



Collaboration of the Health IT Policy and Standards Committees

*Final Transcript
October 5, 2016*

Presentation

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

Good morning everyone, if you could take your seats we're about to get started, that was super-fast, thank you. Operator can you please open the lines?

Operator

Certainly, one moment, 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 the Health IT Standards Committee. This is a public meeting and there will be time for public comment before lunch and at the end of the meeting. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded.

To take roll we're just going to go around the room and then we'll catch the people on the phone. So, to start we'll start with Jennifer Brown.

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

Jennifer Brown, ONC.

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

Nancy Orvis, DoD.

Jonathan Nebeker, MD, MS – Deputy CMIO – US Department of Veterans Affairs

Jonathan Nebeker, VHA.

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

Floyd Eisenberg, iParsimony.

Larry Wolf, MS – Principal – Strategic Health Network

Larry Wolf, Strategic Health Network.

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

Andy Wiesenthal, Deloitte Consulting.

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

David Kotz, Dartmouth College.

Wanmei Ou, PhD – Director, Precision Medicine and Data Science – Merck

Wanmei Ou from Merck.

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

Karen van Caulil, Florida Health Care Coalition.

Kyle Meadors – President – Chart Luz Consulting

Kyle Meadors, Chart Luz Consulting.

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

Carolyn Petersen, Mayo Clinic.

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

Angela Kennedy, Louisiana Tech.

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

Aaron Miri, Imprivata.

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

Raj Dash, Duke University.

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

Kay Eron, Intel.

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

Steve Posnack, ONC.

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

Arien Malec, RelayHealth.

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

Elise Sweeney Anthony, ONC.

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

Kathleen Blake, American Medical Association.

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

Paul Tang, IBM Watson Health.

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

Anjum Khurshid, Louisiana Public Health Institute.

Devin M. Mann, MD, MS – School of Medicine – New York University

Devin Mann, NYU.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Leslie Kelly Hall, Healthwise and the Informed Medical Decision Making Foundation.

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

Kim Schofield, Lupus Foundation.

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

Anne LeMaistre, Ascension.

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

Brent Snyder, Adventist Health System.

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

Patty Sengstack, Bon Secours Health System.

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

Terry O’Malley, Partners Healthcare System.

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

John Scott, DoD.

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

Josh Mandel, Early Life Sciences.

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

Eric Rose, Intelligent Medical Objects.

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

I can’t see is that the last person down there?

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

Yes.

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

Thank you. And on the phone do we have Lisa Gallagher?

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

Here.

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

Hi, Lisa. Rich Elmore?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Here.

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

Hi, Rich. Kevin Johnson?

Kevin B. 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

Peter Johnson?

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

Here.

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

Hi, Peter. Donna Cryer?

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

Here.

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

Hi, Donna. Jamie Ferguson?

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

Good morning.

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

Hi, Jamie. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Here.

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

Hi, Paul. 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. Lorraine Doo?

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

Yes, I'm here.

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

Hi, Lorraine. Steve Brown?

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

I'm here.

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

Hi, Steve and Chesley Richards?

Chesley Richards, MD, MPH, FACP – Director, Office of Public Health Scientific Services – Centers for Disease Control and Prevention

I'm here.

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

All right.

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

Excuse me did you hear Kevin...did you hear Kevin Johnson?

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

I'm sorry?

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

Did you get Kevin Johnson?

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

I did, thank you, Kevin.

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

Thank you.

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

And this is Dale Nordenberg.

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

Hi, Dale.

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

Hi.

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

All right, well, thank you very much everyone. Now I'm going to turn it over to Kathy to make some opening remarks or to review the agenda and to approve the minutes from the last meeting.

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

Thank you, Michelle and thank you to all of our members those in person as well as those who are attending remotely. I think that the introductions show what a diverse group the two committees draw from in terms of organizations, talents and expertise.

Today's agenda is a full one, I think it's a reflection of the very substantial amount of work that's been performed by ONC over the last several months, some of this we got a taste of in the last week at Health IT 2.0, but we'll do a deep dive into the EHR Contract Guide and I think top of mind for everyone is we'll get an update on what ONC is doing with respect to the Zika challenge.

We'll then be moving onto remarks from Dr. Washington, our National Coordinator; he is at another meeting this morning and so will be joining us in a little while.

Then in the afternoon, after our break for lunch, we'll be hearing from the Joint Committee's Consumer Task Force and hearing their review of the Model Privacy Notice and we're looking forward to that as well.

To finish up the afternoon we'll hear about information sharing and analysis organizations and updates on that and then finishing the day a report from Steve Posnack about the Office of Standards and Technology and the work that they are doing.

So, without further ado I'd like to ask the committees for a motion to approve the minutes of our meeting from September 13th. Do I have a motion? And a second? And we'll go by voice vote and see if there are any objections on the phone, but voice vote for approval of the minutes as presented to us?

Multiple

Aye.

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

Any no's? And any abstentions? And on the telephone? I'll take silence as concurrence so the minutes will be adopted and I'll next turn things over to Arien to introduce us to our first subject topic.

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

There was one note on the minutes that we're going to change, the wrong person was noted, so Raj let us know, so we'll make that correction but other than that, I'm sorry.

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

So, minutes as corrected and I'll assume no one objects to that being done. Thanks, Michelle. So, we'll next hear from Lauren Richie about the Health IT Playbook overview and this will be a discussion led by Arien.

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

Go ahead.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Good morning and thank you for having me. I'm Lauren Richie the Division Director for Learning Engagement in our Office of Programs at ONC. Do we have a...

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

Can we get the slides to track?

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

So, I'm really excited to talk to you a little bit about the Health IT Playbook which was released just last week. So, before I go into the demo I just want to provide a bit of context on the Playbook and then we'll go directly to the site.

So, the Health IT Playbook is intended to provide technical and workflow assistance to include tools and resources that providers and practices can leverage when implementing and optimizing health IT.

