



## Joint Health IT Policy and Standards Committee

Draft Transcript

April 19, 2016

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### 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; don't know how to pronounce my own last name there. This is a meeting of...this is a joint meeting of the Health IT Policy and Health IT Standards Committee. This is a public meeting and there will be time for public comment before lunch and at the end of today's meeting. As a reminder, if you are making a public comment, it is limited to three minutes. And we'll go around the room to take roll and we'll start with Nancy Orvis.

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

Nancy Orvis, here. Do I need to say anything else?

#### W

Go ahead.

#### Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System

Brent Snyder.

#### John S. Scott, MD – Program Director, Clinical Informatics Policy, Office of the Assistant Secretary of Defense, Health Affairs – Department of Defense

John Scott.

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

Rich Elmore.

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

Gayle Harrell.

#### Paul Egerman – Businessman/Software Entrepreneur

Paul Egerman.

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

Donna Cryer.

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

Vindell Washington.

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

Kathleen Blake.

**Paul Tang, MD, MS – IBM Watson Health**

Paul Tang. I'm going to announce that I have a new employer; I'm at IBM Watson Health as of a couple of weeks ago.

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

Congratulations.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Lisa Gallagher.

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

Arien Malec.

**Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services**

Karen DeSalvo.

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

Dale Nordenberg.

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

Leslie Kelly Hall.

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

Floyd Eisenberg.

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

Angela Kennedy.

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Josh Mandel.

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

Kim Nolen.

**Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System**

Patty Sengstack.

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

Troy Seagondollar.

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

Lucia Savage.

**Elise Sweeney Anthony, Esq – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology**

Elise Sweeney Anthony.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Steve Posnack.

**Jennifer Brown – Office of the National Coordinator for Health Information Technology**

...Brown.

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

And on the phone...

**Kevin Johnson, MD, MS – Professor & Chair of Biomedical Informatics - Vanderbilt University Medical Center**

This is Kevin Johnson.

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

...we have Kevin Johnson, Anjum Khurshid...

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

Yes.

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

Hi, Anjum.

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

Hello.

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

David Lansky?

**David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health**

Yup, good morning.

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

Hi, David. Anne LeMaistre?

**Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health**

Present.

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

Hi, Anne. Wes Rishel?

**Wes Rishel – Independent Consultant**

Here.

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

Hi, Wes. Cris Ross?

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Here.

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

Hi, Cris. Lorraine Doo?

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

Yeah, present.

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

Charles Romine for Kevin Brady.

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

Kevin Brady for Charles Romine.

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

And then John Derr?

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

Here.

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

Is there anyone else on the phone who I missed? And I think we actually have our new NIH representative in the room.

**Ram Sriram, PhD – Chief, Software & Systems Division - National Institute of Standards and Technology**

Ram.

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

Okay, so with that, I'm going to turn it over to Karen to make a few opening remarks.

**Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services**

Great; thank you Michelle and thank you guys for making time to be here today. We have a really exciting agenda and I'm looking forward to the presentations. I just wanted to say thank you to Kathleen and Paul for agreeing to take over the Health IT Health Policy Committee as Co-Chairs. As some of you are aware we made a decision to transition this FACA to being more truly an advisory committee to the National Coordinator and rather than having me Chair the meeting, to have actually Co-Chairs and to do that, also thinking about succession planning.

As we learned a little bit last year from the Standards Committee that we had had a chair for some time and our vice chair and John Halamka, and the chair having somebody been from ONC that we had some succession issues. So we did some restructuring of the charter, put that through all the proper channels and can officially today announce and thank Paul and Kathleen for agreeing to serve as Co-Chairs of the Policy Committee and Lisa Gallagher and Arien Malec for serving as Co-Chairs of the Standards Committee. So we will remain engaged, however, we think that this sort of sets up a structure for advisory that works into the future.

I do want to take a moment and introduce Dr. Vindell Washington, who we spoke about at the last meeting. He's here in-person today. Dr. Washington is the, not so new anymore, Principal Deputy National Coordinator. I feel like he's been around for a long time; he's jumped right in with both feet and I think gotten to know quite a lot of people in this space. But Vindell, did you just want to say a few words about yourself to let the group know a bit about your background and...

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

Sure. Thanks Karen. And I know we did a little bit of a virtual introduction in our last session, so I won't take much time. I am a fellow Louisianan with Karen from Baton Rouge and was really on the provider side predominantly before coming here; so this is my first stint in federal service, about three months in

at this point, so, only slightly stale, I'm like sort of day-old bread ready for bread pudding or something, but not quite ready to be thrown out.

So, I did want to say one thing, I'm just very excited about the session today. We've spent a lot of time in prep looking at both the agenda for the day, but really the agenda for the next few months. And I had some conversations just before I sat down, just talking about really the excitement of the work before us as we look toward the sort of three pillars, the delivery system reform, which is a broad base that we're talking about moving forward, as well as the work on precision medicine and the Cancer MoonShot that a lot of the work that's going to be discussed today is foundational to that.

So, I just appreciate the opportunity to participate with all of you around the table and I hope to do handshakes and more formal and warm greetings than the telephone allowed at the last session. And, thanks a lot.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you and welcome Vindell to the group. I just want to thank Karen for...it's been an honor to serve with her as Chair of the Policy Committee for these couple of years. I know she is not leaving us but for the reason that she described, we're changing the structure so we have an easy transition during succession. But it's just been wonderful to both be a part of our advisory group, and serving the Office of the National Coordinator and all the great work that she's been doing with ONC and with HHS. So I really want to thank you, Karen, so much.

So before I forget, I'd like to work on approving the minutes from last time. Those were distributed to you earlier by e-mail and would entertain a motion to approve those.

**W**

So moved.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. And second?

**W**

I'll second.

**Paul Tang, MD, MS – IBM Watson Health**

And any other discussions, additions to what you saw there? If not, say all approve, say aye please.

**Multiple speakers**

Aye.

**Paul Tang, MD, MS – IBM Watson Health**

Anybody not approve or abstain? Great, thank you very much.

So let me talk about this agenda that Vindell introduced. It's a lot of really meaty topics and some of them which we're going to present to you for the first time here and then we're going to be actually voting to approve next meeting. But they're so important and have so much content we wanted to put that before the group this meeting.

So we'll start out with the task force on API. As you know, that's an extremely important area to try to free the data so that it can be used for the purposes of improving health and well-being. It also does come with some things we got to be...we've got to look out for in the policy area, such as privacy, security. So we're going to hear from that task force about how they can advance this agenda safely and yet forcefully.

Next we'll turn into Precision Medicine Initiative, which as you know is a top initiative for the president and the administration; again, another exciting area. It has to be done properly so that...again, we also worry about the privacy and security of the data, but how can we make sure that we can support this wonderful initiative going forward from an HIT policy and standards point of view? So we're going to hear from that task force.

Following lunch...we will have a public comment period right before lunch and then after lunch, we can talk about Medicaid, and Tom Novak from ONC is going to talk about how Medicaid can support the health information exchange. So it's an important program, an important need for moving this data around, like for all of the constituents and we have some guidance there from the Medicaid side.

Following that we're going talk, yet more work being done in the privacy area. It's one of those things where as we advance the movement of data around, we've got to make sure that our policies keep up with that, and protect the confidentiality of this information. So Lucia's going to be talking about the privacy and security work that's been going on in ONC.

And finally we're going to close with discussion of the Metrics RFI. We talk a lot about interoperability; we know that that's a top priority really for the country and for ONC and HHS. How can we measure what is being done so that we can know that we're on the right track and that things are improving from that point of view. So that's...we're going to talk about the RFI that's out from ONC. And that will bring us to a close, and we always end with public comments.

Any questions on the agenda? Please, were you going to ask...okay, I just wanted to make sure you weren't asking for...all right, so I think we're going to open up with the task force on API, and this is a joint Standards committee and Policy Committee effort and we're going to hear from Josh Mandel and Meg Marshall?

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

Maybe as they come to their seats and make the presentation, I think for all of you who received the materials in advance, first of all, thank you very much to the Co-Chairs and the task force and to ONC staff for getting this to us early so that, for those of you who I hope have the opportunity to go through it, it's approximately 50 pages. It is content rich and it really reflects the deep dive that the task force and various working groups within it did in order to bring this to us.

As Paul mentioned, these are draft recommendations and what we'd very much appreciate from all of you, both here and on the phone is that as we go through these, we'll cover the report in its entirety first, and then open it up for comments. And if the comments are editorial or if your sense about a particular aspect is, that's fine with me, we don't need verbal confirmation of that. But, particularly critical, we would very much appreciate if you're able to show us or describe for us what you think are

any potential blind spots in the report that they need to go back to the task force and fill in before they come back to us in May with the final recommendations. Or secondly if there something that from your perspective and with your experience and expertise, is kind of a nonstarter, a real no go, then we want to be able to hear about that as well. So I'll turn it over to the Co-Chairs for their presentation.

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

Thank you, thanks for that. My name is Meg Marshall; I'm going to go ahead and get us kicked off; Josh and I will tag team back and forth with our recommendations...better?

(Indiscernible)

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

Okay, fantastic. So, we'll go ahead and get started. The one comment that I wanted to make as well, we had some difficulty, even with 50 slides, our actual work document is a document itself and so we've been going through very carefully looking at, and describing backgrounds of issues and our findings. So even distilling this into the presentation slides, or summarizing it into the slides was difficult for us.

So I just wanted the committees to recognize that our final recommendations will be in the form of that document itself and these...what we'll be walking through today are our slides just for discussion purposes, so that we have something to work with you on. Not...what we found is that not in every case would the slide actually reflect what we were trying to articulate in the document itself. So, a little bit of a recognition there that we do have some work to do, but we've done a lot of work to get to this point so far.

So we'll go ahead and get begin...and get started; try to this a couple of places. We're going to go through these initial slides fairly quickly because we did go through them with you last month, but in short, here's our list of our task force members; a great group of folks, lots of input, lots of expertise there. A couple of definitions that I think are worth walking through just to set the baseline before we do get into our recommendations is that we do reflect a definition of an application programming interface, an API as defined here in the 2015 CEHRT rule.

The task force charge and questions again, these top three, we were really focused on identifying the perceived security concerns and real security risks that are barriers to the widespread adoption of open APIs. And for those that we identified as real, to identify those that are not already planned to be addressed in the Interoperability Roadmap. So we've had a lot of coordination with ONC around activities that were already taking place in the roadmap; didn't want to duplicate or be redundant in those efforts. The same thing for perceived privacy concerns. And then we also had just a very broad view around priority recommendations for ONC that would help enable consumers to leverage API technology to access patient data.

Almost as important as defining what our task force was, was defining what out of scope. We had a lot of discussions around this, but really tried not to get into what an APIs terms of use would be, licensing requirements, business policy formation, fee structures, certifying authorities, as far as an ONC certification type of program, formulation of standards, electronic documentation of consents and issues unique to write APIs. You will find that in our recommendations we did have some overlap with these issues, so where it was appropriate, we would comment, but for the most part we tried to attack the issues with those kind of carved out in mind.

So to do that, we thought that one of the best ways to attack the topics that we would need to attack is through identification of a use case and the user flow, and Josh will talk about that.

**Joshua C. Mandel, MD, SB – Research Faculty- Harvard Medical School**

Sure, and just to give a little bit of context for the story that I'm about to tell, we really used this as sort of a narrative hook. We had a lot of topics that we identified when it comes to allowing patients to run an App of their choice against electronic health record data, and so we told sort of a short story so that we could highlight various aspects of what happens along the way and drill into those as topics.

So in this very short story, there is an App developer who builds an App that is going to do some beneficial job for patients. And the App developer builds into this App support for an API-based connection to the EHR. So they take this App and they register it with a particular hospital, or with its EHR vendor, then a patient learns about this App and reviews its features and privacy policies and decides to connect this App to her health record data inside of the hospital.

And so the patient signs into the hospital and looks at some kind of approval screen and makes the decision, agreeing to share her data, her EHR data with this App for some duration of time and the hospital records this decision, and then the App gets an access token, which is time and scope limited, so it can do just what the patient said. And the App can then use this token to access the EHR over a certain amount of time. And so there's a bunch of highlighted phrases in this story which are the topic areas that we'll delve into when we think about our recommendations.

And just at a high level we can think about lots of variants on this use case, which we'll have a little bit to say about as we go through. So for example, the App that the patient is using could be a personally controlled health record. It could be a personal health App that's scope is not as broad as maintaining all my health data, but it just helps me do one task. It could be an App that a patient wrote herself or for her family or it could be a rogue App, right? It could be an App that's written by some malicious party for nefarious purposes. And these are all sorts of different cases that we'll want to be able to address as we think about where these Apps fit in this ecosystem here.

So with that, we're going to jump in and start talking through 10 topics, in terms of how we arranged recommendations. And as Meg said, these topics are really a view on a 30 page document and so we've tried to extract the highlights to share with you today and get high-level feedback on what we have described here.

So the first topic area we highlighted is general support for APIs. And what we found here was that based on our public hearings and testimony, we heard panelists across the industry who described lots of different health Apps that will likely participate in the ecosystem; Apps authored by lots of different kinds of organizations for lots of different purposes. And when we read the certification requirements, the Meaningful Use regulations, these regulations don't differentiate based on who wrote the App or based on what the Apps purpose or credibility is.

And so our recommendations on this front are pretty simple. First is that we think it'll be useful if ONC and CMS would explicitly state what we just described. In other words, explicitly to state that the type of the App and the organization who developed it are not considerations with respect to a patient's right to access. But rather the relevant concerns are technical compatibility, meaning that the App actually

works with the APIs technical specifications and patient choice. So we want to just be really clear when it comes to patient API access that these are the kinds of considerations that we have in mind. Let me turn over to Meg for the oversight topic.

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

Sure. So as background, I think we're all aware that there is multiple laws, multiple agencies that have oversight over this whole API App ecosystem. A few, we have FTC, OCR, OIG, FCC, FDA and all of these are agencies that oversee the FTC Act, FTC Breach Notification Rule, HIPAA as well as FDA. So one of the challenges that we really had that to some extent very critical, very important but to some extent it became very distracting is trying to understand who...what law would be applicable to what part of this ecosystem to what player or what actor and throughout what process because there are many downstream effects.

As you can imagine, if the App developer, for example, is a business associate of the provider who is a covered entity, then it would then affect other things downstream such as the authorization requirements. It would impact the auditing requirements, breach notification rules and things like that. So we really tackled and we spent a lot of time with, and Leslie was fantastic as well, we worked with the ONC contractors and the OCR support staff as well to try to get a really good baseline for what this looks like; what the oversight potentially looks like, what are the...what could be the triggers that would send an App developer, for example, into an FTC oversight mechanism rather than an OCR or HIPAA mechanism. And I'll be honest, we're still working through a lot of those, we're still getting some feedback.

OCR had, throughout the course of our task force, published some scenarios that gave some excellent guidance and we've asked for a couple of tweaks to that, and have had some back forth. But in any case, I do want to say that there's...we are developing, we are expanding this section a little bit, but ultimately what we're finding is just the need for some guidance to...and transparency, not just for the covered entity who's the provider or for the API developer, but also for the patient himself and the App developer. You know, under what point if you have an issue and something breaks down in this process, who do you talk to, who do you complain to, and what would that oversight mechanism be?

Also within the past couple of weeks, we saw FTC publish a fantastic tool; it was guidance intended for App developers that would...that asked a series of questions. If you...if your App does this, then you fall under FDA's jurisdiction; for example as a medical device. Or if your App does this, but you're not doing it on behalf of a covered entity, you're not under HIPAA, but you're under FTC...we...the task force really appreciated that, thought that it was extremely helpful.

And as part of our recommendations and you'll see this throughout, it'll be a little bit of a theme; we tried to use the correct term where possible, so if it's a HIPAA disclosure versus a HIPAA consent, and tailor our recommendations appropriately. But ultimately this whole oversight mechanism or this whole oversight topic is just really a recommendation that we see some clarification and some clear guidance around what happens when to which actor. So our registration...

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Okay, so this brings us to a topic which we've labeled as registration, and I'll just provide a little bit of background here. So first of all, our task force is not really in a position to provide deep technical recommendations. We don't see our role as providing, you know deep advice about what protocols to

use and, you know authentication mechanisms and cryptographic structures, but rather we're really focused on a framework for privacy and security here. So you'll see a number of examples; we'll talk about using OAuth as an authorization protocol, because we think it's a good choice, we see it used very commonly in the consumer web, but we're not specifically recommending OAuth here; we're recommending OAuth as a process which we think works well.

And so when I talk about registration, I'm going to talk at a high level about what is the problem that we're trying to solve here. So the issue is, when a patient wants to connect a healthcare App to a hospital or to a healthcare provider organization, how much coordination needs to happen ahead of time? Does that hospital or healthcare provider organization need to know about the App ahead of time, before the patient can make that connection? And the answer is it really depends on the authorization protocols you're using. In some protocols, like in OAuth, the answer is yes; those two organizations need to know about each other. And in OAuth, that process is called registration.

In other protocols the answer is maybe not. So for example, you can imagine a portal where a patient can just generate an App-specific password and then copy that password and paste it into an App. And that might be a much wider ecosystem where the hospital and the App don't need to know about each other ahead of time. So we're not trying to opine on, you know whether one particular method or another is...needs to be used, but we want to describe this registration process for the cases where it is used, and OAuth would be one important example.

So in OAuth, for technical reasons, the hospital need to be introduced to each other before any kind of connection can be made, before the patient can approve an App. And in general that registration process is a step that generates some identifiers that the client or the App can use later on, and no patient data is flowing during this registration step. So it's not about sharing information about the patient, it's just about introducing the App and the hospital to each other.

And in most OAuth deployments, registration happens between one deployment of the API, which could be like a single hospital and one deployment of the App, which could be like a web application, for example something like Microsoft Health Vault, which lives out on the web in a Microsoft domain and the registration process introduces the deployment of the API with the deployment of the App to each other. Now in the healthcare domain, we might see EHR vendors actually roll up this process and say well we'll just help you register the App once and make it available to all our providers, and that's fine too. We're not trying to have an opinion on how that piece works. Registration is really focused on just introducing those two parties.

So we have a couple of recommendations in terms of how registration works. And the first is to say that registration must not impose an unreasonable barrier to patient choice. And to be really specific on that point, it shouldn't impose delays, and the registration process itself is not intended to be the point where Apps would undergo rigorous testing or go through some sort of clearinghouse approval or be subject to an onsite inspection or other kinds of high bars of control. If a provider has a registration process for technical reasons, that mustn't be the point at which these policies are applied.

And in general, we know a coupled of patterns that make that the case, that make that really easy. So many API providers offer what's called a self-service registration portal where a developer can sign into a website and just create a new client, can handle the registration automatically by filling out some forms. So that's really a frictionless process. And then the other one would be what's called the dynamic

registration protocol, which is an automated way for a developer to register an App against a provider system. And we think those are both examples that have this property of being frictionless, which is the property that we really think is required for any kind of registration.

A really specific recommendation here is that in the most recent regulatory guide, and it's in the 2015 certification criteria, ONC makes the claim which we think was a little bit overly broad that says that the existing certification criteria are sufficient to allow access without requiring further App preregistration. And we think it would be good for ONC to dial this back because whether or not registration is required, it's really a property of the kind of API a provider organization decides to use. And since ONC isn't requiring one kind of API or another, it doesn't make sense to comment at this level.

But no matter how this registration process works, we agree it should be frictionless and we also think we need clarification that API providers, just like they're not implementing access control policies at this step, they mustn't charge a fee for the App registration step either. That process itself should be a free process. And then of course, healthcare provider organizations can charge a fee to patients to access the data, but those have to be reasonable fees, and in our estimation, paying for the incremental cost of things like bandwidth would have to incur a very, very small fee, really vanishingly low, in terms of what could be reasonably recovered from a patient at that step. We're talking about fractions of a penny or probably pennies at that point.

All right, moving on to the next topic beyond registration is something that we've labeled as endorsement or certification. Because something that we heard very frequently from hospitals and from healthcare provider organizations is that they would feel more comfortable living in a world where they knew which Apps existed and where they knew which Apps they should trust ahead of time. And frankly our task force didn't think it was realistic for us to live in that world where everybody knows about all the Apps ahead of time and can have perfect assurance that they're safe.

On the other hand, we did recognize that there are lots of different attributes of applications that patients might care about. So you might care about whether the App is clinically effective. You might care about whether it has strong privacy policies that are going to protect your data. You might care about whether it's been well engineered. You might care about the on-site security of the servers. There are dozens of aspects of applications that patients could care about.

And what we're recommending here is that ONC shouldn't try to have any kind of centralized certification process or testing process for patient-facing health applications, but instead that ONC should pursue regulations that enable what we have called the secondary market in endorsements. And just to flesh that out a little bit, the idea is that different kind of organizations might endorse an App for different purposes.

So an EHR vendor or a security expert or a consumer advocacy group or a clinical professional society or a hospital should be able to endorse an App by making a public statement saying, you know they trust it for a particular reason or a particular purpose. And those kinds of statements could be issued without any centralized regulatory oversight. And the nice thing about an ecosystem like that is that patients can then access third-party tools that can aggregate these things and give them a view to say, this App is trusted by the following organizations and for the following reasons. So you still get some discoverability benefits, patients can learn about which Apps exist and who trusts them, but we don't try to do this impossible task of centralizing the entire process and building one set of rules for how it works.

And then on the next slide there's just an example of what a patient might see when they're going to approve an App. And this is not intended to be a normative example, it's just showing you, for example, this is the kind of screen that a patient might see when they're trying to approve a new App to access their records. And the point that we wanted to make with this example is that providers might take the list of endorsements that an App has received, and use that to modulate the language that they show patients on the approval screen.

So if a provider sees an App that they know is trusted by a dozen organizations that they like, they might display a relatively friendly and safe-looking authorization screen for a patient's approval. And if a provider sees an App that is endorsed by no one, and that it's never heard of before, it might include additional warnings on the authorization screen. And we think those kinds of modulation are totally fine, but the high-level point that we want ONC to clarify is that providers must not use these endorsements, or a lack of endorsements, as a reason to block the registration of an App or to block a patient's ability to share data with the App. Ultimately whether an App is endorsed or not, it's really up to the patient to make the decision about which Apps to use.

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

So the next process that I'll talk about is how do the Apps communicate their policies to users prior to sharing data? So the background on this, the issue that we identified, there are risks associated with disclosures of PHI that we experience and mitigate and manage every day. So the question is, does API technology introduce something or introduce risks that haven't already been addressed?

