

Health IT Joint Committee Collaboration

A Joint Policy and Standards Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT



Joint Health IT Policy and Standards Committee Final Transcript March 10, 2016

Presentation

Operator

All lines are now bridged.

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

Thank you, good morning everyone. This is Michelle Consolazio with the Office of the National Coordinator. This is a Joint meeting of the Health IT Policy and Health IT Standards Committee. This is a public call and there will be time for public comment at the end of today's call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. I'm going to start with the Policy Committee, well, actually I'm just going to go down the list and they're kind of all mixed in. So, we'll be out of order today. So, do we have Paul Tang?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Yes you do.

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

Hi, Paul. Kathy Blake?

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

Yes, indeed, good morning.

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

Hi, Kathy. Lisa Gallagher?

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

Here.

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

Hi, Lisa and Arien Malec?

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

Good morning.

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

Hi, Arien. Anne Castro?

Anne Castro – Vice President, Chief Design Architect – BlueCross BlueShield of South Carolina

I'm here.

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

Hi, Anne. Donna Cryer? 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

Hi, John. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Here, good morning.

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

Hi, Paul. Floyd Eisenberg?

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

Here.

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

Hi, Floyd. Rich Elmore?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Hi, Michelle.

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

Hi, Rich. Scott Gottlieb?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Scott. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Leslie. Gayle Harrell? Liz Johnson? I believe Liz is on.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation
I'm here.

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

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation
Yes, hi.

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

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Kevin. Angela Kennedy? Anjum Khurshid?

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Yes, here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Anjum. David Kotz?

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

I'm here.

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

Hi, David. David Lansky?

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

Here.

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

Hi, David. Chris Lehmann?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Good morning, Michelle.

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

Hi, Chris. Anne LeMaistre?

Anne LeMaistre, MD – Senior Director Clinical Information Systems & Chief Medical Information Officer – Ascension Health

Here.

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

Hi, Anne. Josh Mandel?

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

Hi, I'm here, good morning, Michelle.

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

Hi, Josh. Devin Mann?

Devin M. Mann, MD, MS – Assistant Professor, Associate Chief Medical Information Officer for Innovation & Population Health – Boston University School of Medicine

Hi, Michelle.

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

Hi Devin. Aury Nagy? Kim Nolen?

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Hi, Michelle, I'm here.

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

Hi, Kim. Dale Nordenberg? I think Dale is on.

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

Good morning, Michelle.

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

Hi, Dale. Neal Patterson? Wes Rishel?

Wes Rishel – Independent Consultant

Good morning.

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

Hi, Wes, thanks for joining. Eric Rose?

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

Hello.

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

Hi, Eric. Cris Ross? Kim Schofield? Troy Seagondollar?

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

I'm here.

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

Patty Sengstack? Hi, Troy. Patty Sengstack?

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

Good morning, I'm here.

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

Hi, Patty. Brent Snyder? Alicia Staley? Andy Wiesenthal?

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

Here.

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

Hi, Andy. Steve Brown? Brian Burns?

Brian P. Burns, MA – Chief Information Security Officer – Department of Veterans Affairs
Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Brian. Lorraine Doo?

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

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

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

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

Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense
I'm here.

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

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Chesley Richards? Kevin Brady?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Kevin and John Scott?

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

I'm here, good morning.

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

Good morning. That was quite...

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Donna Cryer is also here.

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

Hi, Donna.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Hi.

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

Anyone else join after we did roll? Okay, that was quite the list but I thank you all for your patience.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Michelle, this is...

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

Did somebody else join?

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Sorry, this is Jitin I don't...I didn't hear my name during roll.

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

Oh, I didn't call you, I'm sorry Jitin, I don't know what happened. Sorry about that. Thank you, Jitin.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

No worries.

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

Okay, with that I will turn it over to Jon White to make a few opening remarks.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Well, thank you very much, Michelle, and thank you everybody it is always...I'm always just stunned when I hear the names of the folks that are assembled, so grateful for your service and to be able to work with you on a collegial basis.

So, we're moving into the new phase of our working arrangements here with our new Co-Chairs. I have two very important introductions that I would like to make here at the outset and the first is to one of our new Co-Chairs of the Policy Committee, Kathy Blake. Kathy has been a member of the committee but is now serving as Co-Chair with Paul Tang.

For those of you who don't know her Kathy is Vice President for Performance Improvement at the AMA, splits her time between Chicago and Santa Fe. So, Arien, I know your sunset was probably nice out in the bay area but I imagine the Santa Fe sunrises are nice as well. Kathy oversees the AMA's clinical quality initiatives and development and testing of electronic clinical quality measures.

And she also serves as the Executive Director of the Physician Consortium for Performance Improvement which is actually an organization that I have worked with on and off for a long time and has executive responsibility for the National Quality Registry Network.

She is also an Assistant Professor of Medicine at the Johns Hopkins University School of Medicine and holds her Medical Degree from the Pritzker School of Medicine at the University of Chicago and her MPH from the Johns Hopkins Bloomberg School of Public Health. So, Kathy, thank you so much for your service and your leadership and we are looking forward to your work. The other...and that's on the advisory committee side.

Now on the federal side I have an immense...it is my immense pleasure today to be able to introduce our Principal Deputy National Coordinator to you Vindell Washington. I'll just...before I read the formalities I'll just tell you, it has been a real treat getting to know and work with Vindell, he is extraordinarily talented and capable, and focused. We have thrown everything and the kitchen sink at him in the past month and he has caught it all and he is juggling the chainsaws adroitly so I am super impressed and delighted to be working with him.

So, Vindell is the Principal Deputy National Coordinator. He provides high-level executive direction and leadership for ONC programs, operations and policies, and advances key administration initiatives. He came to us, as our National Coordinators seems to be doing these days, from Louisiana.

Immediately prior to getting here Dr. Washington was the President of the Franciscan Missions of Our Lady Health System Medical Group and worked as the Health System's Chief Medical Information Officer, that's in Baton Rouge as opposed to New Orleans. His primary responsibility there was to develop and execute ambulatory strategies for the health system with a focus on transforming ambulatory care delivery models and he was also the Senior Accountable Executive for Information Technology at the health system.

During his tenure the health system has been an early adopter of technology including solutions, including the integration of medical device information into the electronic health record and the widespread deployment of clinical decision support within the provider documentation workflow.

Prior to Baton Rouge Dr. Washington was CEO at Piedmont Healthcare Management Group in Charlotte, North Carolina and he holds his degrees, his Bachelor of Science is from Penn State University. I am super proud to say that his Doctor of Medicine is from the University of Virginia my alma mater and where it may interest you to note he has twins I believe in their junior year of medical school, and also holds a Master's of Science in Healthcare Management from Harvard, and he is Board Certified in

Emergency Medicine. So, when it hits the fan I'm turning to Vindell. So, Vindell, thank you so much for your service and we welcome you to this group.

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

Thanks, Jon, very kind words. I like the chainsaw analogy there are a few of them around here. A lot of work to be done.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So, Michelle, that is all my comments.

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

Thanks, Jon. I'm going to turn it over to Kathy Blake, Paul Tang, Arien Malec and Lisa Gallagher to make a few other remarks and go through the agenda. I guess we didn't decide who would take the lead.

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

Oh, my.

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

Why don't for seniority let's let Paul take the lead.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

All righty. Great, thank you and welcome everyone to a joint meeting and welcome to the new members and to Kathy Blake my co-partner in crime here on the Policy Committee side. Let me just briefly go over the agenda it starts out with the Precision Medicine Initiative we're going to hear from Jon White and Leslie Kelly Hall. As you know this is the President's Initiative to apply all this newfound data and knowledge from genomics and the other data to make sure that we give just the right patient just the right interventions to get just the right result. And there are a lot of implications from an HIT point-of-view and that's why we have this initiative going on primarily under the Standards Committee.

Steve Posnack and Elise Anthony...ONC never rests and so they've been busy putting out more proposed rules for our comments or at least the broader community's comments and so Steve and Elise are going to update us on two recent ones that have been put out.

And then we'll conclude with an update, sort of a summary of some recent hearings from the Joint Committee's API Task Force as you know that's a major initiative for all of us to make sure we can free the data so that it can be applied for good use for people and for patient care. So, we're going to hear an update on what their thinking is right at this moment, they won't be coming back with their draft recommendations until our next meeting in April with the final expected in May. Any additions to the agenda, then we'll be approving the minutes?

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

So, Paul, this is Kathy and first of all I'd like to thank the Office of the National Coordinator and especially Jon for his kind welcoming remarks and to the rest of the rest of the Health IT Policy Committee which I have gotten to know since I began as the quality improvement representative last year.

And I would like to say that I think we're entering into a very exciting and new time. If ONC thought that it was busy up until now I think it will be busier than ever as much of the work that's been done by both committees is now really going to go in...very much into implementation and into taking the lessons that have been learned about usability, about quality measures, about interoperability and really being able to bring the health IT infrastructure and environment to the next level of success. So, I look forward to today's meeting and I look forward to working with all of you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks, Kathy. And Arien or Lisa do you want to introduce some new representatives on the Standards Committee?

Kim J. Schofield – Advocacy Chair – Lupus Foundation of America

Kim Schofield, S-C-H-O-F-I-E...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Whoever is speaking they maybe on mute.

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

Did we lose Arien and Lisa?

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

No, we're here, yes, we definitely have a couple of new members of the HIT Standards Committee. And I think it would be a good idea to have them announce themselves and maybe say a few words about themselves so that we can welcome them officially to the committee.

We have...unfortunately in the Standards Committee had a number of long time members rotate out and that's always sad but the positive piece of that rotation out is that we get to get new talent and new folks involved in the process.

So, you know, I want to take a moment I think we've already noted how sad we were to see Dixie leave and we now do have a replacement for Dixie, those are fairly big shoes to fill and I'm stalling for time because my memory for names is terrible so Michelle...

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

Dale.

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

Help me out here.

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

Dale Nordenberg.

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

Thank you.

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

Dale if you want to go ahead and introduce yourself?

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

Sure, thanks, Michelle. So, I'm Dale Nordenberg and I'm a Pediatrician by training also did EIS to the Epidemiology Training of CDC and so boarded in pediatrics and also recently boarded in clinical informatics, and most recently have been spending my time in the area of medical devices and medical device cybersecurity so I've been pleased to be working with the FDA and Brookings, and now Duke Center for Healthcare Policy on the National Medical Device Evaluation System that I've been sitting on the planning board for and also serving as the Executive Director for the Medical Device Innovation Safety and Security Consortium and we're very excited to be rolling out new platforms nationally and internationally to start collecting surveillance data on medical device and security events and helping to bridge the science gap between the technology and the safety issues related to medical device cybersecurity.

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

And Dale, I started my career in medical devices so I'm super pleased that you're here and Dale is attending, as he noted, on the privacy representative and to some extent the security representative, Dixie of course had a very strong privacy and security background and sort of tirelessly represented the perspective of securing and appropriately protecting health information. So, as I said, Dale you've got some big shoes to fill.

Our second member who is new to the crowd is replacing Becky Kush. Becky, of course, in her role in CDISC had a strong role to play in terms of interoperability in the research sector and so we're very pleased to have a new research representative, Dr. Kevin Johnson. And Kevin do want to introduce yourself?

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

Sure, I'm happy to. I know many of the people on the call but good morning everybody. My name is Kevin Johnson I am a Pediatrician also by training and was an active as a pediatrician until about five years ago. I have a Master's Degree in Biomedical Informatics at Stanford where I got to meet Paul and a few others. I guess I would call myself a clinical informaticist generalist. I've done a number of research projects in medication safety.

I've been somewhat involved with SCRIPT and there is actually an evaluation that we did nationally to study that. I've been involved with computer-based documentation for quite some time and health information exchange and actually have a film that's out that was funded by ONC that talks about HIE if any of you would like to know more about it send me an e-mail.

I currently served a role here at Vanderbilt as Informatician and Chief which was a new thing that eventually I'll write up in JAMIA so people can learn about it. I'm the Director of our Health Information Technology Group the CIO reports to me.

I'm also the Chair of our Department of Biomedical Informatics here and as I think probably a lot of people know we've had a lot of opportunity to talk about precision medicine and the initiative recently and that has been through some of our terrific faculty here. So, I hope that I can contribute and learn a little bit from all of you about the right roles for standards to play as well as the wrong roles.

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

Welcome both to Dale and Kevin and as I said you both have pretty big shoes to fill. So, we welcome assigning you to multiple tasks forces as is the way of the ONC and the way of the Standards Committee. Okay...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you, Arien.