The Playbook is an online, dynamic and interactive source; it is a provider-facing website that includes a suite of tools and resources with the facts, features on this slide as well as the tools. The Playbook is hosted on healthit.gov. We also include other federal resources particularly those within HHS. The Playbook was released in two phases the first of which was back in June at our ONC annual meeting and that was the Patient Engagement Playbook and the second phase just released last week.

The Playbook is open to the public to any and all who are interested, however, the primary targeted audience is that of care teams and small and medium ambulatory practices, particularly those in community health centers, HPSAs and other underserved areas.

We also want to make sure we're targeting providers who have not adopted or are not using certified health IT. And in addition to primary care providers we also want to make sure that we're targeting specialists, physician assistants, nurses, LTPAC and rural providers.

One of the objectives of the Playbook is to make sure that we maintain an evolving framework of tools and resources so making sure that the content is constantly refreshed and revised and appropriate. We want to make sure that we're identifying and sharing leading practices and success stories across various phases of health IT implementation and to help to resolve or address some key issues and challenges that we know providers are facing in the field today as it relates to health IT adoption and optimization.

The resources and tools within the Playbook were originally developed from our Regional Extension Center Program. Those materials were revised and refreshed for the recently released Playbook. The tools are also inclusive of a variety of types so we have templates, videos, infographics, how-to guides, etcetera, we want to keep in line with the dynamic, interactive feature of the site so we do have links to

supplemental information in addition to those tools. So, we want to make sure that the information at their fingertips is actionable with links to supplemental information if they want to review those as well.

We conducted a suite of tools and resources across all of ONC to identify the best of the best, if you will, to help us determine what's appropriate for the Playbook and timely as well as relevant.

The Playbook is organized into the topics that you see here not necessarily in linear fashion but they do have some prioritized order and we'll get into the topic areas a little bit more when we go into the live demo.

Just a note about the design and the features of the Playbook, we employed a human centered-design approach to make sure that we had simple navigation and it's easy to use. We also wanted to make sure that the Playbook was mobile friendly so you can review all the content on a tablet or smart phone. It's searchable, the content and the tools are also printable. And again, most importantly the information is actionable, easy to decipher and of course outcome based.

So, just to reiterate, this is the first release of the Playbook so we are welcoming any and all feedback. If there are recommendations to additional tools and resources we'd like to hear about those as well as the content and the topic areas. The URL to the Playbook is here so help us spread the word and get the Playbook in the hands of those providers that could benefit from it the most.

So, with that I am going to transition over to the live site. Okay, great, so here's the landing page for the Playbook. I'm just going to talk really briefly about the design and then we'll go into some of the topic areas.

Here featured prominently is the search bar so as I mentioned you are able to search particular terms that will result content that's within the Playbook as well as on healthit.gov. In the upper left-hand corner is our link to our healthit.gov homepage. In the upper right-hand corner are social media links and the ability to print the Playbook in its entirety.

Also featured prominently is the introduction here and the ability to click on the arrow to see additional topic areas that I mentioned previously. Since most of the users will...this will be their first time, hopefully, the intent is to navigate to the introduction. And here on the left-hand navigation menu you'll see the same topics that were also on the landing page of the Playbook.

So, included in the introduction is a bit about the Playbook, its intended audience and some of the key questions that the Playbook will address. As I mentioned, the topic areas previously are also here on the left-hand navigation.

I'll demonstrate a little bit about the functionality of the site and then I'll go into a particular tool. So, for example, in the first topic area is electronic health records and in the sub-headers we have EHR contract guide, planning and selection, adoption and implementation, optimization and workflow and EHR replacement and data migration. All of the topics have similar subtopics underneath just click on the arrow to see what those subtopics are.

Going back to the EHR section I'm just going to click on the EHR contract guide and I won't talk too much about this. I don't want to steal my colleagues thunder, they are going to do a deep dive into that later today, but just to show you how the tool is produced in the Playbook, so you would click on the EHR contract guide. Also, for all the tools there is a brief overview, who it's for, and when it's used. This is designed to kind of give the end-user a sense of what the tool is about before they dive into it.

And here what we call an inline view of the tool, so they have the ability to scroll within the document right here on the page or if they wish they can download the document and save or print as well.

I'm just going to navigate briefly to the patient engagement topic area because I did mention the Patient Engagement Playbook so that's the first sub-header here so a brief summary about the Playbook and you just click on the link to the Patient Engagement Playbook and it takes you to what was released back in June. So, as you can see it mirrors very closely the design of the broader more comprehensive Health IT Playbook and includes these four chapters on patient engagement.

So, going back to the broader Health IT Playbook just want to mention here the value-based care section which is really meant to educate and inform on the proposed MACRA legislation. The intent is to come back to this section after the final rule is released to update with more actionable oriented tools.

I just will mention briefly in our privacy and security section we do have the inclusion under HIPAA privacy of one of a handful of videos that we have in the Playbook, so they just have the ability to play the video here and they also have the link to other videos on our home page at healthit.gov.

Under quality and patient safety for example, under patient safety we have another video for our SAFER guides, just press play and they also have the ability to download the full guide.

In another recently released tool is our transformation support where we have here a practice transformation support for clinicians and this is via our health IT dashboard and this is a listing of federally funded technical assistance resources by state. So, the end-user just selects their state and a listing of available TA resources are populated for that state.

While I'm here I'll mention two other features, at the end of every topic area we have a "share your feedback" button. This is where we're hoping to get a lot of feedback in terms of the content as well as the tools. So, they just simply put in their name, e-mail and a comment and these will come directly to ONC.

Also within each chapter you have the ability to print that chapter. So, you can print out by topic area. So, if you just wanted to print for example everything under privacy and security you would just click the print button there and all of the content on the page will produce.

I also want to mention a bit about the feedback that went into the Playbook so from early conception right up until the release of the Playbook we employed feedback from a number of professional societies including the AMA, the ACP, the AASP and a number of other professional societies. We also engaged consumers and providers through focus groups to get early input and feedback and we also have an internal federal subcommittee for the Playbook that also provided input as well.