And we really felt strongly that in order to make an informed decision about whether the App is allowed to access health information; that patients really needed to be aware of the App's privacy practices for the access collection, use and disclosure of their health information. Now we...this is one of those tricky areas where depending on the oversight mechanism, could impact what that privacy notice looks like. We're all familiar with HIPAA and what the providers currently do for their privacy practices there. But we really...we heard a lot, and we did some research to try to look at model privacy practices that were outside of that HIPAA framework.

So ONC has a voluntary personal health record model privacy notice and the comments, ONC closed comments last Friday, trying to receive some information on how they can update that and move that forward. And so again, respectfully not trying to do a ton of redundant work, they were asking some very great questions that the task force didn't organize or mobilize or respond to that in particular, our recommendations are somewhat more at a higher level.

We also looked at OCR's HIPAA model privacy notice. We looked at what FDA does for nutrition facts labels and a Schumer box for credit card disclosures. We recognize that there are some industry best practices right now for mobile App developers; the future privacy forum best practices that the CDT publishes on their website, Apple HealthKit has a...requires a privacy policy; we took a look at that. Google as well; there are some android specific text, Facebook; the point is that we really tried to look at outside of the healthcare field what would a model privacy notice potentially contain.

And the recommendations that we came up with, realizing that ONC, the App developers and their Apps are not currently under the ONC certification program, ONC could play a role in providing or encouraging a voluntary code of contact for App developers to sign up to. Maybe ONC could provide

some of what these ideal best practices would look like or data elements that an App could have within it and then allow this voluntary code of conduct mechanism, similar to the endorsement, so the patient has some notification that the App developer follows these best practices.

The swipe that we took at for ONC around this model privacy notice, I mean, some of this information is very clear, clearly define who is responsible for what. We had several folks who were concerned about indemnification clauses and what would be from a legal liability perspective if a breach were to happen or an unauthorized disclosure is there adequate text or adequate warning of who would be responsible there for what.

Really appreciated the thought around standard definitions and terms; what we found through all of that research is that how a consumer-facing product that's regulated by FDA, they're looking at and defining a term differently than what Apple or Facebook might for the non-FDA ones. So certainly appreciating a standard definition, standard list of terms and to that end thought that it was really important that the patients have the ability to compare the privacy practice notices of two Apps, somehow, so that there was some mechanism that said, okay this app offers this protection, this doesn't. So again, trying to nuance that unregulated world that there certainly are some steps of guidance that ONC could take under.

We really liked the idea of having access to a short form and then being able to link to a longer form later. We heard from a lot of folks and just general experience of the folks on the task force that there's this click through process, that the patients aren't reading, that they really aren't getting the information that they need because the font is too small, or it's inaccessible or there's too much text they're trying to get to there.

So to try to combat that, our recommendations, you know the ability for the patient to save off that privacy notice and maybe access it later, to have that short form where they're getting the relevant information up front, but can access a longer list of policies after the fact. Think that it's really important that the users are informed when the Apps practices change so that the next time they go to login, for example, there's a notification that pops up that says, hey our privacy practices have changed, you might want to know that we're dealing with your data differently now than what we told you when you first signed up.

And we also thought that it was important that the patient understood who to contact if they had problems. I think in this DIY world and where we're seeing a lot of App development, we heard during our testimony that there was a concern that these App companies would...are fly-by-night or wouldn't be around for any significant period of time so we wanted to make sure that as part of this notice to the patient, that they were firmly aware of who the company was, how they practice and how they would be able to contact them. So a name and an address or a telephone number or something like that.

We did ask for some consideration around enforceability of these clicks or agreements and would be...what meets that threshold of reasonably aware or informed consent or what have you, but the same type of consideration that we know ONC has done for other...ONC and OCR have done for other privacy notices, to do the same for these App developers. What is that minimum necessary information for them to move forward?

And then we also, back to the point of usability and accessibility and being able to read and understand these model privacy notices. We have a recommendation that the private market be encouraged to step up and consult with existing guidelines such as the web content accessibility guidelines, for example around recommendations to make these Apps more usable to people with disabilities including low vision, deafness, and things like that.

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

So we want to touch on the topic of when a patient makes the decision to share data with an App, how might limitations be placed on what gets shared? And there were two broad areas we wanted to discuss here; so one is limitations that the provider organization might impose and two is limitations that the patient might impose on what data gets shared.

So on the provider side, we heard a number of concerns from healthcare provider organizations during our test...during our hearings, a couple of flavors of concern. One is that providers don't want to be in a position where they're obligated to check up on every App and police them all and know which ones are trustworthy. But two is that in a case where a provider organization does have information about the fact that an App may have been breached, providers want to know, you know whether it's okay for them to in fact turn off access to protect patients. So this led to a couple of recommendations on our front.

So first of all we think ONC should clarify that while API providers might impose security restrictions on App access, it's not appropriate for API providers to set limitations on what a patient's authorized App can do with the data downstream. In other words, providers should be focused on when Apps can access the data, and not what happens inside the App or from the App developer after approval. Those considerations are really up to a decision between the patient and the App, and that providers shouldn't be involved in that piece.

Furthermore ONC should clarify that API providers are not obligated to protect patients by identifying suspicious Apps; it would be fine for a provider to simply allow the patient to make that decision on their own. That said, you know it should be okay for providers to suspend API access if they do suspect that an App has been breached like a security breach within the App itself or if the App is violating the provider's terms of service, or it's been compromised, or if it's posing a threat to the provider's own system; it should be okay for the provider to suspend access but patients need to have an override to the suspension in the case of where the suspension was notionally for the protection of the patient.

So in other words it's okay for providers to try to protect patients but not against their will and not beyond what patients actually are willing to accept. So that's the fine line that we're trying to walk here with these recommendations. And then finally on that point, we need clarification about what the terms of service for an App can say to restrict what that App is allowed to do.

So if a patient is using an App as part of their HIPAA right to access, is it okay for the API provider to impose certain kinds of terms of service on the App itself? And what might be the restrictions there? It's an area where we don't really have much guidance.

On the next slide, we also thought it would be helpful for ONC to update the certification requirements, specifically to ensure that API providers help patients to impose limitations on sharing. And so here's what we mean. Today in the certification requirements, patients need to be able to effectively share

their data with an App and an EHR or a certified health IT product can simply allow patients to make the decision to share, you know yes share my record or no, don't share my record. There are obviously a lot of use cases for finer grained sharing. So for example, a patient is running a blood pressure application...sorry; I'm being attacked by a fly. A patient that's running a blood pressure application, you know might want to just share a limited subset of their data with that App. And there's this rich and deep world of data segmentation, and fine grained access control where patients might be able to approve very narrow subsets of the record.

And what we arrived at in our workgroup was what we thought was a pretty good kind of middle of the road solution. Rather than saying that patients need to be able to define arbitrarily granular access control policies, what we thought was it made sense to align this with the existing API certification requirements that ONC has put forward. So today in certification, a provider needs to offer APIs at what's called the data category level meaning that an App can query for patient demographics or for a problem list, or a medication list or lab results. So every certified health IT product already needs to offer APIs at that data category level. And so we thought it would make sense to tie access permissions to that same data category level.

So yes a patient could say, share all of their record, but a patient should also be able to say share my labs or share my vital signs, or share my medications or share my immunizations because we know that the vendor products are already capable of doing exactly that granularity of sharing. So we think of that as sort of the pragmatic approach that ties together the desire for granular sharing with the actual certification criteria that we have on the ground today.

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

So we also looked at audit trails and auditing of the disclosures that were made through these Apps and APIs. And this is another topic that really is affected by the oversight mechanism, obviously. So we went through the four different parties that we identified that participate in the API ecosystem; the patient, the provider who we assume is a covered entity, the App developer, and the EHR API developer.

So the patient's...this is an important process. Providing patients with who has accessed their information really is very helpful in the auditing mechanism of the world, giving patients the ability to see who has access fosters transparency and patient trust. We recognize that when they have the ability to see these accountings, they are actually assisting providers in determining whether there are weaknesses in the current practices. And could possibly identify unauthorized disclosures or detect breaches that perhaps the providers haven't had the opportunity to see.

So we recognize that under HIPAA, HIPAA provides individuals with the right to view and accounting of disclosures made by that covered entity, but where this gets a little fuzzy is if the App access is considered a disclosure to the individual himself, then this is not an acc...then that would not be included in the accounting of disclosures. So, more as a third party specified by the individual or to any entity for treatment, payment or healthcare operation purposes.

So there are...I guess the point here is that there are some App accesses that we feel would be covered under HIPAA and would be...the patient would be able to see those disclosures in a typical accounting of disclosures. But there is a whole slew of accesses that wouldn't be. And again going back to the point, we think that this is very valuable to the patient that they are aware of what these disclosures look like.

We recognize that the providers who are very familiar with these processes have HIPAA to contend with, HITECH, Meaningful Use, the Joint Commission; so there are a lot of forces that are going toward a providers' current auditing and accounting of disclosure mechanisms. The EHR API developer must comply with the ONC certified audit-related criterion, which we'll talk about here in a second. But then the API developer is the final actor in this system, has the best idea of what's going on with the data, right?

Realistically they are the only one with enough context to provide a meaningful look at what's happening after that initial disclosure, but Apps are not certified by ONC. There are no requirements for Apps comparable to the ONC audit criteria. And we did notice that there are various sources of guidance for App developers specific to privacy and security, but nothing really that we could point to as clearly as what we did when we looked at the ONC audit requirements. So we did a view there, we noticed that there are two different types of auditing mechanisms. The first one is just the API disclosing the information, but then the second one is auditing the authorization of the patient for that disclosure, okaying that disclosure.

So when we reviewed the certified...the 2015 certified requirements, we felt that from that it really...that from that perspective, really addressed the needs of our API, which was the read access by the consumer directed App to the EHR API. So we didn't have any recommendations that additional information, for example, be captured through the certification program. We also looked at the accounting of disclosures and how that's being supported and ultimately we came up with a set of recommendations that really again kind of walks that path between, there's a fuzzy area of oversight that we're just not terribly certain about that an App may behave differently if covered under one particular mechanism or another.

So our first recommendation is that ONC should expand the certification criteria to require certified technology to make API access audit logs available to patients through the accounting of disclosures section through the portal. And that's something that isn't out there right now and we feel that would be very valuable for patients to have the access to when they go to access a portal. That they would have the ability to see what Apps they've authorized that they would be able to revoke an authorization for any particular App that they've already authorized. That they would be able to see a list of the Apps that have accessed their data, as well as relevant data around that access, including the name of the App and where it was accessing from, things like that.

So we recognize that that might be a little tricky for ONC so we recommended that they work with the appropriate agencies to create this guidance for the Apps beyond the certification framework. And then we also think that it's important that the patient is informed of the process that he or she needs to follow if they need to flag any displayed disclosure. So if within that portal screen they're viewing a disclosure that they suspect is...was unauthorized or suspect of a breach that there's some mechanism that they understand that they can click a button or that they can click a link and they'll automatically get to that process, of a complaint process that will flag that as potentially problematic.

I'm trying to see...I think the final piece that we're trying to say here is the guidance around breach notification rules and responsibilities. There...California is an example of a state that has state specific breach notification rules. We know that FTC has their own breach notification policies, HIPAA as well. So specific to the breach notifications we felt that it was important that ONC take that on separately and try to provide guidance around how an App developer or how...for any of these actors for that matter,

what their responsibilities could be relative to the breaches and maybe there's a way to harmonize or synthesize, or at least provide some education on what those...on how to navigate that environment that could get pretty complex.

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

All right, the next topic number nine out of ten, is identity proofing and user authentication. And this really breaks down into a couple of areas. One is how does a patient sign in or prove identity to the healthcare provider organization? And two is, whether and how an App proves its identity to the provider organization? I'm just going to read recommendations off the screen here.

So we said that ONC should provide guidance saying that patient identity proofing and authentication requirements in this API ecosystem aren't actually different from the requirements that we've seen in the Meaningful Use Stage 2 era where a patient could sign into a portal for view and download and transmit. So whatever process you're using already to let a patient sign in and see their data online, that process should be acceptable for allowing a patient to sign in and share their data with an App. And there shouldn't be a greater burden to the patient for this API access than there is today for view or for download or transmit.

We've commented or made a recommendation that standards like OAuth 2 should be used and to let patients leverage their existing portal account infrastructure to approve an app. So we shouldn't have to have a second way of signing in or sort of a second set of user credentials or a different process when it comes to approving applications.

We've recommended that API providers must not impose patient identity proofing or authentication barriers for API access. Again, that goes beyond view, download transmit and we've recommended that ONC should collaborate with other federal stakeholders to give clear guidance for API developers about appropriate usage policies and security standards, effectively to encourage the development and adoption of these APIs.

So when it comes, on the next slide, to registration of patient authored Apps, this is a little bit of a special case but we said anybody could write an App meaning that among other possibilities, patients can write Apps themselves. We don't want to treat this as too much of a special case other than to say that patients again should be able to use whatever way they have of signing into the portal, signing into the healthcare provider system to do that App registration step; they shouldn't need something special or extra.

And for any other applications the clarification that we would like ONC to make is that the identity proofing process that happens for developers has to be automatable. Again it has to be frictionless, just as we described during registration. So for example, you might verify things like e-mail addresses or domain name ownership; that could be reasonable because you could automate the process and get an okay sort of guarantee, but we wouldn't want to see, you know a review of tax records or an inspection of facilities, because that would impose delay and a barrier in the process.

And the last point that we'll make in terms of identity proofing and user authentication is we'd like ONC to clarify, for situations where you do want a greater assurance, again just pointing back to our recommendation about endorsements to say that we have a non-centralized process for dealing with that kind of elevated assurance and we don't want to have to have a centralized certification process to

do it. And we'd like ONC to recommend that when it comes to approving an App, and when it comes to the App later on then actually using that approval to access data, it should be good enough to authenticate Apps using standards-based mechanisms like the client authentication that OAuth provides; we shouldn't have to invent new or special or healthcare-specific ways that these Apps would authenticate.

And in particular providers, healthcare providers need to ensure that their App approval and data access can occur without active involvement from human beings on the API provider side or on the App developer side. So the only person who should actually have to be involved and take a step to approve an App should be you know the patient herself. We shouldn't have to wait for front office staff or for App developers or for providers to come in and review something manually in order for that sharing process to occur.

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

All right the final one, number 10, talking about the patient authorization framework and we had a lot of discussion actually trying to figure out what is the right term to do use to describe this? Because again, back to that oversight mechanism, we...this could be referred to as consent, it could be referred to as approval, all sorts of different way; but we landed on authorization and we're going to go with that.

We recognize that it was a very strong thought throughout the task force and in our meetings that this, consumer-directed Apps. Specifically the one that we were looking at that was provided through the certification requirements of 2015 for the patient to view their own information that this was...that this supported the patients' HIPAA right to access his or her own PHI from a covered entity.

But we recognize that this could be characterized in several different ways as the individual requesting access to their own, the entity...the App could be the entity designated by the individual to receive the copy of PHI. The App could be the medium on which the individual's request of PHI or there are other alternatives as well. The consumer...App may be a tool for engaging the individual in treatment or it could be a third party formerly authorized by the individual to receive PHI. So there are a lot...the point there is that there are a lot of nuances around this authorization framework and is there an existing mechanism that we could look at and leverage for moving forward?

So our recommendation's really that ONC coordinate with the relevant agencies to publish guidance as quickly as possible for all of these actors, EHR, API developers, App developers, providers and patients around what that's...whether sharing data with this consumer-directed App counts as this individual's access, access by third party or as the treatment, the tool engaging in treatment. We also asked that as far, and Josh touched on it a little bit earlier around granular permissions, we want ONC to continue working on machine computable consent.

We recognized...we had some discussions within the task force around whether or not that was a barr...that's...the fact that ONC is continuing that work, does not need to be completed before we move forward these permissions, I guess is the main thing. So we do want to encourage them to continue moving on with that.

We also talk about a model authorization form similar to the model privacy notification form. Again, a lot of these terms are being used...different terms are being used for the same thing. We recommend that ONC coordinate what this model authorization form looks like with reasonable language and the

ability, similar to the privacy notices for a provider or a patient to be able to compare two different ones and determine where the nuances are.

We also recommend the providers continue to include statements that are typical of the HIPAA authorizations for disclosure anyway, notifying the Apps of their...the patients of their rights to revoke authorization, the role of the covered entity and disclosure of any provider relationships to the Apps, as well as potential HIPAA coverage.

And then we list some of what we thought were the essential elements of the authorization form that...I'll advance here but don't necessarily read them to you. But we did put some thought into it and again, you know, we...a few nuances around the App, whether or not the App is authorized to access the EHR asynchronously or when the consumer is not present. That was new technology brings just new needs there for the authorization.

We felt that it was important that the individual has the ability to display some intent that they're completing the authorization, and that it's done with...that they're able to do that all with clicks or with button pushes rather than having to FAX in a form or support a process manually, for example.

And again, some communication around when an App can be disabled by the provider himself, so a heads up to the patient that while this is...this App access is at your, umm, you're approving this App and it's at your direction, there are certain cases where the provider certainly could limit that and disable the App without your knowledge.

And that brings us to the end. So our...and I'll just explain the next steps and I think we open up for questions. So we're refining, we still have a lot of work to do. We have two more meetings after today before we come back to you and present our final recommendations. So we're looking forward to hearing your feedback, are we on the right path? Are we asking the right questions? Are we flagging the right things so that when we go back and we meet with the task force, we're able to articulate and get these recommendations in a format that we can communicate and have ONC consume. Josh, any other...

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

No, just how's that for a firehose that we just sprayed at you and looking forward to questions and comments. And again, if we could keep them high level; if you've got, you know specific comments about the text, we're happy to take those over e-mail, but we want to make sure that we make the best use of the next 26 minutes that we have here in person together.

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

Thank you both and I'll disclose that our next presenter has donated some time from that presentation if we do run long with comments. So I'll start with Richard Elmore.

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

So thank you very much, that was an excellent presentation and summary of an important new world for all of us. I had a couple of questions for you. One is it seems as though the recommendations are relying on an assumption that the data coming from electronic health record is read only rather than

related to update back into the EHR. I was wondering if there were any implications that the task force had considered with respect to update transactions; would that affect your recommendations.

Secondly, I wanted to just note that...identity proofing, there...I agree with the recommendation but I'm sure at this stage that there are consistency of standards for identity proofing and I think it's happening right now, evolving in pockets and inconsistently. And so while I think the recommendation is right to align it with MU2 VDT, it may be that we don't yet necessarily have a, kind of a clarity on what that identity proofing should be for that purpose.

And then finally as it relates to the OCR guidance which basically said that providers need to be able to allow connect to an App if it was adequa...if it was technically feasible and if there was adequate security. I didn't see in the task force recommendations how the validation of security was being handled, is that...is it viewed that OAuth 2 is sufficient or is there something more that needs to be taken into consideration?

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

So thanks for the comments and for the questions; I'll just respond briefly. In terms of the API access that yes, our task force specifically focused on the scope of read only access; not because we think it's the only important pattern, but because it's what's required to support the Meaningful Use Stage 3 era requirements for patient access, and we thought it would be good to start with something that was important to vendors right now, who are beginning to undergo that certification for their 2015 products. So that's an explicit limitation that we decided to focus on that read only right scope.

On the ID proofing side, yeah we don't have standards yet which is sort of why we arrived at the conclusion that we did which is, just to make a high-level claim about the kinds of things that would be reasonable practices there without naming standards.

And then when it comes to OCR...the OCR language around technical feasibility and adequate security, the main point that we've tried to make in our recommendations is that when it comes to security, the consideration is not about whether the App itself is designed in a secure way and whether the App is going to live on a secure server that takes good care of patient data; those are not the considerations that a provider should be making when it comes to enabling access.

The provider only gets to be concerned about the security of the provider's own system and making sure that the App is not going to cause a security concern there. And so we've tried to sort of highlight those as two different kinds of security issues. The downstream stuff is really up to the patient to assume that risk, but anything that's actually posing a threat to the provider's system itself absolutely stands as grounds for a provider to be cautious.

That said, in a practical sense, if providers are going to be offering these APIs to a diverse set of Apps that are sort of out there on the Internet; then they need to be robust to attacks from arbitrary Apps that might not even be registered in their system. And so that most of the engineering that will go into making those systems robust to those kinds of threats will also make them robust to registered Apps that go rogue. So those are some of the considerations that we sort of outlined in the document.

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

Thank you.

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

Paul Tang?

**Paul Tang, MD, MS – IBM Watson Health**

Umm, thanks to both of you, and to the group for really a comprehensive look at this area; it's extremely challenging, as your number of recommendations illustrate. I'd like to take the perspective of consumer for these remarks, you know we talk about health illiteracy in terms of how a person and a patient need to have a certain amount of understanding in order to really understand what is being said to them, let's say by a provider. It sounds like we should also acknowledge the need for privacy literacy, as illustrated by what you've just presented and the need to educate every one of us around these issues.

I noticed throughout your recommendations there's a heavy reliance on the consumer really being able to access and understand the privacy implications of their choosing an unknown App, in a sense. So let me pose...you started off with a use case, let me propose a use case and see whether you've thought about this and how you would react to it in the frame of your recommendations.

So, ransomware of course is the new hot topic, unfortunately; and most of these cases are from innocent human mistakes, right? Somebody clicking open an e-mail and that causes the havoc that arises. What you think the role is of government in helping the 300 million of us making truly informed decisions in the way you describe of whether I should click that email or essentially donate my data into that unknown App? It's not really like Facebook because you're...each user is voluntarily contributing it to the public domain, in a sense, as they write that.

One out of 20 healthcare startups fail, I mean make it, which means 19 out of 20 fail; what happens if that App that you've submitted your data to goes either belly up or gets acquired by another company? You talk about model privacy practices; those are good assurances if they were adopted, and what would be the backup? Is there a role for an ombudsman, in terms of how do you hear these complaints about the people who don't follow that or don't subscribe at all?

So it's really a consumer perspective because I think there's a heavy reliance in the framework you described of each of...that each of us understanding the implications of our actions and then donating that informa... this private information out to this App.

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

You'll take that?

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Sure. So first of all, thanks for the comment and I agree that the sort of consumer literacy aspects of how we communicate these practices across the border are incredibly important. You know ultimately what we heard in our testimony was that there's a great diversity among healthcare consumers and that population includes people who are writing their own Apps and tools, and exceptionally proactive about their own health and just want to make sure that nobody stands in their way.

