so if there's a way to view those public comments while you're in the document.

The next thing is to link to known profiling entities. So one of the conversations that came up during our discussions is, it's never just one standard that creates interoperability, it's a collection of standards and how they're implemented that creates the interoperability. So if there known profiling entities or profiling documents that could go with a standard to link with that so that it...the standard in that situation, but how they work together as a group.

So really just anything that you could link and reference to how the information was decided to be put in there, the group felt that was really important so that perceptions wouldn't be made that oh, some...a group got together and decided this and that was their decision versus it really came from a referenced source. And even if there's not a lot of information about it, just be clear about that.

In, especially in Section I, we have a lot mentioned about the VSAC, the Value Set Authority Center and linking to different value sets and starter sets, which we'll talk about in Section I. And so that was another important point that we thought, you know as people are creating these lists and cataloging them, you know link people to where they are so that we can be consistent about what we're revealing

and what we're doing and then that also helps with finding gaps so that we can improve with those value sets.

And as I mentioned before, if there's any annotations or references that could be added, that's always important and right now the document is done on a yearly fashion, but if it was in a more dynamic, maybe Wiki-like structure, could it be updated more frequently.

So if we could move to the next slide, and this is where I realized I was cut off, okay good. The...this is a slide that Dan Vreeman, he was one of our members on our group, they created a small subgroup and came up with some recommendations and they're scattered throughout, but I wanted to recognize them and thank them for their contributions with these.

And as I mentioned before, we had talked about linking to different profiling entities and their group put together some examples of these. So like with our base standards you can recognize general patterns with profiles that could be helpful for people, like they're doing implementation. And so they put some of these together for everybody to see and understand.

And next slide. So the ISA structure recommendation, and this slide also came from Dan's subgroup and this applies a lot to Section I with the vocabulary standards. We felt like in the structure it was important to make sure that you separate out the vocabulary standards for the observation and the observation values. And we have some examples that are coming up, so I'll wait to explain that a little bit more. We also listed out, and so we called this vocabulary pairing, pairing of the observation and the observation values is how we talked about it in the group. And so if you look at the third small bullet under the observation and observation values, we listed out all the sub-sections in Section I that we felt like it was important as the ISA document publishes out for 2017, that they clearly delineate the observation vocabulary standard from the observation value vocabulary standard.

There...also in the ISA document they wanted to make sure that with our core standards and the projected additions that we visually and clearly delineate is this a core standard? Is this a projected addition? And we have an example of that in just a minute. And then again to the reference annotation; it was from our group, we...they just really felt strongly that things needed to be referenced.

Also, a new thing that the subgroup came up with, which I think is important also, is the test tool availability. You know, as you have testing tools that are developed, link them into the ISA document so that if people want to test them out, they know where the test tool is. And next slide, please.

So this is an example of the observation and observation value pair structure and this is one that Dan put together for gender identity. So if you look at this, the observation would use LOINC as the vocabulary standard, but the observation value would use SNOMED. So the LOINC would identify we're looking at gender identity, and then the SNOMED code would tell you what the gender identity of that person is. And so in the ISA document today, these aren't always clearly differentiated...sorry, I thought somebody was trying to speak. Is somebody speaking? Can you all hear me?

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Hear you, Kim.

**M**

We can hear you.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

Okay, sorry; I heard a little blip of somebody's voice so I just with the challenges we're having this morning, I wanted to pause for a second and make sure everybody could hear. So...and I think, you know this is really important, I think as people are trying to implement these things that they understand the difference between the observation and the observation value pair. Next slide.

So this is...this slide shows a couple of different things. One, it lays out where geographically are...you are in the document. So you have the caret to show where you are in the document and then it also clearly lists out the projected addition. So this was that second bullet on the slide earlier that said, you know between the core standards and the projected additions that it's clearly labeled out, but as you want to navigate through the document, you can go back to the beginning or you could go back...prior that you were on. Next slide.

So best available standards; we reviewed in the June meeting. And this was another one of our crucial conversations, as I'll call them, where there was a lot of perception around what does "best available" mean, and people's perceptions could be different. So to kind of minimize it being perceived in many different ways, the group came up with the term "recognized standards," and we thought it would be good for the ISA document to label the standards more as a recognized standard versus a "best available," because people were like, what does best available mean? Is it the best standard ever or is it just the best that we have today? And it created a lot of controversy so we thought if we just made it a recognized standard it would minimize people's perceptions being different about what it meant.

And again we mentioned, you know when you have these recognized standards that you want to link it to the applicable standards bodies and the standards maturity, so that people understand where the standard falls in the continuum with its maturity. Next slide, please.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

So one of the things that we found was...

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

So the recommendations to improve use/functions of standards, we reviewed this on...in the June meeting and I'm going to let Rich give a quick summary on this slide.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Thanks, Kim. So if you recall, the MACRA legislation really calls for an ONC report by the end of 2018 on...as to whether or not we've achieved widespread interoperability.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

And Rich...

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Can you hear me, Kim?

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

I'm not hearing Rich well, is...

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

I can hear you, Rich.

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)**

Rich, I can hear you fine.

**W**

We hear you fine.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Okay, well Kim's heard way too much of me, so I'll go ahead. So the report out at the end of 2018, you know to try and report on our progress towards widespread interoperability we think relies in part on continued progress on existing standards and existing work that have already been...made its way into interoperability projects around the country. And from that point of view, we think that to continue that move towards better national scale of interoperability, the improvement, better constraints, better clarity, learning from experiences is an important part. You know, we need to make sure that the standards aren't stuck in regulation and are, you know moving forward.

So with that in mind, we...the task force called out a set of ongoing work that's happening in the community that we think is really important to reference as progress on standards that already exist, and this includes examples of structured documents that includes refinements to Consolidated CDA in R2.1 and the Companion Guide to be balloted later this year. Improvements related to Direct and of course implementation guides related to Argonaut and FHIR, which we'll touch on a little bit more later. And finally the NCPDP Pharmacy eCare Plan. So all of these we thought were important work in the community that needed to continue to make forward progress.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

Rich...

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Kim, I'm turning it back over to you if you can hear me.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

Can you all hear me because I did not hear Rich?

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)**

We can hear you Kim. Kim, we can hear you and we can hear Rich, he's finished.

**M**

Loud and clear.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

I'm not able to understand any words that are coming back at me and I don't know if you all can hear me.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Rich, why don't you take over...yeah, Rich, why don't you take this section and maybe Michelle, can you work out of bandwidth with Kim on her phone issues.

**W**

Yeah.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Okay, happy to do that. Kim, if you're able to dial back in, I think that would be great; if we could move ahead to the next chart, please. So one of the good results in the previous version of the ISA was to establish some sort of understanding of what adoption meant. And so there was efforts made to try and describe what those characteristics should be.

The feeling was that we don't really have the data to make that more quantitative and so we felt that, you know a qualitative approach was more important and probably more useful. And that there should be some sort of referencing as to how that adoption level was determined you know there could be some sort of descriptive field. And that there may be you know adoption level classifications that are available through standards bodies and other sources that would allow us to quantify that adoption level. And we recommended that the SDOs themselves, the standards development organizations themselves, who have in almost all cases published criteria about the standards and their maturity, be a reference for that, that we're actually linking to those maturity assessments; an example of that...of the evaluation criteria for that is the IHE Standards Matrix Criteria.

And we also recommended that under the category of you know standards process maturity that there was a reference to a category which we would call "ballot in development," so that emerging standards which are believed to be important for the industry to understand and appreciate as they evolve, maybe in rapid development are recognized in the ISA. And...but should be understood to be in that early stage of development. Next chart, please. And Kim, if you're back on just let me know and we'll turn it back over to you.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

I'm...

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

And next chart, please. You are back on, great.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

I...can hear you, you sounded like an alien before. I could not hear anybody's voice coming through, so I'm really sorry. Do you want me to pick up here?

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Sure, go ahead. Thanks.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

So for Section I we had some overarching recommendations, and I'm going to go through those real quick before we go through each subsection. In the ISA document there is a piece that says, applicable value set, and it sometimes has value sets that are listed. And so the group thought there's more than just value sets that people use, there's also starter sets. So we wanted to change that to include starter sets also in addition to value sets. And we thought providing a brief definition between a value set and a starter set would be helpful.

There also as I mentioned earlier, throughout Section I with the vocabulary standards, there were recommendations that any place that creates value sets for people to use in the industry, it would be to list those and to link them. So like the VSAC and some others that have public repositories or central repositories that a value set to have that linked in when you recommend that value set. A lot of times they had the value set and a lot of numbers behind it, and you would have to go find it; just to have a link there.

Also a recommendation was for VSAC to have permalinks and what was meant by this is you know sometimes you have a value set and you use it for something and if you had a permalink, you would always know what was in that value set and could quickly...so it was recommended to do that. So then if it changed, you would have a new permalink that went with it. Next slide, please.

Okay, so now we're going to go through the subsections of Section 1; the first one is allergies. We stated this, this is already in the ISA that you...that it should be clearly differentiated because sometimes in conversations people intertwined these two; there's the allergens, which is the substance that causes the reaction versus the actual allergic reaction.

For allergic reactions, we thought we would more define the SNOMED codes that could be used for the allergic reaction with a chosen clinical finding axis in SNOMED. So we thought it would be good if a value set was created for allergic reactions, and maybe it could be created by FHIMS and then considered a candidate starter set, and liaising with an SDO to validate the subset. So it would great to have a starter set for allergic reactions that people could populate into their system. Next slide, please.

The care team member. This one doesn't have a lot in the ISA document and there was some thought that what was listed...this was where one of the references would've played a nice role to know where the information came from. But...and we had quite a bit of conversation, but what came out kind of bubble up from the top of conversation is, there's two different ways to look at a care team member.

There's the care team member who has the credentials, so is it the physician, the surgeon, the pharmacist, the nurse; who is that care team member and what are their credentials? And then there's the role of the care team member; for instance I'm a pharmacist. If I'm on the care team is my role being as the clinical person, as the pharmacist or is my role a family member that's helping somebody out in my family.

So we thought the ISA document should differentiate these two types of roles that could be in the care team member. And then that may be helpful to figure out the vocabulary that goes with them. Because they're two different places or two different ways a care team member role could be. There was a suggestion that you can look at the NUCC to see if they maybe have something with the role as a care team member. So that was a suggestion to look at that. Next slide.

The encounter diagnosis. For this one we thought that in that applicable value set, starter set that we renamed that it may be good to list the three main axes that are used in SNOMED, the clinical findings, the situations with explicit context and event. And that a value set could be created in VSAC to cover these and we just give a potential name for it, "extended problem set value." If you, you know that name could be anything, but it would be nice to at least mention those three axes are the main one...are the general ones that are used. But it would be good to create a value set that you could list and link to VSAC.