So, I know there are a number of topics that I could easily dive into and spend a bit more time about any particular topic or tool but at this time I will pause to see if there are any questions.

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

Great and I'm going to tee up the questions, I first wanted to comment, I had an opportunity when it was first released to browse through the Playbook. There is, I think as you've seen in the demo, a tremendous amount of content that ONC has put together and curated its high-quality. I'm sure that there are areas where folks would want to improve or comment and you just heard Lauren talk about the process to do that, but I want to commend ONC for putting a tremendous amount of hard work and

effort into making a resource that is just a pretty fabulous introduction to the topics of health information technology that can be quite complicated.

The glossary alone is worth the price of entry. So, if you just start someplace look at the glossary and look for example even at the first entry on ACOs and you'll find a really nice primer to the landscape of health information technology.

As another example, again it's the one that Lauren picked out, but the Patient Engagement Playbook isn't just an intro to sort of generic topics on patient engagement but walks you through the kinds of decisions that are the most impactful based on best evidence in terms of enrolling patients, getting patient adoption and utilization on the patient portals and the like.

So, it's not a throwaway content site and it's not a marketing, you know, kind of glossy foot sheet guide that you can look at once and kind of discard it's a very practical set of resources and I'd encourage folks on the committees to get our teams to look at this content and use it as, you know, we all have folks who are newly hired into health information technology use it as an intro tool because I think it's not just a good set of content for example smaller practices who are overwhelmed by health information technology it's a great introduction for folks who are new to this industry. So, with that we're going to open it up for questions and I think we're just going to go all the way from the end on the left with Eric.

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

Thank you, thanks for the presentation. One real quick technical item and then a question. There seemed to be some broken links on the Playbook all of the links that seemed to reference specific chapters give a 404 error so that might...the ones that begin with /hit- then an integer, so that would be something to look into.

I think that a lot of practicing clinicians when they see the great information that's in the Playbook the next question they have is "how do I do this with my specific vendor supplied EHR system" and I'm wondering are you planning anything to help address that sort of last mile issue because without the ability to know exactly how to do it...without just directing them to their vendor, which may often actually not be the best way to find out how to effectively achieve a particular goal with that application, is there any plan for a Wiki or a forum, or letting, you know, individual vendors provide some implementation information or anything to help people figure out actually how to do this stuff?

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Sure, thank you for the question. So, as I mentioned, this is the first release and one of the things that we're hoping to get via the feedback mechanism is just that very thing to help us for the next iteration of the Playbook in terms of what are the next steps that we can take.

In working with some of the professional societies early on through the development of the Playbook there was a premise, if you will, to work with us after the release to not only provide additional content, but to also help us take the Playbook to the next step as best we can.

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

Great, we're going to let Dr. Washington jump in line.

B. Vindell Washington, MD, MHCM, FACEP – National Coordinator – Office of the National Coordinator for Health Information Technology

Thanks, I just want to add one comment to that. I think part of it is strategically we have to decide what role do you want from the federal government in that space when it comes to specific vendors. Do you want us to run for example a Wiki or use this form for individual products, or is it better to sort of leave some of that last mile for folks to work with their individual vendors. I'd be interested in feedback from this group on where we should actually land.

I think we landed in a place that we thought was safe in terms of outlining key points whether it was the engagement portion or the deployment portion but came up relatively short on purpose on whether or not we were going to go and talk about vendor X and how to deploy X tool or what specific actions thinking that there would be some of that piece, but I'd be very interested in thoughts about where we should actually end up.

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

All right, Josh?

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

So, first off let me just say this is a tremendous resource I'm just looking at it for the first time this morning and there is really a comprehensive set of links and digestible information here. I'm wondering if we could hear a little bit about the plan for keeping this up-to-date.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Yes, thank you, very good question. So, right now we're looking at a tentative next release of the Playbook in early 2017 but ongoing having perhaps maybe quarterly refreshers or updates, or really just depending on whenever there is a particular need. For, example, once the final rule is produced perhaps maybe that will be another time to refresh or update the Playbook.

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

Okay, Patty?

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

Thank you, hi, so I'm Patty Sengstack from the Bon Secours Health System. So, as an organization that's really just gone through a big campaign to get our patients and particularly our medical groups to sign on to their...you know, get their patients to sign onto their portals and as a member of the Consumer Task Force I've been kind of involved in this and one of the things that we thought as we looked at this, and experience in the front lines of this, is that it needs to provide kind of a journey or, you know, what do I do first, you know, it sort of assumes that the providers have the resources and that's kind of what Eric was saying. It seems that the providers have the resources to just go ahead and click, turn the switch on OpenNotes for example or turn on scheduling and they have the skills and expertise to do that.

But perhaps something that lays out kind of what's the easiest thing to introduce first, is it results, you know, and is the next thing e-mailing, is the next thing scheduling, is the next thing OpenNotes, then is the next thing patient generated data. I don't know the answer to that, but I think it would be helpful if we help guide, you know, try this first, second, third, it might be helpful.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Thank you for the feedback that is one of the things we took into consideration in terms of the topics in the Playbook. Just in the order that's presented here, you know, what goes first and it's hard to say, you know, what's more important than the other, but we'll certainly take that into consideration.

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

Good work, thanks.

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

All right. Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you for the presentation, also the great work there are a lot of people involved giving comments all across the board and the group did a good job at taking that comment in and incorporating so thank you very much for that.

Along the lines of Patty's comment, as we move into the open API and have the ability to attach Apps to the EHR for the patient that's a very complex thing and I hope that we have enough time, budget and thoughtfulness of process prepared to be able to respond and add that to this Playbook because the Playbook is very concrete, easy-to-read, easy to understand and I think the two areas, well many areas you've already mentioned, MACRA you've already mentioned the Model Privacy Notice, but as we do the open API I think that will be an area of great interest in health.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Yes, we do have an API section in the Playbook but hopefully we'll be able to flesh that out further in the future.

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

All right. Karen?