And then on the other hand, there's a much bigger majority of healthcare consumers who don't understand all the nuances of what they are agreeing to and might just sort of click, click, click yes, okay and click through a series of screens without understanding what they mean. So striking the right balance there, I agree Paul is incredibly important. Effectively the best thing that we know how to do, in terms of enabling consumer choice, is to advocate for better and clearer models about how privacy practices are conveyed to patients and healthcare consumers.

In other words, how can we provide as much structure and as much simplification as possible so when an App is explaining to a patient, you know here's what we're going to do with your data. You know, one of the considerations there for sure would be, and here's what happens if we get acquired. You know, here's what happens...here's the guarantees we're going to make if someone else winds up buying the company or buying our data after we fail. I mean, all those kinds of considerations would absolutely be part of what goes into those notices.

But beyond sort of describing how they could be built, I mean I think we would certainly be open to other suggestions for guarantees that we could build in. But we didn't identify any other strong sort of structural considerations from our task force.

**Meg Marshall, JD Director, Government Health Policy – Cerner Corporation**

So the only comments I that would add to that, Josh; so we did talk a lot about the process of endorsement and certifications. And whether or not the risks posed by the Apps were at the level high enough to require some sort of consumer protection that that type of a certification program would afford. And kind of kept coming back to, it's really the consumer's choice, but no, we think that we can provide enough information that the consumer is making a meaningful choice.

And we heard that over and over again in the hearing. So that's why the recommendations came out on the side of, we really hope to see some third-party private industry endorsement programs or certification program so that, for example AARP can say, hey, this is an App that we've taken a look at and we trust them, we trust what they're doing with their privacy policies.

So between the two from a consumer protection perspective, we absolutely favor the industry endorsement mechanism, but recognizing that this ha...that all of the disclosure elements of the model privacy practice, and of the disclosure forms, and all of this information that the consumer really should see and read and understand in order to meet the threshold of informed consent or meaningful or whatever term we want to use to describe it, they're probably not going to read. So is there a short form or are there basic elements of information?

We did call that out, and we did have discussions around that, but didn't have a specific answer as far as what that looked like. We were hoping that our recommendations to ONC would...for those best practices would help shake out some of those comments.

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

Thank you. Gayle Harrell?

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

Thank you very much, I appreciate it and thank you for your hard work. This opens up a whole arena, and consumer beware kind of thing that I think we need to have. I think we need to have the ONC have some responsibility for education of consumers in this whole arena. As a state legislator I can tell you I am the bottom of the funnel when it comes to complaints. And I can see lots of complaints developing out of the bad players out there. And laws are written for bad players, they're not written when people do good things, they're written when people do bad things. And the potential for bad things to be done is considerable when you're accessing PHI and also you have the privacy and security issues. So my question's really geared to that and safeguards. How are we safeguarding the consumer out there? And what educational tools are we going to provide them other than a third-party endorsement?

Also I would bring up some liability issues. When you look at blocking data, and that is a significant problem, we want to make sure data is not blocked when it needs to be shared, and the consumer wishes it to be shared. What happens if a provider suspends an App from using...from entering their information? Who has jurisdiction over that when there's a suspension? And who has what level of proof? So you have to say, do you go to court? How do you say, you can't suspend my App from your information? And what safeguards are we putting in there to punish bad actors? Do you have any ability to say this, we are not just blocking you, my hospital is going to block this App, but what would the ONC do to punish a bad actor to protect the consumer?

So from a consumer protection point of view, what are we addressing within these recommendations, and how do we specifically address other than a general framework of policy and a general privacy statement; how are we making sure that we have the security within these Apps that they're not going to get hacked, and that that information isn't going to get sold and...or ransomed somewhere? We have a lot of that going on these days. What elements within the recommendations are addressing those concerns?

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

So first off, thanks for the questions, I think they're very helpful in terms of focusing some of our considerations here. You know, when it comes to safeguards for access, in other words, making sure that access doesn't break down somewhere, a few of our recommendations sort of focus on this chain of responsibility.

In other words, at the end of the day, we're recommending that for each thing that could break down, you know the registration process, the approval process, the suspension process, for every point in that chain where data might fail to flow, we'd like the ONC to identify who reports what to whom. You know, maybe the developer reports the activity of the provider organization to the OCR or, you know whatever the details are, but for every point at which it can break down, you know we want answers to those questions to know what are the next steps for resolving it.

When it comes to sort of enforcement actions in terms of what happens after reporting, we haven't made recommendations there; it's something we could consider, although I don't know exactly how strong they could be. But thank you for raising that point on the enforcement side.

When it comes to, you know how do we ensure that Apps are secure and that they don't get hacked, and that they don't sell data downstream? You know, at some point we get beyond the domain of what we can really guarantee, and that's why we fall back so often on this mantra of informed patient choice.

Ultimately...we see this in the consumer world that Apps and services are breached. We see it in the government world as well. We don't think that we can provide access to patient APIs, make the guarantees to patients that no matter which Apps they choose, their data will be safe. You know, we think that ultimately with the responsibility, with the flexibility of that choice comes the responsibility of having to take some of that liability, you know, into one's own decision. I wish we had a better answer there, but that seems to be the reality of what the ecosystem looks like today.

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

We do have a big trigger point as well; we talked a lot about HIPAA and we're assuming that the portals by which the patients are accessing these APIs are offered by providers who are covered entities. So we can start with HIPAA around the disclosure; it's not quite as unruly or unregulated as if I were just to login to an App store and pull down any App there. We do have that trigger point that we can go back to, and to that end, the task force really appreciated OCRs guidance that they was patient-focused guidance around clarifications to the consumer, to the patient around their rights to access their own information through HIPAA.

Knowing...recognizing that that's not going to be applicable for every type of access, it's that type of patient-focused education that we're recommending ONC can help coordinate through the agencies; that was extremely helpful. No whether any patients are actually on a website and reading it and it moves the ball, not terribly sure; that's kind of hard to say. But there are some efforts out there to at least try to get the awareness nationwide around accessibility to health information raised a little bit and that it is a right.

So that I would think that, to answer your question, it would...how it ties into our recommendations, we're really hoping to leverage those trigger points and leverage those points of transparency to say, what are you rights if you feel like you're vio...that's been violated, for example. I think that would be a really good place to look.

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

Thank you, I'm just going to remind the group, even with our additional gift of time, we have 25 minutes and we have nine more people to ask questions. So I'll ask if you can be as brief as possible with your questions and I think for the Co-Chairs also, to take some of the questions asked, all of which are important, just under advisement back to the task force so that everyone does get a chance to pose their questions. Paul Egerman?

**Paul Egerman – Businessman/Software Entrepreneur**

Thank you Kathleen and thank you Josh and Meg for a, as already been said, a very thorough and careful and detailed analysis, which I really appreciate. In the examples in appendix C, were the scenarios that ONC put together and I think you also had some scenarios; all of those scenarios involve data going directly from the EHR system, actually from one EHR system, although there could be multiple systems, from one EHR system directly to a patient. And there is another scenario that's frequently done with Apps in which the data goes to some server first, which is frequently done in cloud computing. So the data first to goes to a server, then it goes to the consumer or the user, who incidentally might not be the patient.

And so that's an important concept in architecture to understand that I think is missing in the analysis because in that structure it's likely that that server has PHI stored on it. And the scenario that we've talked about very briefly, where the App vendor or App developer sells some of that PHI is actually a likely scenario. Because when you think about the business model for an App vendor or an App developer, these Apps are usually given away for free or they like cost maybe 25 cents, it costs very little money, so how does the vendor make any money? Well one business model would be simply to monetize the data and they do have access to the data.

Now the data may not all be incidentally technically PHI. I mean, if you have a situation where your example showed like a cardiac risk App, if you have a situation where patients with a different style of registration register with the App vendor and say I'm interested in this cardiac risk App, well the vendor now has e-mail addresses of people who are interested in cardiac risks, so they can sell that to somebody who sells like diet pills or something; there are ways to monetize these things. And so, anyway, that's first just an observation that I want to encourage you to consider in your sort of like remaining deliberations as you look through this.

Also want to pick up on what Dr. Tang said is you know a patient's expectation in this process. I think a reasonable patient expectation is that when my physician, my provider will carefully guard my data and will not let it go to somebody who isn't trustworthy. I mean, that's a reasonable expectation, and I understand the emphasis on, you know the privacy notices. But as a patient, I don't want to hear that if something went wrong it's really my fault because I didn't read the fine print. You know, I mean basically I just expect nothing to go wrong. I have to say that's my expectation, especially when it's my data. Those are comments.

I actually have also a suggestion for you which is, you really did an excellent job, you laid out what's covered by HIPAA, what isn't and I would suggest that you simplify this whole thing and perhaps address some of these concerns by suggesting a policy that any vendor, any app vendor, any App developer or vendor should...that accesses data through an EHR API, that that vendor should automatically become a business associate. And then if you simply said that, then you're applying HIPAA to a large range of things. And I know some people don't like that, but HIPAA's not that big of a burden, and at least then you have a set of rules that apply to all of these situations.

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

So thanks for the comments and for the suggestion. Just very quickly on your point about the App architecture and whether there's a server involved, none of the scenarios that we described tried to be opinionated about that, and certainly having a server involved where the data go is the most common architecture for Apps. So if you see anything in particular in our write-ups that seems to imply otherwise, let us know and we'll fix it, because we certainly don't mean to do that.

In terms of the BAA question, maybe it's a better discussion to have off-line, but among the many people who testified and among the members of our task force, it seemed pretty clear that expecting a developer to have a BAA with every provider organization would get in the way of patient choice, because suddenly it's not up to the patient anymore to decide which Apps can be run where. There has to be, you know lawyers and contracts signed between the developer and every hospital where patients might want to run these Apps. We saw that as an insurmountable barrier.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, I think there's a solution to that insurmountable barrier which is, OCR or ONC or some group can simply create a business associate agreement that is a standard automatic agreement that will be in place in the absence of any other agreement and that could cover some of these issues about what will happen about selling of data and...these things are important. Somebody asked the question about what happens when a vendor gets acquired? Another question's what happens when a vendor goes bankrupt?

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

I think that's a really very fair point, you know, as we're trying to explain the nuances of this very complicated framework, we haven't made the statement that says let's not have a complicated framework. So maybe that's, to your point is one of our first recommendations is, where possible this should be harmonized, this should be a comprehensive framework. And short of that, then we have the nuances of the recommendation of HIPAA. So I agree, I think that's a really good one that we should take back.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah.

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Fundamentally under HIPAA a business associate who's doing stuff on behalf of a provider organization, whether it's collecting or transmitting or receiving data. And when a patient App isn't doing those things are behalf of the provider, it's doing them on behalf of the patient. So just in terms of the structure of those agreements, it just didn't seem like a good fit to describe the actual model here of patient applications.

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

Patricia Sengstack, you had had your card up; did you still have a question?

**Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System**

Well, it was related to what Paul Tang had said. My concern was just briefly the assumption that our consumers and our patients are savvy enough to, you know access these via their portal. And I was busy online trying to find out at our organization how many of our patients have accessed their portal. And the last e-mail I saw, it was about 100,000 patients, but only a small percentage of them actually use it. You know, we try really hard to get them activated, and then whether they use it or not is a whole different story.

So my concern is that they would be able to go into these systems, look at the Apps and, you know I noticed one of the slides said something about looking at the AP address and location and scope and understanding all this. And I'm thinking uh, I'm not really sure about this. So I'm concerned that, or actually I'm just wondering if any other recommendations might focus on some educational efforts for our consumers about this and maybe even not just the patients, but maybe some of our providers, too that are going to be, you know, interacting with these. Because I think that, you know it's not something that our providers or our consumers have a real, you know intimate understanding of. So, I'm just, you now, I want to throw that out there for consideration. Thanks.

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Great. Thank you.

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

Arien Malec?

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

Keeping up with our own recommendations to keep this short, umm, and focus on strategic issues, two topics of consideration and then one comment on the subject of HIPAA. With regard to considerations for the task force; number one is, ONC has other powers besides, you know making recommendations and regulation. One of the important charges of ONC is coordination among federal agencies and I note that there at least four federal agencies and departments like DOD, VA, IHS, and CMS, that are data holders that may well delegate access to patients for Apps, and have an important role to play in terms of implementing some of these safeguards and potentially verifying and certifying Apps.

And then a whole set of other departments and agencies will be developing Apps themselves. You can imagine FDA, CDC, VA, DOD, and CMS itself developing Apps. So ONC has an important role to play with regard to coordinating the activities of the federal partners and potentially that could be a mechanism for some of the App certification and App guidance recommendations that you have given.

The second is with regard to enforcement. There's been a number of people who have commented that because the legal situation actually is quite complicated, there have been cases where patients have called OCR to complain and been told, well that's actually an FTC issue. It might be an area for the task force to make recommendations relating to coordination of oversight so that there is at least a single place for consumers to make complaints without having to worry about the complexity of the law.

And then the last, with regard to Paul's comment on BAAs, unfortunately in this area the complexity of legal oversight isn't something that ONC or OCR or anybody else can fix, because it's written into the law that you have a BAA under HIPAA if you are...if that activity is under behalf, as you noted, on the behalf of the covered entity. If it's on the behalf of the patient and not on behalf of the covered entity, it's under FTC, unless it's under FDA. And the FTC website does a really good job, I'd encourage people to go through it, does a really good job of working through the flow of what reg covers what use.

And I believe only Congress can fix and simplify some of the regulatory and oversight mechanisms. I'm not sure if that's in your mandate to make those recommendations, but I did want to note that it isn't so simple as saying, Apps need to be covered under HIPAA via BAA, because that's just not the law.

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Thanks Arien and just to follow up briefly on the point of who is...whom are we asking to do what in our recommendations? One of our outstanding action items in reviewing our entire set of recommendations is to make sure we go back to those federal agencies and make sure we've got the right names listed in the right places and in many cases, it's going to be a group of organizations named in those slides. So we've just sort of sloppily written ONC in many places where we need to be a lot more specific.

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

Perfect. Thank you.

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

Leslie Kelly Hall?

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

So I'll be brief. First of all, I want to congratulate these two for leading this effort; this has been a huge amount of work, precision, great listening and participation. You guys have done a wonderful job, thank you.

I just want to put in...back in advisement, Meg; you mentioned the accessibility issues that we talked about for consideration. I'd like to have the task force maybe take some explicit recommendations around that.

And then I echo Arien's comment about HIPAA; we have to think about educating patients about their rights, and about their risks in a way that honors their choice of using it in any way they deem appropriate, and respects the rights of the patient; so choice is paramount. And our organization's been doing patient education for 40 years. And we know that plain language works, and people make complex decisions about their healthcare every single day; to have a mastectomy or not. To have this test or not; it happens every single day. They might I use their portal every day, but they're making complex decisions every day, and they need to be educated about those decisions; this is no different. So strong education, perhaps knowing the rights through FTC, what rights do we have, as well as the privacy practices in plain language, written in a way that people can understand. So thank you.

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

Thank you. Donna Cryer?

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

Again, congratulations to Josh and Meg; this is a tremendous piece of work; two very brief points. To Paul's point about patients being able to have a privacy literacy and health literacy, you know it's interesting. I see in the data we've been collecting at the Society for Participatory Medicine and other places show that in most cases, patients are actually driving the adoption of Apps and APIs into the healthcare settings.

And so I think that you'll see sort of early adopter patients perhaps a level below third-party endorsement programs but more of a crowd-sourcing of experiences, positive and negative with various Apps and I think the point that was just made about making it very easy to centralize those complaints, and those comments about Apps, the good and bad actors would be very, very helpful to sort of regulating, small "R", this area.

On the other side, you...the scenario-based approach that you've created, I think was very, very useful, very helpful, very smart. And contemplating healthcare systems now being the ones driving the use of Apps and APIs through the portal or through whatever mechanism create the natural opportunity to, and really to necessitate the conversation between a physician or the healthcare system or someone in

that provider side saying to a patient, this is why we want you to use this and how we use this. And perhaps creating some talking points that also address what Paul Egerman brought up about, this is what...how your data will be monetized or used or shared for research or other purposes within the institution or without.

And if certain points that a provider or health system could consider in that conversation with the patient about why and how they would want to use that App with a patient for health and other purposes. If we can help them and walk through and think through what the correct talking points would be, perhaps that could be a contribution to this effort. Thank you.

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

Thank you.

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Thank you.

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

Nancy Orvis?

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

Thanks. I was just, one of the recommendations, I thought if you would clarify at the beginning of your paper that given the criteria says it's that it's only for read-only Apps that you put that out there as the way to read through the 10 or so App recommendations. Because my thought was even like going to slide with the OCR use case number two, by the time this hits the public I'm concerned that aren't they going to want to write?

Once they download data from one vendor, provider and then put it on their own computer, and then want to put it in another App, aren't they going to want to store that data or read it combined? And that to me is, maybe it's a millennial question, the fact of certain age populations. But by the time we get there and say all you can do is I can read my data, but I can't save it anywhere, that to me is kind of a problem. I personally am also running into that through PHR Apps where the lab vendor will download stuff in a PDF, but it's not computable and I can't do anything except have a PDF picture of my lab tests. Okay?

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Thanks, I mean on that question it might help to clarify what we mean by read only. What we mean is it's read only with respect to the healthcare provider system, it's pulling data out of that system. But the Apps themselves, we expect are absolutely, many of them, capable of writing data to persistent storage, allowing structured data to be matched up and computed and visualized across different sources. So the idea isn't that the Apps themselves can read and display data, it's just that the healthcare provider system data is only being read.

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

Floyd Eisenberg?

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

So I'll try to make this quick. I agree with the concern about patients should have the ability to get the Apps they want used. I think there's another side to it though because especially you talk about patient-authored Apps; not to say that patients are malicious, but you could have an App, whether patient or other derived, that could be malicious and want to change data within the record and in the EHR; so we have to...there have to be some protections, and you do indicate the provider can say there's a security risk, but I don't know how providers know that. So potentially are we setting up a new industry that providers are going to have to use in order to make sure that what they're accepting is useful.

I think this was a great presentation, a great thing to look at, but I'm a little concerned about the safety of the EHR and the data. And I also want to address if the App is using it, is there any requirement that the App maintain some provenance of where the data comes from that it's using?

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Thanks for those points. Just to say very briefly with respect to the App changing the data in the EHR system, that's not something that the App can do, you know no matter who wrote it through these APIs. We really are focused on Apps that can read data from the provider system rather than writing data back to it.

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

John Scott?

**John S. Scott, MD – Program Director, Clinical Informatics Policy, Office of the Assistant Secretary of Defense, Health Affairs – Department of Defense**

...consistently doing great work and the Apps that are eventually enabled are going to change patient engagement significantly. So, I'm all for it, it's great work. I share the concerns though that people are talking about in terms of allowing the App to directly access the EHR. And I think there's a strategy that I think VA is largely pursuing, U.S. Postal Service has which is a personal health record which has...sort of serves as an intermediary between the EHR and the Apps environment that you're talking about where the patient has made a copy of all of the information from the EHR under their HIPAA right, into the PHR, and then the Apps are basically able to access that.

In such a strategy, I think there's a lot more flexibility for what the Apps can do as well as well-stated patient responsibility for the patient controlled information, and less of a burden on the EHR system itself. Did you consider recommendations that would be specific to that kind of a PHR environment?

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Sure, so thank you for the question. And just to comment briefly on it, we did...so first of all, it's perfectly possible for a healthcare provider organization to segregate their data into two piles, the operational, transactional, everyday EHR system with the database that sort of runs inside the hospital and fuels clinical care. And then next to it a separate database where...which is much more tightly controlled for patient access which is the thing that sits behind the portal, for example, and we see that pretty commonly and there's no problem there, that certainly fits within the model we're describing.

The important thing is that the provider organization makes the data available to the patient and that the data includes all the stuff in the meaningful use common clinical data set. We don't try to specify what the internal architecture looks like. But I couldn't tell from your question if you were suggesting that actually the personal health record that the patient would start from would be outside of the provider system.

**John S. Scott, MD – Program Director, Clinical Informatics Policy, Office of the Assistant Secretary of Defense, Health Affairs – Department of Defense**

Yeah, I mean a physically separate storage of the information which is under patient control, but hosted by the providing healthcare system that enables a great deal more flexibility for the patient to use Apps like we're talking about to download information from other systems, aggregate it in that storage media. Then, you know if a healthcare organization creates that strategy then its ability to allow these Apps to access the information would be through that PHR.

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

So my...

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

As long as the data are available to the patient, and they're provided by the healthcare provider organization and patients can share it through an API, that's fine. It's just an internal architecture implementation decision about whether the data live on two servers or one server inside the hospital.

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

**Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation**

So, I might just...my sense is there's a great deal of interest in this particular thread, so I would encourage you to perhaps send comments that could then be reviewed by the Chairs and by the task force. We have, I think at least one person on the telephone, too. So Kevin Johnson I think has been waiting to comment.

**Kevin Johnson, MD, MS – Professor & Chair of Biomedical Informatics – Vanderbilt University Medical Center**

I'd like to put my ha...

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

He put his hand down, so I'm not sure; sorry Kevin.

**Kevin Johnson, MD, MS – Professor & Chair of Biomedical Informatics – Vanderbilt University Medical Center**

I put my hand down, so we're good.

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

And is there anyone else?

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

And Wes Rishel.

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

That's it on the phone.

**Wes Rishel – Independent Consultant**

I also put my hand down, I think any time I go after Arien, he's probably going to cover what I want to say.

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

Oh my goodness. Well, we have made it within one minute of our planned end time and so I will turn things over next for the Precision Medicine Task Force report recommendations which will be given by Leslie Kelly Hall. And my understanding is that she'll be speaking for both Co-Chairs of the task force; the other Co-Chair being Andy Wiesenthal.

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

Thanks and we are in the very early days of a very visionary project, so the recommendations you'll see today are not nearly as detailed, although we hope thought provoking. Oh great, I am really old, let's see, let me...all the screens, that's the agenda; so Michelle, I assume the slides are next? There we go.

So, as you can see the members of this task force are varied, from a lot of different disciplines and we've enjoyed a good deal of testimony and dialogue through this. There's been a good learning curve; I know I'm certainly operating over my pay grade in trying to understand all of the work going on in these moving targets. The Precision Medicine Initiative is...has a wide variety of projects going on that have a different cadence, that have different reporting structures, that have perhaps different data needs, and so reconciling this at this moment in time is a bit squishy, but we are getting there.