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

Back over to you Paul.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Yes, thanks, Arien and welcome to Dale and Kevin. Now I'd like take up the minutes from last time, it was distributed earlier and entertain a motion to approve them?

W

So, moved.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you and second?

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

Second by Gayle Harrell.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay, thanks, Gayle. And any other additions of corrections? If not all in favor say "aye" please.

Multiple

Aye.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

And any opposed or abstained? Okay, we'll consider those approved and thank you very much. So, now we'll delve into the content and starting off with precision medicine with Jon White and Leslie Kelly Hall.

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

Sorry, just to interrupt, I think we need to do the same thing on the Standards Committee and approve the minutes.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Wasn't it joint?

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

It was a joint meeting last time so we're good.

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

Okay, that's right, thank you. Thank you so much.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks. Okay, Jon and Leslie.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

All right, Leslie, hope you're okay if I roll first? I promise I won't get too...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Absolutely.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you. All right, well actually before I do launch in just want to personally welcome Dale and Kevin both colleagues of long-standing and international repute. So, delighted to have you all on board the ship and to be working with you.

All right, so precision medicine, we've been coming at you about this a little bit over the past several months and who was it, was it Arien or Paul that said that ONC never rests? I think it was Paul that said ONC never rests, well, let me tell you my federal colleagues don't rest either and neither do our colleagues in the private sector so we've got a fair amount of good updates to be able to share with you since the last time we talked.

So, you see here a picture of this first fun topic, the Precision Medicine Initiative Summit. So, on February 25th Dr. DeSalvo and I had the pleasure of going to the White House and participating in a, you know with 200 of our closest friends, fairly intense conversation with the President and national leaders on precision medicine. This has been a signature initiative of the administration for the past year since the President announced it in the 2015 State of the Union.

And there has been a lot of great work that's gone into it, there's been several workshops held by the NIH, tremendous collegiality and cooperation from both public and private sector. It has been one of the most remarkable cross administration initiatives that I've ever been part of and very shortly after the NIH's Advisory Committee provided Dr. Collins a report out of their work and workshop for how the

cohort was allowed to come together. And after our very own HIT Standards Committee provided recommendations about HIT standards that should be used to advance precision medicine NIH released, in very short order, funding opportunities, those have been underway for some time, but we were able to talk about some of those at the summit as well as a lot of the progress that's happened over the past year.

But really kind of the, you know, keystone of all of these amazing folks that were in the room, you know, including Francis Collins, Rob Califf, Secretary Bob McDonald, Dr. DeSalvo, Office for Civil Rights was there, Department of Defense, Veterans Administration, but, you know, the keystone of it was really this panel that the President led and participated in. It was a great dialogue between the President and the participants.

But, you know, I think I want to highlight for you the fact that, you know, he talked for a while about what we do. And he said it with very, you know, pointed interest in it, there were several comments that he made but I exerted one for you here "we don't want data just trapped. If I voluntarily want to join with other people and donate our data to help accelerate cures, I've got to be able to work with the electronic health record to make sure I can do that easily." That's the leader of the free world saying that, which was kind of cool for me.

So, this picture is not the highest quality, but, you know what, I took it, so it's the one I'm using. It was great fun to be there in the audience. I did choose not to include the selfie that I took with Arien Malec who was sitting right behind me as well as several of our other colleagues who were there. So, thank you for those who participated including Leslie who, it's up to you whether or not you want to talk about it, but it was, you know, kind of a great summation of the work that's happened over the past year, there's a lot of resources available on line at whitehouse.gov if you want to take a look at it.

Okay, next slide. Okay, some of what was...some of the many things that were announced that day were two things that I do want to call in particular to your attention and these were the first tranche of awards that were made out of the funding opportunities that NIH has put out there.

The first was an award to Vanderbilt University in collaboration with Verily which was for enrollment of direct volunteers, direct participants. So that is early out in front of the other kinds of awards and other kinds of ways to get people in.

So, Kevin's colleagues led by Josh Denny at Vanderbilt University are going to be working with their colleagues at Verily to stand up the way for folks who want to be able to directly participate and volunteer and like the President said "donate their data." They're going to be working with them to bring that in.

In conjunction, one of the things that you all recommended to us that we do is that pilot means of moving data from people's records directly into the cohort. So, we listened to you and we acted on that. The second bullet here is that NIH will collaborate with ONC and coordinate Sync for Science pilots through an open standards development process with several leading electronic health record developers and this demonstration will inform efforts to scale individual data access and donate for precision medicine research.

That Sync for Science pilot is going to be led by our very own Josh Mandel, speaking to you later today, and his colleagues at Harvard, and if Josh wants to comment on that be delighted to have you do that at

a later time, but those were two of the exciting things that we got to announce that day and more to come later on. Next slide.

So, in addition I want to really highlight some other important developments that are out there for what we're doing in precision medicine. We've talked a lot about the science which has been terribly exciting, we've talked a lot about participants and their role in the Precision Medicine Initiative. We all also equally recognize the importance of data security and that, you know, we're talking about literally, you know, people's, you know, genome and a lot of information about them. So, we're delighted that people are, you know, eager to participate and volunteer and donate their data but need to make sure that the data is secure.

So, the White House working with our colleagues including ONC's Jeremy Maxwell who works for Lucia Savage worked hard on iterating several policy principles and frameworks within which those principles reside. You know we think that starting from the high principles and then moving down to the specifics is the right way to go, those are open for public comment and the links are there on the website. I encourage you to go take a look at them and offer your comments, you know, the incredibly insightful people that you are I know that you'll have good things to say.

You know the second really important development that's been happening on an ongoing basis that I just want to, you know, kind of salute to is the Office for Civil Rights HIPAA guidance on fees and third-party access. Of course this is led by our former colleague on the HIT Policy Committee Deven McGraw working for Jocelyn Samuels who is the Director of the Office for Civil Rights. Deven is the Deputy Director for Health Information Privacy and there has been a tremendous effort underway to provide guidance from OCR. You know Deven left the private sector and joined us in the middle of last year and she has not been idle either.

There has been wonderfully well received guidance that has been coming directly from OCR published in a couple of different places. Deven has been working hand-in-glove with Lucia Savage our Chief Privacy Officer and we've gotten really good response from folks out in the private sector saying "thank you, this is the kind of guidance that we need to be able to effectively implement HIPAA."

You know HIPAA was never intended to be a barrier to the exchange...the appropriate exchange of health information. In fact it was meant to empower people to have access to their data. So, that's what that guidance helps us do and it helps to hear it officially from the Office for Civil Rights. So, links there. Okay, next slide.

All right, a reminder and we're going to talk a little bit about the Sync for Science pilots, but just a reminder of what our role is in Precision Medicine Initiative, of course there is the leadership of the President and folks within the Executive Office of the President, our tremendous colleague DJ Patil, the Chief Data Scientist in the Office of Science and Technology Policy, Claudia Williams formerly of ONC now working at OSTP, Maya Uppaluru shared between ONC and OSTP, but then of course our colleagues at NIH, at the FDA, at the Office for Civil Rights, at the Department of Defense, the Veterans Administration and finally the ONC.

So, I'm not going to read these back to you but this is ONC's role in the Precision Medicine Initiative and we can't do it without your help. So, thank you so much for not just your past contributions in terms of recommendations that you've put out but your ongoing contributions that Leslie is going to be able to talk to you all about, so really grateful for that. Last slide, please.

So, like I said, Josh if you care to comment at some point after we're done in the kind of question and answer period more about Sync for Science or if folks want to ask more questions about it they can ask you, but I just want to highlight that this is...I'm pretty excited about this.

You know we know we can get information from our digital health records, you know, to folks that, you know, can do research with that information and help find those cures and accelerate the finding of those cures that the President said.

The Sync for Science pilot is going to test multiple promising approaches for individual participants to contribute their EHR data to the precision medicine cohort, and again, I'm not going to read back to you but it's based on a lot of work that we've been doing and that we've been promulgating, so, Josh, thank you and your colleagues for your efforts in the future.

So, with that I am going to stop my piece of it. Thank you so much for your attention. Leslie do want you want to just head straight into yours and then we can answer questions after?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sure that sounds great.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Fantastic, thank you so much.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, I would like to first just echo the excitement that was in the room in the White House and how fluid the President was on the initiative and also the opportunities for interoperability. He also stated that anything that was from his body or about his body he should have access to that information and he went so far as to talk about ownership and so he is very articulate, compelling and it was a very exciting day.

Beyond the meetings that we heard from the President hearing the sub-committee workouts were just...was really dramatic and I think I encourage others from the Standards Committee who were there if they'd like to pipe in please do, but learning and listening from all of these amazing scientists, citizen scientists, physicians, researchers about their hopes for the initiative was quite exciting.

And as a patient advocate the need for patient generated health data, phenotypic data to be included in the cohort but also just in the data fluidity at large was quite evident in the discussions. So, I would invite any of our other colleagues who were there to comment quite quickly because it was...it was cool to see the President acknowledge the work that we're doing.

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

Leslie, this is Arien, I just want to double down on your and Jon's comments that it was very clear that the President was incredibly both well-informed and passionate about this topic. He spoke of his own children and the benefits that they will have through precision medicine and I was in a follow-up session with DJ Patil where he noted that the President is very personally engaged in this topic and keeps the OSTP staff incredibly honest in their drive to advance precision medicine.

So, you know, this is an area that we use the term “this is being pushed from high places” but it’s very clearly true in this case and there is an incredible amount of both passion and knowledge that the President personally is bringing to this activity which I think serves us all well as we try to put together the next generation of cures.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It was dramatic, the testimony we heard about the curative opportunities and then further discussion in some of the side groups about the opportunity for prevention and really eliminating unnecessary care when people don’t have a potential for a particular disease was quite interesting in itself. So, there are eyes on this work from everywhere and we are all challenged by this and I think encouraged by this. So, let’s go on to the next slide please.

So, we really are tasked with how we can support interoperability for the federal partners and the broader precision medicine community. It was quite dramatic to hear about what the federal partners are already doing. Some of the awards that were announced in our meeting I think were announced in record time and record review.

We heard from the FDA’s new leader about the conflict between repurposing and reuse of existing tried-and-true medicines for new cures and the challenges that this might bring. And the data movement that will be required to facilitate that work.

We also heard a strong view of support from some key vendors in the community like Allscripts and athenahealth, Cerner, drchrono, EPIC and McKesson and we hope to hear from more organizations. I think we’ll send out a link after this meeting for those of you who are interested in finding out how you can also contribute or pledge to this work.

We really want to collaborate with industry and pilot the uses as Jon mentioned. Patient access to APIs are just going to be imperative as we see and review this work the massive amounts of data is just not conducive to our old style of movement and so the use of APIs will become quite a necessary tool in both this really cohort stage and our eventual design.

And also the idea that results...results and our whole idea of results are also quite different and challenging in movement and what might be necessary in a lab might be very different and necessary, and care might be very different in research and so forth. So, this is really a puzzle master’s problem that we hope to solve.

We’re looking at identifying standards and we really do want to focus on datatypes critical and prioritize the piloting based upon that critical data. Next slide, please.

So, we’re looking at what does the lab need to send to the EHR, what does the patient need to send to the EHR, what does the EHR need to research and the lab to send to the patient. And these are...we’re hoping to get a minimum dataset and we understand that there might be very different standards in each one of these transactions and also high uses of APIs in some of these transactions or queries.

So, we have...it’s early days and we’re still looking at and receiving information about this, but this is really going to be a new model but I think an opportunity for us to apply this in other ways as we think about large data movement or new opportunities for data movement like large claims datasets or data

analytics, or other opportunities that we'll learn. So, this is tough stuff but very necessary. Next slide, please.

So, the presenters that we've seen so far, the NCI, they talked about their challenges and the FDA talked about their opportunities in big data, what they're looking at and needs for testing as well as what opportunities are there for new regulatory policies and there are going to be some. This is a real big challenge, all of this, and the level of federal cooperation I don't think can be overstated. The collegiality, the need to work together is evident in every single meeting and the ONC's role in making sure that there is a way to have computable privacy as we move to those large amounts of data around the country to support this initiative is quite high on the agenda.

So the Sync for Science pilots Jon talked about...and this is really exciting to see people already committed talking about how we might move the data and I think we'll learn a lot from these pilots. Next slide.

So, some of the work that we'll highlight is we really are looking at...or the group would look at and evaluate and hear from things about computable consent with Sync for Science Initiative, the Oncology Initiative, the FDA, the Million Veteran's Program who are...they are very much on their way. The VA is quite active and aggressive in the work in this area.