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

Thank you Lauren for all of your hard work on this and I echo, you know, the comments about it being a great resource. I assume that all of us on the committee will encourage our various constituents to review and comment on the various sections but I'm curious what has been the dissemination plan? How are you pushing out this resource to all the interested parties?

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Great question, so we have a number of strategies. Just last Friday, we held a public webinar. We also have our internal ListServ where we disseminate through various other HHS and federal partners. We also have the Health IT Federal Committee and a subcommittee for the Playbook as well as working with our just ongoing stakeholder outreach engagement efforts and I know that's part of what Dr. Wright and Dr. Mason do at ONC as they're out in the field helping us spread the word as well.

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

If I could just ask a follow-up question. On the webinar that you had last week was that recorded in something that we can access and push out?

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

That particular webinar was not recorded, however, we are planning to do another kind of a guidance, a voiceover guided intro, if you will, to the tools, to the site.

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

All right, thank you.

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

Backtracking to Anjum.

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

Thank you.

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

Sorry about that, your card was flipped so I could see it only straight on.

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

Right and thank you for the work that you have done. My question was related to patient consent. I was looking at the HIE section and then also patient engagement section and I was trying to find places where patient consent and how do you integrate it with the workflow and what are some of the concerns that providers have in setting up HIEs, I think that's one of the major starting points and there are still states where opt in is the default so is there an area in the Playbook where patient consent is mentioned in detail that I probably did not find?

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

In our Patient Engagement Playbook, I'd have to go through this in detail, but if that's something that we don't have in particular to patient consent we can certainly revisit that.

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

Yeah, at least in the HIE section there should be a reference to wherever that is because it's an important part of understanding the HIE setup.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Okay, thank you.

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

Paul?

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

I just want to echo everybody's one, thanks and kudos. I think this is really well done. It's a great example of something done for the public good as well. I mean, it would have been nicer earlier, but it's just something...especially the world is getting more complex and everybody is mentioning our regulations are more complex.

I'll refer to this MACRA legislation where it would be wonderful to have even a Playbook even for the IT side of it let alone for the broader MACRA because it's really important legislation, it's really important regulation and people want to do the right thing they just need a little bit of guidance instead of everybody trying to hire a consultant, so I just think this is a fabulous effort and just the attention you pay to the details. You have everything from the infographic that helps people communicate ideas to the easy read text and you have the video, you just have something for everyone. You've made it accessible and I think that's really, really...I just want to commend that kind of effort and thoughts of doing that.

I'd echo Anjum's prioritization of the things where people get...that are hard like patient consent and just the privacy and confidentiality that everybody...nobody is immune in terms of needing more and more guidance on those so prioritizing those kinds of things are really helpful.

And the last mile question Vindell asked, we did have this prior experiment with RECs and I know it came out of a different situation, right, the stimulus bill, but at least what I heard in terms of results those folks really, one, benefited from it and people who took advantage of it versus didn't there was a clear difference and I wonder if again, because the world has gotten so complex, we actually need more of that to raise the tide for all of the community, all of the country because we all benefit when the whole country comes up.

So, just to answer...I mean, some of this last mile stuff they obviously had some vendor specific...they helped people with vendor specific questions and issues and we do have some results, right. So, I think there's just value and even if you look for health information HIE what we heard of course when we were into that with those hearings is a lot of the organizations had to reach out and literally do for the other organizations, their clinical training partners, in order to do the exchange. So in a sense it sort of...I guess I'm...it's raising the ante to a public good and that's of course where the federal government plays a role. But at any rate, so terrific work and there is so much benefit that could happen not only to the individuals that are being touched but really the country at large especially for HIE. Thanks.

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

Just to tag onto Paul's comments, I know that CMS has made money available for example education support under MACRA and it would be useful for some of that to end up in some MACRA MIPS advanced AP and specific content for the Playbook. We're going to go to Andy, Floyd, Donna. Leslie are you up for a re...we'll go to the phone first and then we'll go back to Leslie.

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

So, at the risk of jumping straight to solutions I was interested in responding to the question you asked Vindell. I wonder if it wouldn't be possible to create a kind of extension space in the electronic document where vendors could add their own material and commentary so that, you know, they don't get to edit any of this but they get to say "well, here if you want to use our product to accomplish this, this is what we would recommend" that way they still have their own communities for comment and for Wiki, you know, and exchange of ideas and so on, but using this as a tool if the government doesn't mind allowing them to adopt it I think it might be very effective.

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

Floyd?

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

So, just to echo everyone's kudos, I think it's easily readable. I love the glossary as well and I will refer people here for definitions of things for a long time.

Moving to a little bit of Eric's comment, as I look through, there are areas for instance in the Million Hearts Program for what you can do to help implement and make this work in your setting with decision support, etcetera and I think that's really helpful.

What I don't see throughout and may be helpful is how can I get involved if I'm a consumer and I'm looking at this how can I get involved to work with what is going on today. I think it would be helpful depending on where I navigate through.

And one kind of nit question, I see Blue Button PSA and I can't see PSA defined anywhere. Can you tell me what it means?

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Lana do you want to take one?

Lana Moriarty, MPH – Director for Consumer e-Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Yes, it's a Public Service Announcement, so we created Blue Button...

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

All right so it's Public Service Announcement, I just couldn't identify the acronym and I didn't think it was about prostate specific antigen, so I thought I'd ask.

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

All right. Donna...

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Thank you.

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

And then we're going to go to the phone and then back to Leslie.

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

Very quickly, thank you so much for the report it's exciting to see the other parts of the Playbook that we've been working on in the Consumer Task Force integrated into this larger HIT Playbook.

To the question that was raised earlier about patient consent and to follow-up on the remarks of my very able Consumer Task Force Co-Chair, that there is specific information about to have doctors and patients talk about the issue of consent of sharing and also the Task Force dealt with discussions of giving caregiver proxy sharing and the benefits and methods to do that so that is an area that is addressed in the patient engagement areas of the Playbook.