Our tasks are to accelerate opportunities for collaboration that we see in both pilots and use, so that we can get to some common interoperable standards used in support of PMI. Remember we're...this initiative is bringing in new players; research being very, very active on the very essence of PMI as well as the patient participating in a very new way. So our group of actors is expanding as we go into this initiative.

We also hope to adopt policies and standards to support the privacy and security of this cohort participation group and advance standards that support participant-driven approach to patient data contribution. It's important to note that the group has a bias for using existing standards wherever possible and for collaborating work that is already going on.

So our charge is to identify opportunities to support all of the federal partners for the PMI efforts, and there are many; the National Institutes of Health, the Food and Drug Administration, and more, all participating very actively and in a very aggressive schedule. We also want to identify standards for ONC to collaborate with industry; we'll see both industry led efforts and government led efforts and a

combination of the two as we go forward. We also want to identify standards and use cases to support interoperability.

So we have heard from a great deal of agencies in this past effort and we were...it's just been absolutely fascinating, I must admit, to hear the work that's going on, to hear some of the patient stories that have been impacted by precision medicine and to learn how this effort will impact both new data movement for cures, and also I think data movement to get to overall population health.

So in our work, we were looking at what are the data sources available? What are the current gaps, what are the known gaps like high-value data that's needed for PMI? And what efforts could be accelerated to help the work in PMI? And are there areas which standards could be recommended to promote scalable and repeatable development for PMI?

So when we think about the PMI Initiative, it's still about two million to three million people, right? But we want this to be scalable; we want what we learn today in the pilots to be able to move to a broader group. The task force discussed some of the work stages and we struggled with how do we get this information very quickly into NIH for the work on the cohort? Where are the likely sources? And we've broken this down into three areas and timeliness and delivery of this information.

The first area is the near-term, and this is data that's coming from the health provider organization and from the individual participant. And this category is very material to our last discussion. So we can envision when EHR data might be sent to the initiative, to NIH through a query-based exchange, and that seems very likely; request for information. We also recognized that for this type of data, patient-specific data, phenotypic data like socioeconomic information, patient history, values; much of this data is not available in the electronic health record where it's mostly episodic care information and rarely contains that sort of general human context that each of us has and would contribute to the effectiveness of any sort of research and/or treatments related to that research in the future.

So we anticipate that the individual participant will be communicating directly into the NIH, where their things like consent will be gathered for participation, where individual information might be sent from the patient to the cohort. So that first sense is we need both of this data, the data coming from the EHR, and the data coming directly from the patient or the participant. And that might be an app like something like the NIH that the patient then connects to the EMR, have that information come from them, the normal medical information, my labs, my meds, my results, and then sent into the App where the patient then might add information needed for research that only they have that information themselves.

Or it could be aggregated from other locations they've also attached an App. So think about this as a patient data exchange of one, as they might be bringing information from multiple EHRs, adding information that they only know, and then contributing it back into the data structure.

The second phase is really about mid-term, it's getting information from other independent, non-provider sources. They might be covered entities, but not directly in the provision of care. It could be a laboratory, it could be pharmacy benefit management companies, it could be claims information where the patient might need to have that information aggregated back into the NIH, but it is not sourced through the EHR. That's that more complex area, and we see that happening the next phase.

And then the third phase is long-term, and that's information coming from the HPO, the patients and other sources, through the NIH cohort, back to the patient and the provider closing that loop. Now we'll have information that the EHR has not seen, we'll have information that the patient might have generated themselves, device data that the patient might have contributed, as well as aggregate data that's now available at the NIH that's never seen before in that sort of holistic view. So we see that data coming back out.

There was considerable discussion about this, and so I'll highlight a little bit of each area. So in the first area we talk about coming from the EHR, and coming from the individual participant, and I think I reviewed that pretty clearly. But we also have to consider making sure that there is alignment and consistency across work today being done on patient generated data like the data access framework, and the Argonaut Project, the PCORnet, NCI and others. And so that we are not starting this work with a hodgepodge, but that we are looking towards gathering information in a consistent and computable way that can be reused and made to scale.

On the second phase, we're looking at the, as I mentioned before, the organizations that are typically not have information held within any EHR. And so things like medication history, the current list of meds that the patient might actually be taking generated by the patient or known to others like a pharmacy benefit manager. And also lab information, commercial labs, and claim information. And then that third stage again is back to information that is coming back to the patient and to the provider from the actual PMI initiative at the NIH.

So this is a very...it's a very complex environment; we're still very much in the early days. We do believe that curing this approach by starting where the EHR data and the data from the patient themselves has a good chance of success. There's that initial phase of the patient registering, consenting, it's already getting work done. I think we...by focusing in this area we just simply have a better chance of success early on and not trying to aggregate data from multiple sources or back to multiple sources until we have a little bit more experience, and success from the pilots.

We do expect that in this next phase that we are going to be hearing more testimony; we have a few more meetings. We will ask a few key groups to come back and answer some questions that we might have and then go forward with the recommendations. There's...its really moving targets going on right now and there's also some procurement processes happening and decisions being made at some of the agencies. So as we have a better handle on things, we expect to come back to this group and show where all the moving pieces are, and how we might influence those moving pieces for better collaboration, and better coordination across each of the agencies as well as for the patients themselves.

So I would invite questions. Where we would like your guidance is, are these three phases reasonable? Do you feel that there are any gaps or areas of concern in particularly the first phase, what would your advice be? Do you have any knowledge yourselves of efforts that are going on that might not have been highlighted in this fine print that we need to keep an eye on and also involve in this work? So we would love your guidance as we go forward.

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

Thank you Leslie and in abstentia Andy and the whole task force. Let's see, why don't we start with Colonel Scott?

**John S. Scott, MD – Program Director, Clinical Informatics Policy, Office of the Assistant Secretary of Defense, Health Affairs – Department of Defense**

Yes, this is...its great work again and exciting to see this moving forward. When you talk about the data flowing from the EHR, you know into the system, you know we, VA and others have an enterprise data warehouse with a copy of the data that is separate from, physically separate from the actual medical record. And is it clear in the consents or should it be, if a patient's consenting for their EHR information to be included, that that consent confers to any copy of the data that the health provider organization has? So in other words we can export it from the enterprise data warehouse to enable the data to be shared?

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

Umm hmm. This workgroup has not looked at the specific language in consent, we've been operating at a higher level than that, but that's something we can take in advisement and go back and seek guidance on.

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

Dr. Washington?

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

Thank you. I just wanted to underscore a couple of items. I was very happy to see the inclusive nature of the ecosystem that you're obtaining, particularly as information flows. And to the Colonel's point, I think that the idea of having a data warehouse is relatively common, but I think this idea of them being linked in that separate and distinct in terms of how people are viewing how that data is used is probably a reasonable start.

But I just wanted to underscore the two points; one was the idea that the work that you have outlined is a bedrock and the phases that you've outlined are a bedrock for a learning health system, so the context in which the information is exchanged, and those APIs if that's where we land, are used, so the importance of standards I think are pretty important to underline; whether it is specifically for PMI or for efforts around delivery system reform and a learning health system, or even the Cancer MoonShot that have been discussed. That sticking to a single set of standards and I was really happy that that was sort of underscored.

And then the last point you were making, I think is the right linkage around the other determinants of health that might come from Apps and other systems that are managed by patients in specific. I would just encourage the continued linkage that you've drawn out in the slide deck between this effort as a bedrock, sorry, this effort as a specific use case that stands on the bedrock of interoperability that's going on across the health ecosystem. Thank you for that.

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

Thank you doctor.

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

(Indiscernible)

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

That's great advice and we do see that this initiative could be the wings with which many consumer projects can fly, whether it's patient-generated health data, device data integration, socioeconomic information. We talked briefly about accessibility issues that Meg and Josh brought up earlier; this group is likely to be a group that will be interacting with computers in a way where they're...they may be frail, they may be sick, they may have impairment of any kind, so we are encouraging that kind of accessibility standards as well in this. And we very much agree that this work can help form a learning health system with the patient squarely involved as a team member.

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

So Leslie and committee thank you very much for...this is an off to the races initiative that is clear with very aggressive time frames. And I'm looking particularly at slide nine and at some of the details there and in looking at the healthcare professional organizations EHR's, I may also consider the addition of patient registries...

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

...great.

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

...because certainly those serve as a very well curated source of data oftentimes focused on some of the rare conditions and unaddressed problems that patients face. In terms of the comments in the detail and looking at the timeframe of completion in 2016, of which we have eight months remaining, I'm wondering about the degree of outreach that has been done already to be able to establish which formats would be required or that participants would be constrained to use...the language here and whether it's going to be achievable to reach the point by year end?

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

It is a very aggressive timeline; there is, however, a good deal of interest and volunteerism of the work that's being done in the Sync4Science effort, the work that's being done. I know there were groups of our...members of our task force who are personally involved in matching data elements across multiple standard organizations to make sure that we have some momentum that's not wasted but collaboration occurs and we'll hear more about that.

I do think the idea of constraint or reducing what's needed initially might be an opportunity for recommendation; we need to crawl, walk, run. So for instance, what's necessary for registration in the cohort for the patient? We have to know who they are; the patient has to identify consent. The patient then might need to enter information that's completely specific to that cohort. Is there an opportunity, for instance, for us to have the top 100 data elements that each of these organizations are likely to use? Could there be coordination around that? To meet this kind of aggressive timeline, we are going to have to narrow and specify scope. And although we have eight months left, we're still in the clearly understanding what's going on.

So we have a challenge. I would say that there is...in general people are very inspired by this idea and we see folks stepping up and participating in a variety of areas, especially in the standards work I see people eager to participate in this, which has been very refreshing.

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

And maybe as a follow-up comment with respect to quality measurement, a particular area of interest of mine is wanting to also keep in mind in the course of this initiative being built that many of the clinicians involved in caring for the individuals who are contributing their data will have other requirements, including reporting for quality measurement and so to align as much as possible your efforts so that I call it, you know collect the data once and use it many times.

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

That's very good advice, thank you. And I failed to mention, I also appreciate the patient registries that there's a tremendous opportunity for good data.

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

Great. We're going go first to Troy then to Donna and then Michelle, I understand somebody's on the phone.

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

David Lansky.

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

Okay. Perfect.

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

Thank you very much. It is very exciting, you know, to look and see that we're moving forward on precision medicine, I mean, this is really basically from my perspective, this is why we've been doing all this hard work for the last many, many years.

I have a question; slide 12 refers to the gathering of patient data from a variety of sources will have implications. Now in here specifically you call out significant efforts are under way to support the capability of patient identification. I'm curious; I mean can you expand on that a little bit? I'd like to know where we're going in that direction.

And then the other question I have, I'll just give you both of them so you can answer them both. The...when you're gathering data from multiple locations is there any consideration that was placed on notifying the patient that data has been harvested? And I refer back to, much like your consumer report; you can actually go in and look at your consumer, your credit report and you can see when a report has been requested, who requested it and gives you the opportunity to actually petition that entity to say, why did you do this? I don't remember giving authorization for this. I mean you can backtrack and try to figure it all out.

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

So on the patient identity; we have heard testimony about work being done around patient identity mapping. This is somewhat different than our conundrum that we have in matching organizations to a patient identity in that we have the patient participating in that identity management; I am who I say, I

can validate that kind of information. Just have to rethink that a little bit. So we have heard from testimony, we have not deliberated on our recommendations yet.

With regard to the data harvesting suggestion, I think that is a wonderful idea for notification. It's a great addition to the use practices that would be available and we'll take that up into the committee. Thank you.

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

Donna?

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

Thank you so much. Leslie, I do appreciate that this is very early days in a very visionary process that a lot of people are very excited about. I have a concern about people asking too much of this effort and perhaps putting too many ornaments on a Christmas tree. And I wanted to pick up on the point about narrowing it down to the most relevant domains and pieces of data, one so that you can meet your timeline, two so that we can truly meet the initial goals of the PMI cohort and initiative.

I think Kathleen's point about use of patient registries cannot be more important. Most of the information, for example in the EHR, you know as I think through my own, would not be helpful when I look at the priority data domains, many of them are not relevant. And I wonder about where sources of family history, where genomic data and bio samples will get, where Geo location so we can look at environmental triggers and a lot of things that will actually have an effect on identification of biomarkers and the types of research that is actually envisioned from that Precision Medicine Initiative would come from; most often patients, and there are some are listed here, but I think a greater emphasis on data sources, data repositories that have the specific type of relevant data fields would help to enrich this initiative and move it forward more quickly and relevantly.

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

It is a real struggle to be both narrow and broad. So as we look at things like where does that data come from; we heard over and over again on the importance of data coming from the patient themselves and that that information is often not in the EHR. So the patient as the supplemental provider becomes very important.

With regard to registries, I think Kathleen's point is well in hand and as yours is as well, Donna. Disease-specific registries give us a different set of information perhaps than others. Or there may be commonality across these. And I think it's important in this first phase to see what's in common first and try to narrow scope to where we can get an agreement and accelerate that data work. And we're just beginning to learn about that right now. But it is a Christmas tree with a lot of ornaments and they're all bright and shiny and new. And it is hard to be both narrow and immediate and broad and inclusive; it's a struggle.

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

We'll go first to David Lansky on the phone and then to Rich Elmore and anybody else...okay so that'll...

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

Kevin Johnson.

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

...oh, and Kevin Johnson, okay.

**David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health**

Thanks Arien. Thank you Leslie for this really interesting work, it'll be a fascinating program as it develops. I wanted to highlight, you know the aspects of this that are not really the clinical or biological results, but about the context of the patient. And particularly I know I'm glad you highlighted the potential to access claims and self-report data, essentially economic information, but I...particularly in these days when so much of medical care utilization is constrained by cost-sharing, coverage, benefit design, high cost drugs, etcetera; especially some of the new therapies that'll be of most interest are very much constrained by cost and access to those drugs and we don't really know where that's going to go from here.

I would encourage you to accelerate the timeline for sorting out how to acquire claims data and patient self-report about their economic circumstances or benefit design circumstances because I think that'll be a significant variable in the actual utilization of therapy. We're seeing, especially for lower income populations and poorly covered populations, you know huge amounts of sort of self-management around dose splitting and foregoing care and delaying care and delaying diagnostic testing that is going to affect results. And so somehow capturing that data stream into this model early would be really valuable. Thanks.

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

Thank you for that comment; I remember we, at the Standards Committee heard some testimony a couple of years ago about how to share cost information, because your point is not just relevant to this particular task group, although because this work is so new both in care and in research and for the patient, the questions will be never ending.

The idea of having cost information available at the point of decision for the provider, the patient or benefit design information is one that keeps reoccurring. And although today has not been considered part of this task force, I would encourage that that's some work to be done perhaps at a standards at large. However, that said I think that the comment of accelerating claim data information and benefit design information we can take back to the task force. Thank you.

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

Great. Rich?

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

Thank you. I think we're in the...we can stipulate that we're in the early days of learning about how distributed queries are going to work and I was wondering what the task force's view was on the decision for genetic information to be maintained where it lives today, in many of these cohorts, which I think creates a potential failure point based on current state of the industry. And I was wondering if that had been discussed?

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

What's been discussed is when is the data by design simply too large to move? When is it that you're querying information to retrieve it and get to specificity needed and then store it at another site? When

is an information simply a result of the sequencing report similar to another kind of clinical finding? And those have been discussed.

But the nature of the genomic data is that it is so huge and largely not easily computable by an EHR or received by it; we have little standards at the lab level of getting information to the EHR. We have a few standards of how it's stored and used, so in one area we think this might be a real boon for query-based exchange simply because the data is huge and getting access to it and using that data in a more fluid way is more likely. However, we did discuss somewhat when is an information just defining a result and encourage that the use of existing methods, existing standards be used in that case.

But it is a different ecosystem by the breadth and volume of the data and by the fact that the researcher and the caregiver, in order to provide the best care or research, has got to have patient information generated by the patient. So these are new inputs that we have and new breadth and size of data that we've discussed. So, we're still early but we do think that there is a variety of answers based upon the type of information, the volume of information and the source. So I guess that's a long-winded say, I don't know yet.

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

So Kevin Johnson on the phone; and Michelle, anybody else on the phone?

**Kevin Johnson, MD, MS – Professor & Chair of Biomedical Informatics – Vanderbilt University Medical Center**

Okay. Thank you...so Leslie, thank you very much, this has been a terrific conversation and exciting about this initiative. As I was going through the slides I can appreciate the conundrum you all must...we all are in with regard to slide eight, this areas of opportunity and the sequencing. You noted on slide 12 the importance of the return of aggregated data to the sort of sustainability of the effort. And I'm curious whether you considered or whether there's opportunities to consider another sequencing that more quickly aligns return with submission, in terms of how quickly our recommendations come out.

I also appreciated the fact that number two, which is lab, PBM claims may potentially be the easier set of recommendations to create, simply because of relatively smaller number of groups that are affected. So I was curious if you could say a little bit more about the sequencing.

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

Of the item that has been most hotly discussed, it is when do we sequence getting data back to the patient. There is this idea of quid pro quo, what the patient is consenting, which they have to consent to participate in this cohort; if they are consenting wouldn't they expect access to or knowledge of how their data's being used, back to Troy's point.

And this has been discussed. And often we're reminded as we look at our terms here, we're still only talking two years out so what is likely and reasonable to do faster. I think based on your comment we will revisit that. There is a high degree of interest specifically to get that information back to the patient but also then to make that closed loop learning environment, we think might actually be the harder task initially. So thank you for that guidance.

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

One other small point, Surescripts or data aggregators, for slide 10, might also be groups that could be addressing some of the needs, for example of medication return to us.

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

Thank you. We heard a little bit about that in our...in one of our presentations I believe from NIH talked about that that new...the aggregator ecosystem could help in this effort.

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

Great. Before we go to public comment I've got one question or one comment. And somebody mentioned the notion that the horse is already out of the barn; I forget the right metaphor. And Dr. Washington noted the need to centralize on a common set of standards. I wanted to point out that Josh is already coordinating the work for Sync4Science and we're there around I think a pretty common sense notion of using HL7 FHIR and using in particular the resources that align to the API requirements for Stage 3 Meaningful Use or Stage 3 associated certification requirements. And that's a very pragmatic place to start because all of the EHRs through the Argonaut Project or other are already aligning around those standards and taking effort to open up those APIs.

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

We agree and we think not only that helps in the provider to the NIH communication path, but also the Apps for the patient to participate and those Apps may be developed by agencies themselves. So we do think that's a great starting point and agree.

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

Great. And so Michelle, I guess now we go to public comment?

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

Yup. If there is anyone in the room who would make a public comment if you could please come up to the table and I will turn it over to Alan to open up the lines for public comment.

## Public Comment

**Alan Merritt – Interactive Specialist – Altarum Institute**

If you'd like to make a public comment, and you're listening via your computer speakers, please dial 1-877-705-6006 and press \*1. Or if you're listening via your telephone, you may press \*1 at this time to be entered into the queue.

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

Well it looks like we have no public comment, so we actually ended early. I didn't think that was going to happen this morning. So we'll go to lunch a little early and we'll come back a little early if that's okay. So, we will come back at ten of, so an hour from now. So at 12:50 we'll come back and reconvene. Thank you all.

You all ready to get started again? All right, well the lines are open and so I'm going to turn it over to Lisa to introduce our...I'm sorry not Lisa, I'll turn it over to Paul to introduce our next speaker.

**Paul Tang, MD, MS – IBM Watson Health**

Okay, thanks Michelle. Welcome back from lunch. And this afternoon we're going to hear from Thomas Novak, Lucia Savage and Talisha Searcy with some updates from ONC. We're starting out with Tom who's going to talk about the State Medicaid Director Letter on how we can support Medicaid providers getting connected to health information exchange. Tom?

**Thomas Novak – Medicaid Interoperability Lead, Office of Policy – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Thanks Paul. I don't know if you remember, but...so Paul actually called him to get some thoughts on some of the care plan exchange elements in this, a little behind the scenes assistance with this, which was very helpful. I'll just also mention quickly that says CMS also, because I am detailed 50% to the Data Systems Group, and I only mention it because it's sort of germane to how we were able to get this going.

As you may or may not know, the HITECH Act also included administrative dollars for the state Medicaid agencies to establish not only the attestation portals and such for a Medicaid agency to collect the information from the providers; they're also able to build some systems. That's what we want to talk about, some of the guidance that we've been able to update.

So, with that initial administrative sort of bolus to the state Medicaid agencies, we also allowed the states to build health information exchanges, but it was sort of a narrow universe of providers who could be supported by some of that health information exchange funding. It was just the eligible providers and eligible hospitals; so that sort of small universe of providers who were able to be supported by the state Medicaid agencies were very thankful for this and the state Medicaid agencies did aggressively and continue to aggressively request these funds.

And as of 2012 it was approaching about \$350 million that had been supported by CMS thus far. And that was sort of always increasing; it had gone from \$45 million from 2015 to 2016 and we maybe would like to see that continue increasing at that rate every year; we're not sure, we're optimistic. So sort of encouraged by that, but there were some limitations of it, given that sort of narrow universe of providers, because working closely with the Medicaid providers they wanted to do transitions of care and meet their meaningful use objectives coordinating care with other Medicaid providers.

They wanted to pull in behavioral health, substance abuse treatments, long-term care, rehab, labs, pharmacy. And so it sort of began approximately 14 month affair of doing a fair bit of research and work internally at CMS, HHS, ONC to sort of figure out how to do that. And we were sort of fortunate that the statute was written broadly enough that it just sort of supported Medicaid interoperability and Medicaid providers. So, we were able to sort of effectively argue that since this funding in the statute is to support Medicaid providers and the statute itself doesn't limit this health information exchange funding to providers who are just incentive eligible, why don't we expand it?

And when we first released that funding, it sort of made sense for that sort of narrow interpretation because it was only State 1 that was in effect at that time, so the emphasis was on adoption. But with

Stage 2 and Stage 3, it sort of made our argument all that better internally and lo and behold, they agreed internally. So we were able to release this, and...Medicaid Director's letter at HIMSS among the many other pieces of information flying was this blog by Dr. DeSalvo and Andy Slavitt about this expanded eligibility criteria for health information exchange funding for state Medicaid agencies so they can now support all sorts of new kinds of provider types using these administrative dollars, which is a 90/10 federal match.