We also want to identify needs and opportunities to advance interoperability. Ideas for acceleration are going to be important and we welcome them from everyone. The lab data interoperability and patient access to that data, the patient's rights and ownership of genomic data, this is something that is a swirl that we need to get a handle on. The demographic data as well as the phenotypic data how do we capture it. This is a greenfield opportunity.

Could there be a standardized questionnaire both a structure as we recommended earlier, in early days, about a questionnaire structure in the Consolidated CDA but more importantly are there some data that we can collect in a uniformed way that's pretty common across all patient generated health data questionnaires and perhaps look at a way to codify that more clearly from the get-go rather than having sort of a fluid mess.

So, we're hoping to hear all of this and make recommendations back to the Standards Committee in June of this year. Next slide.

And just to give you an idea of the people involved, we have a very large cross section. And I invite you to provide any comments if I've left anything out or anything you'd like to add?

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

No, Leslie, you're on a roll.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, here we go. And then Dixie Baker can run but she can't hide so she is involved in this as well and as you can see we have a lot of continuity from the standards community both from previous Standards Committee members, current Standards Committee members and also others that have been invited to participate that bring us a broad spectrum and view.

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

Yeah, I would offer...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would like to also acknowledge...

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

This is Andy...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, Yes?

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

That Maya has offered to be contact person for anyone else, any other vendor interested in thinking about being part of the Sync for Science work.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, Maya has been tremendous staff and trying to herd us also and I would like to thank her as well. Next slide. And any Q&A?

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

This is John Scott from Department of Defense, I didn't see our member listed there, I believe that's Dr. Terry Rauch who has been participating in the Task Force from the DoD.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you for pointing that out I'll make sure that's corrected.

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

And I had a question also.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sure, perfect.

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

The data flows that you're showing on slide three it seems to me there's an important role that a more versatile personal health record like what's being advocated in the New England Journal editorial in January, and what I think the VA and US Postal Service are developing, a PHR that would allow the patient to download all their information from their healthcare providers and then share that forward with a study like any other PMI studies. Is anybody looking at prototyping that or how to use the PHR in that way?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think that what we're concentrating on is not a specific HIT technology. We will assume that data will come from a patient in a variety of ways that could include device level data, it could include data from a PHR, it could include data coming from an application of their choice or coming from the research community. So, we need to focus on the how and not necessarily...and be somewhat agnostic to the HIT type that's my feeling that's the kind of the information that we're getting. Andy do you want to add to that?

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

I...

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

This is Arien...

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

Having a freestanding personal health record that you download everything or enter everything into is a possibility or a way of handling this but there isn't actually a real need for the patient to assemble everything if the patient understands or the patient's App let's say understands where everything is and causes it to be assembled at their discretion for a specific purpose so...

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

And...

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

Sends it all to someplace rather than pulling it down constantly maintaining it and then at a later date deciding to send it to somewhere for a specific reason. So, there are...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And there is...

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

Lots of technical...

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

We certainly wouldn't want to burden the patient with that...

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

...

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

But there are many patients, parents especially, and I know there are pediatricians on the group who...

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

I am one them.

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

Are having to do that already.

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

...

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

Yes, sir.

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

Yes.

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

And I think there is very much a role for a PHR that would do that...

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

Oh, no, I'm not denying the role for the PHR...

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

Yes.

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

We're not just...we're just not saying that's the only way to do this.

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

Of course, certainly not the only way of course.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

This is Arien, I want to point out...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, what...

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

...

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

Sorry, I want to point out that the Sync for Science activity actually is that capability, the notion of a patient App that can pull into the patient's whether it's the PHR or their EHR portal and forward their data to the PMI cohort so that the basic technology model using the work that we've already done in FHIR and OAuth and SMART is exactly the work that's going under Sync for Science and can support the workflow that you're noting.

And I'm 100% sure that the President would love for the VA's portal or PHR, as well as the DoD's portal or PHR, to be able to support that capability and support participant engagement in using that Sync for Science App to pull the data into the PMI cohort.

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

Thanks, that's...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Let me introduce...

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

What I was perceiving from some of that and of course, you know, then patient consent can be incorporated into that flow so nicely. Thank you very much.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Let me...this is Paul, I'm going to introduce the tool that we have in front of us which is hand raising. In a virtual conference it gets a little hard to sort of figure out who should go next. In the upper left you have a hand sort of icon and you can raise your hand and what happens is Michelle can see who is up in the queue.

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

Paul that mechanism is not enabled today, at least not for me.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Altatum is it...can you...enable it? Yeah, I think it is.

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

Yeah, I think it's working. A bunch of people...

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

No.

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

Just raised their hands.

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

This is Josh I have the same problem though.

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

Okay.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

So, are you seeing in the upper, sort of upper left?

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

Yeah, I know where the button is it's just I'm unable to click it.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Oh, yeah...there's an arrow to the right of it and that says "set status" and then one of the choices is raise hand.

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

I just had to reload the browser and...

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

Yeah, but that's not available to me right now.

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

Reload your browser and it should work.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay. So, I'll turn it over to Michelle who will call on people who are in the queue.

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

Thanks, Paul. There were a few people with hands raised I think they were just checking to see if it worked but we do have David Kotz.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay.

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

I think David Kotz does actually have a question.

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

I do in fact. I was interested in the PMI research cohort which I think only came up as an aside. What role does ONC or these two committees have in that program as distinct from the overall PMI Program?

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So, it's Jon, I'll take a stab at it. So, the PMI cohort is primarily at this point NIH's responsibility, they've got funding opportunities out, you know, I just mentioned the awards that have been made.

I will say that there is an advisory group to NIH as they stand up the cohort and Karen DeSalvo and I are both ex-officio participants in that advisory group so there are regular meetings that are held where NIH kind of gives us regular updates about what's going on and we give them input and advice.

And then beyond that for the...within the cohort program if you delve a little bit deeper down into the different awards that are being made there is a coordinating center funding opportunity that's out, the coordinating center has a lot of responsibility with respect to creating a database of core data elements for members of the cohort, participants in the cohort.

And we're...ONC...so the recommendations of our advisory group were actually incorporated into that funding opportunity. So, folks who apply have to talk about how they're going to be using our standards and the ways in which they're going to be using the standards that we've recommended.

And once the projects are awarded and as they go on to do business we're going to be paying pretty close attention to what they're doing and keeping an open dialogue with them about how they're implementing it. Does that help?

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

Yeah, that helps. What I saw in the slides for ONC's role then was to ensure that there are computable privacy standards and policies presumably. Is there a role beyond that part?

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yes, so hang on, so I put my slides in the recycle bin so you've got to allow me to pull them out for a second and read them back to you.

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

Sorry.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Okay, so...

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

I saw your first three points accelerate innovative collaboration, adopt policies and standards, and advance standards that support a participant-driven approach is that what you're referring to?

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yes, that's exactly the one, which actually I should probably mention, you said computable privacy standards...

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

That was in the second presentation.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yeah, it should be here. So, those three bullets are kind of my, you know, my boiler plate for what we do that's...and that's how it's described in both the 2016 and the 2017 President's budget as well which is kind of how I define the way in which...and here's what I would say, earlier I did say that we've got...it's been a tremendously collegial effort across the administration and that's true. I've actually...like I said I haven't been working for forever for the government, but close enough, but this is...it really is...we've been working very well as partners and each of us have our specific roles and the three bullets that are on the slide that I showed you is ONC's specific role, then beyond that as we work with NIH, with FDA, with Office for Civil Rights, right, with OSTP, you know, we work with them in a kind of advisory collegial capacity. So, I hope that makes that clearer.

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

Yeah, I have other questions but I'll defer to others for now.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Okay.

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

Josh Mandel has a question I think?

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

No, I was actually testing the hand raising feature after reloading my browser.

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

It works now.

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

And I can see that it works now.

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

Thank you. We actually don't have any other comments or questions in the queue.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Michelle, Rich Elmore, I guess my hand raising is not working.

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

Go ahead Rich.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, just a couple of questions as to whether or not the Task Force has considered these or considers them to be part of scope. There are two observations that link to that, one is that there...I think we're in a unique opportunity, unique time in terms of being able to align on how we...what the processes are for, you know, level of assurance, identity proofing for patients. And, you know, this is both something that is being addressed by folks that are trying to use, you know, the Direct Project it will come into play in a distributed environment and my understanding is that some of the genomic data would stay distributed so that, you know, having good identity proofing as a foundation I think would be, you know, a good thing for us to have addressed as a Standards and Policy Committee.

And the second thing is that by the very nature of this now looking like it's going to be, you know, a distributed research database as opposed to, you know, kind of a combined national research database, you know, I think we have some challenges.

We're not the best at, nor do I think we necessarily have standards around, distributed queries that would address the kinds of questions that are going to want to be asked in terms of the research and what we want to try to get out of them. So, I'm just wondering if that has...what's the feedback from the Task Force at this point?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's still early days and we are discussing all of this because I think you're bringing up really great points people are concerned about identity proofing issues, the whole federated notion of multiple databases to query. This is record locators services on steroids and so we're still in the early stages of discussing

and understanding the unique themes and what the emerging architecture might be and I invite Andy to add further to this.

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

No, I have nothing to add, thanks, Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks, Andy.

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

Kathy Blake has a question.

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

Yes, a question and kind of comment. So, first of all it's heartening to hear about the close collaboration amongst the various federal agencies. Those of us who are mostly outside of Washington DC think that this is absolutely crucial at this point in time.

But just to really bring the thought to the group, across the agencies there are many efforts to develop what I would call these extra-large cohorts of individuals for the purposes of data mining, for safety surveillance and a couple of these initiatives are fairly advanced the one coming to mind being the Sentinel Initiative through FDA that now has, I think, about 152 million people that it is able to, in a distributed network, query their health records to be able to see if there is a safety signal emerging. And so standards, particular data elements, a lot of that work has, I would say, a good head start that we could take advantage of.

Similarly, there's the Medical Device Epidemiology Network also supported by FDA, PCORnet and then moving outside of either the governmental or quasigovernmental agencies to think about groups like PatientsLikeMe.

And so my hope would be that as this Precision Medicine Initiative goes forward that we would...one could almost put in quotes "steal shamelessly and often" from a lot of the very strong work that has already been done in some of the groups or initiatives that I've mentioned.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you so much for that, I agree, you know, we have heard from PatientsLikeMe in the earlier phases of the committee and that's always top of our mind. This group is quite vocal about patient participation, access and movement of data.

And your recommendations around Sentinel and others I think are well noted and we will definitely borrow shamelessly where applicable as they, I think, have also borrowed from standards work that's been going on under the ONC. So, thank you.

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

John Scott?

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

Yes, I had a question as to whether the Task Force is looking at the kind of complex consents that I think are necessary in terms of whether someone's doing a whole genome for research or for a specific clinical application, you know, what is the patient consenting to in terms of information that will be shared back to the patient or to their healthcare system. Is that being looked at?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes. Jon do you want to speak a little bit about that? We are focused and our task was really around the standards to enable things like this. Jon, do you want to talk about how we're thinking of this in the future?

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yeah. John Scott, ask me that question one more time so I make sure I'm clear on it.

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

Well, I'll sort of...when someone gets a genetic study there is a lot of information that, you know, we don't know what to do with yet that's sort of what makes it different than other lab results. So, you know, as we're struggling with principles to apply in the DoD for this we're thinking that there's a small set of information that if you discover this you must tell the patient, you know, channelopathies, etcetera. There is another group where genetic counseling ought to be offered and there is most of the rest of it where we don't know what to do with.

And I'm thinking, you know, some of us were talking about consents ought to, for people to participate in a study or to get their full genome when they're looking for something specific, ought to acknowledge that sort of hierarchy of what information might be sent back. That's just the sort of thinking we're doing. Are we looking at any sort of national recommendations or best practices in that regard?

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So, that's a great question. Those questions I am 95% sure, living in a probabilistic world, are being addressed both by the current award to Vanderbilt, which is the direct volunteer enrollment, as well as by the, to be awarded, other awards like health care provider organizations that are going to be enrolling individuals in the cohorts. Kevin Johnson, there is...you're not, you know, the PI for it so I don't know that you know about that specifically, do you have any extra information about it?

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

Yes, hi, this is Kevin Johnson, I have two comments, one is I do know a little bit about that Jon and you're correct that the award that we invariably received will be specifically, literally trying to bring up that entire model. The idea was that this was a very rapidly awarded proposal so that it could stay ahead of the larger proposals that are going to be awarded to individual nodes in the network to specifically address these questions. It's a cooperative group and that's the plan.