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

Okay, Michelle, do we have...no? Nobody on the phone? Okay, back to Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would just encourage us to use some of the communication tools and methods we used way long ago with Medicare Part D, we had churches, we had all kinds of organizations catalyzed around communication of change and let's get those activated again to distribute this knowledge more broadly.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Great, thanks for that.

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

All right, thank you Lauren for a great discussion and for all the great work explaining the Playbook.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Thank you.

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

Sorry, Rajesh, I'm sorry, yeah, we have one more question, two more.

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

Thank you, so to feedback on Andy's comment actually I like the concept of being able to continue to grow this resource which is fantastic but in addition to the vendor section I think having access about a specialty society that help contribute to this I think would be very helpful because we have a tendency to operate in our own groups and take leadership cues from others in our own specialty because our workflows are so different. Being a pathologist versus a surgeon, versus and anesthesiologist or radiologist is very different and I think that the excerpts from the different specialty societies that can comment on how this applies to those groups of providers I think would be very helpful. Thank you.

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

Aaron?

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Thank you.

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

Aaron Miri, so first of all echo that it's a good job, great job. As a hospital CIO for a long time this would have been helpful many years ago so thank you for doing this it helps a lot of folks in the field.

From a privacy and security perspective I was looking at this section it's very good and links back to more detailed information. But I was wondering if there's perhaps an opportunity to explore some areas around medical devices and other things that float within the ecosystem at a very high level. Again, you can link back to more detailed information behind the scenes but there's some really good work going on especially as related to the FDA and the FTC and others as they then interact back with HHS on trying to get a handle around some of the nuances there around medical devices so giving hospitals and organizations sort of some guidance there and some bumpers and then of course linking back to some of that detail.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Okay, great, we'll definitely take that into consideration and bring that back to our Office of the Chief Privacy Officer.

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

All right, one more, Kathy? And on the phone, great.

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

I keep thinking of things to suggest in terms of next steps so the list I'm sure is getting to be quite long, but one that comes to mind is we've learned in conversations with CMS that they are also working very hard on developing a tool to assist physicians who are getting ready to participate in the MACRA Quality Payment Program and so I would just urge ONC as you do further iterations of the Playbook that there be really close harmonization of the work and the tools being developed by CMS with what's being developed by ONC because it sounds like really the sum will be more than the parts if there is that kind of coordination. So, thank you again for all of the hard work.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Absolutely.

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

And we have Lorraine Doo on the phone.

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

Hi, thank you, this was...I have a lot of playback so sorry about that. The presentation was wonderful and I wanted to echo the comment about MACRA and someone else had mentioned the MIPS training and education that's going to be going on with providers so thank you for commenting on that.

And interesting, we had just done some focus groups with providers related to the administration of standards talking to them about how we could better help educate and inform them on some of the information because providers, and particularly small providers, are very busy.

And one of the comments that had come up related to reading contracts, which I think was one of the items that you had referred to in this tool, a couple of the small providers had talked about how they just flip through the contract and they go right to their fee schedule because they don't have time to read through all of the information and sadly they had said in particular the HIPAA privacy information that they just didn't have time to look at it.

So, I wonder if this kind of thing, given that it's consolidated and seems like it would be very easy to use even though it may also appear as if it's time-consuming, might be the kind of thing because it's consolidated that it could be the kind of resource that would be very useful for them, so based on the information that we got from the focus groups even though they say that they really need to focus on their patient care, that this might be a really wonderful tool for them.

So, I just wonder if in this last mile if people were talking about the kinds of additional user groups that might be taking place to talk about who and how it will be tested for the kind of resource consumption that it might be taking up and how that will continue on. Like any other new App it's exciting at the beginning and then will it really continue on being that kind of exciting tool and wonder how that's going to be tested? Do you have plans for that or is that part of the next series of tests that will be going on?

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Yes, thank you for the question. I'll definitely let Elise and team address the contract guidance later in the agenda, but as far as additional ongoing user groups, the answer is "yes" we do plan to engage particularly the targeted audience for the Playbook and ongoing focus groups throughout the life of the Playbook so just to make sure we're getting that constant feedback and incorporating that feedback into future iterations.

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

Thanks so much.

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

Let's save that conversation for the contract guide for a couple of minutes, but I did want to touch on the MACRA piece. So, I think in the same way that we have worked with CMS very closely in development of the EHR Incentive Program I just want to encourage people to know that same relationship has continued with MACRA. We've been working very closely with them through the proposed rule and now as they develop final policies and I think that will also come through should the rule be finalized when you see that I hope that that's part of the component.

And also in terms of the rollout materials, in terms of the educational materials that would support providers as they are moving towards the MACRA landscape that's also something that we're working closely with CMS on.

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

That's the ultimate in regulatory obfuscation is providing ambiguity as to whether they're even discussing finalizing the rule. So, anyway, now that we actually are done with the discussion Lauren thank you for teeing us up.

Lauren Richie, MA – Division Director, National Learning Office – Officer of the National Coordinator for Health Information Technology

Sure anytime.

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

And thanks to you and to ONC for a wonderful Playbook and I'll turn it over to Paul the contract discussion was a good segue.

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

Before we do that, sorry, I'm going to come around and grab, if people are interested in ordering lunch, I'm going to come around and do that as we transition, thanks.

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

Thank you and yes it is a good transition into another topic that has been hard for organizations large and small in terms of getting the EHR contracts right and there are provisions in these contracts that can be hidden and just sharing the knowledge and expertise around the country can help us all achieve a better contract.

So, we have a Playbook in a sense for EHR contracting and the other thing, just another kind of public service, public good kind of an effort is to deal with Zika virus. Health has become...has always been it's just becoming more aware that health is a global effort and to the extent that we can track what's going on and act appropriately with timely information would just be good for all of us. So, we are going to hear about both of these activities, thank you.

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

Thank you, Paul. So, we are really excited...usually I'm loud enough, okay, not today, much better, there we go. So, we are really excited about this release. Before we start I want to give a couple of thank yous because this is really a product that took different hands to get to a really substantive piece, so first I have Karson Mahler with me today and he's a Senior Policy Advisor on our team and worked really closely with the contractors that we had develop this. And to that note, I wanted to thank Elisabeth Belmont, Marilyn Lamar and Rob Dearn for their work in developing this. All three of them are lawyers who have been very involved in different phases of the EHR process including developing contracts, implementation and general policy related to EHRs.