A precondition should be added for medical diagnosis, so that they could handle older code sets. So you know, in October we had the conversion from ICD-9 to ICD-10, so people need to understand if they're trying to get legacy data or go back retrospectively that you're going to have to be able to maintain older code systems to be able to do that.

We thought a link with the mapping from SNOMED to ICD-10 would be a great addition in the ISA document. There also is that CORE problem list subset, it's a starter set for SNOMED codes and we thought that should be listed in the ISA document.

And then for dental diagnoses, today there's CDT-2 and SNODENT. And so we thought that a mapping between those two would be good, so if people are using one or the other, would be able to map back to what that means. Next slide.

Family health history. This was one that there are some pre-coordinated terms in SNOMED for family health history, but as we get into more predictive medicine, and want to understand the family health history, not only just from, have they had hypertension, is there a history of cancer, and those kind of things, but maybe some genetic preconditions. It would be really important to structure this in that observation/observation value pairing. So we wanted to make that recommendation so that as we evolve in medicine, the standards and the interoperability needs can evolve with it and handle what those things are.

So in LOINC they actually have the observations, you know is it a twin, is it a sibling, a brother or sister; a mother, father, those type of definitions. So you could have that as the observation, and then for the value pairing you could use something...you could use SNOMED like we do with others, but then they're paired together and you can quickly identify, this was a twin that has this or this was a mother who had this diagnosis with this person. Next slide.

Functional status and disability. For this one, there are a multitude of surveys and assessment instruments that are used for functional status and disability. So that has made it difficult to create new vocabulary codes, not a vocabulary standard but the codes within the standards that we already have for this. So the group thought CMS or someone not to mandate certain ones, but if they had a preferred set of survey instruments, you could start to build the code sets or value sets for those and it could help with the interoperability needs, with defining and assessing the functional status and disability.

We didn't think the vocabulary standards should change; it should still be either LOINC or SNOMED, depending on the observation/observation value pairing set. But there definitely needs to be some consensus about which survey or assessment instrument are the most preferred, so that we can...so the industry could move forward to build those out and have those available for people to use and exchange. Next slide.

Gender identity, sex, and sexual orientation. For consistency, the group said this would be better titled as sexual orientation and gender identity. We also wanted to just put out and ask the ONC to solicit feedback from the community on appropriate genetic identifiers and gender determinants, because as we move forward with precision medicine, there's an increased focus to document granular and specific information about the patient to target their delivery of healthcare needs. And we need to start thinking of other ways to determine gender outside of our traditional approaches that we have today.

So we had a lot of discussion about this, but we wanted to bring it out into the public for people to start thinking about. And ask the ONC, you know to get feedback from different stakeholders and communities about which would be the appropriate genetic identifiers and gender determinants to include in the ISA document. Next slide.

Lab tests. For this one, we thought the title should be changed to be the interoperability need representing laboratory tests. And we also thought you should remove the term numerical from the need name and instead use the general paradigm of the observation and observation values where the LOINC standard is the question or the observation and the SNOMED code is the answer observation code.

There also were some misunderstandings about LOINC, so we wanted to offer additional clarification for this. The observation codes are not needed when a test report a numeric quantity. Some observation values, particularly in genetics are best represented with a syntax or an identifier rather than a code drawn from an enumerated terminology. And some observation values are reported as a short text stream, which should be permitted.

So those were some of the recommendations and clarification points that the group wanted to make, and then also label the LOINC top 2000 lab observations as a starter set in the category of applicable value set or starter set. Next slide.

Medications. The task force acknowledged that RxNorm is the vocabulary standard that should be used for the exchange of information. We also wanted it to go a little bit further beyond the exchange, but also be available for export and import by end-users.

Some of the discussion on the group was RxNorm codes are used for exchange, but they're not always surfaceable or externalizable to the organizations so they can't use other higher-level functionalities like clinical decision support or for analytics to use those codes. So it would be nice if there was a way to make those more available to use them for different functionalities outside the exchange of the medication information. Next slide.

Numerical reference and values. The task force recommended a precondition to help stakeholders better understand that UCUM is syntax rather than an enumerated set of codes. Again, this is just a clarifying point for people to understand, because they sometimes go and look up UCUM and they expect to find a list of vocabulary terms, but it's really a syntax. Next slide.

Patient clinical problems. For this one again, in general there were three axes from SNOMED that are used to identify the clinical problem or condition; those are the clinical finding axes, situations with explicit context and the event. We thought it would be nice to have a value set that represented these or a starter set. We could also add the CORE problem list subset into the applicable value or starter set.

And we just wanted to mention that SNOMED does support the combination of codes, which is post-coordination to generate new meaning, but a code from other axes can be used in post-coordination. So when you pick these multiple codes, it can be seen as a disadvantage and this could be avoided if post-coordination is limited to the back end, exposing that single code for the user to pick. Next slide.

Tobacco use and smoking status. This was one that came from that subgroup that Dan led and some of the recommendations that came from that subgroup up to our main group was with smoking status there definitely should be the observation/observation value pattern. We should include a LOINC code that corresponds with enumerated SNOMED-CT value set. We should develop guidance about using the SNOMED-CT codes in the value set.

And really I think one of the biggest conversations that came up is that there are other variables beyond the SNOMED-CT value set that are used that are really important to identify the smoker or the characteristics of the smoker. And that we need to know more about what people are collecting for that to characterize the smoker that helps with their clinical judgment and we have codes that we can use to represent that. And so one of the things that the ISA Task Force wanted to ask was, could the ONC put together a stakeholder group that could discuss what those surveys, instruments or tools that are used to help collect smoking status information, so that we can have that more consistent across the continuum. Next slide.

We got through race and ethnicity, immunization, industry and occupation and preferred language and we had discussions on all of these. But in the end after the discussion, we felt like what was in the ISA document fairly represented what needed to be represented, so we had no additional recommendations on those sections. Next slide.

So we have three subgroups; two of them we presented at the June meeting, the API and the patient matching. And then Clem McDonald led a research group and this group came up with these recommendations, and these are in the projected additional needs for interoperability. And so for the research recommendations, here are what that subgroup recommended and brought back to the group and we were in agreement on.

As we mentioned at the beginning that the ISA document is really limited to the focus on data standards and interoperability needs that of the certified health IT technology, and that different standards for clinical care data and research will create barriers for research efforts. The following projected interoperability needs should be included in the ISA itself, and an appendix for additional research standards made to be more appropriate.

So to represent analytical data for research purposes, research submission of analytical data to FDA for research purposes; pre-population of research case reports from electronic health records, and integrating healthcare and clinical research by leveraging EHR and other IT systems while preserving the FDA requirements and registering a clinical trial are things that would be more appropriate in an appendix.

A cautious approach should be used in including the vocabularies which differ or conflict with vocabulary standards listed in Section I, as this may obstruct much research dependent on data present in EHR. The FDA has moved toward adopting LOINC as part of a larger FDA effort to align with the use of data standards for clinical research with ongoing national health information technology initiatives. And we should be aware and evaluate for future inclusion efforts underway using FHIR-based approaches to better support research and interoperability needs.

So those were the recommendations that came forth from that smaller subgroup to our group on the research recommendations.

And then the next slide is the patient matching; we reviewed this in June, so I will leave it here for people to look at real quick, but I won't go into detail, due to the time and our technical challenges we had this morning. Of course we can answer questions if someone has a question.

And then the next one I believe is on APIs, and Rich did you have any comments in addition to what we mentioned in June on the API-based interoperability approaches?

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

No, but just to refresh the joint committee, this was really...we felt it was important that APIs are going to have an impact on what standards are selected for new applications. They're going to have potentially impact on existing standards which ought to be deprecated. And making sure there's an appreciation for what an API-based world will mean we thought was an important element of the next generation of the ISA.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

Okay and if we can go to the next slide. Okay. So priority recommendations that came up in Section III-A, the push exchange should explicitly reference the leading trust communities that help ISA users better

understand where to turn to ensure the right implementation can communicate effectively with other users. And again, we did not get to Section II and III, so this was something somebody brought up that we need to look at and we should link to DirectTrust for provider messaging and NATE for consumer-mediated exchange.

And then for Phase 2, we have three sections in sect...three subsections in Section I to complete and then Section II and III. So, we'll be taking care of that in Phase 2 and reporting that back to the committee when that's completed. And I believe that is the last slide, yeah. So Arien, I will turn it back over to you and Lisa.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Excellent. Yup, thanks so much for that update. I hear we put the Policy Committee to sleep, but this is the level of detail that is required to improve interoperability in this country and I think this task force has done an amazing job at getting to the level of specificity required to make the ISA maximally useful for HIT developers in this country.

Michelle, given the technical issues, we're over time; just want to get logistics from you in terms of when we should be going to the voting route and how much time we could allocate for discussion.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yeah, I think Arien, so we have five people in the queue with questions, so I think that we should go through those questions. We had originally scheduled toda...today's meeting went back and forth because of the change of the agenda items, so we originally at one point had this meeting scheduled to go until one. I'm hoping we don't have to go that long, but I'm also helpful that people might have a little additional time to go beyond 12 today, especially with the technical difficulty that we had.

So I think that in order you know in order to give this the full time that we need, I'd suggest maybe 20 more minutes to go through the five questions and to vote. And if we finish sooner than that, that would be wonderful.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Excellent. Thank you. So let's go through the questions, would ask members to keep your comments and questions brief, unless you've got something that is sort of foundational or a significant concern. And then we'll reserve time for voting at the end. So Michelle, why don't you go through our question list or our questioner list?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Arien. So the first person is Andrey Ostrovsky.

**Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand**

Thanks guys; this is a great level of detail and I think it will be incredibly useful. My question pertains to understanding the scope of what like implementation guides mean and also to the earlier part of the presentation, I think a few times I heard reference making this information linked up online almost in a living document fashion. And so that question around the scope of implementation guides and putting things into context, I would...I guess a comment and I'd love to get your response to this, is it reasonable to request that implementation guide or use cases also tie in kind of the next step of not just how people have used these standards, but also what is the business case and alignment with kind of the dollar flow from the regulatory perspective?

I think that may be out of scope for recommendations that we would put in here, but I know that would be incredibly helpful for entities that want to take the next step with utilizing emerging standards and existing standards, but just don't have the technical expertise to connect those dots, so any thoughts on that folks?

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Maybe I can take this one Andrey; it's Rich. So as it relates to the implementation guides themselves, there are a number of examples out there where the standard in and of itself may not give you enough specificity about how to implement it that it ensures that it's constrained, that it's well-formed, that it's consistently understood how it's to be implemented by developers with examples, whatever.

Implementation guides help with that, and there are many different examples of that. IHE has done a lot of good work in that area. And that is part of what we've recommended needs to be brought into reference as part of the ISA, because we think that that's really crucial to you know, execution...good execution of interoperability.