The other thing that I would encourage people who are interested to think about or to watch is the BD2K Initiative because so much of what we are actually going to be trying to do with precision medicine

Phil Bourne and the group at the NIH have been thinking about for the last couple of years. So, this is very much a classic moonshot where there are research activities going on at the NIH and at the NSF that will be feeding with relatively fast turnaround to production systems that are trying to bring this other initiative up. So...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

There's a lot of moving parts still.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Right.

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

I mean, I think about, Josh Mandel is on the phone, but I think about the role SHRINE is going to play in helping us to understand some of the distributed query-based standards as a great example of where there are things actively happening in the research world that we're going to need to pay attention to, to decide are they ready, how would we add an additional bit of oomph to them to get them to be ready, etcetera.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

One of the many reasons why I wanted Kevin Johnson on the Standards Committee. Thank you, Kevin.

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

It looks like David Kotz has another question?

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

Yes, thank you and in fact it follows on very well from the previous comment. As a researcher myself, and as a researcher focused on security and privacy, and mobile, and cloud technology, I'm very excited by the potential for the PMI and also the PMI research cohort because it will drive a lot of interesting challenges.

As I understand it the research cohort, at least, and maybe the program as a whole, will involve not just clinical data but also physiological data collected from subjects and of course genomic data but also exposomic data, a word that I learned in the process of attending one of the advisory committee meetings, meaning data about the person's whole environment in which they live and work. And so there's a tremendous amount of data that will be collected about these subjects and stored and processed, and used for research.

And so I guess what I'm wondering is do we...do you as a Task Force or do we as the Policy Committee need to start thinking beyond our normal scope of clinical data towards these broader kinds of data and the privacy and policy issues that come up?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's a really great comment and I think that it has been clear from all the testimony we received that receiving patient generated health data for the phenotypic or the exposomic, did I say it correctly, data from the patient is key to having this cohort and beyond be successful and so it has been under discussion, ongoing, it's threaded throughout this work.

It does create challenges but I think it also gives us an opportunity to say how this is done in a standards-based way, in a way that can be codified, how can we apply this then to data needed in other types of clinical uses inside the EMR. So, I think there's great opportunity for sharing those kinds of data. The discussion that also...

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

This is Andy, if I could add a comment?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

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

To some extent though we have to be aware of the fact that we may be making policy in a situation, if I can use the metaphor, where the horses are already out of the barn. We have data scientists that talk about all the publicly available data that can be assemble without any consent from anybody to create a picture of every individual in the United States that's actually quite accurate in terms of predicting their health status and so on and has nothing to do with what's in electronic health records and everything to do for tax records and appointment records, and purchase records and things...data sources that are just for sale based on all the different things that we do that are assembled by computers today.

So, if we really have some policy ideas here it actually may be policy recommendations to create new regulation and not to create standards around existing regulations. I don't...this is a discussion that can be very lengthy, but I don't know that it has an obvious end or conclusion in this meeting this morning.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well said.

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

Well, it's a big issue there.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, yes.

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

Yes, it's a big issue and no we have no jurisdiction.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Other questions Michelle?

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

Yes, Floyd Eisenberg.

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

Hi, I just wanted to say this is wonderful work and I see other applications we spend a lot of effort on quality measurement and frankly it's hard to find some of the data that are needed but I can see the information not only being used for individual care and research but also being used to evaluate outcomes without having to create additional data just for measurement. So, just very good effort.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you.

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

And Wes Rishel.

Wes Rishel – Independent Consultant

Thanks. I just wanted to build a little bit on Andy's comment and I can't even attempt to pronounce the new word we just all learned, it would be helpful if somebody spelled it, but the data that might be gathered from commercial sources or other sources that was not originally thought of as medical data. I think that we're in a time when we've seen on sort of the least regulated areas of applications huge progress in terms of acquiring, refining and bending this data to specific purposes.

What I wonder is, as often happens, when we want to look at data for clinical purposes or for scientific purposes we need a rigor that is different, I don't want to say more rigorous, but we need a way of structuring the data that is different than what has been accomplished in the non-medical world.

And I actually am thinking that we run the risk of doing what we have done before which is to try to over specify the outside world that rather than creating based on sort of a hypothesis of how the data would be useful, a structured medical version of this external data, that we develop ways that incorporate a variety of different ways of representing the data so that the same sort of opportunism that has happened in non-medical fields is available in the medical research that's going on now.

It may be that specific pieces of data correlate well and through that correlation we discover some causality or some other medical relationship that's important but we have to expect that this data will come in a lot of different forms and we don't get a chance to structure it to our needs. Thanks.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Good comments, thank you Wes.

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

It looks like that's the end of our queue.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

All right, thank you, Michelle, thank you everyone for the great comments.

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

Thank you Jon and Leslie. So, if there are no further questions we'll turn it over to Steve to be the first to do our ONC update.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

All right, thanks a lot. This is Steve Posnack the Director of the Office of Standards and Technology at ONC and I'm going to do a few updates for you and then turn it over to my colleague Elise. Next slide, please.

So, right before HIMSS we published a couple of blog posts, one that covered the approach that we're using to reshape how we take on standards and technology work and to kind of put that simply, we laid out that we would be approaching our work from a principled perspective that would represent four focus areas standards coordination, testing utilities, pilots and innovation.

And the way in which we conceptualize all four of those together is something that we call the ONC tech lab and that's really the kind of single term and framing that we used to represent the way in which we'll organize and approach our work from a standards and technology perspective.

We also feel that by framing for everyone the four focus areas that we'll have it will allow for us to create more clear and common connection points to our standards and technology efforts going forward.

This transition and this reshaping really reflects I think a lot of the recommendations that the Standards Committee issued to us about a year ago. I have a running joke with Arien about what it means for us to be agile in the government, that being said, a lot of this is in process after those recommendations it just was both an internal and I think my team would say, you know, culture change for us to think differently about how we approach our work as well as how we were then starting to integrate in the types of changes that we're going to be pursuing from a standards and technology perspective into our FY16 budget execution as well and so the timing was right to really put this out in the beginning of the year and start to frame the way in which we're going to approach our work going forward.

The transition really lays, as I discussed in the blog post, the operational groundwork for ONC that's going to be necessary from our perspective to implement what we've committed to in the interoperability roadmap, the other near-term health IT strategy items that we're working on, as well as a longer term version that's been laid out in the Federal Health IT Strategic Plan.

From a standards coordination perspective we've got work going on now with HL7 on improving the Consolidated CDA. We also are assembling folks together in April to what we're calling a provider directory workshop, which is really a get your hands dirty, roll up your sleeves type of event. We're looking at working with SDOs and other stakeholders in the field to discuss improving feedback loops related to on the ground experience in implementation of standards.

And then the standards advisory obviously fits into the standards coordination area as well and I framed that for myself in my notes so that I would make sure that Michelle didn't send me an instant message while I was talking because two things on the standards advisory, the comment period on the 2016

standards advisory is still open for the next couple of weeks. If you need additional time please get in touch with Chris Muir or my team, there's information on our website about how to do that.

And that's also to note, as we go through this annual process of the standards advisory, we'll be kicking off a Task Force for input to the draft 2017 advisory which will be published in the beginning of the fall of this year. So, that's something on the docket that will be coming up for folks going onto the future.

I'll segue now into the other bullet here that I've got on this side. During HIMSS ONC announced a three-part strategy to invest in community-driven, user focused innovation to spur the development of market ready Apps and we launched a \$625,000.00 strategic investment to connect and accelerate the industry's use of FHIR-based APIs and Apps for consumers and providers.

So, there are two App challenges, one focused on how we can help consumers get and use their data and there's another one on improving the user experience and the utility of the applications for healthcare providers. So, those are two challenges that are represented there in the hyperlinks.

And then we have a third funding opportunity announcement which will be a cooperative agreement around finding ways to improve the availability of App discovery, we're calling this kind of an App discovery site, that makes it easier for developers to publish their Apps and for providers to discover and compare them from a perspective along those lines.

So, all three of those got released on February 29th or March 1st, sorry, March 1st. And I would encourage anyone that's interested in applying for the challenges you can check them out on challenge.gov and also go to grants.gov to check out the funding opportunity announcement if you are in the App discovery site market game.

The last thing that I would touch on in terms of updates, one of the other blog posts that we put out right before HIMSS as our first release related to the ONC tech lab approach is something that we're calling the interoperability proving ground.

We know that every day across the nation all of us, and I know I'm preaching to the choir here, are collectively tackling a lot of interoperability challenges and I'm sure many of you are involved in pilot activities in other types of prototyping and as far as we can tell a lot of that work is hidden in plain sight.

And we were looking at ways in which we can help the broadest community across the nation showcase their work and allow for collaboration in connection across the nation in a lightweight way and so there's a good Clay Shirky TED talk that I think I referenced in the e-mail that Michelle was kind enough to send out when we launched the interoperability proving ground where he references Wikipedia and GitHub and how the Internet as a communication platform has really enabled cooperation without coordination and that's really an underlying theme that we hope to achieve with the interoperability proving ground.

So, really as a lightweight kind of web component this is an open community platform where people can share, learn and be inspired by interoperability projects taking place across the nation. It is open to everyone to add in their projects no matter how big or how small, the point being that you should be able to share your work and let people know and they should be able to find it in a pretty simple way.

So, the IPG allows you to provide a succinct set of basics, a snapshots about your projects, a title, a description, a hyperlink to more detail, there is a contact and then tag it as well with keywords and, you know, in essence a standard that you may be using as you work on your project. So, that allows for some faceted navigation, some simple filtering that you can dynamically do on the webpage as well.

You can go to my next slide as I'm starting to do all the narrative here because I have a home page screenshot here. The data that gets populated, you know, anyone can filter that's kind of the bottom part as well and the one other thing that I'd note is that we have an interactive map so as projects get populated you can go to the map as well to see "hey, who is working on the interoperability projects in my state" and then you can click on those projects for more detail.

There are a number of improvements that we've got a wish list of things that we'd like to do to improve this going forward to make it more valuable to people as more projects get added in and as we enrich that community overall. We've been very pleased with the interest and I would encourage people to take a minute because I think that's about as long as it would take to add in a few snapshot information about your projects.

We've basically doubled the amount of projects that we had in the listing in the past couple of weeks really by word-of-mouth and social media. So, again, to end my public service announcement on that, if you're working on it please take a minute to highlight your work and share it with your colleagues. This is really for you and ONC being there to stand up this platform and to steward it for your collaboration and cooperation.

And I think I will turn it over to Elise in the interest of time and then if folks have questions for either one of us I think we can take them then.

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

Thanks, Steve. Hi, everyone, Elise Sweeney Anthony here, I'm going to give a quick policy update on two key things that ONC recently has released out into the health IT sphere. Next slide.

The first one is our proposed rule on Enhanced Oversight and Accountability and the Certification Program, we affectionately call this the oversight rule for short. Next slide.

And the goal is...we'll talk about the goals generally, but it's really enhanced oversight. It's the accountability and it's the transparency that attaches to the Certification Program and the pieces of that. Here is the agenda of what we will discuss but I think one of the key slides is the next one.

And this one shows what the rule is and what it is not and I think this important because this was actually released during HIMSS and some of the pickup of it and the how it was described was a little bit inaccurate or I don't know if it's a little bit but it was just not exactly accurate in terms of what the rule covers and the scope of the rule. So, I wanted to take a minute and talk a little bit about how the rule is structured and what the focus areas are.

So, let's do the what it is not side first. So, one it does not establish new certification requirements for health IT developers. It also does not establish new certification requirements for providers under HHS Programs for example like the EHR Incentive Program. There's no new certification health IT requirements in this rule for that program or other programs.

Third, it does not establish a means for ONC to directly test and certify health IT and I know this was something that we got a couple of questions on from folks at HIMSS is whether we would be directly certifying and testing health IT. So, what does that mean? You know many folks would say “don’t you already do that?” Well, not exactly. ONC has accredited certification bodies and they are actually the ones that do the testing and the certification and that will continue as this proposed rule is drafted.

The last piece is it does not establish regular or routine auditing of certified health IT by ONC. So, now we have that out of the way, the what it does not do, let’s talk about what it does.

So, one it enables ONC to directly review already certified health IT products. So, a product that has already been certified by an ACB, if there is a need, we at ONC would be able to come in and review that product and review its operations.

Second, it would increase oversight of the health IT testing bodies similar to what’s in existence now for ACBs it creates a balance between the ACB structure and the accredited testing lab structure.