So, when we were thinking about developing this tool we wanted it to be something that was truly substantive but also balance that against the need for it to be user-friendly and I think that dovetails with the concept of the Playbook.

So, before we go any further I did want to note, for those on the phone, if you're interested in taking a look at the guide as we talk through this, if you go to healthit.gov/playbook, plug for Lauren, and type in contract guide into the search bar it will come up.

So, with that, so, why the guide? So, first this is actually an update, we did a guide in 2013 that provided some kind of high-level looks at things that purchasers should and could consider as they were developing contracts and negotiating with vendors related to what their EHR would provide.

This guide would be kind of a progression of health IT technology, the diverse uses, as well as some of the problems that we were hearing from stakeholders in terms of concerns that they had. We wanted to make sure that guide addressed the broader landscape and also that we were providing a tool that, again, was very substantive in terms of the information that was in it so you'll see there is a big difference in terms of the page length of this. However, we did divide it into different parts so that we understand that when you're practicing on a daily basis reading through a 50 page document may not be the easiest thing at the end of the day but we wanted to make it so that you can search for the things that are of interest to you and also that you have a high-level understanding of some of the things that you should consider as you step into these negotiations with the vendors.

So, let's see, so a couple of high-level concepts behind the guide, one, the goal was to understand the fine print. I think, you know, everyone here has probably had a story from some type of contract were they didn't feel like they were in a position to really push back. They didn't really feel like they understood the components of the contract and that's not necessarily in the EHR world there are many scenarios where we are all signing agreements whether it's a rental agreement, a lease, a mortgage, whatever it is.

In this genre we wanted to make sure that we were providing enough background and knowledge for purchasers so that they could really feel like they had a voice in the conversation. We've heard a lot about standard form contracts pretty much the contract that is not developed by the provider but put in front of them for them to sign and that's not the end of the conversation in our mind.

We wanted there to be improved communication between the vendor and the purchaser, improved communication between the provider, for example, and their consultants and improved communication even between the practice administrator and the provider, and all of those pieces of the puzzle, all of those individuals and many more are involved in the contracting process when it comes to EHRs. So, we were thinking about a diverse audience when we were developing this. So, actually you can go back one more.

So, a couple of other things to note here, this is not a legal resource so I'm putting my lawyer hat on here. This is not a legal resource. The goal of this is to encourage conversations, it is not legal advice, it is an educational resource that we hope will allow for purchasers and others involved in the contracting sphere to ask the right questions, to engage with the vendor, to be able to better explain the things that they need their technology to do and to have a better understanding of some of the terms that may be used in the contracting world around them. So, that is the goal of this document. We think that it does provide that resource in hopefully a very easy to read way.

So, I wanted to talk a little bit about the different parts. We divided it into two parts, Part A and Part B. And Part A is more of an overview of things that you should be aware of as you step into the contracting process.

We recognize that particularly in the new environment of MACRA for example that there are providers who may be new to this world, may be new to purchasing an EHR and there may be some who are veterans but are considering switching an EHR, which we'll talk about a little bit later, or need their EHR under a new contract to address things that are broader than their initial scope. The contract guide considers all of those things.

So some of the things we say in Part A is to think about the type of model that you're going to be purchasing whether it's a cloud-based model or whether it's more of an installation client/service type model. These are all things that could affect the functionality and what your product covers ultimately.

We also wanted providers and purchasers to think about what potential operational needs might exist and the technical needs as well as what programs they are going to be using. So, if you are a provider who expects to report to the EHR Incentive Program and you have an idea of what objectives and measures you want to meet those are things that you should consider as you're thinking about the contracting process. So, that is kind of the scope of Part A.

Part B is where you get into like the real nitty-gritty as we say, right, so this is where you see things like example contract terms and this we think is really important. While this is not legal advice we wanted to provide a really tangible way for providers and other purchasers to look at the guide and say "hey, this is a framework in which I can consider whether my contract helps me accomplish my goals in my practice" and the example contract terms are a way to do that. It's another way to encourage the conversation with the vendor.

Ultimately presenting the contract guide to the vendor as a conversation tool in terms of "I would like my technology to do X" is a mechanism to encourage the conversation and I think that's also a good segue into the importance, we hope, of this guide to vendors as well.

Again, we want to encourage conversation and a lot of what's reflected in the guide is what we have heard from stakeholders are of concern whether it's switching EHRs, whether its safety concerns,

whether its security concerns. So having vendors understand the landscape of what providers are concerned about also helps to improve the contracting process from both sides.

So, Part B, so in addition to the contract terms it also includes strategies and recommendations for negotiating and I think that's a part that we want to make sure that we are addressing in the guide in terms of the ability of providers to feel like they have a true seat at the table as it were.

So, do you feel like you have the information you need to suggest or request things as part of the contracting process so that when you walk away from that contracting table not only do you have a clear understanding in your mind of what your technology is going to do but that it is written down on paper so that it is understood by also the vendor. So, that's part of how we thought about Part B and making it also capsuled as different sections related to areas that might be of interest.

Let's see, so, all right, I'm going to talk a little bit about the safety and security component and then I'm going to turn it over to Karson. So, there is a section on safety and security in the guide, B2, and one of the things that you'll see as a highlight in this is that we don't treat these two issues of safety and security as something that is only assigned to the provider that the vendor and the provider have a shared responsibility to ensure that the technology is meeting the appropriate needs related to safety and security. So, what does that mean?

So, in the safety aspect it could mean maintenance or upgrades. So, if a problem is identified how long does it take for that to be corrected and is that represented in the contract so that the provider or the purchaser has a certain expectation of when a problem would be addressed and awareness about when the problem actually occurs. So things like that are addressed.