As it relates to the idea of linking to a business case and dollar flow, you're correct that that would be out of scope. But wha...we do think that the Interoperability Proving Ground will give folks that are interested in those kinds of questions access to the hands-on work and the real world experience that would allow you to evaluate that. So the task force was very clear that the use case foundation of the ISA that exists today is very valuable and should continue as the framework from before. Did that address your question?

**Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand**

Thank you. I think it does, yeah. I think as much as we can make this information, which is super technical as accessible as possible, particularly for stakeholders in provision of care that typically have less resources to invest in IT, namely LTSS providers, home and community-based service providers, I'm trying to think through their perspective, this is really interesting stuff, especially with the 90/10 Medicaid match for technology investment. They wa...a lot of them want to leverage this information, but I know that most of them can't because they don't have the capacity resources, etcetera, so as much linking up and kind of putting ourselves in their shoes in terms of the user experience and even navigating a website to access this information, I think that will go a really long way.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Yeah, I think that is consistent with the structure recommendations from the task force and I appreciate that feedback, thank you.

**Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand**

Thank you, Rich.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks Andrey. Eric Rose.

**Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects**

Hi, I just had to take myself off mute. I...so, I really like most of what was presented this morning, particularly the bit about connecting ISA to the Interoperability Proving Ground, so I think that should be you know maybe the flagship point on the transmittal letter. The one thing that gave me pause when I first heard about ISA, and still gives me pause is the ambiguities, the murkiness around where regulation

leaves off and ISA picks up and I think that I'm confused about the references to...or the recommendation to stick to certified EHR technology as the scope of what ISA covers.

And the thing is that if there's something...if there's a requirement in regulation, it shouldn't really be covered under ISA because the regulation says, this is what you're going to do there really isn't any scope for further advice, unless it's...unless it goes beyond the scope what's in the regulation. So for instance the regulation says use this implementation guide, the implementation guide has a little bit of wiggle room about what you do to populate a particular data element, then I can see ISA having a role in saying, well it seems that the best approach is to do X.

But I guess what I'm asking for is, I think it would be good if you tightened up the...precisely what ISA should cover regarding certified EHR technology and in particular that it assiduously avoid any overlap in what's in regulation, otherwise it's just going to cause massive confusion and be assumed to be an extension of regulation, and I don't think that...

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Maybe Eric if I could just clarify our understanding as this was teed up for us with the ONC., the thought was that the Interoperability Standards Advisory is a landscape view of all standards. So whether they're in regulation or not, that they're there so that people can understand them. They're recognized standards is what we're recommending are the ones that are included. And it becomes kind of a, if you will, an on-ramp towards standards which may be considered for future regulation, but that is in fact, a separate process and not tied at all to the ISA.

Now to the extent that, you know the regulations puts things in cement, the ISA also represents an opportunity for us to identify, you know how do you un-cement that with newer kind of standards that should be understood by the industry and potentially considered for future regulatory adoption. So they're...they are very distinct in that regard. I don't know if that's good clarification.

**Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects**

Yeah, I guess...I would just hope that part of your recommendation be that the...that ISA has to bend over backwards to make it painfully clear where the regulation begins and ends and where the soft recommendations or helpful information begins.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

That's a good comment, thank you.

**Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects**

Thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Leslie Kelly Hall.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

Thanks Michelle. I have a couple of small items and one concern. So we mentioned the precision medicine in the dialogue and I appreciate that, but one of the recommendations from our team was that a part of the ISA include an amend...or an addendum that specifically started to catalog and advise people with regard to precision medicine standards. So I'd like to see that as part of the recommendation.

Also another small item on the slide regarding, or this slide that's up regarding DirectTrust and NATE. Both NATE and DirectTrust are offering consumer-mediated exchange. So I think this appears to be an either/or and I think there's more opportunity for both.

And then the other areas where I would hope to see more guidance in the ISA, one is on consumer-based vocabularies. As we start to accept patient-generated health data, there is a need for how to translate that data into medicine, so that the ability to collaborate and cross-collateralize consumer vocabularies and medical vocabularies is important. I think the work needs to continue that was started by Kaiser's donation to SNOMED; would like to see some mention of consumer vocabularies in this.

And then my overall concern is how standards evolve, particularly with regard to the FHIR introduction. And I am concerned that although a standard is named and its fixed to the moment in time, let's say the Consolidated CDA which we think of today as just document-based exchange, but we use that structure then going forward to do queries-based exchange.

And as new entrants to the marketplace then, who wants to participate would have to certify to this document-based exchange, although delivering a FHIR-based exchange, which may or may not be referenced in the standard as a next iteration of the standard but something that sits completely new because it's a new platform. So as FHIR becomes more important, especially in consumer-based, Open APIs and others, we really need to address how standards evolve more than just backwards compatibility in a particular named standard.

But when we have a compatible or equivalent standard in a new technology, there needs to be guidance. I hope that this is something either this task force can take on or we could take on as a larger subject in the Standards Committee, but it needs to provide some advisement to the industry, and I think the ISA is a perfect place to do that. So, those are my comments. Thank you.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Leslie, if I...first of all thanks, those are terrific comments and you did reference the precision medicine addendum recommendation the last time; we should have picked that up in here. So...and that was discussed with the task force and I think that there was general agreement that it should go in that direction. So we...I believe that we can, Kim if you agree, that we can probably add that recommendation, based on the prior task force conversation. I would just ask if you could clarify on NATE and DirectTrust, what you were looking for with respect to the ISA.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

We were saying here that it's DirectTrust for provider and NATE for consumer-mediated. DirectTrust also offers a Partnership for Patients Initiative which is consumer-mediated exchange as well.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Okay thanks, we can...that.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

So it's not either/or, I mean...yeah, it's an either/or.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay...

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

And is there it relates to...again if I can just, kinda just kinda just go down the list here, just so we make sure we have a disposition of these...consumer-based vocabularies, we can bring that back to the task force; that may involve, you know a proposal to put that in as a contemplated future edition, but I would suggest that that probably needs further task force conversation that we have not yet had.

And as it relates to the FHIR introduction and compatibility and kind of linkage to existing standards, there's probably an informational role for the ISA that's already reflected in these recommendations, but I guess I would yield back to the Standards Chairs as to how that should be addressed.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Great, yeah; in general we have been able to approve recommendations with clear and suggested amendments. So is there a...

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

So Arien, this is Leslie. Do you think that this idea of the standards evolution as we introduce FHIR as a new platform, which may not be part of an actual named standard, how do we accommodate new entrants and what advice can we give them? Is the ISA a place to do that? Does that warrant further...discussion?

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

That's definitely, yeah, so that's definitely been historically part of the mission...

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

Okay.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

...for the ISA is to serve as a mechanism for introduce has been one of the explicit ONC asks of the ISA is to be a means for introducing new and emerging standards. And obviously FHIR is already listed in the ISA in that level of emerging standard. I just want to do a time check with respect to the questions in the comment queue and with respect to our need for a voting round, Michelle?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yeah, so we've had more people get in the queue, so we now have five folks in the queue, so I'm not sure how to proceed. I guess I would ask if the questions that remain will alter the recommendations in any way, then we should probably go to those questions. And if not, then maybe we could have those questions be answered as we also let the Standards Committee members start to formulate their decision on whether to approve the recommendations.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Yeah, so if anybody who is in that question list has a set of questions or comments that would materially affect the recommendations, please speak now; otherwise we'll go through the voting round and let people do questions and comments in parallel.

**M**

Hi Arien, it's...sorry.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Sorry, so a number of folks dropped; sorry, and so there's three folks still left in the queue, so it sounds like those questions may affect the recommendations.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Great, let's go with those.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, so Raj?

**Rajesh C. Dash, MD, FCAP – Director of Laboratory Informatics Strategy, Office of CIO – Duke University Health System**

Yes, thank you. So this is Rajesh from Duke; I'm a pathologist and I'm new to the committee. I'm excited to be here and this was a very exciting presentation for me to listen to. I do have a question, because it will affect how I vote. You know there's the focus of ISA, I mean obviously some standards but you know the broader question is one about interoperability and there are many standards, but you know I think we've all seen that standards alone are clearly insufficient for interoperability.

The point that was made early on and in the discussion about implementation guidance and profiles for articulating use cases for interoperability, I do think is really important, but there wasn't a lot of time spent on that. Even organizations like IHE struggle because there is a missing component and I think what we really need to recognize, is that the importance of creating an infrastructure for creating, curating and using, providing guidance for the clinical data elements and the value sets that are used in clinical information systems, that work in conjunction with standards, be it vocabulary, messaging, document display standards, what have you, I think is one that we perhaps haven't spent enough time on.

Because if we just elaborate standards, I mean for clinical care and the information systems that I provide guidance for deployment at Duke University, I don't utilize the standards. I don't utilize SNOMED-CT and I do use LOINC only because it's required for Meaningful Use, but it doesn't help me take care of patients. And I think we need to ask ourselves, why that is? There are data registries out there like the caDSR, but no one mandates that we use them and if we just focus on the standards, which standards are the best standards to use or the recognized standards to use?

And even if we provide implementation guidance, I think that still remains insufficient for interoperability, for establishing interoperability. We really need to talk about which you know data fields are important to achieve interoperability and then come up with a data registry that speaks to ho...to the important ones that reflect the data that we want to interchange among systems. And so I just want to ask about the scope for the Standards Committee and whether that is within the scope or really outside the scope? Thank you.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

(Indiscernible)

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

So I think that, let me take that first one then I think maybe...I'm sure Arien's going to have something to say about that as well. But as it relates to the ISA, our job here is to try and...or our recommendation here is really to try and broaden the understanding of standards, recognized standards in terms of, you

know real work that's been done, real standards that have been established, real value sets that are relevant and have been...that have been made available, potentially identifying, you know gaps or emerging standards as well.

But it is not the function of the ISA to be the foundation for how we as an industry address those gaps. So it is more of landscape view than you know, the mechanism within which you know we would necessarily create a new infrastructure for addressing those.

**Rajesh C. Dash, MD, FCAP – Director of Laboratory Informatics Strategy, Office of CIO – Duke University Health System**

That's very helpful, thank you.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Yeah and definitely the comment on more appropriate implementation guidance, value set subsets and the like definitely is in accordance with the ISA and I suggest maybe for the next round of ISA updates that it sounds like you're volunteering to participate in the ISA Task Force to make sure that we can raise somebody's more important considerations for future developer use. Michelle, why don't we go down to the next comment in the queue?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

All right, thanks. Floyd Eisenberg?

**Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC**

Thank you; so I'll try to keep mine just to two limited comments and one is, slide 21 the discussion about functional status and I think the standards are fine, the concern is asking CMS to specifically identify and I'm assuming that means place into rules specific evaluation forms and tests that should be used. And I think these will change over time and trying to codify any of that into a rule could be very problematic. Perhaps providing examples in the standards advisory of things that would work would be helpful, but I'm a little concerned about defining individual functional and other status forms that would be required.