And then last, it would increase transparency and accountability as it relates to surveillance results, in particular making surveillance results identifiable surveillance results available on our CHPL. So, let’s go into a little bit more specifics about what that looks like. Next slide.

All right, so direct review of certified health IT, the proposal focuses on, as I said, ONC’s ability to directly review already certified health IT products that have been already certified by an ACB. It also allows us to set in motion corrective action, suspension and termination of certified health IT products as needed.

One thing I do want to emphasize here is that our goal is to work with developers should the need arise where a potential nonconformity or nonconformity is found. Our goal is absolutely to work with the developer community and that’s why there is kind of a step-by-step mechanism one starting with corrective action which we think would be key should any issue or nonconformity be identified.

So, a couple things to note here in terms of the structure of the program. So, one, the ONC direct review could be independent of ABC review. It could be in addition to an ACB review. And it can also be exclusive of an ACB review where we decide to exert exclusive review to avoid any inconsistencies and analysis for example.

Second, ONC’s direct review would extend beyond the continued conformance of the certified health IT. So, while we would be able to look at certified health IT another key component is that sub-bullet three where we would also be able to look at how interaction of all capabilities, so the interaction of capabilities involving certified health IT as well as that certified health IT’s interaction with other capabilities of the product that may not be certified.

And the goal of course is to think about public health and safety as well as other exigencies that might be identified. So, in essence, you know, as we move toward health IT being a key part of many different initiatives that are happening in the private sector as well as in the public sector everything from PMI to MACRA we want to make sure that we are well placed to address a need should the need arise.

One of the things we’ve all noted, and if you’ve taken a look at our press release and so forth, is that we don’t expect this to happen as an everyday occurrence but we do want to make sure we are well placed to address it should it arise. Next slide.

So, some of the goals, and I've noted these to some extent already, and these are noted further in the proposed rule and maybe this is a good place to say that as many folks have probably heard us ONC folks say in the past that it's a proposed rule so we are pretty much bound to stick to what we've discussed in the preamble and the text of the proposed rule and are limited in the type of questions that we can answer regarding the proposed rule particularly if it goes beyond the bounds of what we've already identified, should that happen, you'll probably hear me say "we welcome comment on those questions" which we of course do and at the end of this presentation I'll give you a couple of...I'll give you the link in the slide deck for where you can comment and how you can comment and by when.

All right, so, back to that, the goals are greater accountability for health IT developers under the program, also greater confidence that the health IT is going to perform and conform to the program requirements under which it was certified and how it works across public health and safety of course.

And then also we want to be able to work directly with developers in some instances to address any identified nonconformities and this will give us the mechanism to do that in a robust way. Next slide.

So, these are some of the examples that might warrant ONC direct review and I think the two key words here are "examples" and "might" so these are examples that we've included in the rule. We also note that there could be other situations that might arise.

So, one could be where a developer has products that are certified by two different ONC ACBs, so certified by two different accredited certification bodies and maybe the potential nonconformity that's been identified, and it could be identified to us through a complaint, through something that's noted from an external stakeholder as a concern, it could be a number of different ways that a problem is identified and from there if we deem it to be reliable and actionable that we could then start this direct review process.

But let's say there's a product for example that...or there's a developer that has products that are certified by two different ACBs but the problem or the nonconformity could possibly exist across the different products that this developer has certified with us. It might make more sense in that scenario for ONC to engage in a direct review as opposed to having multiple ACBs during the review.

Another potential area could be where there is a systemic or widespread, or complex issue that's involved...that the nonconformity involves in which case ONC's expertise and what we might be able to bring to bear might be more timely and effective in terms of review.

Risk to public health and safety, I've noted that one already.

Other exigencies, so that could include, for example a security or protection issue related to a patient's health information but it could also be a number of different scenarios as well.

And then also where there might be issues related to confidential information, information that may not be...should not be shared with an ACB for example that's another area where ONC might step in.

So, these are examples that are noted in the rule. I do encourage folks to take a look at the rule in its entirety. I will note that as many folks know are prior rules are...our certification criteria rules are usually pretty long. This rule is actually pretty short it's a little over 100 pages so hopefully it makes it a little bit more tangible for folks to read. Next slide.

So, here this specs out kind of the flow process for direct review and I'll highlight this a little bit, this is more of a slide for kind of a quick use for those who might be interested, but one, I want to note a couple of things here.

So, one, in terms of how the direct review process would go you see the first alert to a developer who might have a potential nonconformity happens and once that happens that kind of triggers opportunities for us to work with the developer and take a look at what the issue might be and then a notice of the potential nonconformity and nonconformity...potential nonconformity or nonconformity can then happen, and that's that middle chevron that you see there, and that is kind of the official notice stage.

You'll notice on the top that suspension can occur pretty much anywhere in the process and that's because, particularly if there's a public health or safety concern, we do want to be able to step in quickly and address that in terms of provider use and potential impact on the patient.

There are opportunities for appeal as you will notice throughout this process and I do again want to highlight that corrective action area as key. We really do hope and intend to work with developers to figure out how to address the concern across the product so that the termination stage...it would not be kind of the first area that we go to, to try to address a nonconformity. Next slide. So, that was direct review.

I want to talk a little bit about two other provisions of the rule and there really are three major areas. The second one is here and that's the ATLS. The Authorized Testing Laboratories currently don't have the same kind of oversight structure as Accredited Certification Bodies.

These Authorized Testing Laboratories, the ATLS, are NVLAP accredited and what we're saying is not that we would take away the NVLAP accreditation but we do want to create a more aligned process with what we have in place for the ACBs. So, what does that look like? Next slide.

Okay, there we go. All right, so this is another flowchart, we love flowcharts, we love charts here, we try to make it as simple as possible to kind of quickly look at how these systems would work and how these operations would work.

So, as you can see here on the top side we have what is the ACB process. And the ACB process is what is already in place. The bottom part is the proposed ATLS process and you see that there's very much going to be alignment between what we have in place for ACBs and what we are proposing for the ATLS.

You'll also note that in that gold box, which shows up as gold on my screen, is that we are proposing the same violations and revocation process that attaches to ACBs would attach to the ATLS as well. And you'll notice that the NVLAP accreditation would still exist but you'll see in that middle area that the ATLS would then have to apply to operate under the certification program. Go to the next slide.

Okay, all right, so in the last key piece I wanted to talk about is identifiable surveillance results and to us I think this is a little bit about balance and you'll see that in our wonderful image at the bottom slide that shows that what we have now is a situation where there is a correction plan identified, where there's a problem with surveillance results, that this would be posted on the CHPL.

But there are many products that are certified that do well in surveillance continually and often. And we want to be able to have those developers show that as well, to show that they are doing well with their surveillance and when they are surveilled that they're coming out with flying colors, right, for lack of a better word, and not just showing where there's a negative in a product and we think that provides some balance.

And then also for those of you who have heard me talk about the 2015 edition rule that we released in October a lot of it is about transparency and this is somewhat a continuance of that, being able to make sure that we're putting as much information as we can out there for providers to use and making decisions about products. And also this is a good platform for developers to showcase their product and the maintenance efforts that they have underway to make sure that their product continues to do what it is supposed to do after it is certified and after it is tested. Next slide.

So, public comment, so we encourage, you know, FACA members, as well as all stakeholders, to comment and you can comment independently, individually by May 2nd. All comments are due by May 2nd.

There are a couple of resources that we make available, one, obviously you can see the link here to the actual proposed rule. There's also a press release and a factsheet that we have on healthit.gov that summarizes the rule.

And then, lastly, we've Word versions...a Word version of the proposed rule available in a public comment template. Of course you don't have to use the public comment template but, as we've done in previous rules, we think it might be a good resource for folks to be able to comment. So, feel free to use those resources. Next slide. And here's a link to the factsheet and the press release.

I now want to talk about something completely different which is the Model Privacy Notice. So, as you can see we've been pretty busy end of February and the beginning of March. So, the Model Privacy Notice, next slide, please, this is an update. So, Model Privacy Notice 1.0, the first one, was released some time ago and here's a link to the blog that was co-authored by a number of us here at ONC and I think that's an indication of how important we see the Model Privacy Notice and the importance of consumers having information they need about how their PHI would be used. But, anyway, so the Model Privacy Notice was published some time ago and focused very much on PHRs. Next slide.

Okay, there we go. And focused on PHRs because that was the prevailing technology at the time but now as we move forward where we have new technologies and we have a new platform for health technologies, I mean, the one that folks talk a lot about is fitness trackers but there's also mobile health monitors, there's a number of different mechanisms that...or technologies that take in PHI and our goal is to Model Privacy Notice 2.0 in recognition of all those different types of health IT to making sure that the patient or the individual has information about how their technology will be used.

So, what exactly is the MPN. So, the MPN is a voluntary openly available resource for developers and consumers. The goal is that a company, for example, would be able to use the Model Privacy Notice to pick the pieces that are relevant to them and construct a notice that consumers would have access to about how their PHI would be used by that particular company.

Right now we've released a Request for Information that is out right now and the goal of that Request for Information is really to work with stakeholders to hear from them about what is important for us to

consider, include, not include even in terms of the Model Privacy Notice. What type of technology should be addressed or uses of PHI might be useful to consider. So, we really do look forward to hearing from stakeholders about updating the MPN as a 2.0 version. And then next slide, please.

There are a couple...so here's the Federal Register notice but also look at the website because there is some information and some background on it as well and then there's the mechanisms available for how you can comment and we've done creative things like reddit is a way that you would be able to comment as well, as well as sending a direct e-mail.

So, take a look at the Federal Register notice which has all the information about how to comment and we, of course, encourage feedback on what would be important to stakeholders from across the spectrum.

So, with that that's pretty much the summary for today and I guess we can open for comments Michelle?

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

We have lots of questions. Thank you, Elise.

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

Okay.

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

So, we'll start with Paul Tang?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks, Michelle.

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

Hi, Paul.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Hi, Elise and thank you for that update really, really liked the version 2.0 Model Privacy Notice. As you explained the world has gone on quite a bit in the past five years and there's lots of ways to collect information and giving people both the consumers and the developers some guidance on how...what your responsibility is with this information is really important.

Also liked the oversight rule and I have a question particularly the transparency you talked about not only publishing the things where...the events where things go wrong but also wanting to highlight when things are going well in your surveillance stage.

And I'm wondering, that's really good information, could you extend, why would it have to be limited just when things are under surveillance versus as they go through certification?

Is there a way to make the results of certification more transparent for the same reason you wanted to make results of surveillance transparent, that is both to inform the market as well as to provide some sort of peer pressure on constantly improving your products and being innovative?

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

So, I'll let Steve jump in here as well, but when you say results in certification do you mean whether they passed certification?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

No, how they pass. So, I assumed your surveillance transparency was how did they stack up in your review after they're certified. Could we see how they...how well, in a sense, how well they passed certification initially not just a black box did they pass or not pass?

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

So, I'll lean on Steve a little bit here on his thoughts. That obviously is not covered here, you can obviously feel free to comment on the extent of the identifiable results we're seeking to include, but, Steve, do you have thoughts on...can we talk a little bit about how it's structured now that might help?

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Yeah, I mean, I think, I guess the simple answer to Paul's question is, there isn't a grading spectrum in terms of how well someone does. You either pass a tool or don't.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Right.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

And so in a lot of cases...and so there's those types of things where we have automated or, you know, electronic testing tools that the developers products will interact with and they will need to make it through the tool in its entirety in order to meet the criterion.

In other cases where there could be more subjective analyses, you know, there are other challenges in terms of exposing the intellectual property associated with that part of the process. But that being said, there's a good public service announcement opportunity for me, we are migrating and transitioning the certified health IT product list to what we call the open data CHPL that is now live and available in kind of a soft launch form because we are transitioning and it's still in attestation period so we don't want to confuse people with two certified HIT product lists.

So, for anyone that still needs to attest still go to the old CHPL please to get your CMS EHR ID number. But the new one is up, it's chpl.healthit.gov you can check it out and there will be a lot...as the 2015

edition products get reported in a lot of the things that we specified in the 2015 edition rule is computable granular data access to information about each certification criterion, as well as, I would say as a highlighter or spotlight, much of the user centered design information will be broken down into its constituent parts so that, you know, it can be used by others as they see fit.

So, we're looking at making all of the work that's done through the certification process open and available in as much data as possible so that others can use it.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Maybe can I just make a little bit more concrete my suggestion? So, a common response is protecting the IP. Let's take like Apple watch has a lot of IP. Apple makes a watch, Samsung makes a watch but it's open in plain view and even Consumer Reports or some review agency can talk about it and that promotes competition and innovation naturally.