Another aspect that's addressed is training and education. So, that's something that we want purchasers to think about. When you purchase a product getting it into your practice, implementing it amongst your different providers, all of those things are questions that can be answered through the contracting process so that you can work with the vendor to discuss how training will happen, what is the timeframe in which that can happen and what are my expectation of the type of training you would provide. So, those are some of the issues in that component.

In the security component we want the purchaser to think about how is the security of the system assessed. We want them to think about things such as encryptions. As the security of the systems become more and more important as EHRs are deployed in various settings and across various programs as requirements we want security to remain top of mind both from the perspective of the provider as well as the vendor, this is something we cover through a number of different activities at ONC and we try to include some of those questions and some of those things that we've learned along the way as part of the guide.

Encryption methodology I think is important because it's an area that we understand the concept of encryption but we tried to build that out a little bit so that from the purchaser or the provider perspective that they can really understand a little bit about the different types and how they can have a conversation with the vendors in that vein. So, with that I want to turn it over to Karson to talk a little bit about some of the other sections of Part B.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Thanks, Elise and thanks everyone it's good to be here today. So, I think that's probably a good segue and I'm really just going to walk through some of the substantive sections of the guide. And the section

that follows the safety and security section is the section on really how providers can ensure that their systems actually meet their expectations.

So, I think, as Elise mentioned, a lot of this guide is informed by real-world feedback that we've gotten from providers. And often we hear things like, well, you know, when the system was demonstrated to me, you know, as it is, when it was implemented, you know, it no longer met my expectations, it's not doing the types of things that were promised to me or that I expected that it would do and so part of this is trying to sort of bridge that disconnect.

So, you know, making sure that both parties who are entering into these agreements have the same expectations up front but part of it is giving the providers who are purchasing these systems the tools to know how to ensure that this contract ensures that those promises that were made, those representations during the marketing, the demonstration of the product carry through and so the system is going to continue to meet their expectations not just when it's being sold to them but when it's being implemented in the field.

So, in this section we talk about things for example that you can do to help bring about that sort of level of assurance. So, for example, making sure that any promises, representations are expressly made in the contract, a lot of these standard form contracts they don't include, by design in many cases, specific representations about what the performance expectations are going to be.

Also, when thinking about the acceptance of the technology itself, before the contract kicks in, as it were, providers have to accept the technology and there is an opportunity there, and we learned a little bit about this from the DoD's procurement, by building in rigorous requirements into your procurement and into the acceptance phase of the contract you can really make sure that you're receiving a product having testing as part of the initial acceptance of the technology so that before you sort of are responsible for executing your side of the bargain you have the technology, you know, tested, vetted, implemented in your production environment and you feel comfortable that it's going to meet your workflow and meet your needs.

There are a variety of other strategies and specific contract terms in this section around ensuring that the system sort of meets your performance expectations but we won't dive into them just in the interest of time so I just want to sort of highlight a couple of high-level ideas. I think we should move on, can you...okay, Elise is steering here.

So one of the real focus areas of this guide that we spent a lot of time on, a lot of...we give a lot of treatment to are the topics of data rights, interoperability and integration of other technology and other data with healthcare providers, health IT system or EHR systems and obviously this reflects some of the frustrations we've heard around for example, information blocking but it's more than that it's trying to provide a framework, again, back to the idea of sort of the shared responsibility between the vendor and the provider, so that everybody can have a shared expectation as to what the provider is trying to accomplish with the use of the system.

So, we have a variety of strategies and recommendations essentially, best practice contracting recommendations for providers to ensure that they are securing their data rights up front, securing, you know, as between the provider and the vendor, obviously we're not talking about the patient, the provider can't reserve to self-rights under HIPAA that belong to, you know, the patient, but as between the provider and the vendor that the provider is securing those data rights and then giving the vendor the types of rights that the vendor needs to do its job and to be able to provide the services that it

needs to provide. Just approaching the contracting process in that way provides a much more balanced approach that, again, manages expectations and avoids some of the concerns that we hear about a lot.

For example, if it's a contract dispute and a provider's system is locked down, you know, the use of disabling technology, you know, their data is essentially being shut off. Also, you know, a provider is trying to use the data for a particular purpose exporting it maybe use it with an HIE or something of that kind and it turns out that that's not really covered in the contract and wasn't something that was negotiated in advance. So, sort of flipping it around and starting from the premise that the provider owns the data, owns the operational data, owns the clinical data just at a high-level and, you know, again, we have very specific strategies in the guide, but just as a high-level that sort of approach can be incredibly useful for providers and sort of again being more empowered and having more leverage to really negotiate terms that are going to meet their needs.

So, as a continuation of that discussion of data rights we spent a lot of time on this guide talking about really what I think is a critical piece, which is how do you structure your EHR procurement contract to support your interoperability and data integration needs going forward into, you know, a value-based payment system, you know, as you're trying to meet the demands of these new requirements. How do you make sure that the contract that you signed today is going to support your need to continually improve and expand and upgrade and make sure that your system is meeting your needs in the future?

And so, again, drawing on what we've heard from stakeholders, from the legal expertise of, you know, the health IT lawyers who put this together and from some of the lessons again learned from the DoD's acquisition we have sort of developed a framework in this guide and specific terms and strategies that can really help around your interface strategy and your ability to integrate third-party products and services.

And just to give you a little bit of a flavor, you know, the guide recommends/suggests that the contractor define interfaces very broadly any sort of technical means by which the system is going to communicate with another system or product so we're not thinking in sort of the very limited sense of an interface like a point-to-point interface, having a strategy that's broader than that and that's up front in the contract and it's an understanding of both parties that when we're talking about interfacing and connecting different pieces of technology we're talking about sort of an outcome and not, you know, I'm going to build you, you know, an interface and I'll tell you later what it costs.

We have strategies around sort of how to negotiate reasonable expectations up front around what the development of interfaces and the connectivity is going to look like. A suggestion in the guide is that the cost of developing those solutions should be known up front, typically should be linked to the actual costs and not seen as an opportunity sort of to renegotiate the terms of the contract later where the provider is really at that point locked into the technology and doesn't have the ability to sort of be on the same playing field as the vendor.