I guess the other question is really about things like problem lists where perhaps advice on yes, there are standards, but some advisory about what's an appropriate way to make sure the data are correct when they're there, because we can share problems, but if they're not appropriately managed by workflow, they might not have the meaning we're looking for. That's it.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Is there a suggested amendment for the first comment, Floyd?

**Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC**

Yeah, I would suggest where it does say specifically ask CMS to work with stakeholders to choose some, let me look at the exact language, I had it up here. It says CMS should work with stakeholders to choose a preferred set of survey instruments. I think I would be concerned about having CMS specifically choose instruments, but maybe to provide examples, rather than choose.

**Larry Wolf, MS – Principal – Strategic Health Network**

Hi, it's Larry, I wanted...I want to jump in on this piece on CMS because CMS is going through a round of...they're reviewing their mandated assessments and trying to get them better aligned across care settings and to reference generally recognized standards as part of those assessments. So I think that

needs to somehow be recognized in here and I'm almost thinking as federal agencies do implement standards, that the ISA becomes like a back reference to where those standards have been used in federal regulation. I know that's a big undertaking, but it might be really helpful to keep everybody up to date with how all this is interconnected.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

Arien, this is Kim. For Floyd's suggestion, I think that would be fine to change the language because that was the consensus from the group, we just didn't word it well.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Right.

**Steven H. Brown, MD, MS – Director, Compensation and Pension Exam Program (CPEP) – Veterans Health Administration**

This is Steve Brown from the VA; I'd also like to make sure that it's recognized the VA has its own disability assessment systems that are largely unrelated to what CMS may have purview over so I'd hate there...for there to be confusion between the two systems and have system owners think that they can send us things that we're utterly incapable of accepting or vice versa.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

All right.

**Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.**

Arien....

**Larry Wolf, MS – Principal – Strategic Health Network**

I think we're pointing out the existing federal landscape where there's a lot of agencies that do put in place very specific requirements and it would be great if the standards community and the federal agencies actually had an ongoing and active dialogue that was heading towards better...

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Yeah.

**Larry Wolf, MS – Principal – Strategic Health Network**

...synchronization across all of them...

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Just a...

**Larry Wolf, MS – Principal – Strategic Health Network**

...so we don't have these issues.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Just point of order, I think that's a really valid and important point, but a little out of scope relative to the needs and goals of the ISA and the ISA Task Force. So, you know let's take that as a future point of consideration for how to make sure that the US federal agencies better align their standards, which is definitely a part of...been aligned with Standards Committee comments in the past. Michelle, how are we doing on the comment queue?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

The last person is Jamie Ferguson, but I just want to check with Jamie because he is now a Policy Committee member, so I'm not sure if his comment will impact the Standards Committee as he's not voting as a Policy Committee member.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Old habits die hard.

**Jamie Ferguson – President, Health Information Technology Strategy & Policy, Fellow, Institute for Health Policy – Kaiser Permanente Institute for Health Policy**

Well, it's true, it's true that I'm not voting, but my comment is about something that I think is missing that we talked about in our last in-person meeting, it's actually reflected in the minutes that we just approved which is, in our in-person meeting we talked about adding that eHealth Exchange implementation guidance for query-based exchange. Because if you got implementation guidance from DirectTrust and Argonaut and others, then it would be in sort of balance if you will, to also include the eHealth Exchange. I think that was the gist of that, but I did not see that in the transmittal letter; so because it was something that we talked about, I wanted to point it out. I thought that had been agreed to.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Jamie that is consistent with task force conversations and it would be an acceptable amendment, yeah.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

All right, so with respect to voting, I think now we're ready, we've drained out comment queue and we're ready to start voting. We have two suggested amendments, Floyd's with respect to CMS examples rather than recommendations and Jamie's with respect to adding eHealth Exchange as an example of an implementer that has produced implementation guides. So with those amendments assumed, let's go through a voting round. Michelle, can you remind us again on logistics of the voting?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Sure.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

Arien, just before you get to that...

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Yeah.

**Richard Elmore, MA – President, Strategic Initiatives – Allscripts**

...just before you get to that, I think Leslie had also recommended the...from the Precision Medicine Task Force that there be some ISA addendum for evolving precision medicine standards as a recommendation.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Great, okay; so three suggested amendments that we'll take as given and go through voting. And Michelle again remind us on the voting procedure.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yeah, thanks Arien. So just a reminder, the vote is only for Standard Committee members and if you are logged into the webinar, the same...the little man that you use to raise your hand, there's a drop down arrow next to him. If you could please select either you agree using the green little check or if you disagree, that would be appreciated.

If you aren't logged into the webinar, if you could verbally let us know your vote, or send me an e-mail, either way. And also, just a reminder, because we have a number of new folks on the phone as well, ex officio members who are federal partners, you do not vote. So, if you all could do that now, it would be appreciated.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Excellent and then Michelle, just while we're waiting on voting, I think we're going to have a little bit of a pause here, do we want to move on to Lucia and tabulate the voting at the end of Lucia's section; how do you want to handle that?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Actually that would be great Arien, just to give me a little time to make sure that all is okay.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Great, okay. So thanks everyone and thanks to the ISA Task Force for your excellent work and for your recommendations.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So Lisa, are you on to turn over to Lucia now?

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Yes. I am on. And is Lucia on?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

I am here.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Hi, Lucia.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

And I'm one of those policy wonks who just woke up from a nap so thank you for the wonk. No, I'm just kidding, actually its stuff I should probably know more about but I defer that to the technologists that work for me. So, could we bring up my slides please? Actually could you go to the first slide because I have a few...I'm going to try and go through the slides pretty quickly because I had some yieldy questions but I had a few moments of gratitude that I wanted to cover.

So, just for the whole Standards Committee and Policy Committee to know this report that we issued a week ago was a very long undertaking by ONC and many, many people who you know and have worked with in the past had a hand in it. When I called Joy Pritts and told her it was going to be published she

was very excited, but I wanted to call out three particular people who really pulled everything for us first Devi Mehta on my team, Devi is a Privacy Analyst and she joined us about a year and a half ago and she really did a stupendous job getting a very complicated report through about 20 rounds of internal review.

Secondly, I want to thank the OCR Policy Team Jocelyn Samuels, Deven McGraw and Christina Heide without whom we could not have done this in terms of their precise explanation of OCR's authority.

And finally I want to thank and note a couple of things about the FTC. We had a lot of support in developing this report from the Federal Trade Commission from the Commissioners on down to the senior staff who handle health at the Consumer Protection Bureau, but I want to be really clear this is not an FTC published report, they have a very specific process for publishing reports that have the FTC brand on them and while there have been some media reports that this was an FTC report it is not, we did it in conjunction with FTC, a lot of great collaboration from them but this is straight up an ONC report.

So, and then thanks also to the immediate office for its patience with me as we worked over those 20 versions to get this out to the public.

Turning to the report itself, can I just have...I need the slide preceding this one please? So, just what I'm going to cover really briefly today is kind of what this report did, the identification of the problem, what the scope is that's identified in the report, why we're covering it at time and then I do have one slide at the end to sort of give you some further updates about what we've been busy with on cybersecurity since we had some public releases about that this week and I'm going to reserve a fair amount of my 25 or so minutes for your questions. So, now I'm ready for the next slide.

All right, nope, slide three, all right, so, on the 19<sup>th</sup> of July, and the link is provided here if you haven't already received it from Michelle, we published a report called, examining the oversight of the privacy and security of health data collected by entities not regulated by HIPAA.

In this report we identified an executive summary of five particular areas where there are gaps in the oversight of privacy and security between what HIPAA does and what things...how things outside of HIPAA that are collecting health information about individuals are regulated.

And those five things, which I'll go over in detail in just a second, have to do with an individual's right to access their data, the security conditions under which the data is held, what can be done with the data in terms of sales of the data or marketing to the people that are reflected in the data, whether consumers understand these differences and whether this environment is facilitating or impeding innovation. Next slide, please.

I wanted to briefly tell you what the scope is of the report and what's inside and outside of the report. So, we had a very long set of robust discussions across our stakeholder internal groups about what we were trying to cover and we want to be really clear, we are covering obvious development in what we called mHealth technology, you might think of it as what are you wearing on your wrist today, so exercise trackers, mobile devices, health related trackers that you carry with you that you purchase yourself or that are embedded on your phone, health social media, so social media sites where people are actively disclosing health information about themselves as opposed to sort of casual disclosures, you know, in your private messaging on Facebook, and then personal health records not hosted by covered entities and you'll remember that was a topic of significant discussion at the time HITECH was enacted.

There are some things that are digital information about health that we specifically excluded among those, you can read more details in the report, are, you know, GPS data where you go on your daily route and whether your GPS is on your smart phone can be correlated to health events but we did not include that here because we didn't think of it as direct collection of health information.

Another example would be pollen counts and of course those two things go together, where are you and is the pollen high could yield important information about your respiratory health but we kept it out of scope for this report. And then finally casual social media disclosures, I feel lousy; I had the flu today on Facebook those are out of scope. Next slide, please.

Okay, so here's some background information or high-level summary information about what the problem is. On that point of consumers are confused the research shows, and our own anecdotes that come to ONC, and the dialogue that was had in the API Task Force, and with this committee, as we discussed the API all confirm, pretty robustly, that consumers don't really understand that the boundaries of HIPAA and with certain kinds of economic activities are really limited to traditional health care and HIPAA doesn't really reach to all of this new technology except in some very limited circumstances which we do describe in detail in the report and we worry about that because we want consumers to make knowing and thoughtful decisions about what's going to happen with their health data and we worry that the confusion is preventing that knowingness and that thoughtfulness.

Secondly, on the use of data, so HIPAA has very specific rules about whether the information collected about individuals can be used to sell products to those individuals. Those of you who work in covered entities or business associates will be quite familiar with that. There are not specific statutory or regulatory rules on that point outside of HIPAA.

There are fair practices that the FTC will enforce and I'll get to that in a second, but there isn't a statutory or regulatory scheme that says you can use it to market things this way but not to market things that way.

The other aspect of this that I think is really important, which we highlight in the report is HIPAA also says that you can sell the data itself once you de-identify it according to particular regulatory standards and those requirements for minimum levels of privacy protection through de-identifications do not apply to the sale of data collected in other environments and by way of example of our FTC collaboration the FTC has done really fantastic work on data brokers and the Internet of things and we didn't reinvent any of those wheels we just sent people reading the footnotes on the reports straight to the FTC's work.

A third area is security and I know this is a very important area in healthcare in general, we have to mature our own straight up traditional healthcare responses to security but for the collection of this digital health information outside of HIPAA while there are definitely engineering best practices for security there aren't, again, statutory or regulatory requirements that create security minimums for how data is held. There may be security minimums embedded in the terms of use for an App Store or that a developer asserts they will adhere to, as they make their product available to the public, but there is no minimum set by law.