We're a bit hamstrung in the EHR world because even though you go through a certification including testing for medication reconciliation, as an example, part of the lack of being able to openly compare things is that the prospective customer doesn't get a chance to look at really the comparison and there is no sort of peer pressure to innovate and to improve in particular usability, which as you know is a common complaint about EHR systems.

So, just trying to find another way to help open the market just like any other consumer product faces and yes people can look at other people's ideas but that sort of drives the whole innovation space.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Yeah, I mean, I think the one thing to add, we have a number of criteria that are required to comply with the safety-enhanced design certification criterion which requires them to convey their user centered design processes and as part of the open data CHPL approach they need to list the tasks that were used in assessing the capability.

So, for like a drug-drug, drug-allergy interaction checking, I think medication reconciliation...clinician information reconciliation one is also a part...you will be able to see now in a more, I think, efficient way the tasks, which may be different by EHR developer, that were used in assessing the functionality from a user centered design perspective.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

All right, thank you.

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

Sorry, we are running out of time and we have lots of questions so if I could ask folks to be as efficient as possible that would be great.

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

Yeah and I would also...I'll also say that we plan to do a webinar in the next week or so and if folks have questions they can also ask them there if we're running out of time.

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

Thanks, Elise. Okay, Eric Rose?

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

Hi, I'll try to be brief. First of all, I think the direct review is a great idea. I'm very encouraged to see ONC getting into it. I think you may be surprised by the volume of requests you get so it may put a strain on ONC resources but you're probably already aware of that.

Also, it may...I think it's extremely important to ensure that the review from one EHR vendor to another is done in a way that is fair and consistent and almost as important, perceived as fair and consistent, and so it's probably worth thinking about ensuring that there are processes and guidelines to do that.

But most importantly, I want to emphatically echo Paul's comment that this is great and the initial certification should be made more public and transparent. And I think without any regulatory change ONC could start releasing or having the certification bodies release recordings of the certification testing. You would have to get permission from the EHR vendors if there are...to address perceived IP issues but it could become a competitive advantage if somebody is trying to sell me an EHR, I can say "well, have you made the recordings of your certification testing public" and if not I might move onto the next vendor. I think that would be an enormously valuable and easily implemented lever that ONC could pull to make the market more transparent and help physicians and hospitals choose the right EHR for them.

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

Thanks for your comment. You know I appreciate kind of all the perspectives. I think also, just as a reminder, we really encourage folks to comment as well through the public comment spectrum. So, if that's a comment that you would be willing to make we would love that as well, as all comments.

Phone ringing

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

Hello?

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

While our operator...

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

That's not me.

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

Tries to fix that...

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

I'm still here.

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

We're all still here hopefully we...

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Yeah, we'd better hope we don't have some weird thing pick up on the other side.

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

This is Eric, not guilty, that's not my phone making that noise.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Yeah...

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

This is Gayle Harrell...

Operator

I'm sorry...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

...

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

...

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

It's sending us...call...

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

Well, it's Gayle.

Operator

Is not available. Record your message at the tone. When you are finished hang up or press # for more options.

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

Well, somebody's going to have a fun voicemail.

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

This is Gayle Harrell...

Wes Rishel – Independent Consultant

Let's all tell him what we think of his phone system on the voicemail here 1, 2, 3.

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

So, hopefully our operator has disconnected that line. And so Paul Egerman you're next.

Paul Egerman – Businessman/Software Entrepreneur

Yes, as efficiently as possible, I want to say thank you for a good presentation. My question for Elise, on the review processes it seems that this review process, the suspension and termination is oriented towards vendors. What about self-developed software and open source software will ONC be reviewing that also?

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

We would only review products that are certified by our program.

Paul Egerman – Businessman/Software Entrepreneur

But those are...yeah, but there's self-developed software and open source software can be certified.

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

Yeah, right, so we would...so the ability...so you are correct in that...I guess a better way to say it is that the direct review is of certified health IT. So, if the product has come to us and been certified than ONC would have the ability to do the direct review...

Paul Egerman – Businessman/Software Entrepreneur

So, that means...

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

Whatever the process is.

Paul Egerman – Businessman/Software Entrepreneur

So that means you could review a provider who does self-developed software and if you don't like the review you could terminate that provider's or suspend that provider's ability to do future certifications?

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

Yes. If the product is certified by us we would be able to step in particularly...we're looking very much towards public health and safety and other exigencies but we would be able to step in, take a look at the

certified health IT, also how it might interact with other systems, and then decide a path forward. Corrective action would obviously be our first step.

Paul Eggerman – Businessman/Software Entrepreneur

Thank you.

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

Thanks, Paul. Wes Rishel?

Wes Rishel – Independent Consultant

I have to admit I'm pretty confused. I'm looking at slide eight which has two paths, well it has a path through the middle ONC is alerted, notice of potential corrective action and it has suspension and termination appear above and below.

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

Yes.

Wes Rishel – Independent Consultant

What's the difference between the top track and the bottom track? I mean...

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

Well, it's more the top track shows a suspension track and then the bottom shows a termination track. The suspension you see is broader because we would be able to suspend at any time during the process and that goes back to, you know, particularly...

Wes Rishel – Independent Consultant

All right...

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

You know, for example the public health safety concerns.

Wes Rishel – Independent Consultant

Okay, I got that. So, ATLS, did I get the acronym right, are new laboratories that in many ways are similar to a ATBs is that right? That is that their position in the process is different but the testing they do and the criteria they use for testing are the same is that correct?

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

Maybe the better way to look at it is that the goal...the focus of the ATLS and the ACBs would not change. It's more how we get to having the accredited...the accredited ACB process does not change. What we're doing is we're kind of mapping or aligning the authorized testing lab process to that ACB process.

Wes Rishel – Independent Consultant

I understand...

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

Does that make sense? So, it allows additional oversight of ONC by ONC to be able to make sure that the ATLS are going to operate the way we think that they should.

Wes Rishel – Independent Consultant

Yeah, so a product has been certified and ONC is alerted to a potential nonconformity. Does that mean it's alerted that although the product was certified it doesn't meet the certification criteria or does it meet...or is nonconformity a broader term?

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

So, I think nonconformity could be a number of different things and the other term is potential nonconformity, right?

Wes Rishel – Independent Consultant

Right.

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

So, if someone...

Wes Rishel – Independent Consultant

Yeah.

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

Let's take the complaint for example. Someone just comes directly to ONC and says "look my product is not doing what it's supposed to do and in fact I think there's a safety concern with it." That's a potential nonconformity that ONC can start looking at and determining whether we think that the information we've received is reliable and actionable, and if it is then we would go back to slide eight and we would go through that process to try to learn more about what the potential nonconformity is, whether we think there is in fact a nonconformity and if there is then to institute a corrective action process.

Wes Rishel – Independent Consultant

Yeah, appreciate that and I think it would be great. Is it done by testing or is it done by hearings? I mean, is this a...

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

Oh, the review? Are you talking...

Wes Rishel – Independent Consultant

It's a review?

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

About the review process?

Wes Rishel – Independent Consultant

Yeah.

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

I see what you're saying...

Wes Rishel – Independent Consultant

Yeah.

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

Okay, so we'll test...the provision in the rule on the testing labs is completely different and separate from the direct review...

Wes Rishel – Independent Consultant

Okay.

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

Proposal, so that might be where the confusion...so the direct review process involves a number of things such as talking and working with the developer, it also involves looking at the system itself to figure out what the concerns might be and giving an opportunity for the developers to say "okay, this is why this is that way" or in some cases to appeal as we've noted here. The testing lab provision is completely separate. And I could...I guess I could have done a better job of explaining that when I presented it.

Wes Rishel – Independent Consultant

Okay. Then I just wanted to share some experience that I've had with regard to the issues of transparency. For 15 years I worked for a company that has a pretty well-known methodology where they describe vendors on a 2 x 2 grid and they put dots somewhere in one of the four quadrangles in order to compare vendors and it has been our experience that vendors will do everything up to threatening legal action to get a quarter inch difference in the location of their dot.

And so I think that the ability to display Consumer Reports kinds of comparisons out of mandated government testing is going to be challenged and I would advise, you know, going slowly, starting easy and trying to ramp up over a period of years as opposed to, for example, making recordings of the testing available because of the tremendous backlash from the marketing side of the vendor houses. Thanks.

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

This is Michelle, so we have four questions left and three minutes so as quick as possible, please. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, hi, thank you very much Elise. I would just ask that as you look at the model notice of practice...privacy practices that we think beyond the scope of just the use assuming the EHR or even assuming the covered entity, or a BAA relationship, but the future use of APIs where people will be attaching their App to that, an opportunity to have the standardized model for public privacy for that specific use case could be quite important and useful as we go forward in our API Task Force.

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

Yeah, absolutely. I think that's definitely something we're considering as well. We're really looking forward to receiving comments on that point as well and the API, you know, impact and considerations, so, yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks, Elise.

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

Chris Lehmann?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Thank you, Michelle, I have a really quick question. First of all I think it's a laudable initiative but I was left puzzled wondering what will happen to the private office pediatrician who has an EHR product installed that now is either terminated or suspended?

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

So, I think...there is a piece in the rule and this is where, you know, there's limited parts we can go beyond the rule, but we do note in the rule that we have decertified in the past, at the time it was through the ACB, and when that happened, you know, we did work with our counterparts at HHS for example and they released an FAQ related to what happens if you're in the EHR Incentive Program for example and your product is decertified.

Again, I think, you know, there is obviously the possibility that this could happen. Our goal however is really to work with the developer to go through the corrective action process to address the problem and make sure that this product can still be used. That is our first step and that's really where we would love to end up whenever we have to do these types of reviews.

At the same time, if there is a public health and safety concern we do have to think about that in terms of a product remaining in our program where there is a safety concern at play.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Thank you and I assume you also use patient safety organizations as input, right?

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

What do you mean “as input” in terms of how we would find out about a problem?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Correct.

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

Okay, so, I think it...issues could come to us or potential nonconformities can come to us through any different...through a number of different mechanisms. However, they come to us though we would definitely look at whether it is reliable and actionable. We’re not placing any limitations on how that information gets to us.

Now, there could be limitations from external groups about what they share with us and that would be beyond our scope. We’re just looking at what comes into us and then what we do with that information.

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

Rich Elmore?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, first of all, great presentation. I think the focus on consumer certainty about what it is they’re buying and patient safety are super important and appreciate your taking the lead on addressing those issues.

One thing that I just wanted to ask about is that most of the health IT developers treat patient safety concerns extremely seriously. They have rapid response plans, they have, you know, corrective action processes, all kinds of capabilities to ensure that those are escalated and resolved extremely quickly and effectively, and I want to make sure that, you know, whatever regulatory process we’re putting in place is not slowing down the ability for us to be able to address patient safety issues as a broad group of stakeholders.

And one other, I guess question is, it appears as though there is overlapping investigation potential between ACBs and ONC both investigating maybe some gray jurisdiction about FDA’s role as it relates to patient safety. I mean, it sounds like there could be a lot of hands in this maybe and I was wondering if you could clarify how this is going to work?

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

Right, so, okay, so I have to stick pretty close to what’s in the rule but one thing we did note in the rule is that while it’s possible for the ACBs and ONC...for ACBs to have their review occur and for ONC to have a direct review happen, those could happen independently of each other, they could be...our review could be in addition to what happens with the ACB, but we would consider whether we exert exclusive review in circumstances to make sure that we’re avoiding inconsistencies.

So, it’s definitely something we’ve thought about but would definitely encourage, you know, public comment if there’s additional considerations we should think about there.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

And is the review on, you know, appropriate jurisdiction vis-à-vis FDA as relates to patient safety and ONC, just how is that being thought about?

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

So, our review focuses on the product and whether the product can still be considered certified that's where our focus would be. You know we always tend to reach out to our counterparts and work with our counterparts. If there are specifics that you're referencing I definitely invite you to comment through the public comment process for specifics.

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

And Gayle Harrell, is Gayle on?

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

Yes, I am, thank you, I just was...

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

Sorry, Gayle, we accused you of a ringing phone that wasn't you I'm sorry.

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

The Model Privacy Notice I am delighted that you're going to be expanding that and I'm hoping it goes to a basic model for EHRs as well as consumer things if you can address that and exactly to make sure that it is very understandable in simple language for individuals to read, but also are you going to do it in Spanish and Creole, and other languages so that it can be picked up by many of our non-English speakers?

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

So, that's a good question. I think that's all part of what we are looking for to hearing back through the RFI is thoughts on how it would be both useful. So, if we are hearing that having it available in different languages is beneficial and, you know, necessary, you know, I think we would definitely consider that.