The 10% has to always come from the state Medicaid agency, so that's really not new, it's basically the eligibility is changing from an existing program; it just sort of broadened significantly. So the 10% still is the responsibility of the state that updated guidance now lets the state build any system that sort of supports an incentive eligible provider meeting a meaningful use objective with any other provider. So, for example, if an eligible provider wanted to do a transition of care with a behavioral health provider, they could support the architecture or the onboarding that sort of led that to be. Or if they wanted to do some sort of system that supported drug-drug reconciliation they could, as long as there's an eligible provider on one side of that transaction, they can use those 90/10 federal dollars to build that system.

That's sort of a test is, does this system that you are proposing to CMS support an eligible provider achieving Meaningful Use. If the answer is yes, then it is worth considering whether or not this updated guidance can support your new activity. And we sort of left it on the state, we, CMS we leave it on the state to sort of define the parameters of what they want to do, because the states have a lot of autonomy in the Medicaid Program, so the states sort of say, we're going to try to meet this meaningful use measure with this sort of piece of work. And then it is up to the state to sort of prove that they are doing that and then after the fact, CMS not only approves it on the front end, on the back end they go and sort of verify that these systems they created actually do what they say they are going to do.

So it's umm, as I said it has to connect the eligible provider to the...for purposes of meeting Meaningful Use; you can't build anything that's sort of a standalone, you couldn't build like say an island that was only long-term care; like there has to be an incentive eligible provider in the mix somewhere. The funding process, uh this is esoteric but it's an annual, at least annual process called an implementation advanced planning document that the state submits to CMS. But if we update it as often as quarterly, any time a state wants to update to do more things, they can do that.

The funding is for...only for the HIE interoperability piece; you can't use it to provide EHRs. It is implementation only, so it is not an operational ongoing administrative support; but, you know CMS is actually taking a very sort of liberal view with implementation and I think rightly so. So for example, if the state wanted to onboard behavioral health providers onto an existing health information exchange, they could sort of set their own metrics; so they could sort of define implementation and say, okay, we will consider ourselves implemented once we have 90% of all behavioral health providers on our HIE. And then, you know CMS would approve that kind of a metric because that is sort of a good, robust definition of implementation of health information exchange, and you're putting all those providers onto an HIE that can then support transitions of care with your incentive eligible providers.

If you are using this money to support a health information exchange that involves sort of non-Medicaid payers and providers, you have to do a cost allocation. This is a...sort of a standard OMB requirement. So if you have a statewide HIE that is 40% Medicaid, you can use this 90/10 for that 40% only and then you have to do a cost allocation as a state. So it can't really carry everything.

But the way of describing it that CMS is fond of which is that Medicaid is completely willing to be the Macy's, but we will not be the whole mall. So we still have to have the other...we have to have Foot Locker, we have to have everybody else come along, but we're willing to sort of be the anchor of the health information exchange, but we do need that list of memorandum of understanding from other payers and providers who may be benefiting from that health information exchange.

So there are really sort of two sort of big kinds of work that this can support, the first of which is architecture. I won't go into sort of what all these things are, because I think we're pretty fluent in that in this room. And it's not an exhausted list; we actually sort of generated our own list based on what the states have historically asked us for, and we are already getting states asking us to help support these kinds of use cases with the 90/10 funding. It is something that states have sort of long wanted the ability to do and it sort of made sense to the states for some time now, so they are excited.

I have probably five states already, I would say within two or three months of submitting proposals; 20 states all asking questions and sort of gathering information about ways to sort of scale up their health information exchange interoperability to include all these new kinds of providers. Sort of worth emphasizing is that we're really taking a standard-based approach, and will go into that a bit later, but that's really sort of helpful when you consider that we're building all these new pieces of architecture, for the most part, using ONC standards, they're ONC standards or anywhere there is sort of an applicable standard that we can lean on. I don't know if the recording caught my air quotes on ONC standards.

Onboarding is sort of the second piece of work. The definition of onboarding is sort of both technical and administrative, so a state could hire and in many cases they hire a former regional extension center because they have that existing relationship with the providers. So they hire an entity or hire the HIE itself to do the technical process of establishing the secure connections, coordinating encryption standards, doing that sort of technical work as well as the administrative work of looking at things like your consent model, your business associate agreements, making sure all the contracts are in place to onboard providers onto an HIE.

This is one of the more popular ways the states are utilizing the funding because in many cases they have an HIE that maybe is statewide, but they just want to sort of add volume to it. So they'll add behavioral health providers or long-term care providers and I think the very first way the states will take advantage of this new funding will be in that respect. We already have states asking to add long-term care providers to their HIE using this considerably enhanced funding, so that 90/10 will really sort of blow up the ability to onboard providers and add this sort of more robust coordination of care system.

So the CMS interoperability world is slightly different, but we're sort of always working to draw them a little closer and sort of find ways where we can partner. The governance model behind Medicaid is called MITA, the Medicaid Information Technology Architecture. And it's...has these, well, they're called standards and conditions that the systems must adhere to which emphasize things like industry standards and interoperability. So there's already sort of this framework in place for the Medicaid enterprise to be interoperable. But it's only sort of recently within say December of 2015 that we sort of have been able to pull the ONC standards and the CMS standards closer together. And we're making more and more of an effort on the CMS side to pull in ONC standards into some of these Medicaid systems in these statewide enterprises.

So we put in a requirement that, you know industry standards and Medicaid used to be sort of undefined; industry standards just sort of meant that. But then in December we put in a final regulation for CMS that industry standard sort of equals 45 CFR Part 170. So all of the standards contained within there, the transport standards and what not, bringing us closer together so we're not building anything that's going to be a silo, we're building interoperable pieces in the Medicaid enterprise sort of...before this FMB came out, sort of a good example of sort of things working well behind the scenes of getting one piece out and then the next piece sort of following nicely.

So I think we're all pretty familiar with the things in there, in 45 CFR Part 170. But now these are in Medicaid, so now Medicaid has transport standards, functional standards, content exchange standards, vocabulary standards, in the Medicaid Enterprise System. And the Medicaid enterprise spends four billion to five billion a year in systems, health IT systems, many of which are very HIE-like. There's obviously less of administrative data in these systems, but it's a considerable spend and a considerable investment in systems that now will more and more support interoperable standards that we've all sort of worked to advance.

CMS has an existing oversight process. Like I said, this isn't really a new program, it's basically we blew up in eligibility requirements, in a good way, for these purposes; so the existing oversight will continue. There's, you know there's site visits, there's OIG, there are, you know, there's various audit requirements that we have and those are going to remain in place. They have to continue to do the cost allocations; continue to meet with their CMS regional office liaisons and such.

So, we do always require that the states are going to commit to a particular measure when they build these systems, so they have to say, okay I'm building a provider directory and it's going to help transitions of care and it's going to help medication reconciliation. So they are aware of this and this is sort of within the existing model anyway, for them to provide these sorts of data points, so it's not particularly onerous, but it is, obviously, in the interest of proper oversight that we ask for these data points.

And then there's also the sort of opportunity to revisit the things that the CMS money sort of always could pay for before this. So this funding has sort of generated more interest in some states that maybe were, you know maybe dragging their heels on doing more with health information exchange; but now that it's sort of opened up. Some states are sort of going back to the beginning to see, like the subsequent State Medicaid Director's letters of like 2010 and 2011, we outlined all these things that states could choose to do, and we had a good amount of states do it, but now sort of we find a lot of sort of going back and saying, oh you know what, I am curious about doing, you know some business process modeling or some environmental scans to get really aggressive and granular about adoption within my state.

And, you know personal health records are actually something that states can support with some of this 90/10 funding, but very few states have sort of done the work to make that happen. I believe at the moment we only have one state that has supported personal health records with this 90/10 funding and now we are finding more states are getting more engaged with this update in the eligibility requirements. So we're happy to support them. And, you know the current model as we sort of sit down with the states and we have probably four or five meetings before they are submit a request, where we really help make sure that they are thinking through all of the funding models, all of the cost allocation

requirements, making sure they're sort of building their health information exchange the best way they possibly can.

So that's a joint effort by both CMS and ONC where we sit with the state and we also make sure they aren't leaving any federal dollars on the table that could help with their sustainability or their implementation. Because there are different kinds of approaches a state could take, so we're really making sure that the states have a lot of guidance in these efforts. And so obviously this also leads to, you know the bigger picture of delivery system reform; so we're very excited about this.

We, as I said have a lot of buy-in early on from states. The states have been overwhelmingly excited about it. It's something we're working on in the Office of Policy in coordination with CMS's Data & Systems Group. It is sort of ongoing and we had a bit of a roadshow where we sort of worked state-by-state, one-by-one sitting them down and having these sorts of conversations. But it could end up being a sort of a huge influx of HIE capital, depending on the state's willingness to sort of increase that 10% that they have to provide to build these systems or onboard these kinds of providers.

So, we're very excited. It's going well so far. States want to build cool things. We want to support them and we are very aggressively helping them walk through the process of getting these funds approved and supported by CMS.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you very much. This is quite an exciting program and it's sort of a relook at the authorizing legislation and giving you some latitude to help build out the infrastructure. Arien?

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

Thank you and just great presentation and certainly new information to me. A couple of questions; number one is, the way that you framed the Medicaid Director's letter and the increased flexibility that you're offering was framed around states building and onboarding to a particular architecture as opposed to providing flexibility to the state to use a variety of mechanisms.

So for background, in some states, states have been very successful building a single statewide architecture. In other states, states have been successful at partnering with organizations on the ground. In other states, it's a little of the wild West and very chaotic, and yet many of these activities that you point to still are occurring and there's activity to connect Medicaid providers to other actors in the ecosystem. So one question is what kind of interpretation can you give relative to flexibility of states to use that funding to onboard to activities that may already be taking place, regardless whether they're literally state-based architectures or state-based infrastructure?

**Thomas Novak – Medicaid Interoperability Lead, Office of Policy – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Right, and you've I think very accurately identified something else we have also identified with regard to the way states are building some of their health information exchanges, which is sort of this need for governance. And so it's maybe not always an onboarding role, but one of the other pieces of work that we sort of got more explicit about, in terms of our ability to support with some of the HISP activity.

So, if a state all of a sudden wanted to get sort of more aggressive and sort of drop a governance layer over say two HIEs or two RHIOS within their state, to help better coordinate and maybe establish a shared service layer or coordinate some of their activities; the state is within the interpretation of the state Medicaid Director's letter to do that. And that's sort of what we're seeing is that states sort of want that ability to sort of go in and maybe they aren't a state that it's just a statewide HIE, maybe they sort of became a bit of a network of networks, but now they didn't really have sort of a strong state level presence over those networks and that's what they are asking us for.

And so the HISP activity was sort of explicitly drafted with that in mind, so states could use that as one of their many levers. And so it's a bit of a carrot and a bit of a stick that the states now have that they didn't necessarily have before. And it's over this broader universe of Medicaid providers; like you could always sort of do some of that with Medicaid providers in general with your provider agreements, but now they can get more much more aggressive with some of the interoperability governance that they can do.

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

Yeah, I'd encourage CMS to look at ways of making that more flexible, because as I said, some states have been very successful with central infrastructure, top-down governance models. Some states frankly want to use those tools, but haven't been successful in the past and sometimes they are driven to create the tools as a way to spend the money that they have allocated as opposed to spending that money to achieve the desired outcome. So just a plea to think about the level of flexibility you're giving and the level of direction that you're giving so you're not inadvertently asking states to do something that may not be the right fit for that particular geography.

I guess the other question is relative to the standards and implementation guidance that are named in regulation. At this point ONC has established some sub-regulatory mechanisms for naming best available standards. In ISA we're now going through I think our second round, third round, Steve, umm of updating the list of best available standards in the ISA. So I was interested in your comment on whether tying the program to the regulated standards as opposed to the sub-regulatory guidance is or isn't the right strategy?

**Thomas Novak – Medicaid Interoperability Lead, Office of Policy – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Right, so...and that's a good point and sort of the adherence requirement of standards in CMS is a little bit different, but they...because they can always...state Medicaid agency could do a, sort of a notice of alternative consideration. So if they were asked to follow a standard and they sort of did the due diligence of looking at the standard, looking what they wanted to build there is sort of a feedback loop there for...that is existing in Medicaid, which is sort of really helpful and informed a lot of the work we do here, where a state actually is going to go buy a product that does some of the things that we want it to do. And they could say, we found nothing or it doesn't meet our needs. So that's one benefit of the Medicaid program and our investment in that.

And we sort of reference in the State Medicaid Director's Letter the ISA sort of more as a resource, not tying it to anything it to anything specifically. It's more part 1709 that's sort of a stronger tie-in, and it's actually sort of part of the sort of broader efforts we're doing at CMS looking at the Medicaid Enterprise System. And there's a series of State Medicaid Director's letters that are sort of underway where we

look at moving all of the Medicaid enterprise to a sort of more modular system and within that sort of definition of modularity, some of those modules are very a HIE-like, so some of them are things like provider directories or match a person index.

Some of them not, they're not at all, right? They were administrative. So wherever they exist, we want to think about modularity and part 170, but it's not a perfect fit, but we do want states using them when they can use them. And if they can't use them, we want them to sort of tell us why, like give us that information because that'll help inform better decision-making on our part in future State Medicaid Director's letter and in future guidance on the CMS side of the house.

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

Great. Thank you.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. Gayle?

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

Thank you Paul and this is very exciting. I am just delighted to see us moving into the behavioral health and long-term care arena. Of course HITECH didn't provide any dollars there for that area as far as EHR's go, but at least to start with the Medicaid population and start to be able to do this. But I do have a couple of technical questions on especially long-term care.

Are...because we are...we would very much like to see that those transitions of care that are so important and to have long-term care facilities as part of the...an exchange would be terrific. But are there requirements in that letter that say you have to have a certain percentage of Medicaid patients or do you just have to be a Medicaid provider in order to become eligible? The same question for behavioral health it's do you have to have...do you have to have thresholds that you have to meet in order to onboard and be part of this exchange?

**Thomas Novak – Medicaid Interoperability Lead, Office of Policy – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Right, that's an excellent question, one that has come up. So the crux of the legal argument has to do with the incentive eligible provider. So if it is...If you are another Medicaid provider that an incentive eligible provider wants to coordinate care with for purposes of Meaningful Use, then you are inbound like that it is something that we can consider; so behavioral health providers who are Medicaid providers absolutely worth considering as well as substance abuse treatment providers.

And it's also maybe worth mentioning that we worked closely with Lucia and the Office of the Chief Privacy Officer to sort of think through some of this because we're going to be giving states money for things they've been asking for for a long time. They want to build behavioral health information exchanges or substance abuse treatment and like add these sorts of use cases and populations to health information exchange and for a long time they sort of had two big obstacles to those efforts; one of which was money and the second which were the very sort of legal obstacles or the perceived legal obstacles.

And so we're sort of working on, you know we've taken away the first one we think largely with the state Medicaid Director's letter. And the second one, we sort of have some ongoing guidance, you know that we're working on that we think can really help with that second part of getting that data flowing, helping the states with understanding data segmentation and Part 2 and behavioral health and HIPAA. You know we linked to some of the work that OCR did with Office of the Chief Privacy Officer so we've been sort of aggressive in that respect because Medicaid, as you know like this is a very meaningful population to Medicaid that we want to aggressively support with their health information exchange.

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

Thank you.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. And Kathy?

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

So I'll share my regional affinity which is for the Southwest, for big rural states and actually with a great deal of healthcare that is delivered to state residents to...in an adjacent states so New Mexico, a large crossover to West Texas, also to Southern Colorado and to Eastern Arizona. And so even though this is a program that's very geared toward state-by-state, and I understand, you know that has to happen. Can you share with us anything about what I might call learning collaboratives or experience collaboratives among states, particularly those that are adjacent to each other?

**Thomas Novak – Medicaid Interoperability Lead, Office of Policy – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Sure. So this...the letter actually also...I spent a year with it, I know every line. There are two sentences that call for the specific support of multistate collaboratives. And what we were thinking of then was something that we already had with the HITECH Act, which is a 14 state collaborative using Hewlett-Packard. Because they had a common vendor, so like why don't we get all the states together; this will only simplify the process and sort of drive some standardization if we have this collaborative work together to do things at once.

And then we sort of have this consolidation. The emphasis there is a little bit around like sort of quality metrics. So like then we have all these various state Medicaid agencies doing quality in a very similar way for the Medicaid side of the Meaningful Use Program, and that's something we want to continue to support. And we are sort of already having states that are ahead of the game a bit, so like DC, Maryland and Virginia sort of already have a bit of that kind of dynamic and there is sort of the ability with some of the encounter alerting to sort of do that. Or you can do encounter alerting that you'll need to get a feed to give you sort of an out-of-state code.

And we're trying to actively encourage that. I mean, you sort of always run into, how willing is the state to invest in some of these solutions, so the state sort of does their own sort of, you know soul searching to see, okay, is it worth the time and money to build a connection to my adjacent state? And wherever it is, and we do actively lobby for it, we are absolutely able to support multi-state collaboratives, and we in fact call out for it because we also see it as a way of using some of our standards, our CMS standards the

sort of emphasis on leveragability, interoperability in our MITA, our Medicaid Information Technology Architecture really calls for that sort of scalable, shareable services.

So that's something that has sort of long been one of the seven standards and conditions for Medicaid. So we're on the same page there, it's something that we do see happening and we're trying to encourage it further.

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

Great, thank you.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. And is that Anjum that's on the phone, Michelle?

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

Yeah, thank you Paul.

**Paul Tang, MD, MS – IBM Watson Health**

Thanks.

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

This is Anjum; thank you for the presentation and obviously these exchanges are very welcome and needed, especially as someone was mentioning, expand this to behavioral health and long-term care. So my question was that in the last few years and since the initial state HIE funding happened through HITECH, there have been new private and regional HIEs that have also sprung up in different states. So are you expecting then these funds to cover new HIEs in states as well and would there be then some requirements for those HIEs once they decide or receive being...providing coverage to Medicaid beneficiaries?

**Thomas Novak – Medicaid Interoperability Lead, Office of Policy – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Yeah, absolutely. So this is...there's no sort of no real relationship between the sort of former HIE...ONC-supported HIEs and anything that can be supported by this. Obviously that created some architecture that we're leveraging. But if a state wants to, like I live in Pennsylvania so if the state all of a sudden wants to add not only some of the Southeastern Pennsylvania HIE, but you know UPMC and Geisinger and you know the various sort of pockets of HIE innovation within the state.

As long as the state can provide sort of their documentation showing their relationships with these HIEs and sort of their governance strategy for how they're going to, you know sort of maintain and ensure that there are ways to make sure the providers are achieving Meaningful Use within these various HIEs, then that's fine, like there's no sort of limitation on which HIEs the state can support. Like the state can support any HIE within the state so long as they meet all the eligibility criteria. So we really sort of have opened it up to include the private HIEs, or HIEs that are new or, you know are maybe more nascent during that original ONC HIE investment and now are able to participate.

And they actually, it even goes further, so now whereas that funding maybe didn't sort of meet all shapes and sizes of HIEs, now we can support say query-exchange in a way that the states have been wanting to do, but, you know wasn't always a perfect fit for some of the ONC work. So now there's an ability to sort of be a little more flexible in the kinds of HIE we can support.

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

...thank you.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you, any other questions or comments? Well thanks for enlightening us Tom, this has been very interesting in terms of...and gives us a whole new dimension to what we can help achieve. Thanks.

**Thomas Novak – Medicaid Interoperability Lead, Office of Policy – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Thank you.

**Paul Tang, MD, MS – IBM Watson Health**

And turn it over to Lisa to moderate the next panel...or presentation.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Thank you, Paul. Next up we have Lucia Savage, who will give us a report on the Officer of the Chief Privacy officer on relevant activities. Hi Lucia.

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

Hi there, it's nice to be back. Let's see, okay, let's even go back one. Nope, not quite what I had printed but I'll go with the flow here; this agenda, all right. So I'm going to cover...just kind of telling you what we've been up to besides the API Task Force, and I've reserved time for questions. And I've split up my presentation between so privacy first, security second; but I'm prepared to take all questions you guys have.

And some of this you have seen before from OCR, but one of the things we've really been working on in my office is how to ensure that people actually are using the rules that we have in the rulebooks instead of making stuff up. And it kind of has a three-pronged approach this year. First of all, we really focused a lot on the individual right of access. I know that Deven McGraw was here earlier this spring giving you a long conversation about that, so I'm not going to go into detail, but I do have some summary.

Secondly, I...we're had a very big drive in my shop to remind the professional healthcare stakeholders who are regulated by HIPAA, what the rules actually say so that we can focus in on how HIPAA supports interoperability. And thirdly, sort of reigniting our conversation about the complex privacy environment we have due to state law.

And this first slide just kind of illustrates, you know why we're doing this, right? We have this environment where most people have a need to have their health information moved for them, but it's not really moving for them. And as you know, in response to that ONC sought the commitments of stakeholders to address some of these things with three basic commitments. One was to support consumer access so that consumers could easily and securely access their data.

Secondly to not having blocking and have transparency about data practices and there's a key phrase buried in there that I put in red which is, we really want people to take advantage of the permissions law already gives them to move this data for patient health and learning. And thirdly we want people to use best practices and identified standards and in my shop particularly those related to privacy and security. And so all of our work really kind of weaves through what ONC does. Sometimes I think about we're kind of the grass on the playing field and a lot of stuff happens on the grass and we're kind of underneath it all.

So as you know, in January and then a second tranche came in in February, OCR issued some new guidance on access. I will say this, it is extremely rich and in your spare time, for those of you who flew in great airplane reading with a highlighter, it's designed with a narrative document and the primary audience for this was, in fact lawyers and compliance officers within healthcare organizations.

A key thing here is we're already working on turning this information into consumer friendly videos and pamphlets and brochures that will be bilingual that should be out later this summer. We're hoping by the annual meeting, but our schedule is very tight some more to come on that; and that's a great partnership we have with OCR. And of course this is really fundamental to precision medicine and to what ONC is trying to do with this API requirement, as you've heard today. So, Karen and I blogged about it.

I do have a couple of slides in here that I'm going to give you just brief highlights of that rich detailed information. But again, I know that Deven gave you a very long discussion about it earlier this year, and its 18 pages if you print it out. So I can't possibly condense that into a half hour and I think you would find it really boring.

But anyway, the fact sheets that they've created are designed as fact sheets so that they can actually change each Q and A, as things get...come up and they can add Qs and As; for example maybe they'll be additional Qs and As that get added in response to the API Task Force recommendations, which they are anxiously awaiting. But those fact sheets cover what is the scope of the right? What is the form and format and manner by which a person can access their data? What the timeless is.