Lastly, and almost most importantly, on the substance, within HIPAA as you know because we've talked a lot about it in the last 10 months, individuals have a right to access the data about themselves in a way that has meaning to them and to require that data be sent to places they choose, that is not true for non-covered entities. So, you may have, again, if you're wearing something on your wrist that

organization may make some promises to you about accessibility of that data but you don't have a legal right to it, you have a right to it based on the product's terms and conditions.

So, those are kind of the four substantive areas. As you can see there is some pretty significant differences and we worry that those differences are in fact impeding innovation. So, again, this is based on research as well as what comes to us by way of information.

Developers, some of them really want to do the right thing and they're not quite sure what the right thing is and we've been doing a lot of collaboration on that with the FTC and OCR, and the FDA over this spring to help developers have a better understanding of what they're doing but we worry that there's such a desperate need to innovate and bring better information to consumers and providers in dialogue with each other, is this confusion, are these differences impeding that innovation? Next slide, please.

So, this is just kind of high-level summary of the protections that exist. I'm going to go over this pretty quickly for those of you who have participated in the API Task Force you had a lot of discussion about this, this is also set forth in that recommendation and the bulk of the report is about this slide in terms of who does what.

So, I know that as we talked about the API Task Force recommendations earlier this spring lots of questions about who does what I would recommend that report to you, it is only 35 pages, hopefully it won't put you to sleep, but even if you read it in chunks it has really definitive information about the state of this law today.

So, HIPAA, which is enforced by OCR and state attorney generals, provides a nationwide privacy, security and breach notification minimum for health information that's accessed, used and disclosed when it's held by covered entities and their business associates, all of those terms of course have lots of detail in their meaning.

The Federal Trade Commission has its Consumer Protection Bureau, and what it does is it has a well-developed body of law primarily through administrative enforcement actions and litigation in which they enforce some consumer oriented privacy and security minimums when they believe those minimums are unfair and deceptive. For example, they have brought law suits against organizations that have asserted that they'll behave in a certain way but in fact don't behave that way or the way that they've asserted they'll behave is kind of fundamentally unfair.

They also use that authority to bring actions against companies that fail to have reasonable and appropriate data security policies regarding consumer data including health data and they also use that authority to bring actions against businesses that have made false and misleading claims to consumers.

An important limitation on the FTC's jurisdiction however is the FTC's jurisdiction reaches only to for profit companies. So, a charitable company, an academic medical center may not be within the scope of the FTC's jurisdiction.

And then finally, we actually have our other sister agency at HHS, the Food and Drug Administration, we talked in the past about helping you guys have a better understanding of where the FDA authority ends and OCR begins or ONC's begin, but they oversee the authority, the safety of medical devices and sometimes that is, you know, something that you wear that connects to an EHR and sometimes it's an implanted medical device and their focus is really on, from a regulatory perspective, the safety of that activity, their authority doesn't reach to the privacy conditions under which those pieces of equipment are collecting data. Next slide, please.

So, why now? You know like I said this report has been a long time in the making but I'm actually kind of please, I don't think the timing could have been better actually. It fits very well with the work we're trying to do to advance automation within the healthcare system through the "read only" API portion of the certified EHR technology rule, our work to help people take advantage of mobile Apps in a private and safe, and secure way, what Precision Medicine is trying to accomplish, where they specifically want to take advantage of this technology to make data available to researchers and of course consumers have gone mobile.

If we had done this report in 2010 just focused on PHRs we would not have the same level of detailed help in charting the course forward from here. Next slide, please.

So how does this fit with other ONC efforts? Well, number one and probably fresh in your minds is the API Task Force where both in your discussion of it and in the Task Force itself there was lots and lots of discussion about what was fair for those unregulated Apps relative to consumers and privacy and security and I think this report, which gives a very definitive description of the environment we actually have, which is a result of statutory enactments, really helps fill that gap in knowledge.

Secondly, I think it helps us as planners and advisers for the Secretary and for the Administration here at ONC to help chart this course forward. We've got this "read only" API in our 2015 edition certification rule but we know that as patients use whatever App they want, which is what the standard is in CMS, we have to be constantly thinking about the fact that Apps have different privacy and security policies.

And then lastly, I think it really compliments the work that we've been trying to bring to the market with the FTC and with OCR so that we can move the developers of these new technologies farther along the path of doing the right thing as it relates to consumer's privacy and the security needs. Next slide, please.

All right, so I'll just pause, I know you have questions, I'm sure going to queue up, let me do my brief cybersecurity update, it will take just a minute or two, and then I'm happy to take questions.

So, just updating you on the Cyber Information Sharing Act of 2016 Task Force, it met again on July 21<sup>st</sup>, just last week, progress is being made. The next in-person meeting will be October 26<sup>th</sup> I think that's the right date, I will have Michelle send out a correction if I've gotten it wrong and I provided a link here for the pages on the HHS website where updates will be posted.

I am told by Co-Chair Emery Csulak that they will be starting to post Blogs with comment boxes so please keep track of that URL and look for Blogs from our friends at the Assistant Secretary for Preparedness and Response.

The second item that I wanted to your attention is last week, the day after the non-covered entity report in fact, ONC published a funding opportunity to help establish a more broad-based information sharing and analysis organization within the health and public health sector and ASPR followed suit with a FOA on July 25<sup>th</sup> so links are provided in your PowerPoint as well as the Blog from Dr. DeSalvo and Dr. Nicky Lurie who is the Assistant Secretary for Preparedness and Response.

This is another piece of work that has long been in the making and I'm really happy to announce that it fulfills a commitment we made in the roadmap to actually get this funding opportunity on the street and I hope that the stakeholders who really want to dig in and improve cyber threat sharing for the health and public health sector will take a good look at it and see how they can collaborate to put together a great response.

And I believe, Michelle, that is my last slide, yes, absolutely, happy to take questions now.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Lucia, before we go to questions, Lisa did you have any thoughts or comments?

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

I had a question but no additional comments but I did have a question.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, I give you chair's prerogative, go ahead.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Okay, chair's prerogative. Lucia, if we could go back to the last slide please whoever is controlling the slides. So, here I see that there are two funding opportunities one from ONC and one from ASPR. Can you clarify the difference between them and/or the relationship between them?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Sure.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

So that we understand what each organization is aiming at and what kind of organizations they're looking for?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Each grant really derives from the granting agency's authority. So, the ASPR Grant is really focused on helping this ISAO build infrastructure that enables better receipt of information from HHS, and we of course get it from DHS and the FBI, as well as pushing information out, technology to push information out, to the members of the ISAO. So, it's very much sort of infrastructure oriented and of course ASPR is our agency responsible for critical infrastructure.

Our FOA goes hand-in-hand with ASPRs but it has a different focus because of our authority, so our FOA is really hoping that this ISAO takes, obviously that infrastructure, but uses our grant to help make the information meaningful to a wider...available to a wider group of participants than currently participate in cyber threat training and also meaningful to a wider group of participants than currently receive it. So, we're trying to solve two problems one is how many people and the second is the meaningfulness of the information they receive, it's got to be something that, you know, healthcare organizations from the gigantic multistate provider organization to the small locally based office can all take advantage of and understand. Is that helpful, Lisa?

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

It does help. A couple of other points of clarification both of the FOAs are for not-for-profit organizations, correct?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Honestly, I don't have the terms and conditions memorized.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Yeah.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

And they would be subject to whatever the normal federal rules are for grant making.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Yeah, and then I'm also curious as to whether one organization can apply to both of them or if they're meant to be separate types of organizations?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Absolutely, there are no restrictions on one organization applying for both if it thinks it has a qualifying proposal.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Awesome, okay, thank you. Those were my questions Michelle so let's open it up to any other questions that may be out there.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**

Hey, before we do that, Michelle, just a point of order to raise your hand for a question you've got to clear out your vote so I just want to make sure that you've counted all the votes and that that's okay?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yes, we are all good there.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**

Okay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Since you bring it up I might as well say, there are 19 Standards Committee members on the phone, 17 approved and 2 abstained, I'm not sure if they didn't vote, but I've reached out to them just to see what happened there, but those recommendations have been approved.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**

Thank you, very much.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Arien. So, the first person in the queue is Jamie Ferguson.

**Jamie Ferguson – President, Health Information Technology Strategy & Policy, Fellow, Institute for Health Policy – Kaiser Permanente Institute for Health Policy**

Hi, so I have three comments, I'll be quick, the first is, so Lucia I just want to thank you very much for an excellent report and very timely.

The second is I wanted to touch on the exclusion of the geolocation data and I feel that should be reconsidered, but also I think it should be considered in the broader context of Federal Communication Commission regulations because these FCC regulated anti-use that provide the geolocation data are in many cases business associates as well as data providers to healthcare entities.

And then staying on the theme of the FCC Regs, my third comment is about the recent or I guess from April the FCC NPRM for privacy regulations that applies to broadband service providers who are these BAs and data providers, you know, some of the things in that NPRM were different definitions of individually identifiable data, different breach definitions and breach notification provisions, as well as different consent requirements and I think, you know, you can just imagine the confusion from a consumer perspective of getting duplicate and conflicting breach notifications as well as multiple authorization requests and so I just want to recommend coordination with the FCC on that.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yeah, so let me just...I'll just go serially down there, first of all, the report is finished which doesn't mean that interested stakeholders cannot take the information in it and use it however they want, it's 100% public, you don't even have to ask me permission to download it, somebody did ask me that, I'm like "it's on the website, go get it." So, I would really...and people have asked me about that, I'm like the report is there to help facilitate people's discussions with clear and decisive information. So, have it, Jamie.

Secondly, let's just say geolocation is a very complicated issue and when we do a report like this, which is filed with congress many, many different components of the administration weigh in on it so that we can make sure that we are accurately reflecting authorities and certainly the administration's policy view-points and so all of that occurred and I will say definitively FCC had a bite at it through the clearance process, it's a very detailed process here.

I think that, lastly, what I'll say is, a lot of people are watching this space as we get deeper and deeper into the Internet of things through the rules we have been working with and the ways we have structured our laws continue to serve our need for information, consumer products and an economic growth and I think those are all really valid things to be discussing.

**Jamie Ferguson – President, Health Information Technology Strategy & Policy, Fellow, Institute for Health Policy – Kaiser Permanente Institute for Health Policy**

Thanks.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Lucia. Paul Tang?

**Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health**

Thanks, Michelle, and thank you Lucia for really a great report and as you know I'm very interested in this topic. In your introduction for the report you said this report was going to analyze the scope of the protections, identify the gaps and recommend addressing the gaps in ways to protect consumers. So, are you just recommending that we address the gaps and that's the recommendation or did you also make recommendations in how we could protect consumer information when they're in non-covered entities?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, the content of the report, like I said, is final, and it does not contain specific recommendations for legislation or Task Forces by ONC or regulatory revisions by OCR or a particular activity of the Federal Trade Commission.

**Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health**

So...