In terms of use, the goal is for it to be accessible to consumers and I think accessible to me in particular also means how we are phrasing it and making sure that it's phrased in a way that is useful and easy to understand by a broad spectrum of consumers. So, that would be our overall goal.

And in terms of companies that can use it, it would be, you know, openly available as a resource so we would encourage any company to point to our Model Privacy Notice.

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

Thank you. I want to really emphasize the need for it in multiple languages, you know, representing the State of Florida I think that it is extremely important that you have the ability for people to read it in the language they're most comfortable in.

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

Okay.

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

Okay, that was our last question so thank you so much Elise and Steve for your presentation. We have gone over so my apologies to Josh and Meg. We have stolen a bit of your time but if you are ready we can send it over to you.

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

Hi, Michelle, thanks, we'll see if we can get you caught back up. This is Meg Marshall and Josh Mandel is on as well we Co-Chair the API Task Force and we're going to give you a little bit of an update on what our Task Force has been up to, what we're working on and then what you can expect from us in the next couple of months. So, next slide, please.

Here's a list of our Task Force membership, a couple of these are going to be familiar to you, Leslie Kelly Hall in particular on the Standards Committee as well as Josh, we're very grateful and appreciative for this group of folks with lots of experience and certainly knowledge at our table. Next slide, please.

So, a little bit of background around what brought us together. For those of you not familiar APIs are Application Programming Interfaces and refers to a technology that allows one software program to access the services provided by another software program.

And what makes this important today is that we saw its inclusion in the 2015 Edition of the Certified EHR Technology Rule where ONC has included criteria for fully functioning APIs to support patient access via view, download and transmit. So, it's an extension of the VDT requirements.

ONC received a lot of feedback from that rule, from those requirements in CEHRT specifically toward concerns around privacy compliance and the security of APIs. So, this Task Force was created, and little drum roll and switch to the next slide, please, to address very specific questions within our charge. So, there are three.

The first one identify perceived security concerns and real security risks that are barriers to the widespread adoption of open APIs in healthcare and as we go through our work we are very cognizant of the work that is already being planned to be addressed in the interoperability roadmap as well.

So, for example, we did spend some time talking about and considering identity proofing and authentication, however, they are not unique to APIs and are being addressed in other places by ONC and others and guidance in other rulemaking.

The second part of our charge is the same question but specific to privacy. So, identifying perceived privacy concerns and real privacy risks that are barriers to the widespread adoption of open APIs in healthcare.

And then our third charge or a third part of this charge is a little bit of a more broad bucket where we're essentially identifying priority recommendations for ONC that will help enable consumers to leverage API technology to access patient data.

So, those are how we've been framing our discussions, we keep going back to these three components of our charge as we address the work that we're trying to do. Next slide, please.

This is just to provide a little bit of background, the CEHRT rule that we are working with specific to API access, the sections are up here. It does only require read only APIs so we are not extending our discussions to write APIs at this time.

The CEHRT criteria is split into three separate criteria with each one focusing on specific functionality. We have the patient selection, we have data category requests and then an all data request. Next slide, please.

So, to be considered certified for the API criteria three privacy and security criterion must be met and we talk about...so the first one is authentication access control and authorization and we have trusted connection and then we have auditing actions on health information or auditable events and tamper resistance. Next slide, please.

So, the certification rule does include language from ONC that their intention is to encourage dynamic registration and that they strongly believe that this registration should not be used as a means to block information sharing via APIs.

And just a little note about dynamic registration what it means is that applications should not be required to preregister or be approved in advance with the provider or their health IT module developer before being allowed access to the API. And we know that this is supported by the CMS Meaningful Use Stage 3 Final Rule and I have a couple of slides in here to talk through what that looks like, but basically the intent there is providers may not prohibit patients from using any application including third-party Apps which meet the technical specs of the API including the security requirements of the API. Next slide, please.

So, a little bit of framework around the Meaningful Use Stage 3 Final Rule. CMS included two objectives that reference the use of APIs. Objective five, which is the patient electronic access to health information and objective six coordination of care through patient engagement.

Within those objectives there are four basic actions that the patients or the patient's authorized representative should be able to take. So, the VDT which is the view, download or transmit their health information and then this adds in the additional one specific to API which is access their health information through an API.

CMS noted within the rule that they believe these actions are supported by a wide range of system solutions which may overlap in terms of the software function used to do the action or multiple actions. And they also proposed the objective to allow providers to enable API functionality in accordance with the 2015 Edition Proposed Rule.

So, basically what...the intent of sharing that with you is, you know, our scope is somewhat narrow, we're focused on security and privacy issues. We're focused on those issues as they pertain to the 2015 CEHRT criteria for APIs and then that's of course supported by the Meaningful Use Stage 3 requirements for API use. So, if you could please advance to the next slide.

Also to kind of help frame the discussions that we've had we very early out looked to define issues that would be considered out of scope so terms of use, licensing requirements, policy formation, fee structures, certifying authorities, formulation of standards and issues unique to write APIs.

So, we've kind of been exposed to quite a few of these issues throughout our discussions. There is quite a bit of overlap. What we tried to do is not spend a ton of our time chasing these specific issues referring back to them recognizing the areas where we want to call out but just as far as out of scope how we tried to approach it is, again, you know, just not investing a ton of the workgroup time but feeling like we could identify where certain areas within these out of scope issues warranted additional conversation. So, next slide, please.

So, a little bit of what we've done to date, we've had seven Task Force meetings held, we've had two days of virtual hearings that we'll talk about here in a second. We've heard from OCR, they joined us for one our Task Force calls to present on some of the HIPAA specific issues and how we could frame some of that feedback and guidance into what our recommendations will ultimately look like.

And then we just recently this week defined a generic use case and assigned different categories or different parts of it, that use case, within our team to come back and help flesh out a recommendations.

One thing that's worth noting is that we did ask, as a Task Force, to extend our work plan. We added two additional workgroup meetings and I think when we first set out our work today's meeting to you was to present our draft recommendations and we've actually pushed that out a month. So, next month we'll be meeting with you to present our draft recommendations and take questions and then ultimately gearing toward our final then the month after that.

So, today, again, you know, this is to really give you...to inform you of where we are at and to get some early feedback from you and certainly entertain some early questions around what we're doing.

So, at this point, if you could advance to the next slide. I'm going to ask Josh to speak a little bit about the hearings and very quickly go through some of the learnings that we've been able to take from the hearings and how they are scoping our work and then he is going to walk you through our use case as well.

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

Okay, perfect, thanks, Meg and we're doing kind of a tag team thing here. So, let me try to go very quickly through information about our hearings that we've held so far and then share with you the framework that we're using to shape our recommendations and I want to make sure that we leave time for questions. So, very briefly, we had two days of virtual hearings were folks testified across a few major groups. Next slide, please.

So, we had two panels from the consumer technology industry, a panel of consumer advocates, a panel of folks on the healthcare delivery side and then the health IT vendor side and I won't go through all the names on the list here but if we could have the next slide here.

Briefly, I want to highlight some of the testimony that we heard in the group. So, we heard some very important general points about APIs. We heard that APIs provided a well-documented way for organizations to share data and that when it comes to security APIs actually give organizations a place at which they can impose consistent security rules and policies.

We heard that there are a number of technical problems but also technical solutions for working with APIs and that there are many best practices that have emerged through the industry for making data access through APIs work in a secure and controlled fashion.

We heard that there are still business and legal considerations. We talked a little bit about ownership of protected health information. We talked about liability on the provider's side if there is a data breach either through APIs or through other mechanisms by which data are exposed online. If I could have the next slide, please.

We also heard from some very passionate consumer representatives who are consistently asking for more access and more patient control and more engagement. We heard from a panelist who accessed his own healthcare data and created a library of his records from many different sources which in the end actually helped save his own life and he asked "why is it that patients can't have access to more of their own data?"

So, we heard from the consumer representatives that choices should be given to patients and that systems should account for diverse kinds of consumer perspectives. So some people want to personally control every decision and some people just want health information to flow where it needs to go without detailed management.

We heard that transparent data practices were important across the board and that it was important for consumers to understand what was the role of HIPAA in protecting them versus other protections that exist outside of HIPAA. If I could have the next slide, please.

And then we heard from healthcare provider organizations who generally supported the use of open standards-based APIs but had some pretty broad questions about how they knew which Apps they could trust and how did they know which person was actually accessing their systems.

So, there was a strong concern on the organizational side about knowing how identity proofing and verification would work and there were questions about how to know whether a particular application should be trusted. So, a lot of business and legal issues on the healthcare provider organization side. And, you know, a question about the long-term protections that would be in place for varying levels of access to data.

And we heard as a kind of persistent theme on the provider organization that if they were going to expose data to any App that the patient selected they would want to know that there was some recipe or some set of steps that they could follow that would protect them from liability for anything that might happen downstream of sharing the data with an App. If I could have the next slide, please.

So, I want to share with you in this last couple of slides a little bit about the framework for how we're thinking about organizing our recommendations because we touched on many different topics through the hearings and through our discussion and we wanted some kind of a rubric to organize those topics.

So, what we're thinking about doing is organizing them around kind of a use case. And so the use case here just tells a very short story and then we've highlighted many words and phrases in the story and in each of these we can zoom into and identify a set of themes that need to be dealt with in order to make the various pieces of a story actually work. And so the goal is not to say that this story is the only way

that API access can happen, but just to give us a focus for discussion in this Meaningful Use Stage 3 timeframe.

So, very briefly, this is a generic use case where we have an App but we don't say what it is, but we say there is some developer who built an App that could use patient data and the App will support for API-based connections to the data and registers that App with Hospital A or with the EHR vendor system that Hospital A uses.

And then the patient takes a look at the App, they review its data use and privacy policies, and eventually decide to connect that App to her EHR data in Hospital A. To make that happen the patient signs into the Hospital A patient portal and Hospital A shows the patient an approval screen asking if the patient wants to approve access so that the App can see her record and the patient agrees to share her data or some of her data and for some duration of time with the App and if the patient does make that approval then the hospital records that decision in their system for record keeping purposes and then hospital's portal sends the patient back to the App, and the App gets some kind of access token which it can use to access the patient's EHR data in a structured way for as long as the patient said.

And so we can think, at a very high-level, about a few variances on the use case. We said it was just a generic App at the level of our generic use case but maybe this App is a personally controlled health record that's designed to aggregate lots of records in one place provided by, you know, a big company. Maybe it's a much smaller scoped personal health App that just does something specific like tracking lab results or diabetes testing results, or blood pressures.

Maybe it's a patient authored App that a patient or family member has written for very personal purposes and implementing a really unique or one-off kind of workflow because we heard from a number of consumers who want to build their own tools, or maybe it's something else, maybe it's something malicious, maybe it's a rogue application that's been built specifically to steal data or maybe it's an App that used to be good but now it's been hacked and so now it's in the control of people who want to use it to steal data and so those different variances may require different treatments when it comes to these considerations.

So, let me pause there because I know we're running out of time and I want to make sure we have at least 10 minutes for comments and for questions on the charge and the plan for putting together these recommendations.

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

So, Paul Tang?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Yes, hi, thanks. Thanks for that quick overview of the Task Force and your charge. Looking at the use cases on the screen now I think one of the key things that is highlighted says, the patient reviews App data use and privacy policies, as you know typically that means there's something that scrolls off the screen and you're requested before you go any further to click "I agree." Are you going to specifically look at that action and potentially we heard from ONC about the Model Privacy Notices, could there be some baked in, it's voluntary, but baked in code of conduct that an App developer can subscribe to and

then of course be held accountable to? So, I worry about the...how do you do something that's more than "I agree?"

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

Yes, absolutely and so just from the perspective of the kinds of recommendations we could make we want to understand the pieces that already exist in terms of making these things easy. There has been a lot of great work on Model Privacy Notices and I'm glad to hear that there will be more work and there's also been parallel work in the research space on consenting practices in the team at Sage and Apple ResearchKit has put together some excellent usability guidelines for providing a high-level summary with points that research participants can understand and then the ability to drill into the legalese language for people who want to. And so I think we can recommend some best practices and we'll want to work with the community on that.

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

Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Yes, thank you for a great presentation of a very important topic. I have a lot of questions as it relates to the privacy aspects to this process. To pick up on what Paul Tang just said, you know, you look at the use case that you have up on the screen and my guess is that most users do not read the fine print but the fine print is set up in such a way that if something goes wrong the provider can say to the patient "well it's your fault because you didn't really read that stuff carefully."