And I want to pause on that for just a second to remind the public and the joint FACAs that, you know there's a regulation and it says that covered entity has 30 days and that won't be changing unless the regulation itself changes. But what OCR has done in its guidance is kind of given some color, to flesh that out, you know. It's one thing if you have to go to a warehouse and pull a manila folder and stand in front of a photocopy machine and it's something else entirely if a patient is logging on to their view, download, transmit porta, clicking a few buttons authenticating themselves and transmitting it. And so we really expect that as we automate this process, the 30 days will come the outside time limit, not the minimum that people...not the one that people try to use, you know use all the 30 days.

Obviously there's a lot of data that has to be made available, it's anything in a designated record set. In our world, the data components that are required to be available under the view, download, transmit portal are part, sort of subparts of a designated record set. And this right of course extends to those items, but extends far beyond that as well. There is some great new guidance about fees. My pithy tweet was T, meaning transmit, T should be free. Again if you automate it, it should become a microscopically costly or no cost at all to the individual.

And then lastly a very long set of FAQs about who is that third-party that the patient can transmit their...direct their data be transmitted to, and it can be a competing healthcare provider, it can be a family member, it can occur through an unsecured e-mail, it can be an App. So I really applaud this think...this forward thinking guidance that OCR has done and it's really made our lives a lot richer and given us a lot to work with for the API Task Force.

This is a slide that just gives you links, if you want to link through. And I'm going to move on to sort of what's the corollary work that ONC did. So those of us who are students of the HIPAA regulations know that buried in those regulations are a list of basically verb clauses about how providers and covered entities can share data with each other permissibly. And what that means is there are certain rules that allow the covered entity to share data with each other without first getting a writing from the individual who's the subject of that data. And those rules are cleverly designed in two ways; first, they are media neutral. So they're privacy rules and they apply the same whether the data is on paper, in a FAX through a secured electronic transmission.

The second thing about those rules is they actually are kind of the fundamental data movement features of the healthcare system since 1997. You can, you know a provider can send to a payer the billing record, that's chock full of PHI. We can use billing records to do HEDIS measurement; that all existed in 1997. So there's all this activity that was really designed to run in the background. And what we observed is that we found a lot of people were afraid to exchange, even though they were permitted to. And we wanted to call out for stakeholders that there are these capabilities they can take advantage of.

So what we did is we took all those verbs in the regulations and turned them into scenarios which are illustrated and we published two fact sheets. One fact sheet is really focused on exchange for treatment and the other fact sheet is focused on exchange for healthcare operations, particularly between payers and providers, such as you might need for an ACO or advanced payment model or for activities like quality measurement, population health and training.

So I want to drill down on a couple of those for you. This is an illustration from the facts sheets of the permitted uses and disclosures, and this one is, you know pretty vanilla transaction. I've told a lot of people I work with my mom just got out of rehab and I know for a fact that her hospital like called around to several different skilled nursing facilities to find out which one was the right one for my mom and that is what we expect the healthcare system to do as patients.

And me, 3000 miles away I don't want to fill out a piece of paper for each one of those phone calls and I was thrilled that they were doing that work. And HIPAA supports that, and this is kind of an illustration of that, two hospitals exchanging data for a patient in common where they need to both consider the best way to treat that patient.

So among the items that are in these permitted uses and disclosures, I'll just kind of tick them off. Obviously quality assessment activities; we've...as I said, we've been doing HEDIS measurement for our health insurance plans for a long time. The measures that we're trying to re-engineer through MACRA, which you'll hear about soon, are also in part conducted through...the way we use all this health data in a use addition...in addition to the treatment and payment functions.

We have used this data for years to do case management and care planning, we tended to do it by FAX, but we can do it through electronic exchange. In this day of Zika, it's important to recognize that we actually have the ability to do population health management and disease surveillance in these manners. We can use this data to develop the protocols and clearly understand the best ways to treat our patients. And we can also use them to evaluate both our health plans and our health providers. And so I would really encourage you to sort of drill down on the fact sheets; there are links provided at the end and if anyone has further questions about it, happy to get an e-mail and direct you to people in my office who can help.

But I wanted to show the last one because it is a Zika world. This is an illustration we put in there about three hospitals that are trying to share data to figure out where are the readmissions coming from. What's causing...they're independent facilities in a community and they're trying to...they all have high readmission rates and they want to reduce that. And this rule allows those hospitals to collaborate to figure out what are the protocols that they need to put in place to prevent the readmissions and what are the sources of the readmissions. And this is all illustrated in this fact sheets.

So our next task is to get the word out. We're a small agency, we don't have an advertising budget, wish we did, but we're working a lot with...partners. We participate in the CMS stakeholder calls. We worked a lot with healthcare organizations and we're happy to do webinars on this with any other organizations that want to invite us.

So lastly, what does this have to do with certified EHR technologies? So two things; I think you have a pretty good sense of the API technology and consumer right of access from the morning's presentations; I'm not going to belabor that point. But I think the other thing to remember is that at the end of the day, even these permitted uses can be automated when the business partners decide to exchange data.

They can be automated through APIs, just like right now they might be automated through Direct protocol accounts. And I think that's a really significant thing when we think about the API requirements in our 2015 edition rule, which of course include, umm looking up the patient, retrieving all or part of the patient's record and a transmit feature within that.

So that's kind of the HIPAA basics and if you were on the Policy Committee last year, you will remember that we sort of forecast we were going to work on that when we did the roadmap. And the other thing we forecast we were going to work on was the problem of state law.

So as you'll remember from the roadmap, we have situation in which in our American legal system, HIPAA is kind of the bottom baseline federal law. And there are a few federal laws that sit on top of that that are more privacy protective, 42 CFR Part 2 is the most famous one. And then in addition to that, states did at the time HIPAA was enacted and since then have taken advantage of their right to pass their own privacy laws.

And we observe two things about this in the roadmap, which is validated in the input we got from the public; on is that there's a lot of confusion about what those laws mean and they're really diverse. So a great example is we have more than 18 states that have their own way of describing mental health or substance abuse law that may or may not be consistent with Part 2, that would apply to non-Part 2 regulated entities. We have a wide variety of states, in terms of what age do minors get to control their health data, etcetera. I think the physicians in the room are certainly familiar with this problem.

And ONC last tackled this prior to HITECH in the 2007-2008 timeframe with the HISPC activity. And if you ask me what that acronym means, I guess probably 80% accurately but I'll try, Health Information Privacy and Security Collaborative, something like that. Anyway, we did a great report back then where we gave a grant to the NGA to do a big report on it and in the wake of HITECH, we were really focused on interoperability under federal rules and it's an issue that we didn't spend a lot of time on.

Now that the data is ready to flow, and as Tom described, now that states are really bringing the full force of HITECH to their Medicaid populations, it's sort of time to start that conversation again. So this year, effective Septem...October 1, we awarded a grant to the National Governors Association; I'm going to talk a little bit about that grant. That grant includes several things; one was a very long process of interviewing stakeholders, probably 30 to 50 interviews were had with state representatives, key healthcare leaders, organizations such as the AMA, CHIME and HIMSS were all interviewed.

And from that the NGA was tasked with developing a draft roadmap by which they would sort of identify what were barriers to the movement of information within states and among states with a particular focus on privacy and security. And that...they just finished that phase recently. The second phase of the grant starts this week with a convening of 5 to 8 states and a full day workshop, it's actually about 11 hours all in; it'll be later this week where they'll be working with...these 5 to 8 states will be working with experts to validate the roadmap content, make tweaks on it and identify, in that roadmap, in particular models that a state has undertaken to tackle this problem for itself that other states might copy. So that is later this week, Thursday and Friday.

After that the NGA will finalize that roadmap and make it available to the states that participate in a center for best practices; that'll come in phase three, probably we'll be done with that in about the end of May or early June. And then in the next fiscal year, the NGA is funded to support up to two states who actually want to do something to change their environment, to take these tools and put them into place. So, we're pretty excited about this. The issue of state law is something which, when I read in the trades, a lot of people are talking about, so if we wanted to restart a conversation, we certainly accomplished that.

But, the nice thing about the NGA is it's a really well-regarded organization from the state perspective and we really trust them to know what their constituents need and deliver something that for their constituents is actionable. So, more to come.

And this last slide is just some more links if you want to prior information. We don't have publically available information about the NGA grant at this time. But when they release their roadmap, obviously that will be an important milestone.

Moving on to cybersecurity; so very busy space cybersecurity is, I'm going to talk about three things. I'm going to talk about the Cybersecurity Information Sharing Act Task Force. I'm going to talk about

Information Sharing and Analysis Organizations and I'm going to talk about what is ONC's role with regards to Health and Human Services security efforts.

So what I wanted to start with was just to remind you about the four things we've committed to regarding security in the roadmap. One was we committed to coordinating with the Office of the Assistant Secretary for Preparedness Response on priority issues; that is the agency within Health and Human Services that has direct responsibility to the Secretary for health, public health sector security activity. Secondly we committed to supporting and promoting information sharing.

Third, we committed to working with NIST and OCR to finalize and publish a mapping of the OCR Security Rule to the NIST Cybersecurity Framework. You'll see a little check box there because we published that on February 25; actually OCR and NIST did, so mark that off the list. And then we're also working long-term to sort of develop more, with ASPR, more best practices for small and medium sized providers in the security space.

Which takes us to the Cybersecurity Information Sharing Act of 2015; this is passed by Congress last fall. In it is section 405, which has four parts; it's all about the healthcare sector. And in particular, there's section 405(c) which tasks Health and Human Services with creating the Healthcare Industry Cybersecurity Task Force in collaboration with NIST and the Department of Homeland Security and that also specifies who should be on that task force.

So the charge of the task force is to analyze how other industries have implemented strategies and safeguards for addressing cybersecurity and information sharing. Analyze the barriers that private entities in healthcare face in securing themselves against cyberattacks. And review the challenges that HIPAA covered entities and business associates face in securing networked medical devices and other software systems. Plus, they have to inform the Secretary of how best to make recommendations to the Secretary about how best to prepare to cyber treats and come up with a plan for HHS to implement the cyber sharing features of CISA.

At HIMSS the Secretary announced an, excuse me, open application period for this task force and that closed on February 9. There was a group of staff from HHS, Homeland Security and NIST who then reviewed the applications and came up with the membership, which I'll get to in just a second.

The things we are looking for is that applicants were serving in a position of influence as a member of an organization that was representative of one of the required components of the healthcare system or in other appropriate health sector organizations. That they had experience dealing with technical, administrative management or legal aspects of health information security; that they had knowledge of major health information security policies, best engineering practices, organizations and trends. And that they could participate actively in the task force. This is not a task force you just get to put on your resume; people have to show up and do a lot of hard work.

So...I missed a slide, sorry, I'm missing a slide. Let me...I had a slide in what I submitted that has the members on it. There it is, okay, there we go. I'm not going to read the members; this is for your erudition. I will note that we have some really great people on here. We have a senior engineer from FireEye a leading cybersecurity analysis firm. We have some great provider organizations. We spent a long time sorting through hundreds of applicants to come up with the list and we're really pleased about it.

The committee first met telephonically on March 17, but their first in-person meeting actually happens Thursday. Yes, this is a very busy week in my portfolio. It is a public meeting for the first four hours and I've provided the address here. I will say that it's probably a smaller room than this and seating will be limited. I do believe that there is going to be Web audio participation and that would be available at the link I provided on the slide, that's an ASPR webpage. And then I've listed the other days that they'll be convening in person and by telephone throughout the year. So they'll be working regularly every month, through the end of the year on their tasks.

So, in addition to the CISA task force, ONC committed to supporting information sharing and analysis more widely in the health and public health sector. I know Lisa knows this well but for the rest of you, the...an ISAO is an organization that's a group that gathers, analyzes and disseminates critical infrastructure information, particularly on health security. There are...I won't go into the details of the Executive Orders and the many layers underneath that today, but there are a couple of key benefits there. The design is that within an industry, people share. Now when I was talking about this publically several months ago I kind of likened it to a neighborhood watch, right? So, you're...everyone on your block is organized and somebody's casing the neighborhood and you all get an e-mail on you neighborhood list saying, hey, the guy in the beat-up brown Buick is casing houses or I caught him trying to jiggle my doorknob, you know, watch out for him and then you can all take steps.

And i...the idea is to create timeliness and an information flow so that somebody who has not yet discovered that threat is manifest in their organization can, in fact, remediate it. So I'll give you a second example which has to do with phishing. You guys all have read about ransomware and phishing e-mails and a great example of proactive information sharing would be the organization who suffered the phishing e-mail that some poor employee clicked on by accident that caused the ransomware describes what that e-mail looks like and sends it out so other people can say, oh yeah, that looks a lot like, you know VISA, but it's not VISA. That's what we want to have happen.

Healthcare is delayed in its maturity in this space compared to some other industries and that is why actually the CISA Task Force, their first order of business on Thursday is to hear from, I believe it's energy, transportation and finance that have robust information sharing organizations. How did those organizations do it and what can we copy from them? And those of you in the room will recognize that, you know, we don't want to reinvent the wheel on information sharing governance, right? We just want to copy what somebody else is doing effectively and get it going quickly.

So we don't have is good information sharing in the healthcare system as we would like. There are some of the problems. One is that we have some competition for information sharing. We have a couple of ISACs. The information is not really accessible to the smaller providers which is part -- of particular concern. They compete so maybe we can do something to facilitate better cooperation are bring a more collaborative tone to that space. Also the information sharing is a little bit ad hoc.

So we don't have as good information sharing in healthcare system as we would like and here are some of the problems. One is we have sort of some competition for information sharing. We have a couple of ISACs; they are not...the information they share is not really accessible to the smaller providers, which is of particular concern for ONC. And they compete, so maybe we can do something to sort of facilitate better cooperation or bring a more collaborative tone to that space. Also the information sharing is a little bit ad hoc, and we want to, per the Congressional dictates of CISA, sort of make it more systematic

and more timely. And then lastly, of course, we have an Executive Order that directs us to do this, so we'll be supporting that as well with our ISAO efforts.

So what are we doing? So two things; last fall ASPR awarded a grant to Harris County Texas to do essentially a landscape analysis of where was information sharing working well in the healthcare system and where was it working poorly? Those findings, they just finished a private presentation on their initial findings. We will be working with them on whether they're comfortable coming and making a presentation, for example to our Standards Committee; so if we can arrange that, more on that later. And they're actually really well equipped, they're the largest public health system in the country and they have an incredible cybersecurity infrastructure compared to other public health agencies. So we're really pleased with the work they're doing.

And what is ONC doing? So umm, well we have plan, because we want to solve a few issues. The biggest problem we have is this lack of access to small businesses; and I'm not going to go into the details of the slide. Our solution is, we do have granting authority and we expect to award...publish a grant opportunity and may eventually award a grant that would be seed money to start an ISAO that would bridge this space where information is not timely and accessible to small businesses. And we believe that ASPR will be making some grants at the same time. So hopefully that will be enough to move the system along in an expeditious way.

All right. Lastly sort of...so what is ONC's role here? I get a lot of inquiries about where's my magic wand on cybersecurity and I am sorry to say, I do not have one. Wish I did; but we have sort of four basic roles. One is, my entire team of the cybersecurity specialists, we...our job is to advise Karen and Vindell and the rest of the National Coordinator's office on cybersecurity issues, whether it's ISAOs or ransomware or security hygiene or the API architecture, all the things you've been hearing about. We work with various federal meetings from the Critical Infrastructure Partnership Advisory Council, which is under Department of Homeland Security to a Government Coordinating Council, which is among interagency. We serve on the Sector Coordinating Council. We work on various HHS offices that are handling this topic.

Our primary role there is to bring the outside perspective in. That's our special gift to the world, is connecting with you on the FACAs and our stakeholders and bringing their perspective in and sharing the internal perspective out. There are other people on those committees who have specific responsibilities. For example, the data systems run by CMS or the data systems run by DoD or the data systems run by HRSA. We're really lucky at ONC; we don't actually manage a data system.

So among the things we've been doing, obviously we've been working with ASPR on its grant. We serve...I have staff on a privacy incident response team so when something happens in the healthcare sector and staff are convened to get briefed on it, we are looped into that briefing and we also work to support how the Secretary develops her own Cybersecurity Preparedness Response Programs. And, that is the end and I do believe I have time for questions.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Okay. Do we have any questions in the room? Arien, anyone else? Go ahead Arien.

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

It's the two cybersecurity geeks with the questions. So first of all Lucia, I want to commend you and OCR and FTC for the wealth of information that's available now on what HIPAA actually says. Although the reg text itself is surprisingly readable and as a person who works with me with a double E degree said, I read it and thought it would dry and boring and it's actually fascinating.

But you know, the part of the unsung news here is that HIPAA provides actually a lot more than people think it does and it is a lot more sensible law than it ever gets credit for in various comments that are 99% of the time, completely misinformed about what HIPAA actually is; so that's number one, just thanks.

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

You're welcome.

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

And then an encouragement for people to read it, absorb it and understand it. Relating to cybersecurity, this is a big topic. The ransomware attacks have gotten a lot of the headline press. I would suspect though that the bigger issue here is identity theft. As many people understand, because of the wealth of information that's available in registration systems at hospitals for example, the data that's contained in healthcare enterprises is fabulous for committing a variety of forms of fraud, including credit card fraud, you know financial fraud, as well as insurance...health insurance fraud . There's been a lot of concern about people stealing my med record and, you know, doing nefarious things with it.

The real threat here is identity theft and subsequent fraud and that's driving a substantial amount of commercial traffic. There's a dark net ecosystem; there's an underground economy for buying and selling digital records in order to monetize them, generally through some form of fraud. And the healthcare system is probably not too strong to say woefully...it is inconsistently prepared, I think would be the way that I would phrase it. I've made a number of comments in the past that there are really well defined frameworks. PCI, DSS, for example is a great, well fleshed out framework for protecting information security systems.

HIPAA itself provides a risk-based framework, and many people have looked at HIPAA as primarily a compliance mechanism rather than actually doing the hard work of accepting and remediating the threats. So to the...a plea to the CISA Task Force, we've been, for some reason afraid to make more substantive guidance and recommendations. But if there's any time that we should be making those, that very concrete guidance, it is now.

And then the second thing that I didn't see you address is the federal government has a role as a purchaser of healthcare services and it has a role as a payer for healthcare services. And I wonder why the federal government doesn't use those two roles to better enforce cybersecurity. Part of this would require the federal government to have a common set of approaches. FedRAMP is getting a lot there; DoD is getting closer with a more actionable set of guidance.

But, you know I think it's a role here for if in its activity as purchaser, if DoD and VA could make TRICARE contracts and other fee-basis services contracts contingent on a cybersecurity posture. If CMS could man, you know the ultimate hammer here is if CMS could make its claims activities contingent on maintaining a cybersecurity posture, industry would flip very dramatically. So, you know a suggestion to

potentially look at the use of appropriate federal power relative its role as a purchaser and as a payer for healthcare.

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

So just a couple of things; so on the CISA Task Force is a member of the Federal Health IT Advisory Council and I will definitely take that back to them. I think the reason we...I was asked what we should do and I said, put somebody from the Council on there to really connect the CISA Task Force to our federal partners.

I will say that, you know for federal agencies, what their authorities are is a very complicated set of rules. If it's connecting to a federal system, there are pretty severe rules that apply through FISMA and other rules. But outside of that in just sort of a purely payer role, each agency's going to have to look at its authorities and make very judicious decisions about how it uses those authorities and where the use of those authorities lines up with various priorities. And it may be that this becomes more of a priority than it has been given current events.

The second thing I want to say about the CISA Task Force, one of the reasons I wanted to supply you with the names, and I get this question a lot is how can I participate? So we would not have had a functional task force if we had let more than 20 people on it. But I would encourage you to both use the CISA Task Force e-mailbox to provide comments, participate in the public meetings, which is why I've supplied the dates. And if you know people are on the task force, connect to them. They are serving for the entire industry in this role and it's important that they hear from you, their colleagues.

Last thing, and I forgot to say this earlier, relative to the HIPAA basics, just to pivot on that umm, and going back to what Tom was saying. So one of the things we've really been trying to do with this HIPAA education is kind of help people understand that for the behavioral community, it's not really a HIPAA problem. HIPAA doesn't really regulate behavioral health information; it basically specifically regulates only psychi...psychotherapeutic notes maintained separately.

There are a lot of privacy issues related to mental health and behavioral health data, but they don't derive from HIPAA, and that is one of the reasons why we worked with Tom to put those fact sheets on the back of the State Medicaid Director's letter is to sort of help the state Medicaid directors identify, if you're going to diagnose something for the doctors, I mean you want the right diagnosis so you can get the right cure. Lisa.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Okay, Kathleen.

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

So first of all, thank you for getting this launched and so quickly. Um really a process or a forecasting kind of question which is that I see the timeline for the task force for its deliverables, but I think everyone in this room knows that cybersecurity breaches will be with us forever and it's just a matter of they're...what nature they will be and how severe they will be. And so is this going to be task force that continues or does it have a set time in which it will do its work?

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

The congressional charge has it running until I think its 15 months, so I to want to say March of 2017 is when its final report to Congress is due. So the congressional charge has a specific time in stature. The Secretary I assume, but do not know for sure, will continue to have her Government Coordinating Council, Sector Coordinating Council and all of the different ways that we participate with stakeholders to keep our eye on the ball for the health and the public health sector. And there may be recommendations that the CISA Task Force makes that turn into longer term activities. I don't know.

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

Thank you.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

And Lucia, this is Lisa Gallagher. Question on the ISAO related work. So first of all, glad to see that ASPR and ONC are really looking at the information sharing issue; it is a challenge for the industry. I wanted to just get some clarity on the grants that will happen going forward. So we know the Harris County planning grant, but I think I heard you say and ASPR will have a grant and ONC will also have to seed information sharing?

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

I can tell you definitively that ONC will, we made that commitment in the roadmap and we'll be following through on that. My understanding is that ASPR also will, but I cannot speak definitively for them and do not know exactly what their plans are.

**Lisa Gallagher, BSEE, CISM, CPHIMS – ice President, Technology Solutions – Healthcare Information & Management Systems Society**

When will we be able to get any detail on the ONC grant?

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

Our plan is to publish the grant sometime this summer so that we can award it by the end of this fiscal year.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Okay. And are there any...is it not for profits like I think the planning grant was? Or is it open?

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

Pretty typically it would be some kind of not-for-profit organization, yeah.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Okay. Any other questions?