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

I think that...but just to sort of follow on, I think that, as I said to Jamie, you know, the report was...it really focused on giving people a definitive picture so that the stakeholders involved here consumers, providers, business associate businesses, legislators, innovators, venture capitalists, whoever wants to join in the conversation can collectively figure out how to move the need to innovate forward, the need for more even-handed privacy and security regulations forward.

**Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health**

So, maybe that was sort of a setup for saying, do you see a role for this FACA group to weigh in on...to what you've laid out?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

You know the one thought that crossed my mind, and I'm not making a recommendation at all, I haven't really sat down and had a chance to talk with ONC leadership, is I think there's kind of a sweet spot for ONC moving forward, at least from my perspective, in kind of bringing the need identified in the API Task Force for consumers to better understand what this all means, this report, ONC's work with the model privacy notice and what actually helps consumers make good choices about privacy together. I'm not quite sure what that would look like but to me that would be helpful to hear from, you know, a Task Force on that point because that helps me do my work and planning what is OCPO going to do next to help consumers understand that, you know, HIPAA basics apply in covered entity land and other things apply outside of that land.

And I'm happy to hear ideas that you all have as well from the co-chairs or that bubble up to the co-chairs from committee members.

**Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health**

Okay, thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Paul. Wanmei?

**Wanmei Ou, PhD – Director, Product Strategy in Precision Medicine - Oracle**

Hi, hello, it's Wanmei here, Lucia, thank you for the presentation. I have a question regarding the scope of these reports especially the definition on your slide number four, the non-covered entity. So, yeah, number four, thanks.

So, in the past few years a number of pharmaceutical companies started disease specific programs to coach the patient, especially the patients taking their specialty drugs, to help them to manage daily

activities. So, these types of programs usually have a web application or maybe even involve a wearable device to communicate between the patients and the people working in the pharmaceutical company. So, is it this type of application or is part of the definition that the NCE that is covered in this report or because the pharmaceutical company is a for profit organization, so these kind of web applications or wearable use is covered in the FTC?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, I'll say two things; that was definitely in our sights when we created the report base definitions of mHealth technology and health social media, we specifically talked about that activity and pharmaceutical companies are not regulated by HIPAA.

That being said, a pharmaceutical company may also be regulated by the Federal Trade Commission and so the...you have to remember the report is trying to say, OCR does this, ONC does that, Federal Trade Commission does this third thing and one has to be cognizant of the way the Federal Trade Commission exercises its authority and how its authority works, but, yes, that was exactly one of the types of activities we had in our sights when we wrote that first and second bullet on slide four.

**Wanemei Ou, PhD – Director, Product Strategy in Precision Medicine - Oracle**

Thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So, Lucia, I just wanted to check with you, I think you have to leave at 12:00 and there's a number of questions in the queue.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

I can stay a little bit longer and just, you're going to hear a little key clacking while I delay my next meeting by about 15 minutes, but go right ahead.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

All right, thank you, we appreciate it. Aaron Miri?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata**

Thank you very much. Lucia I appreciate it as always, excellent job with your report. So, I have two questions related to the ISAO and one question related to your non-covered entities.

Related to ISAO, looking down the path as the grant and all that take hold and whatnot and the industry begins to start sharing information do you foresee any provisions or type of support for a safe harbor mechanism for covered entities to participate in sharing data?

And my second question related to ISAO is related to information blocking. Do you see or foresee any provisions to address that particularly see as maybe contractually forbidden to participate and not able to share information? I personally can think of several circumstances with a strategic vendor such as an EMR vendor that would have forbidden me to share crucial data that was security related just simply because I was contractually limited.

So, I share those two questions with you and then on the covered entity one do you foresee any approaches that a state may take a more stringent stance from an FTC perspective on looking at non-covered entities like an mHealth technology and how that may play into a national strategy?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

All right, so working my way from the top to the bottom, in fact, Aaron, in the Cyber Information Sharing Act Homeland Security was charged with developing guidance for exactly the point you specified which is, what should people who are sharing cyber threats be expected to share and how much liability protection do they have in certain methods of sharing.

So, we can take that as a “to do” item in conjunction with Michelle and Elise and the co-chairs, you know, attempts to bring that back to...DHS does have guidance on the street, it is general, it is not specific to the healthcare sector, that guidance is in fact going to be part and parcel of the work the Healthcare Cyber Information Sharing Task Force, under 405c, will be working on for their report in March, due in March so a lot more to come on that.

We put this FOA on the street it’s been long in the works before congress acted and we’re happy that it’s out in time for the HHS Task Force to account for what the grantee will be doing.

Secondly, on information blocking, see prior answer, I think that we have to look to the governmental policies trying to facilitate the creation of threat sharing for all of our economic sectors and I can absolutely imagine that whatever intellectual property contract restrictions might exist in healthcare are not unique to healthcare so that is part of what the HHS Task Force is working on is how do we make sure people have the space they need to share the threats that need to be shared.

Okay, last, purchase by states, we did not do a comprehensive analysis of state law relative to non-covered entities. We do know that some states have much...state specific breach identification laws that relate to any digital collection of information that’s identifiable without getting into the technical legal definitions there and of course under HIPAA states are free to do that as well, so I have no idea how states will react to our report or even if they know about it, but they certainly have those powers right now.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata**

Thank you so much.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Is it okay if I add to that Lucia?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Sure, no, go ahead, Lisa, you’re the chair you have a prerogative.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Aaron, just so that you know this is a bill actually that has some specification regarding the types of information that can be shared, cyber threat indicators or defensive measures shared for a cybersecurity purpose and also there is a list of the types of liability protections that they intend to afford. So, I think, you know, from that point-of-view you can look to the actual statute to see what congress intended in terms of the liability protections. And I also have a summary that I could send you if you want.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata**

Absolutely, and I definitely appreciate that. I would just quickly state in the interest of time that contractually I can imagine, especially covered entities being very reluctant, again, because of the contractual obligations that exist and the risk to business if they share too much or over share so I will look to guidance for how to educate the general populace of this is okay, you can share this data because it's for the common good and nobody...

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Right.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata**

Can really come after you and attack you for that.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Right.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

The other thing I would add to that...the other thing I would add to that Aaron, again, and I think, you know, DHS has already taken the statutory construct and added a lot more detail, you know, we're really talking about sharing the threat indicator not sharing the health information. I make this editorial correction all the time don't just be sharing information because...

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**

Right.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

In healthcare people will get confused, so, we're really talking about sharing the threat indicator and there maybe incidental circumstances in which it's connected to a person but the DHS guide is pretty clear that the times in which the identifiable individual information has to be included with the threat indicator are very minimal.

And the last thing I would say is, if you've been following certainly OCPOs work on this as well as some other organizations, you know, a key place we need to go for cybersecurity improvement in healthcare is, you know, where does it all come together in the c-suite and while, you know, an organization might be reluctant to share because of an intellectual property term they also have to think about what happens if they don't share that means they're not going to get sharing and they may have a system which has a security problem which has its own liability manifestations.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata**

Great points, thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Kathy Blake? Kathy are you still there?

**Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association**

Yes, I am, I just went off mute, thank you. So, a couple of things, which sorry I'm also working with a phone and computer, I'd like to go back to the non-covered entity opportunity and draw support for us actually seeking this report and translating it into a Task Force charge and I'd envision that Task Force having a very strong consumer focus because I think that's the opportunity that we have to have computers...

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Hey, Kathy, we lost you.

**Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association**

Consumers have to their health information. So, thank you very much.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, Kathy, this is Lucia, I lost about 20% of your question so could you repeat it please? It was just an audio problem.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

I think...

**Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association**

Hi.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Kathy is really hard to hear so maybe I can follow up with Kathy to get her recommendation.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Okay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Sorry.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Absolutely and Kathy, you know, give me a call I'm happy to talk.

**Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association**

Great, thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Gayle Harrell?

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**

Thanks so very much I really appreciate it, this is an amazing report and I can't wait to read the entire thing. I have a very...a lot of concerns about the problem it's presenting and especially where we're kind of in that wild west of so many things going on in so many different devices and the ability to use them that I foresee some ability issues and perhaps some covered entities not wanting to participate because of those liability issues...indefinite who has the responsibility and whether the FTC really would come in and protect consumers.

Could you comment a little bit more on liability issues and where you see that and perhaps what role ONC could play in clarifying it or developing policies or guidance, or something, especially for covered entities when you're dealing with non-covered entities?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, thanks for the question Gayle, just as a reminder of course, ONC's rulemaking authorities are constrained to certified EHR technology and related activities so we don't write rules about liability in fact pretty typically just in the federal government in general if there is a regulation about liability it has to do with the way a regulator who wrote that regulation and forces the regulation it doesn't really have to do with the liability that might arise in an argument between two private people.

So, liability between two private actors is pretty typically handled by case law or potentially by legislative enactment either by the state or the federal legislature. So, there's not too much we can do about that Gayle within our authority.

I think that what you're...underneath really sort of that issue is some of what bubbled up as we were talking about the API Task Force and we listened very carefully both to the Task Force itself and to the Joint Collaborative Committee on this issue of, you know, on the one hand adults are allowed to pick whatever App they want and we don't particularly regulate private behavior that way, and maybe there's three hands, we want them to make those choices with full knowledge about what's going on and that's a clear theme of our report which is, please just tell the consumer what you're actually doing with their data so that they can make a knowing choice about their products.

And I think there is more to be done in that space that's certainly consistent with the authorities of my office and the way ONC has pursued this in the past. Obviously we have some activities in the pipeline like the model privacy notice and the way that would work is if we...when we publish that it will have terms in it as we proposed in our request for information and a developer could adopt those terms as it's notification to consumers and then a failure by the developer to adhere to what it adopted would be actionable by the FTC. So, there's actually a very solid and well-worn path in place if you can get the developers to adopt terms that are favorable to consumers.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**

And, one of the things that I did want to address was that education component which I think is key and ONC probably is the best entity out there to do that and I think there needs to be more discussion among, you know, perhaps the advisory committees as to what role that ONC might take in that arena.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

And I'm flattered by your compliment but I will also say that, you know, if you have not had a chance to go to the Federal Trade Commission's Consumer Protection Bureau pages on privacy and security for the Internet, which this is, right, non-covered entities are the Internet it's just that it's health information in the Internet, they're really fantastic and they have great tools for the consumer and infographics, and obviously the developer portal, you know, which guidance applies to your product is there as well, so that's why I started by saying we had a very strong collaboration here across the three most salient federal agencies and I think that collaboration will continue.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**

I think that's absolutely necessary. Thank you for what you're doing.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Gayle, so we have two more or one more question in the queue, I just want to thank all of those who have stayed on with us and let you know we appreciate your patience so we'll get to our last question and then for those who can stay on we do have one more presentation. So, Leslie Kelly Hall?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

Hi, thanks, Lucia, great work as always. Just one question for either future iterations or to see if this was considered in this report and that's the Precision Medicine Initiative in that many of the new actors are not covered entities in the traditional sense, but data will be quite personal, health-related, and persistent over time and more valuable over time. I think it warrants specific call outs with regard to all of the players in the Precision Medicine Initiative at large and beyond that for instance the biobanks, the technology transfer companies, how the HPOs actually act in this behalf and also the data repositories.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Thank you, Leslie, so one of the great things about the timing of this report is we got to actually make it relevant for precision medicine. So, you have to imagine a universe when this report was in process and precision medicine manifested and we were able to really take all the work we've done in preparation for this report and bring it to Kathy Hudson, to the White House team working on precision medicine, so lots and lots of dialogue has been had with them in our capacity as sort of expert, subject matter experts, for the rest of the administration. So, that all happened, you know, starting January of 2015, and I know for a fact because I've given them personal copies of this report that they have it in hand.