And to think about the way these APIs work is a developer, an App developer, has the ability to access and retain PHI and they retain it sort of outside of HIPAA. As I understand it, in the environment they are not included in any of the HIPAA privacy concepts and as a result there is very limited capability for either ONC or OCR to in any way audit what they're doing. They can be selling identifiable data and there's...it's very hard unless you go through the FTC to do anything with them.

And so my observation is, while your approach does not include policy recommendations it would seem to me that one recommendation that would be very important would be to say any developer or any entity that is accessing, you know, PHI through one of these APIs should somehow automatically become either covered by HIPAA or automatically become some sort of a Business Associate so there is some ability to regulate and monitor what goes on with that data.

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

All right, well, thank you for those comments. Certainly where the protections come from and which kinds of Apps are covered by HIPAA and which by FTC, and which none of the above is an important issue that we'll be highlighting when it comes to who is liable for what could go wrong downstream.

Paul Egerman – Businessman/Software Entrepreneur

But it seems to me a patient's perspective on this could be that I as a patient trust my physician to take care of my data. So, regardless of what the fine print says, I might be very unhappy with my physician if somehow the physician allows data to migrate to some untrustworthy source.

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

Yes, so it's true, but also as a patient I might be very unhappy with my physician if they prevent me from

sharing data with the App that I choose and so that's sort of the balance that we need to strike and I absolutely agree with your point that we need to make considerations on both sides and ultimately address a patient's right to access in a coherent way.

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

And Paul, this is Meg, so the one thing that I would add is OCR has been fantastic and they spent a good hour with the Task Force answering these types of questions, you know, when is an App developer covered by a BAA of the provider and when would they not, so we've been getting some fantastic guidance from, again, OCR and ONC. So, hopefully, we'll hit the right spot with the recommendations.

Paul Egerman – Businessman/Software Entrepreneur

Thank you.

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

Kathy Blake?

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

Thanks, Michelle, I'd like to go back to just a couple of points that were mentioned and one being the very long small print, small font approvals that we all unfortunately sign too quickly. And so a little down in the weeds saying that there should be sort of a series of sequential, shall we say, checkboxes that include also the hold harmless types of clauses that a provider would expect if somebody is bringing in a new App to their...to access their electronic health data.

And secondly, looking very closely at what the options would be in terms of indemnification so that if an App developer does have a breach unfortunately what then happens is that everybody that has anything to do with that record gets sued. And so although you might be legally well protected as a provider I think what everybody worries about is that there could be just mounting numbers of cases and legal cases that, yes, in five years you could prevail and you could win, but you've meanwhile spent an enormous amount of time, energy and monetary resources to defend yourself.

So, I think having language that really assigns responsibility and has the individual accept responsibility, has the App developer accept responsibility and to limit the ability to sue when it's the other party that has created or caused the breach.

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

John Scott?

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

Yeah, this is John Scott from DoD, I'm a Pediatric Cardiologist myself and I think any pediatric subspecialist will recognize what I'm going to say is, patients are frustrated all the time about not being able to have access to the information and share it who have to move between healthcare systems and we've got to, as people have said, balance the great need for these kinds of tools with the need to protect people's privacy.

I wondered if it would make sense for there to be some sort of ONC seal of approval for Apps or for PHRs and then patients would be encouraged to use something that had such a seal of approval but not prevented from using whatever they felt was helpful. Does that make sense?

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

Yeah, it does sense, thank you for the comment and it's something that we're certainly thinking about for our recommendations. The general framework was quite similar to what you just said except we're not imagining that ONC would be supplier of these seals of approval or certifications, or endorsements. We're imagining that lots of outside organizations including some of the professional societies, including companies that actually know how to do security audits and others, various kinds of organizations...

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

I think we at the DoD and the VA would have an App library of what's approved and we would have DoD or VA approved PHR...

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

Yeah.

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

And we'd encourage those used but we wouldn't prevent patients from doing other things. We just have to be very clear with the consents as people have said.

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

That's right and so we want multiple sources of endorsements and we want to make it clear to patients when they're choosing an App which organizations might have endorsed it but we don't want to use those endorsements as a limitation or to use the lack of an endorsement to prevent a patient from running the App. And so that's exactly the framework that we're thinking about.

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

Rich Elmore?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, first of all this is such an important topic and really great to see the level of participation, engagement and feedback you've already gotten and endorse your work plan for moving forward.

A couple of areas that I'd just like to make sure that you're covering in terms of your scope. One is that in the earlier comments around identity proofing, obviously would apply here, identity and consent are kind of real challenges, you know, is the person requesting the data who they say they are and if it's not the patient do they have the patient's authorization for the information.

There are differences that are allowed or not allowed by various states and jurisdictions and to the extent we can keep it from becoming complicated, you know, that there's a simple method for dealing with some of those questions I think it will really help to make it more feasible and more likely that patients will actually be able to connect their preferred Apps to the health IT systems that they want.

Secondly, I just wanted to ask if you could be looking, in the use cases that are outlined on slide 15, what is the healthcare organization's response or App developer's response that would be needed if the use cases themselves breakdown? I mean, are there hotlines that everybody...you know, so it would be good to have some best practices guidance on how all that is going to work in this new world. Thank you.

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

Yeah, thanks for your comments and just in a quick response to the first comment when it comes to identity proofing it's an area where we agree we need some simple guidance. And we also want to make sure we're focused on areas that are unique to APIs and I think our current outlook here is that identity proofing of the patient is not actually unique to APIs. Anybody who has managed to stand up a patient portal today for view, download and transmit already has some way to do the identity proofing and to authenticate the patient and what we're proposing here is whatever you feel comfortable doing within your portal you should be able to sign patients in that same way when they want to approve an App and we think that portals are actually a good place for that approval process to happen.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, thank you for that clarification and I agree with you that the identity proofing...standardizing identity proofing, kind of what level of assurance, should be in place. I think it is a challenge for ONC, Federal Advisory Committees and HHS to try and work through. I think that if we can get ahead of the need for this, which I think we're right at the cusp of it becoming a much greater prevalence, I think it will really help the overall developer and user community of health IT systems.

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

Okay, that was our last question. I think we might actually end on time.

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

Michelle, just a...sorry, I was trying to get myself in the queue I'm not sure that my push button is working.

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

Oh, you're up higher, so I might have missed you I'm sorry Arien.

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

That's okay. So, rather than...I want to point out, because I'm not sure that this came out already, that OCR has release guidance relating to mobile Apps relative to some of the concerns that have been raised, noting that there is, if you will, a provider side and a patient side of a boundary and that disclosure or other activities that occur on the patient's designated side of that boundary are the patient's concern and don't constitute breach relative to OCR oversight.

To sum up some of this discussion I think there's been some really interesting considerations on the notion that a provider could offer some pre-certified set of applications but that there might need to be some level of disclosure or other to protect from...even though OCR may not exercise oversight relative to breach, protect other legal liability relating to provider obligations to protect patients and clear notification for that.

I do want to ask a question relative to some of the considerations that OCR has raised in areas where provider organizations have a legitimate reason to shut down access. One of the examples that OCR gave was making sure that there's not an obligation for example to put USB thumb drives into devices when that could provide a security risk and particularly, Josh to you, wondering whether the Task Force will consider what level of security proofing is required such that provider organizations...such that this level of security concern is not a legitimate concern from the provider organization's perspective of inadvertently causing breach and disclosure on the provider organization side?

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

Yeah, so thanks, Arien, and it's something we certainly will be thinking about. I think the general framework is that providers should only be limiting access to a particular App if it actually threatens the provider's system itself.

And when we think that in general a well-engineered system hosting an API it's going to be on the Internet anyway, which means that a malicious hacker can try to reach it even if they're not an approved App and so then the question becomes, well what does approval actually get them that a malicious attacker otherwise wouldn't have.

So, yes, we will be grappling with those questions and we're going to try to narrow them down as much as we can.

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

Great and I assume you're also going to be grappling with the question of fair notice and liability relating to non-approved Apps and I think the reasonable desire of healthcare organizations to limit that liability.

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

Yes, I could describe a framework where non-approved Apps can play in the ecosystem but where there's very clear warnings that everybody understands and everybody understands the implications.

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

Thank you.

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

Thank you to Josh and Meg we appreciate you trying to get us caught up. We're a little bit over so we're going to go and open up to public comment and while we do that if any of the Chairs want to make any closing remarks while we open up. So, first, Lonnie, can you please open the lines?

Public Comment

Lonnie Moore – Meetings Coordinator – Altarum Institute

If you are listening via your computer speakers you may dial 1-877-705-6006 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time. Thank you.

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

So, while we wait for people to make a comment Lisa, Kathy, Paul or Arien any comments from you?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

This is Paul, I just want to thank the presenters. These are really highly important and highly engaging topics we've been talking about. APIs has been a dream but it's wonderful to see this Task Force go down and look at some of the details and say "how do we make this dream happen but also happen safely."

Precision medicine is also another dream from the President's point-of-view that really has a huge application to populations in improving health. And, again, it goes down to and then how do we make that happen at some of the detail...at least the detailed policy levers, so thank you so much everyone.

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

Yeah, this is Arien, my only comment is that it's very clear that we are in a post Meaningful Use era for the Policy and the Standards Committee and that the agenda here really plays that out.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

And that's not...

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

And this is...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

To ignore the ONC updates, sorry.

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

And this is Kathy, just to say that I think that meetings such as this one today really speak to the value of having the joint meetings from time-to-time because of the significant areas of synergy and shared interest. So, thank you for setting this up.

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. There was a message left in the chat we're going to share that with the committee members via e-mail if that's okay because of the time. So, again, thank you to all of our presenters, thank you to everyone for your patience as we went through today's call and enjoy the rest of your day.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you, Michelle for everything.

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

Thank you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Bye-bye.

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

Bye-bye.

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

Thank you, bye.

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

Bye, everyone.

M

Thanks, Michelle.

Public Comment Received During the Meeting

1. David Kotz: The exposome encompasses the totality of human environmental (i.e. non-genetic) exposures from conception onwards, complementing the genome. It was first proposed by Dr. Christopher Wild, a cancer epidemiologist, in a 2005 article entitled "Complementing the Genome with an "Exposome": The Outstanding Challenge of Environmental Exposure Measurement in Molecular Epidemiology". [Wikipedia]
2. Dr. Jude Haney: Jude Haney , William Carey University, great presentation. This is the point the I was interested in. A lot of rural areas simply cannot afford the highly certified EMR systems and are working with systems that may or may not be up to date on certs. More oversight will directly impact their bottom line. If the larger EMR firms don't work something out there may be an issue in quality of care.
3. Dr. Jude Haney: Also, yes patient portals in other languages is crucial.
4. Thompson Boyd 2: Expanding on Paul Egerman's comment: What is the provider liability if patient has a bad outcome using a new App? For instance, the patient later finds that the API developer sells the patient's information to a third party? In addition, what if the patient finds that their information is an "'surprise" location?
5. Thompson Boyd 2: There should also be guidance (education) for the patient , regarding their handling of their personal information (e.g. best practices).

Joint Committee Meeting Attendance		
Name	03/10/16	01/20/16
Alicia Staley		
Andrew M. Wiesenthal	X	X
Angela Kennedy		X
Anjum Khurshid	X	X
Anne Castro	X	X

Anne LeMaistre	X	X
Arien Malec	X	X
Aury Nagy		
Brent Snyder		
Brian Burns	X	
Charles H. Romine	X	
Chesley Richards		
Christoph U. Lehmann	X	X
Christopher Ross		X
Dale Nordenberg	X	
David Lansky	X	X
David F. Kotz	X	X
Devin M. Mann		
Donna Cryer	X	X
Elizabeth Johnson	X	X
Eric Rose		X
Floyd Eisenberg	X	X
Gayle B. Harrell	X	
James Ferguson		
Jitin Asnaani	X	X
John Halamka		X
John Scott	X	X
John F. Derr	X	
Jon White	X	X
Josh C. Mandel	X	X
Karen Desalvo		X
Kathleen Blake	X	X
Kevin B. Johnson	X	
Kim Nolen	X	
Kim Schofield	X	X
Leslie Kelly Hall	X	X
Lisa Gallagher	X	X
Lorraine Doo	X	X
Nancy J. Orvis	X	X
Neal Patterson		
Patricia P. Sengstack	X	X
Paul Egerman	X	X
Paul Tang	X	X
Richard Elmore	X	X
Scott Gottlieb	X	X
Steve H. Brown		
Troy Seagondollar	X	X
Wes Rishel	X	X