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

I will work with Michelle to make sure that when we let the announcement it's circulated to the Standards Committee, certainly so that people are aware.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Okay. Troy, did you have a question?

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

Yes I did.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Okay.

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

Yes, thank you. I'm curious but from the OCR's perspective, is part of the work that the task force will be looking into is, umm, you know, when you look at APIs, when you look at the interfaces and the Apps and things like that, I only mention that because you mentioned it in here; I don't want to rehash old stuff. But I'm really curious; you know we do have in Stage 3 Meaningful Use we have testing and some of that responsibility falls on the vendors, some of it falls on the providers and the EHs. From the OCR's perspective, when we start talking about the cybersecurity breaches and things like that, are they looking at the App developers, are they looking at the EHR vendors, are they looking at providers or EHs? Where does the liability fall? I mean, are they...

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

So I can't officially speak for OCR...

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

Right.

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

I'll give you my best guess and I'll tell you a couple of things that they have announced publicly. But I think the best thing would be to have them come back and sort of tell you how they go about either investigating or what their audit program is.

So they have announced that they will be starting a desk audit program, which I'm sure will look at organization security. Remember that OCR's authority reaches to covered entities and their business associates. So a developer, meaning a person who writes software, may or may not have one of those two capacities. And I think we've heard at length today from task force members and the API Co-Chairs that there is this very complicated regulatory environment, some of which is covered by HIPAA and therefore subject to OCRs jurisdiction and some of which is not. And that's just the environment that we have.

In terms of the CISA Task Force, the CISA Task Force is really something quite different. It's really for the health and public health sector as a whole and it's really focused on information sharing, which was the thrust of the congressional enactment. And I don't...having read CISA the bill, a few times, I don't see particular changes to OCRs authority, so when organizations have reportable breaches or when it's appropriate for OCR to perform a compliance audit, they will; whatever happens with the CISA Task Force. I'm not sure that 100% answered your question but if you have a follow-up one, I'll be happy to entertain it.

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

Okay, thank you.

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

Okay.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Any other questions in the room? Michelle, do we have any on the phone? Okay. All right, then I'll turn it over to Paul for the next session.

**Paul Tang, MD, MS – IBM Watson Health**

Great, thank you Lucia. Okay, this next section is going to be in response to the RFI for metrics, having to do with interoperability. So it's really important to both know where we are and know if we're improving in our interoperability. So Talisha's going to be advising us on the initial recommendations, the final of which we'll hear at our next meeting.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Well thank you all so much for having me today; this is my first time presenting to you all, so I'm super excited. I am also excited to follow Tom and Lucia, because a number of the points that they've raised I will allude to in my presentation as well. So, it's nice to know that we're all of the same accord.

So what I hope to cover with you today is to provide you with a general overview of MACRA section 106(b), describe the purpose and key components of ONC's request for information or the RFI. And also discuss steps to ensure the development of the next generation of interoperability measure.

Okay. So MACRA Section 106(b)(1)(A-D), Congress declares that a national objective to achieve widespread interoperability through the exchange of health information using certified EHR technology. Now what's important is that no later than July 1 of this year, in consultation with stakeholders, HHS should...must establish metrics to be used to determine if and the extent to which that objective of widespread interoperability has been met. If we determine that the objective has not been achieved by December 31, 2018, then by December 31 of the next year, 2019, we must...HHS must submit to Congress a report that identifies the barriers to interoperability, as well as recommend actions that the federal government can take to achieve the objective.

So ONC issued an RFI to solicit input on who and what aspects of interoperability should be measured. How can we leverage our current available data sources and potential metrics to meet this objective, especially given the pretty tight timeframes in which we're under? And to also get feedback on what other data sources and metrics ONC should consider to fulfill the MACRA mandate and also interoperability measurement more broadly. Specifically, measurement as it pertains to the Interoperability Roadmap.

So how does section 106 of MACRA define interoperability? Interoperability, according to MACRA 106, is the ability of two or more information systems and components to exchange clinical and other information and use that information that has been exchange using common standards to facilitate coordinated care and improve patient outcomes. Additionally, interoperability occurs between certified EHR technology systems employed by meaningful users under the Medicare/Medicaid Incentive Program and other clinicians and healthcare providers. And again, this is a nationally-scoped measure that we need to develop.

So how do we measure this? Exchange and use, as we've interpreted from reading the statute, captures the ability to electronically send, receive, find or query and integrate or incorporate information received into a patient's medical record and the subsequently use of that information. And the population of focus, according to MACRA section 106, is meaningful EHR users under the CMS Medicare/Medicaid Incentive Program and their exchange partners in a clinical sense.

So at a higher level, the scope is to determine the extent to which meaningful EHR users are electronically sending, receiving, finding, integrating information that is been received, and subsequently using that information. Right? So if you're like me and you've read the statute, you'd say wait a minute Interoperability is far broader than that. Shouldn't the scope include other populations beyond MU? How does this relate to the measurement efforts outlined in the roadmap? Are we missing something, right?

So just want to remind folks of what was stated in the roadmap in terms of the near term and long-term measurement framework. And we've presented to you all last year on this framework that's on the screen now. So what we describe in the roadmap is that in the near-term, from 2015 to 2017, our focus is on measuring the movement of health information. So basically the sending, receiving, query and integration of health information and the barriers to interoperability as it relates to providers along the care continuum. So hospitals, physicians, behavioral health, long-term care and individuals, right? And in the near-term what we care about is do people have the information available to them from outside sources that they need and how do they use it for decision-making. In the highest level, right?

Now for longer term measurement framework, what we care is again the movements of that information; again the send, receive, query, integrate and the barriers, but for populations beyond that care continuum, right? Expanding it to the broader ecosystem to include some of the folks that were alluded to today, so EMS, first responders, social services, resource consortiums and the like. We still care about whether or not folks have the information that they need available and that they're using it for decision-making.

But we also want to know are, what are the impacts of that availability and use on care processes, health outcomes that are sensitive to interoperability. Basically, how does this lead to us achieving the triple aim; better care, smarter spending, lower costs and help your people, right; better health outcomes.

So again, as stated in the roadmap, near-term we want to increase the proportion of individuals, office-based physicians, hospitals, behavioral health, long-term care and acute care providers that can do those things we talked about; move information, have it available, make it available to others and use that information for decision-making.

And in the long-term, we want to increase that population, make sure that they're moving information, have information available from outside sources, make it available and use that information to inform decision-making. And that that ultimately results in positive impact on outcomes sensitive to interoperability.

Now this is where MACRA fits in. So MACRA, if you kind of think of interoperability as this big circle. MACRA is a small circle within the big circle. So MACRA Section 106 specifically calls out the movements of interoperable health information, I will sound like a broken record, and I apologize. The send, receive, query and the integrate and the barriers to interoperability, but as it relates to eligible hospitals and physicians under the MU program and how they exchange with everyone else and ultimately, how they're using that information, right?

So that leads me to the first discussion point that we have noted in the RFI which is basically, is this right? Is the scope that we've described in the RFI, does it...is how we're planning to capture exchange and use or how we're thinking the MACRA statute requires us to capture and use, adequately address MACRA's definition. We just want to confirm that we got that right.

And then should the focus be limited to use of certified EHR technology? Again, certified EHR technologies are called out in the statute, but we want to get some external feedback on that. And we also want to get some feedback on the population of focus. Should the focus of measurement be limited to meaningful EHR users and their exchange partners as is outlined in the statute, or be a little bit more consistent with the roadmap, so include groups like individuals?

So now I'm going to talk a little bit about the current data sources and potential metrics that could perhaps address section 106 of MACRA. So currently, and my team has come and presented data updates regularly to this group, using some of these data that are on the screen right now. So we have access to national survey data from key stakeholder organizations and federal entities, such as the American Hospital Association, Health IT Supplement Survey, the National Center for Health Statistics, National Electronic Health Record Survey, as well as CMS MU Program data; in addition to a few other data sources that we have available that aren't on the screen.

So using our national survey data that we currently have available, we could propose the following measures to address the MACRA mandate. As it pertains to exchange and integration information we could use the proportion of healthcare providers who are electronically sending, receiving, finding and easily integrating key health information, such as summary of care records. And in terms of use, a proxy could be the proportion of healthcare providers who use information that they electronically received from outside sources for clinical decision-making. Additionally we could use the proportion of healthcare providers who electronically perform reconciliation of clinical information. And these are some of the options using the national survey data that we have available.

And with any data source, there are going to be some strengths and limitations and we tried to specifically call out in the RFI what some of the strengths and limitations are, because some of this is going to be a bit of give and take. So the national survey measures are the data source, is nationally representative, and we've seen over time there's a relatively high response rate.

We can conduct longitudinal analysis which basically means for some of these measures we actually have data and metrics now and then we can carry it forward. We also will learn from the national data sources, the national survey data sources, interoperability as it's experienced by the providers, right; self-reported experience of providers. However, that's one of the limitations, right? Self-reported data has potential biases. National survey measures do not represent all eligible professionals under the MU program, so random sample, so you may get some folks who are MU participants, you may not. And it does not report on transactional...or transaction volumes.

So, as was mentioned before the transitions of care using those summary of care records, we would not be able to...or the number or proportion of transact...transitions of care that move the summary of care records, we wouldn't be able to get that currently from our national survey data sources. It really is self-reported physician and hospital accounts of what they do and how they use that information.

So that leads us to the second discussion point of the RFI. So basically, do the survey measures adequately address the exchange and use components, per MACRA section 106 and could the office-based physicians serve as an adequate proxy for eligible professionals under the or meaningful EHR users under the MU Program?

So as I mentioned, we also have access to program data through the Medicare/Medicaid EHR Incentive Program and unlike the survey data, this will actually allow us to report out on the proportion of transitions of care or referrals or summary of care records moved. So one potential measure is the proportion of transitions of care or referrals or summary of care records were created using certified EHR technology and exchanged and transmitted electronically.

The second and this is based off of Stage 3 upcoming measures for 2017 and subsequent years, the proportion of electronic summary of care records received that are incorporated by the provider into certified EHR technology. The emphasis is on Incorporated. And then in terms of use, the proportion of ToCs or transitions of care where medication reconciliation is performed; and for 2017 again, as it relates to Stage 3, the proportion of transitions or referrals referred where healthcare information perform clinical information reconciliation.

So again, there are strengths and there are limitations of this data as well. It addresses the population, this is a pro, specified by MACR. It enables reporting on the extent to which exchange activity is occurring; again the transitions of care and the movements of summary of care records. However, Medicaid EHR Incentive Program performance data is not available at an individual provider level, in the aggregate and we've been working with CMS, Medicaid group, Tom, we've talked to him quite a bit, on ways to try to use and leverage Medicaid data.

But we specifically ask in the RFI, whether or not we could in fact get provider level information from the states that are reporting Medicaid information. Not all aspects of exchange are measured through the Meaningful Use measures that we've mentioned. So the goal of the MU objective is to ensure that summary of care record and the transitions are sent to receiving providers when the patient is transitioning to a new provider and however that receiving provider receives that information, either through query or receiving or however, the goal is whether or not it's been incorporated, right? Has it been incorporated into the system?

So we may not know something like the number of Meaningful Use providers who electronically received a summary of care record; we'll know how many are sent and we'll know how many have been received, in air quotes, through some...however its captured and incorporated into the system. So this is like, very nuanced but it's explained in the RFI to kind of explain what one of the potential limitations of that measure may be. And the program participants may not represent all providers. Again, there may be, especially in the eligible providers base, something very different about MU eligible providers and everyone else, right, those that participate in the program versus everyone else; so using CMS data kind of limits us to those eligible hospitals and eligible providers under MU.

And that leads us to discussion point number three that is noted in the RFI. What we want to know is do these...again, do these measures adequately address exchange component per MACRA? And do the reconciliation measures serve as adequate proxies for the use component, as explained in MACRA section 106? And we also asked some questions about the population of focus. So under the MU Program, we're focused more on encounters or transitions of care rather than the proportion of providers that do "X," right? So we look at the proportion of the transitions of care versus the proportion of providers.

And that's because there's some limitations with their ability to use Medicaid data at the provider level. So the question is, should we develop measures to evaluate progress related to interoperability across healthcare providers, even if it means limiting things, taking out the Medicaid and just limiting things to the Medicare EHR Incentive Program where we have currently have provider level data?

So what other data sources and measures should ONC consider for Section 106 of the MACRA or interoperability measurement more broadly? What we're trying to do in the RFI is acknowledge what MACRA is asking us to do, acknowledge the scope. But we're also hoping to get information that will feed the work that we're are doing as it relates to measuring interoperability more broadly.

So we are asking in essence, what are we missing? We're requesting feedback on other data sources for MACRA and also beyond and examples include claims-based data, performance data, other surveys; also electronically-generated data from certified EHR technologies themselves. So we're asking vendor communities and like, are there data that you all are willing to provide to us or measures that you're willing to report that's based on that system-generated data that could help inform our measurement

activities more broadly. Additionally, as was mentioned earlier, measures and data that's collected through HIEs and HISPs and all of that, we're also asking for feedback.

So comments on the RFI are due on June 3. And so what we are planning to do is come back to you all in August. We will unfortunately spend the month of June part of July trying to meet the congressional deadline. But we want to come back to you all and share the measures that are ultimately selected to fulfill the needs of MACRA, but also to come to you all and explain some of the feedback that we received through the comments of the...on the RFI.

So with that, umm, if you have any questions, I can take them now. Also Senior Advisor Vaishali Patel from my office is on the line and between the two of us, if you have any questions offline, we're happy to address them.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you very much. Clearly stimulated some interest; start out with Floyd.

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

Thank you. So, this was great actually great and thank you for the very concise summary of all the things you're looking at. The comment I might have is some of these things are an example of the devils in the details. When, I mean we look at things like the percent of reconc...items reconciled, medication, I saw allergy on slide 19, I saw problem list and even medications, which is probably the most straightforward, which it isn't. but more than the others, is challenging.

I've been doing some work with the immunization registry reconciliation in the EHRs and how to evaluate that and see how it works. There are significant usability issues, which might impact a provider's performance. And what is considered reconciliation happens...basically it's a cognitive process; I might not have to do anything, I might have to do a lot and I'm just going to attest I did it, but how would I actually measure that and what's the value?]

I...when I look at some of these, that's one, the number of information things I sent out versus how many I received and did I incorporate them, what do we mean by incorporation? I think there's a lot of definition that's missing. And I think this is good to think about, but I'm not sure the measures really are going to be helpful. I might propose kind of an off-topic...off-line proposal that perhaps the same way as hospitals can test their own implementation to say, can their EHR do something using say the Leapfrog type testing. They're given information and they have to...and they're looked at to say, is the information there, can you do this? Did you get the right answer?

Perhaps something similar in the ambulatory world could make sure their EHRs are capable. But to know how often they're doing it is going to be really complicated. I wish I had a good answer, but I think except for attestation, I'm not really sure how to evaluate, except to go back to slide 9 in your outcomes...

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

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

...and maybe it's looking at the one outcome that I seem to think is missing is health of your population. A lot of them are process steps so, we should look at health. Just a comment, I don't have an answer, I'm just...I think it's challenging because of the detail that would be required to make these work.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Yeah, thank you so much for that comment and I totally understand. And something, especially use, is just something that we've been spinning our wheels to try to figure out the most appropriate metric that could serve as a proxy. Um, you were spot on in that the only way that we could measure from using the CMS data would be through attestation data, but we understand the limitations of that.

We've had pretty lengthy discussions with CMS staff and recognize that reconciliation at least currently med reconciliation also involves, you know, activities that may or may not be as a result of electronically sending and receiving that information. So we understand it could be someone gives you a piece of paper and you're...in addition to what's in your EHR and you're making decisions based on a combination of information. Umm, so we...

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

One thing I might add is just maybe look at how they work with registries...

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

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

...especially patient-centered registries, to look at are they actually getting outcomes changes working with the registries? Because it may not be exac...all about interoperability, but it's about patient improvement that I think we really want to look at.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

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

And interoperability is a step to get there; just a thought.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Right. Yeah. No, that's very helpful, thank you.

**Paul Tang, MD, MS – IBM Watson Health**

Great; thank you. Josh?

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Thanks and thanks for the introduction and the overview and the careful analysis of options; I really appreciate the perspective there. One set of questions that I wanted to raise just for me is that it seems to be an effort in making a lot of yes or no, up or down, right or wrong distinctions against what is ultimately a whole bunch of different system behavior and lots of different users who will have different experiences working with these systems.

And if I understood it right, at the end of the day we're supposed to say either like yes, we have interoperability in the country or no we don't. So there's binary distinctions on the level of each individual practice and then sort of the whole country. I wonder if there's room for more just sort of experience survey; in other words, have you thought about how to incorporate data like, do the users of these systems feel like they are interoperable and useful in these ways

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Yes. So, and that's really the nuance between what we need to report for the purpose of MACRA and all of the interoperability work that we're doing more broadly. So for the meas...for the surveys that we have ongoing right now, we do ask some of these questions. So we ask, how are you able to...are you able to send, receive, find, use and then, does that mean you have the information? Do you say that you have the information that you need? If you don't, you know, what are some of the barriers to interoperability? What are some of the barriers...are you getting too much information? Is it not enough?

So we are asking some of these more attitudinal questions of providers about their EHR use and some of the barriers associated with them. So yes, it's important to measure all of those different aspects and that's something that we're doing. For the purpose of MACRA, the scope is a little more narrow and so between the two activities, which is another reason why we're asking for external feedback; between those two goals the hope is to get information that'll help inform not only MACRA, which is narrowly scoped, but also interoperability more broadly.

**Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School**

Thanks.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. Leslie?

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

And I would like to echo both Floyd and Josh's comments, look for the unintended consequences, especially for instance, you mentioned critical decision-support in several areas of measurement. And that could be taken to an interpretation that says, boy every time I have an alarm and I get that alarm

and that alarm comes from a document outside the organization, I'm more interoperable than not. What you would have is more frustration than not.

So there are significant unintended consequences in some of these measures and I would encourage you to speak to physician groups specifically around those. And then also I think that we cannot underestimate experiential information because when you lay down infrastructure, as we have laid down infrastructure today, measuring the nits generally doesn't give you a lot of value. Once the infrastructure is laid down, we say is the infrastructure working? Are we more confident in our healthcare? Is our provider more confident they have information to make appropriate decisions? Is the patient feel that they've been treated as a complete human being because all the information is there?

I really encourage you to get rid of this and the emphasis on going back to potentially claims-based measures takes us way back to, we're going to measure a claim data and the effectiveness of someone who doesn't have the da...that data to even measure its effectiveness. So, I would encourage you to revisit and get more on experience and look at every one of these things for unintended consequences.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. Arien?

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

Thank you, so I just want to endorse...so first of all, great presentation; I want to endorse the previous run of comments that I'd sum up as saying that both hard and attitudinal data are going to be useful and just recognize that they're going to be measuring different things. We might discover that we have a lot of transitions of care and we might also discover that physicians hate them; and that's really useful.

I guess the second corollary comment on this is, I understand you're under the gun relative to some legislative deadlines. But to the extent that we can be using survey data to improve and take a cart...a cold, hard look at what's going on and whether it's actually working is really useful. Because I don't think anybody would say that the healthcare system shouldn't have information flowing on transitions of care. It's really useful to find out that we have a lot of information flowing on transitions of care and that physicians hate it. And that gives us then, okay, now we've got a PDCA loop, why do physicians hate it? What do we do about that?

A plea to look at the existing measures that exist and help people map what one measure is measuring and what another measure is measuring. My favorite example of this is that if you look at the ONC Data Brief on Acute care EHR adoption, you'll find that adoption of the certified EHR is at...in 2014 was about 97% and adoption of a basic EHR was at 75.5%. And then when you look at the details, you discover that a certified EHR has more functionality than a basic EHR.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

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

So what is that measuring? And what's going on with that discrepancy? The more we can understand, and I really appreciated your presentation and looking at the biases of these measures, but the more we can understand what systematic bias exists in a measure and then help people map, well is it, you know where are we with acute care adoption? Is it 97% or 75% will be useful rather than kind of where we are which is, we've got a bunch of methods, we have a bunch of data and we're not helping people connect the dots.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Thank you so much for that comment. We will be updating that data brief pretty soon, so we'll...we're slated to share those upcoming adoption numbers with you all; I think we're on the agenda for later this year, so yeah.

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

Great and...and hopefully you can spend some time disambiguating basic and complete.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Oh yeah, it'll be a good time; it'll be a regular old party. But no, you're absolutely right and that's one of the reasons why we've been really trying to dive deeper into some of our survey data. And that data brief that you highlighted we issued a data brief last year that broke down interoperability for acute care hospitals, too and we presented that to you all as well. The kind of looking at, all right, how many hospitals can do these four things? And of those that can do all of these four things, how many hospitals report that they have information that they need available.

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

Thank you.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

**Paul Tang, MD, MS – IBM Watson Health**

Thanks. Lisa?

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Oh, sorry, no.

**Paul Tang, MD, MS – IBM Watson Health**

Okay, I'll take my spot in the queue. So thanks again, excellent presentation; very clear and I can...I share your...the challenge that's before you, having gone through the meaningful use exercise.

So one a data point and then two learnings from that; one data point, I was at a statewide sort of HIE kind of a meeting and one interesting stat was, now that data is flowing across, clinicians clicked on, just clicked on, and we have no idea whether they used it like 5 to 15% of the time. So one sort of lesson learned is, it would be nice to measure use as a byproduct of use rather than trying to measure the, I think that's part of what's been said here, too.

And the other part, big lesson from meaningful use is, the attestation which we, you know we didn't have a choice at the time and I don't, well, and the attestation turned into checklists and checklists turned into really bad adverse consequences, as Leslie was talking about. Because it just created the need to do something that didn't appear to have value to the individual. And what happens, it's just counterproductive in the attitude and actually the behavior.

So just a couple of lessons, and one is if we could measure the use as a byproduct of use, not as an attestation of use, I think it's tough, but that's almost the only way to get to the point you're trying to assess which is, hey, are we doing good with this? And I think it does go back to usability; how do you make all this TMI now, valuable at the point of decision-making? And I know that's your goal and it's a challenging one and I know the timing's fast, but we're at least all sort of echoing the same sentiment of, what did we...how did we...what did we learn for the meaningful use experience?

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

**Paul Tang, MD, MS – IBM Watson Health**

Some of it anyway. Ah, Vindell?

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

Well, I...I'll just use...I wanted to tell an anecdote or two that I think just tells of some of the work that we've been doing in the office together, this is for the committee members to let you know this sort of more than most, as we sort of struggled through it. But I do want to underscore that we have had this very discussion; number one about interoperability is being the goal, right? So the goal is really this better care and that becomes a byproduct.