The other thing I would say is that I think, you know, as we look at projects like Sync for Science, you know, we dialogue all the time with non-traditional healthcare organizations doing digital health businesses ranging from, you know, Oracle and Apple to small developers through their association and they've all kind of been waiting for this to come out so that they can see what the landscape looks like, and again, sort of back to what I was saying, you know, with Jamie and Paul, our job...the essence of our job was to give everyone a reliable and definitive picture of what actually is the case legally from a privacy and security stand-point and then let people take it where they need to go. If precision medicine needs some more consumer protection to really recruit those million people I have no doubt that they will pursue that.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

Thanks, Lucia.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, we do have one more question, I'm sorry Lucia.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

That's okay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Dale Nordenberg?

**Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science**

Hi, thanks, Michelle. Two, maybe quick questions, one is how do you see the privacy relating to safety with security being the common root cause? And then secondly, is there a possible role for this FACA around establishing data standards for what kind of...how the data regarding threats and cyber surveillance, if you will, is shared amongst entities?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, on your first point I think that, you know, my staff and many other HHS agencies support this HHS Task Force and I'll just say if you participated on the 21<sup>st</sup> of the public session and welcome to come to the public session later afterwards, this is a key point that many people are acutely aware of as they figure out how to respond to that congressional charge and you'll have to go back to my June slides to get to that charge, I wasn't prepared today and I don't have them memorized, but in fact, yes, right, data integrity, the fact that data could be rendered not...have its integrity taken away through a cyber threat results in a safety problem as well as being a privacy effect but more importantly, right, we don't want people harmed or dying.

And so I think...I'll just reassure that the people we're talking, which is a very great group of volunteers, very aware of that problem and really kind of framing it around that, you know, thinking about, for the healthcare sector is that the core problem we need to solve because sharing so that your intellectual property doesn't get stolen, well we can learn how to do that from other industries but sharing so that people don't get hurt is a unique problem in healthcare. Hopefully that answers your first question.

And your second question is, so I think we have to wait and see. The authority for this clearly rests with ASPR they are the sector specific agency so they interact regularly with DHS on the cyber threat landscape and they are the HHS agency responsible for infrastructure and for really getting this threat sharing going we're adding to it within the scope of our authority to help out and so I don't know what they're going to need when they finish that HHS Task Force.

Happy when the Task Force is done in March to do whatever is appropriate to help you guys understand what that Task Force has concluded and again you should definitely watch the Task Force webpage for Blogs where you can comment they're going to be actively soliciting public comment on a number of things in the next few weeks. But I think that there's so much good learnings to be had from finance and transportation which have pretty good threat sharing systems as well as the new DHS guidance under...itself that we have a lot to chew on right now.

**Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science**

Thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, so I think that was our last question. Thank you so much Lucia we appreciate you staying on and bearing with us.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

You're welcome.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So, we have one more presentation from Vaishali for the ONC data update. I know some folks have already had to drop because we were supposed to end earlier. I think we're going to go ahead and have Vaishali do her presentation; she can try and do it as quickly as possible leaving more time for questions than walking through the presentation. So, just want to thank you all for your patience and take it away Vaishali.

**Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

Okay, great, thank you so much. Today's presentation is a follow-up to a presentation I had done a couple of months ago related to interoperability of hospitals and today just diving in a little bit deeper into interoperability among hospitals, you know, just trying to be responsive to some of the questions that committee members had and digging into areas that we really wanted to better understand.

So, today's presentation will focus on three specific aspects of interoperability. One, how does interoperability vary across hospitals, particularly as it relates to rural, small and critical access hospitals?

Who are hospitals exchange partners and what are levels of exchange with those partners?

How are hospitals exchanging data both in terms of their means of exchange and the entities that they're using to enable exchange?

And finally, just want to mention and point out that the results of this presentation are based on the 2015 American Hospital Association Health IT Supplement Survey and the results are published and available on ONC's health IT dashboard and relate to data briefs 35, 36 and 37 that's the latest one that has a lot of what I'll be discussing today. Next slide, please.

So how does progress related to interoperability vary across hospitals? Next slide. So nationally, as I mentioned a couple of months ago, the percent of hospitals electronically sending, receiving and finding key clinical information grew significantly between 2014 and 2015 and about 85% of hospitals nationwide are sending summary of care records electronically and about 65% are receiving summary of care records electronically and about half, 4 in 10 hospitals, are able to query and integrate summary of care records electronically within their EHRs respectively. Next slide, please.

They decided to examine how that varies across different types of hospitals. Amongst smaller hospitals, rural hospitals and critical access hospitals we found that they had significantly lower rates of electronically sending, receiving, finding or querying and integrating information summary of care records and as you can see here in this table we compared small hospitals to medium and large

hospitals, critical access hospitals to non-critical access hospitals and rural hospitals to suburban and urban hospitals.

And across each of the four domains of interoperability that we examined the smaller hospitals, critical access hospitals and rural hospitals had significantly lower rates of engaging in all those four domains of interoperability compared to other hospitals within that category. And we can see specifically that rates of querying data, integrating data specifically has, you know, much bigger gaps as compared to sending data across these different hospitals. Next slide, please.

And, you know, that has an impact on outcomes that we looked at as well. What we found was that electronic availability of the outside information at the point of care and the subsequent usage of information that's received from outside sources was significantly lower amongst rural, small and critical access hospitals as well.

You know about three, you know, between 39% to 35% of small, critical and rural hospitals had information available electronically from outside sources and between 46% and 41% were actually using information that they received from outside sources as compared to half of hospitals nationwide. Next slide, please.

We tried to take a perspective in looking at how EHR adoption has varied over time amongst rural, small and critical access hospitals and we can see that, you know, from 2011 to 2015, you know, the gap between rural hospitals, small hospitals and critical access hospitals, and hospitals nationwide has been closing and there's been significant increases in EHR adoption amongst these hospitals, you know, for example critical access hospitals basic EHR adoption rate has increased fourfold from 2011.

And so, you know, as it relates to gaps in interoperability it maybe that we'll have to track this over time to see how this evolves and it maybe that similar to EHR adoption some of these gaps may narrow over time but that's something that, you know, remains to be seen. Next slide, please.

The next point that we wanted to discuss was who are hospitals exchange partners? Next slide, please. So, one of the things that we pointed out last time was the lack of exchange partner's capabilities to receive, electronically receive, data was amongst the most frequently identified barriers to interoperability in 2015 and although this significantly declined from the prior year where about 6 in 10 hospitals were reporting this as barriers this remained a significant barrier and one of the things that we wanted to look at was, you know, what are hospital's rates of exchange with different types of partners. Next slide, please.

What we found was the rates of sending and receiving summary of care records electronically between hospitals and other types of providers significantly increased between 2014 and 2015.

On the left is a graphic that shows rates of electronically receiving summary of care providers from behavioral healthcare providers, long-term care providers, outside ambulatory care providers, as well as outside hospitals and the graphic on the right shows rates of electronically sending summary of care records to these different types of providers and what we can see is that compared to 2014 rates of both sending and receiving have significantly increased across the board for all different types of providers including behavioral health providers and long-term care providers.

However, rates of sending and receiving summary of care records to behavioral healthcare providers and long-term care providers is lower compared to rates of sending and receiving summary of care records with outside ambulatory care providers and outside hospitals. Next slide, please.

So, how are hospitals exchanging data? This was the next question that we wanted to examine. Next slide, please. So, what we found was we took a look at hospital's methods for sending and receiving summary of care records and categorized the methods as either a mix of paper-based methods and electronic methods exclusively using non-electronic methods only such as fax. And then exclusively using electronic means of either sending or receiving data and what we found was compared to 2014 hospitals significantly...the proportion of hospitals that are using exclusively paper-based or non-electronic means of sending and receiving data significantly declined.

And what you can also see is that there's a corresponding increase in the proportion of hospitals that are using both paper-based methods as well as electronic means of sending and receiving data. Next slide, please.

So we delved into the different methods that hospitals are using to electronically exchange summary of care records and what we found was that using secure messaging with EHRs was the most common method of both electronically sending data as well as receiving data. The next frequently most used method was health information exchange organizations or some third-party to send and receive data and finally the least frequently cited method was a provider portal to either send or receive summary of care records. Next slide, please.

Another aspect of exchanging data that we examined, the mechanisms to exchange data that we examined, was what outside entities are hospitals using to enable exchange and we found that 6 out of 10 hospitals nationwide are participating in state regional or local health information exchange organizations and using an HIE specific vendor to enable exchange, so that's 6 out of 10 hospitals are using both these mechanisms.

Another 3 out of 10 hospitals are using an HIE vendor alone and they are very few hospitals that are using only one or the other. So either are using a HIO and not using a vendor rather and only 5% of hospitals are not using a HIO and not using an HIE vendor. So, most hospitals, about 9 out of 10 hospitals, are using either an HIE vendor or participating in a HIO to enable exchange. Next slide, please.

So, some of the key takeaways are that, one that rates of both sending and receiving information and other aspects of interoperability, such as finding and integrating information and the subsequent outcomes of that, electronic availability of information at the point of care and subsequent use of that information that's received from outside sources, was lower amongst small hospitals, rural hospitals and critical access hospitals and that's something that we'll want to track and monitor over time.

Additionally, hospital's rates of electronically sending and receiving information to and from a variety of providers across the care continuum significantly increased between 2014 and 2015. However, hospital rates of sending and receiving data electronically were lower with behavioral healthcare providers and long-term care providers compared to other hospitals and outside ambulatory care providers.

With regards to the methods of exchange exclusively using non-electronic means of exchange declined significantly with hospitals really transitioning or shifting towards using a mix of paper and electronic means of exchange and a majority of hospitals are using both HIOs and HIE vendors to enable electronic exchange of information. Next slide, please.

So, some of the implications of this, rural hospitals, small hospitals and critical access hospitals have nearly closed the gap in EHR adoption but lag behind with regard to interoperability, and again, this is something that we are planning to analyze further to delve into understanding why these gaps exist and

we also plan to continue monitoring that to ensure that these hospitals close this gap similar to what they did with the gap in the EHR adoption.