So then we talked a lot about the outcomes measures versus these interim process measures. So is it important that this information travels or is it more important there is an increase in the ultimate outcomes, even not just in the outcome of interoperability, but did care improve because of the data being available? And part of that, literally I'd been on the job about one month or so, we went to HIMSS, the Secretary made her discussion about challenges. And I don't know how well any of you know her, but it took her about two minutes to grab Karen and I by the lapel and say, how are you going to tell if this has been successful?

And think that sort of brought us back to the table that there is all...there's this congressional mandate, but there's also this idea of, if you're going to do this, if 90% of the EHR vendors who said that they're going to participate in this, how will you know when it's done? I got an email from one of the vendors that said, literally it said as kind of a headline, 1.8 million bits of data had been transferred. To which I looked at Karen and said, what the heck does that mean? Is it good? Should it have been 4 million bits of data? You know, sort of like an interesting piece. So I think just to underscore that we're...I think we're struggling with that same sort of set of questions.

The second one is this idea about whether or not subjective data is sufficient. So, what I mean by that is, right now it seems like the best data that is not burdensome to collect is just ask people how they think it's going. On the other hand, you have this sort of big push to say, how do I measure that that is actually happening in way that's not just a subjective measure?

And the third point I wanted to underscore is, our colleagues at AMA and others have come to us and said, and I guess it's the point you were just making Paul, that if this ends up being a numerator and denominator game where I'm going out to measure how many times this thing happened and put a numerator on top of that, that there's pressure again to say, again for a measure that we're all...a process that we're all sort of underscoring is that, it's not the end goal. What's the value proposition for me as a provider to measure the number of times this thing happened when I'm not quite sure what a good percentage in that space is?

So I'm just going back and maybe sort of opening up the jacket a little bit and telling you some of the varied conversations we've had about this, at least in the last three months about, how do we meet the goal of having something that is an outcome measure that is an objective measure that we could possibly use, and that really does not place undue burden on providers to get their data. So I think it's a difficult problem.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. Paul Egerman?

**Paul Egerman – Businessman/Software Entrepreneur**

Thank you and first Talisha, I want to echo everyone's comments; this was an excellent presentation...

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Thank you.

**Paul Egerman – Businessman/Software Entrepreneur**

...on a topic that is very difficult, because it's um, I mean interoperability is by itself a means to an end, it's not the end and then how you measure that has been, Vindell just said, you know you could count the number of bits of information that's interesting, but it doesn't necessarily tell you anything. And I just had a couple of suggestions, I don't know if they're good suggestions.

But in terms of trying to find something that is like a tangible result of interoperability, one of the benefits that has been described with interoperability is a reduction in duplicate laboratory tests. And so

I'm curious to think about, well, is there a way to evaluate over time, is the number of duplicate laboratory tests declining, which would seem to imply that interoperability is having an impact.

And another area that I know is a major public policy issue right now is the whole the issue of substance abuse and opioid abuse. And one of the ways that occurs is with patients getting multiple prescriptions for these medications, presumably over a short time period from physicians. And if there was any way also to track the incidence that that occurs and see if that is declining.

And these are, I don't mean to suggest that these would be the sole measures, but they would be some very interesting things to measure and maybe people could think of others that would also perhaps give a direction for some interoperability activities, but would also show some evidence that we are making progress. Because I think we are making great progress, but we...when we just look at the number of clicks or the number of bits of information, it's very hard to see.

**Paul Tang, MD, MS – IBM Watson Health**

All right, thank you. So I have...okay?

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

I just want to say thank you for that. And duplicate tests is something that is definitely on our radar as well as we've been working with folks in HHS as it relates to working with folks like at Surescripts and the like to come up with measures related to opioid abuse and e-Prescribing. So the two recommendations that you made are very good and they're definitely on our radar and things that we're trying to tackle as well.

**Paul Tang, MD, MS – IBM Watson Health**

Troy, Dale and Kathy.

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

Thank you very much, I mean, you've started on a path that it's going to take a lot of detail to figure out and get everyone on board with. One of the things that's primarily concerns me is we look at...there's two things, interoperability and then the concept of integration. I noticed early on, and I mean integration, the term integration was brought up but then it kind of fizzled out as you went through the presentation.

Without real strong operab...interoperability, I'm very concerned that this integration piece, which is really, I mean Paul kind of...he dabbled on it a little bit, I mean, you have two heterogeneous pieces of information and they need to come into an homogenous area. And then of course utilization after that, but right now, I mean we are struggling so hard with interoperability, I have no idea how this integration is going to play out.

So, when you start looking at the measures of use, I'm kind of at a loss that the medication review and reconciliation aspect, is difficult enough as it is, even just bringing a patient in with a piece of paper. So I can't imagine how that's going to be with disparate systems that are sending information in different formats, being able to integrate that information into one homogenous record. And if we do it

electronically, which is really where we're supposed to be heading, it's...I get a feeling we're still a long ways away from that.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

And I would agree that the integration piece, the data brief that I mentioned that we used, some of our access to AHA data, where we looked at hospitals...non-federal acute care hospitals and the extent to which they were able to find, send, receive and integrate. And integrate was one of the lower percentages of hospitals that reported that they were able to do that. So we understand that the query and the integrate, it's harder for folks.

So definitely think you're raising a good point that if integration is challenging, then whatever measures that we select for the purposes of use may be impacted by that, right? So they may be less likely to be able to do some of the med rec stuff because they're limited in their ability to integrate information from outside sources in a way that makes it usable.

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

Well I think just a clear definition of what integration means.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

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

I, you know, we can receive a PDF and we can put it into a media tab, is that considered integrated into the EHR? Really I don't believe so because you still have it...it's still a separate document that has to be referenced, it is not been integrated into the actual EHR; it's just sitting in a subset of data that I can retrieve and I can look at. So I think those definitions need to be clearly defined as to what does integration involve? What does that mean?

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Right. And for the surveys, we've defined integration as the ability to electronically integrate or use information without manual entry; so we describe to the respondents that it is about you being able to electronically get that information without doing anything.

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

That's a lofty goal. It's a lofty goal. I hope.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

We can dream, we can dream.

**Paul Tang, MD, MS –IBM Watson Health**

Thanks; Dale please?

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

Thank you. So, thanks very much for, you know lots of great ideas. So as an epidemiologist, one thing that I keep coming back to, and this is actually something that's been amplified over some experiences over the last couple of years working with data inside of, you know large healthcare systems is that the ability to move, and this has been addressed already, quantity is one issue. But then also the ability to move quantity with quality is another really important issue.

And I don't know what other people are seeing, but I think we all recognize that whether it's the way data's entered by hand into the EHR and there's an opportunity for misinterpretation of that data; I think it's still surprising to clinicians when they see that. So sometimes even source to destination starts out bad, even though you have interoperability. And then you can have issues related to the mapping or other types of things that are required to get the interoperability. And then you can have issues related to the security, which we've talked about previously this afternoon where maybe the integrity of the data is being compromised so you think you got it to destination perfectly fine, but maybe you didn't. None of this could...might potentially, all of this might be potentially missed if...depending upon how you structure your surveys.

So I think that there needs to be an emphasis on safe data or safe interoperability or quality data. And the same thing, even though this is maybe downstream a little bit, the whole notion of safe analytics. Because we're developing more and more of these analytics and in fact, what we're really building is a system of systems, right? We're building now a machine and when we build a medical device, it's regulated. When we build through this really complex network or networks, this interoperability, I'm sure we have all seen projects where you might have a 100 different interfaces for a population health system.

And how do we...we're really not really very efficiently, I think, policing and quality assuring all of these complex interfaces. When you take a look at your suggestions around surveys, it's very interesting. One way to address some of the types of concerns that I am expressing right now might be through sampling

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

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

So you might say, let's do the quantitative measurement, okay, that's...we want to know that, right, that's the primary thing; we want to know how much interoperability is really going on. But maybe take

a small samples, representative samples, small systems, large systems, so on and so forth and say, let's go in and see what kind of quality are we experiencing in the context of this interoperability. So we don't have to make it a big project, but at least you get some assessment of quality as you're moving forward.

And then the last comment I would make is that we may have a methods issue here, and what's interesting is that Sentinel was created, you know through the FDA to actually develop methods to do pharmacovigilance. And then MDEpiNet was created by the FDA to create methods to look at medical device evaluation. So maybe there needs to be some attention to developing methods for doing this so it's both quantity and quality. And I'll just give you one caveat; we did a study in a very large system to look at the impact of EHR on patient outcomes. And it's clear in the literature that there are reports or there are...there is peer-reviewed literature around the challenges around the methodology.

And when we presented this back to the physicians, they all said, well this is really interesting but it's not true or we don't believe it because, well we had this program going on and we had this program going on and they just...they weren't willing to really take a step back. So I think there's a real need for folks to take a step back and develop the methods that we could accept as a community. Say yes, there are limitations on how we assess the impact of interoperability; there are limitations to how we assess EHRs on outcomes and, you know quality of care, but we have to do it, and these are the best methods that we have today.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. Kathy?

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

Um, so I'm thinking back to, and almost having a bit of PTSD related to my days in practice and reconciling lists of medications. And though we might think that that's a relatively straightforward exchange of information, it's not as simple as it looks, in part because what is, as far as either the physician or the patient are concerned, it's exactly the same vitamin D pill or vitamin, multivitamin or calcium supplement or what have you. It comes in so many different versions that, yes you could reconcile, but really it's all the same stuff. So I would just exercise some caution or maybe dampen the enthusiasm about using medication reconciliation is a good marker.

In terms of looking at what the overview slide says, slide number three, and I have to congratulate your office for saying that we're willing to be courageous in terms of how we would respond to this mandate. Because one could interpret it very narrowly and say, well, all we have to show is that we have interoperability and we get to establish our own metrics. But this group certainly and I think from your remarks, is trying to do something much greater and bigger than that.

So maybe a couple of objectives or outcomes to look at; level of satisfaction with one's electronic health record system; and actually, certainly in clinical practices, colleagues of mine, my own former practice, we're now on our third electronic health record system. So maybe looking at what I would call the need to purchase a new system in an unusually short period of time. It's just like the need to replace a metal-on-metal hip sooner than expected was an indication that there was a failure in that system. So I think looking at that level of churn might be a metric work

I think that the other potential metric, but again would require perhaps survey data, is asking a simple question, just pop me up a question at the end of the day, did you get a piece of information from outside your organization that you know changed the treatment that you gave an individual patient today? And then another type of question might be, did you receive information that you had no other way of getting it? So that actually all of that flood of information wasn't just repeat, repeat, repeat, which I think does wear people out, but is actually something that they truly needed and they actually had to act upon; so, a focus on the problem of duplicative data.

And then lastly, and I'm sort of proceeding a little bit with caution here because the article is now in...has been submitted for publication, but AMA has done work recently actually looking at the amount of time tracking that clinicians are spending relative to their face-to-face time with individual patients. And I'll go so far as to tell you that the time they spend on administrative, looking at the computer tasks, in our time series it's more than 100%. It's more than...it way exceeds the amount of time that they are in face-to-face interaction with their patients. So you might consider as a metric doing some repeat studies and seeing is that ratio getting back below 1, because I think we would then consider that a real win.

**Paul Tang, MD, MS – IBM Watson Health**

Thanks; Brent?

**Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System**

Um, appreciate your presentation and definitely a challenging topic. One thing that I would say based on our RL systems experience where we have had both internal and external HIEs, a lot of this comes down to ease-of-use. It's...I know that seems basic but the reality is if a lot of data has been transferred, transition of care that like wasn't...didn't create a lot of value I think as intended because it was overwhelming in the amount, and it wasn't easily integratable. And I think it's...a lot is going to be, can it be easy for the physician or the healthcare provider to accept, reject or integrate it into the record?

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

**Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System**

And it's one click away to access it and easy to do that. And surveying or measuring that, I think is going to be critical.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Thank you for that.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. Patty? Patricia, do you have a...

**Patricia P. Sengstack, DNP, RN-BC, CPHIMS - Chief Nursing Informatics Officer – Bon Secours Health System**

Oh, me?

**Paul Tang, MD, MS – IBM Watson Health**

Yup.

**Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System**

Oh, thank you. So first of all, thank you very much for your presentation and giving us the opportunity to vent a little bit because it's kind of what, you know, you've heard people. You know, nobody wants to have another, you know experience where we're counting the checkboxes and none of us want to create workarounds for our care providers so that we can say we checked a box. So, you know, it seems to me that we're all kind of on the same page here and I think you're hearing it loud and clear that we want less focus on kind of the what and the how, the processes of interoperability and counting those.

We want more metrics around why; why are we so concerned about interoperability? Why are we wanting to push this agenda forward? You know why...what's the problem that we're trying to solve? And so I really, you know it makes me think about something that I've been working at Bon Secours recently and that's the work around our patient experience and our HCAHPS. And so we're working with Press Ganey and you know, I've been looking at their surveys and they're...and it's qualitative, so you know I'm putting the plug in there once again for looking at, you know, how some of these organizations like Press Ganey and Gallup conduct some of these more qualitative polls on what's really making a difference, and getting feedback at that level. So I think, you know, getting to why is really important.

The other thing that I thought of was that I know our particular vendor, yes, we are an EPIC shop, you know we use something called Care Everywhere. We get, and I'm wondering if there's a way to partner with our vendors because they actually give us on a routine basis, a report on how many times we've had data coming in to us from another organization. So we get statistics on the kind of the how and the what from them. So I'm wondering, you know it hasn't gelled yet, but maybe there's an opportunity to partner with some of our vendors on helping to look at the data.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm. And we do have a question in the RFI specifically geared towards that, because it really would open new opportunities for measurements and analysis if we were able to get some of the information that we know is available within the system. And we've looked at some of the literature on administrative burden; we know that there are researchers out there who through their ability to access information within a facility's EHR, can actually say how much time was spent doing the administrative activities versus spending time with the patient.

For us right now, ONC, we don't have access to that granular level of data. And so the hope is that the RFI and some of the feedback that we'll get back will hopefully move us a step closer to at least understanding what's available and then enable us to follow up in terms of gaining access.

**Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System**

Thank you.

**Paul Tang, MD, MS – IBM Watson Health**

Okay final question's Leslie.

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

I'm just echoing more ideas is, did a manual process get eliminated as a result of now having an automated integration step? So I've eliminated that fax machine that goes to that long-term post-acute care. Just even eliminating fax machines would tell us that they're getting some electronic. And then, is the information received computable? Then that gets us to quantity of data coming in and is it actually usable, rather than defining the use by the provider, we're making sure the information itself is usable.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Mm-hmm.

**Paul Tang, MD, MS – IBM Watson Health**

Did you have a quick one, Floyd? Okay. A lot of feedback.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

I know.

**Paul Tang, MD, MS – IBM Watson Health**

But that shows how important this is to all of us. Maybe I can contribute, I mean what we need a love-it button. I have a clinic on Monday morning and if I have a patient who's been seen in the ER over the weekend, in the past, it was just...it was horrible because I had no idea what really happened. Now that we're connected, it's a dream and so I would click on love-it button every time that happens.

But at any rate, thank you so much for taking the time and also for listening because clearly this involves a lot of us and we really do want this to happen and we're searching, just like you, for the byproduct way of measuring whether we're being effective. Thanks.

**Talisha Searcy, MPA – Director, Research and Evaluation – Office of the National Coordinator for Health Information Technology; Medicaid Data & Systems Group – Centers for Medicare and Medicaid Services**

Thank you for this opportunity and again, we welcome any and all feedback that you have in response to our RFI; comments are due on June 3 and we plan to present...come back to you all in August, to share the measures that are ultimately selected, as well as to walk you through some of the feedback that was received. I think some of what will end up happening is some measures will be very appropriate to meet the mandate and letter of the law, which is great. But there's going to be a whole lot of other activity and feedback that we get and we will be given through the RFI that will ultimately require a lot of extra work to kind of flesh out; but could hopefully lead us to a measurement framework that's comprehensive and incorporates a number of the things that you all have brought up today. So, thank you so much for your time.

**Paul Tang, MD, MS – IBM Watson Health**

Okay. Elise, were you going to make some announcements?

**Elise Sweeney Anthony, Esq – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology**

...not to mention now, no big news today. So one, just thank you to all of the committee members for joining us today; it's always a pleasure to kind of hear your feedback and help us to integrate that into the many activities that we have underway across ONC. I think you heard a lot of that through the presentations from ONC today.

So a couple of quick updates; one is that we are initiating two new task forces, or getting ready to do so; one would be the Consumer Task Force, and this would be convened on an as needed basis depending upon issues that are kind of floating at ONC that we could use some help from the Policy Committee or the Standards Committee to help think it through. The initial focus would be on providing feedback on ONCs Blue Button Connector Site and then also on a tool that we're working on that will help providers with patient activation and engagement. So those are two activities that are coming down the pike. Michelle, I'm sure, will be in contact in terms of membership, etcetera that...well, two issues under the Consumer Task Force.

The second task force would be related to upcoming NPRM. So as many of you may have heard, there is this thing called MACRA, that we've been working very closely with CMS on some of the provisions and the development, in terms of implementation of the legislation. We anticipate when that does become public, whenever that would be, that we would love to have feedback of the Policy and Standards Committee members in terms of thoughts on key pieces of the kind of MACRA puzzle. So with that in mind, we just wanted to give a heads up to folks that that is our intent, no timing at this point, but we do want to put it on the radar.

So those are two key things. The other is the Oversight Rule. Now, I think a couple of meetings back now, I presented on the Oversight Rule that we released, it seems like just yesterday, but a little bit ago and the comment period is about to close on May 2. So we did want to remind members to please feel free to comment directly through, there's a link in the proposed rule how to comment and we would really encourage your thoughts, whether you are in favor of what we've proposed or not in favor; it's always good to hear the feedback of how it affects you as well as those that you represent through your various organizations.

So please do comment on that. We have number of resources available online regarding the rule including a presentation that we've done summarizing it.

And then on, I think it's April 21, I am looking for the time now, I think it's April 21, we'll be presenting a presentation, another presentation. We did one already and we'll be doing a subsequent presentation on the Oversight Rule. So please, also please participate in that. It's a good opportunity to get an overview of what the rule would focus on and some of the key provisions related to that. I'm going to see if I can find it really quick, yup, okay April 21 at 2:00 PM, they'll be a webinar. There should be a link on healthit.gov and if you do receive our Listserv, then it's also a link in there as well.

So just a couple of quick updates in terms of key things coming, that we expect to be coming down the pipeline. And also please, please, please comment on the Oversight Rule, we look forward to receiving your comments. And I think that's all I have. Do you have anything else Michelle?

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

Just quickly on the task forces; if any of the members of the committees are interested in participating, you can just send me an e-mail. And to members of the public, if you already have an application in the FACA database, you just need to go in and select one of the new committees that you're interested in participating. And if you aren't already part of the FACA database, you can put yourself in there to be selected for future task forces.

**Paul Tang, MD, MS – IBM Watson Health**

Thank you. And could we open it up to public please?

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

Yup. If there's anybody in the room who would like to make a public comment, please come up to the table. As a reminder, public comment is limited to three minutes. And I'll turn it over to Alan to open up the line.

## Public Comment

**Alan Merritt – Interactive Specialist – Altarum Institute**

Thank you, Michelle. If you'd like to make a comment, and you're listening via your computer speakers, please dial 1-877-705-6006 and press \*1. Or if you're listening via your telephone, you may press \*1 at this time to be entered into the queue.

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

It looks like we have no public comment. So thank you.

**Paul Tang, MD, MS – IBM Watson Health**

All right, thank you and thanks to the committee members for showing up on a very warm day in Washington, DC, but non-humid. And we look forward to seeing you next month, May 17, for an in-person meeting for a joint meeting for the Policy Committee and Standards Committee. Thank you so much and happy travels.

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

Thank you. Goodbye.

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

Thank you everyone. If you haven't walked out back, there's amazing flowers back there, you should take a look.

## Public Comment Received During the Meeting

1. Alan Viars: Alan Viars, Videntity: I agree with the recommendations, but I would imagine some pushback. Perhaps state/regional HIEs can meet the requirement on behalf of health organizations? Data from an HIE is likely to be broader. This could provide a new revenue (sustainability) model for HIEs.
2. Julie Maas: Julie Maas-EMR Direct: It's difficult to balance ease of access with oversight of app trustworthiness. Perhaps a patient should also be able to opt out entirely (or first opt in to?) any automated process to grant Application Access.
3. David Tao: Suggestion for Leslie Kelly-Hall on PMI Task Force. You mentioned the need for data sources such as PBMs and retail pharmacies to provide dispensing data to evaluate patient adherence. Does that go far enough? Prescriptions may be filled but not taken. What about PGHD capture to get as close to the patient and caregiver as possible?

## Joint Committee Meeting Attendance

Name	04/19/16	03/10/16	01/20/16
Alicia Staley			
Andrew M. Wiesenthal		X	X
Angela Kennedy			X
Anjum Khurshid	X	X	X
Anne Castro		X	X
Anne LeMaistre	X	X	X
Arien Malec	X	X	X
Aury Nagy			
Brent Snyder	X		
Brian Burns		X	
Charles H. Romine	X	X	
Chesley Richards			
Christoph U. Lehmann		X	X
Christopher Ross	X		X
Dale Nordenberg	X	X	
David Lansky	X	X	X
David F. Kotz		X	X
Devin M. Mann			
Donna Cryer	X	X	X
Elizabeth Johnson		X	X
Eric Rose			X
Floyd Eisenberg	X	X	X
Gayle B. Harrell	X	X	
James Ferguson			
Jitin Asnaani		X	X
John Halamka			X
John Scott		X	X
John F. Derr	X	X	
Jon White		X	X

Josh C. Mandel	X	X	X
Karen Desalvo	X		X
Kathleen Blake	X	X	X
Kevin B. Johnson	X	X	
Kim Nolen	X	X	
Kim Schofield		X	X
Leslie Kelly Hall	X	X	X
Lisa Gallagher	X	X	X
Lorraine Doo	X	X	X
Nancy J. Orvis	X	X	X
Neal Patterson		X	
Patricia P. Sengstack	X	X	X
Paul Egerman	X	X	X
Paul Tang	X	X	X
Richard Elmore		X	X
Scott Gottlieb		X	X
Steve H. Brown			
Troy Seagondollar	X	X	X
Wes Rishel	X	X	X