Hospital rates of electronic exchange across a variety of providers increased. This indicates progress as it relates to these partner's HIE capabilities. Even though we're not able to currently directly measure the HIE capabilities of behavioral healthcare providers and long-term care providers at the moment what this shows us is it's likely that behavioral healthcare providers and long-term care providers have increased in their capabilities and again this is something that we'll continue to monitor over time.

With regards to the gap between long-term care providers and behavioral healthcare providers with outside ambulatory care providers and other hospitals in terms of their rates of exchanging with hospitals this gap remains and, you know, is likely related to the fact that many of these providers are not eligible for MU incentives and, you know, with the future provisions of MACRA and Medicaid funding for HIE amongst non-MU eligible providers may help accelerate the improvement of this and, again, this is something that we'll continue to monitor over time.

And as more exchange partners engage in interoperability they'll be an increasing shift from paper-based to electronic means of exchange, however, until there's a big improvement and exchange partner's abilities to electronically send and receive information hospitals are likely to continue having to use both electronic and non-electronic means of exchange.

And finally, what we found was that a majority of hospitals are having to use both HIE vendors as well as, you know, participate in health information exchange organizations to enable exchange and certainly this has implications for cost as a complexity of exchange although overall it's encouraging that, you know, 9 out of 10 hospitals are really trying to...are using these organizations to enable exchange and this has likely had an impact on increasing rates of sending, receiving and being able to find information from outside sources.

So, I'll stop there. I think the final slide just want to mention that, you know, I've had to go through this material very quickly but if you have any further questions and want to know any more details you can take a look at our health IT dashboard and the information is available in data briefs number 35, 36 and number 37 which was just posted today on the dashboard.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks Vaishali, so we do have a question the queue. I just wanted to quickly check to see if we could hear Kathy on her line and if not I'll just go through the queue of questions.

**Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association**

So, Michelle, can you hear me now?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yes.

**Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association**

Oh, alleluia, thank you, well, first of all, Vaishali, thank you and I think we're all aware of the progress that's been made and appreciate your efforts. So, Michelle I'll turn it over to you for the questions that you see in the queue.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Kathy. Raj?

**Rajesh C. Dash, MD, FCAP – Director of Laboratory Informatics Strategy, Office of CIO – Duke University Health System**

Yes, I actually have two questions, but I'll just ask one and then if we have time we can come back. I was wondering if the data on the data exchange reflects communication only to potentially other hospitals with the same information system. The fact that I can share records for any patient in North Carolina, which is great by the way, but it has nothing to do with my EHR's vendor's effort devoted to interoperability but more to do with the market penetration in this state. Do you know if the data separates that or was specific to data interchange between different information systems or that was not part of the question?

**Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

Yeah, that was not part of the questions. I mean, the...yeah, in terms of the rates of exchange for example with behavioral healthcare providers or long-term care providers. We didn't ask them, you know, did those behavioral healthcare providers or long-term care providers have a different or similar EHR system than your own, it was agnostic to that, it's just basically overall regardless of whether the exchange partner had a similar or different vendor or what the marketplace concentration of the vendors are.

There is a paper that has been published on this topic that you're referring to. Dr. Julia Adler-Milstein recently published a paper looking at rates of exchange amongst hospitals using the same dataset although using 2013 data I believe in health affairs. So, if you're interested in examining that topic in further detail I would suggest you could take a look at that paper.

**Rajesh C. Dash, MD, FCAP – Director of Laboratory Informatics Strategy, Office of CIO – Duke University Health System**

Oh, yes, thank you that's very helpful. The other kind of related thing was whether the HIO and HIE was being used to take care of patients or for reporting to the government because we do both obviously, but, you know, we focus our interoperability efforts on the HIE side for reporting to the government not really for taking care of patients and I was just wondering if that was shifted in the questions and the data as well or not really?

**Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

Well, we were specifically asking about the mechanisms they were using to electronically send and receive summary of care records. So, my assumption would be that this would be for patients and not for government reporting.

**Rajesh C. Dash, MD, FCAP – Director of Laboratory Informatics Strategy, Office of CIO – Duke University Health System**

Okay, thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Terry O’Malley?

**Terrence (Terry) O’Malley, MD – Medical Director for Non-Acute Care Services, Partners Healthcare System – Massachusetts General Hospital**

Hi, thanks, Michelle, and Vaishali, thank you very much that’s a great presentation. I had a question based on slide nine which was a lovely graph of the reasons why adoption was so difficult and it really brings to mind I think two broad categories, one is sort of rows 1, 2, 6, 8, 9 and 10 all seem to be issues related to the technology, to the EHR capabilities, workflow, cost, but if you look at items 3 and 4, so the difficulty to find provider addresses and the difficulty of exchange across platforms, I guess 5 as well, difficulty to match patients, really seem to me to be more care community issues as sort of the infrastructure that needs to underlie the exchange of information.

And I’m just wondering if there are opportunities there to create sort of the infrastructure of provider and patient identification and then the means to exchange information between platforms as sort of an area of focus for moving this forward. I guess that’s a question.

**Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

I mean, I guess, you know, from my perspective as a data person, you know, this is something that we’ve, you know, been tracking over the past couple of years. And, you know, you’re right to point out that there are some issues that relate to things that are specific to the technology itself, there are other things that relate...barriers to interoperability that relate to the infrastructure, things that are financial in nature or operational in nature.

So, I mean, to answer your question as to like what should come first, I’m probably not the right person to answer that in terms of like, what we need to do to solve this with regard to, you know, whether the infrastructure should come first versus the vendor piece.

I know that with regard to the interoperability roadmap and the efforts that are being made we’re trying to work on all these issues. So, I don’t think it’s necessarily like a chicken/egg thing, but I’ll leave it to others to really address that further.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, thank you Vaishali, I don’t think there are any other questions in the queue, so thank you for your presentation. I think I’m going to go ahead and open it up to public comment and then we’ll come back and make some closing remarks. So, operator can you please open the lines?

## Public Comment

**Lonnie Moore – Meetings Coordinator – Altarum Institute**

Most certainly. If you’re listening via your computer speakers you may dial 1-877-705-6006 and press \*1 to be placed in the comment queue. If you are on the telephone now and would like to make a public comment please press \*1.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, so while we wait for public comment I do want to let all of our new members know that this isn't normally how meetings go, but today was a lesson in adaptability as well learning from those who presented today. So, thank you, all for your patience, we greatly appreciate it. We do have a public comment. Just a reminder to our commenter public comment is limited to three minutes. Shelly Spiro, please go ahead.

**Shelly Spiro, RPh, FASCP – Executive Director – Pharmacy Health Information Technology Collaborative**

Thank you. My name is Shelly Spiro I'm the Executive Director of the Pharmacy HIT Collaborative and we appreciate the work of the 2017 Interoperability Standards Advisory Task Force especially in reference to NCPDP and HL7 standards related to medication and medication related efforts.

As an NCPDP Workgroup Professional Pharmacy Services Co-Chair and Lead of the MTM or Medication Therapy Management Communications Task Group who's working on the Pharmacists eCare Plan Consolidated CDA guidance document I'd like to provide a correction to slide 13, the correct document name for the NCPDP HL7 Guidance Document is the Pharmacists eCare Plan version 1.0 not the Pharmacy eCare Plan. Thank you very much.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you, Shelly. So, we have no further comment. I just want to defer to our chairs to see if they have any closing remarks before we wrap up?

**Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association**

So, this is Kathy, and I would echo Michelle's thanks...robust discussion and we'll look forward to our next meeting in September.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Kathy, yeah, so our next meeting will be virtual and it is in September, you all get August off, so, I hope you all enjoy your summer in August and I look forward to meeting in September. And thank you again for being so patient with us and bearing with us through all the technical difficulties and all the changes that we had today we really appreciate it and thank you so much. Have a fabulous rest of your day.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**

Thanks, all.

**M**

Bye-bye.

**M**

Bye-bye.

**W**

Thank you.

**W**

Thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, everyone.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**

Bye-bye.

**John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative**

Bye.

### Public Comments received during the meeting:

1. Tom Bizzaro: Tom Bizzaro FDB - I don't understand the comment on RxNorm not being available for higher functions like Clinical Decision Support. Behind the scenes in an EHR are numerous codes that are not visible to the end user that can be used for CDS and other functions. RxNorm codes would be no different.

## Joint Committee Meeting Attendance

Name	07/27/16	06/23/16	06/08/16	05/17/16	04/19/16	03/10/16	01/20/16
Aaron Miri	X	X					
Andrew M. Wiesenthal	X	X	X	X		X	X
Andrey Ostrovsky	X	X					
Angela Kennedy	X		X	X			X
Anjum Khurshid	X	X	X	X	X	X	X
Anne LeMaistre	X	X	X	X	X	X	X
Arien Malec	X	X	X	X	X	X	X
Aury Nagy							
Brent Snyder	X	X	X		X		
Carolyn Petersen	X	X	X	X			
Chesley Richards		X					
Christoph U. Lehmann		X	X	X		X	X
Dale Nordenberg	X	X		X	X	X	
David F. Kotz	X			X		X	X
Devin M. Mann							
Donna Cryer	X			X	X	X	X
Eric Rose	X	X	X	X			X
Floyd Eisenberg	X	X	X	X	X	X	X
Gayle B. Harrell	X	X	X	X	X	X	
James Ferguson	X	X	X				
Jitin Asnaani	X	X	X	X		X	X
John Scott		X	X	X		X	X
Jon White		X	X	X		X	X
Jonathan Nebeker	X	X					
Josh C. Mandel		X	X	X	X	X	X
Karen Desalvo		X	X		X		X
Karen van Caulil	X	X	X	X			
Kathleen Blake	X	X	X	X	X	X	X
Kay Eron	X						
Kevin B. Johnson					X	X	
Kim Nolen	X	X		X	X	X	
Kim Schofield	X	X	X			X	X
Kyle Meadors	X	X					
Larry Wolf	X	X					
Leslie Kelly Hall	X	X		X	X	X	X
Lisa Gallagher	X	X	X		X	X	X
Lorraine Doo	X	X	X	X	X	X	X
Nancy J. Orvis	X	X	X		X	X	X
Neal Patterson	X	X			X	X	
Patricia P. Sengstack		X	X		X	X	X

Name	07/27/16	06/23/16	06/08/16	05/17/16	04/19/16	03/10/16	01/20/16
Paul Egerman			X	X	X	X	X
Paul Tang	X	X	X	X	X	X	X
Peter Johnson	X	X					
Rajesh Dash	X						
Ram Sriram	X						
Richard Elmore	X	X	X			X	X
Scott Gottlieb	X	X		X		X	X
Steve H. Brown	X						
Terrence O'Malley	X	X					
Troy Seagondollar	X	X	X		X	X	X
Wanmei Ou	X	X					