Relatedly, and I think a critical issue as we think about scaling this technology to new alternative payment models and really just connecting health information across multiple organizations, multiple systems is really the ability of providers to take their EHR system and platform and to integrate other services, other products of the technology and we hear a lot of concerns about this and probably the biggest barrier at the moment, putting aside cost and fees, are really intellectual property issues.

So, it can be difficult for a third-party vendor to come in and provide a service if the EHR vendor is not providing access, subject to reasonable nondisclosure provisions and those sorts of things, to the data dictionary the sorts of things that you would need as a systems integrator or as a, you know, population

health vendor, to be able to get access to the basic data, you know, in a useful format, to be able to sort of take that and translate it into, you know, some value added service.

So, we suggest negotiating reasonable intellectual property protections up front so that there aren't these surprises later when a provider, you know, has installed, they've got their EHR system and now they're trying to participate in an HIE or they're trying to participate in an ACO with, you know, a population health platform and they're finding that they can't do that because of the intellectual property, sort of morass that they might find themselves in.

And again, this is not necessarily a...you know we're not trying to sort of suggest that vendors are doing this, you know, sort of maliciously. A lot of this is just, again, up front having a clear understanding of sort of what the goal of the customer is and, you know, what the obligations of the provider of the technology and the services are and both parties can really benefit from having that clarity up front. So, I think, let's move...oh, you've got to...sorry, can we go back one, yeah.

So, I just really briefly touch on this, again, sort of seeing the intellectual property as kind of a key theme in this guide. There are sort of some traps for the unwary and so some of what we do in this guide is try to provide providers with...we try to flag some issues that they're not necessarily going to be thinking about when they're entering into an agreement for an EHR system or for any other class of health IT system and so this is just as an example, think about the situation where you might have an EHR with clinical decision support and that CDS content has to come from a content vendor and sometimes it might be the EHR vendor but often times their licensing it from someone else. If the EHR vendor at some point doesn't renew its license or has a dispute with the content vendor the provider is actually now in a position where they don't necessarily have the license to use the clinical decision support functionality that they expect to use in their day-to-day care of patients on essentially a pure technicality to do with their contract there is no way a provider would have any clue that this is something that, you know, was in the cards when they were installing the system.

So, we try to flag some of these sorts of issues and how do you, you know, through sort of simple best practice contracting techniques you can avoid those situations, so in this case there is sort of a warranty from the vendor that they have the rights to have the IP rights to provide that content.

We do have a section in the guide on managing risks and liabilities and this ties back in many ways to the shared responsibility to safety and security. You can't have shared responsibility if you don't have shared accountability and really if one party is liable for all of the exposure for a security breach or for a patient safety incident, irrespective of whether another party's negligence led to that injury or that breach then that other party doesn't necessarily have the same incentives to take ownership of mitigating those risks.

So, we recommend a balanced approach. Recognize that common law that each party should be responsible for its own acts and omissions and to the extent that one party is in a better position to control risks that party really should be accountable for those risks. At the moment the playing field is unfortunately very tilted and providers are assuming a lot of liability, a lot of exposure for risks and we feel that is not a balanced scenario so the guide has a number of recommendations in that regard.

And finally, you know, we've sort of covered these two, well, actually, we'll do them separately. So, the guide also discusses dispute resolutions. So, ideally you will not have disputes if you have a well-crafted contract but in reality disagreements arise. It's really important when thinking about the way you're structuring your relationship and your contract with your EHR vendor and other vendors that you have mechanisms in place to mediate and to work through problems so that you're not having to, you know,

go to litigation or to arbitration and so there is not a breakdown in the relationship. So, having really good processes in place to work through issues as they arise is really critical to getting the most value out of these systems and to sort of just getting this whole proposition to work.

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

I would just add on that one, I think the continuity of service component is really important there as well. So, if a dispute does arise, and maybe it's not even at the point of arbitration, maybe it's not at the point of litigation, but wherever the dispute arises what happens to the actual functionality of your EHR during that dispute.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Right.

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

I just want to flag that as well for folks to take a look at because that's an important part of the contracting process.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Yeah and we should probably...and so that links us a little bit back to the data rights section as well and we should probably also mention that the Office for Civil Rights recently put out some guidance on business associates obligations to maintain the availability of the information and not to misuse information that they maintain on behalf of covered entities and this guide actually addresses sort of the issue from a different perspective and so it complements the OCR guidance in a nice way because the OCR guidance talks about your business associate agreement and sort of the vendor's obligation to the BA, business associates, obligations under that and this guide can be used to help you craft a contract that's going to help you protect some of those rights.

So, the final topic that the guide discusses is transition issues and this is a real pain point that we've heard again and again from providers which is they're using Product A, they're trying to upgrade and move to Product B and they can't get their data across, you know, either it's not structured data, the vendor is not able to provide it in a format that's usable that can be consumed by the new system or in many cases the outgoing vendor simply doesn't facilitate a transfer of that data at all which is, you know, hugely problematic when you're relying on a longitudinal record of your patients to deliver appropriate care.

So, the guide really emphasizes contractual mechanisms by which a vendor would agree even in the event that the contract has wound down that the vendor has ongoing obligations to facilitate the timely and smooth transition of the data and the services to a new vendor. And the same principles would apply if a provider were upgrading the system it could be within the same vendor's suite of products upgrading from one system to another and making sure that your expectations as a healthcare provider that your data is going to move with you as you move to new technology. So, I think that's...

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

I think that's it. I think we'll open for questions and we might be able to fill in a little bit more of the blanks with questions.

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

Good, thank you very much to both of you and like with the IT Playbook I think it's very, very helpful. This is a gnarly area and you pointed out, and Karson just covered, the things that you run into after the fact.

So one of the challenges we have, and I've been through this a number of times, is contractors usually postpone, and a lot of times deliberately, to the very last minute and what happens is, you know, you've already decided there's not going back anyway and you get thrown into signing something that's handed to you and most of which you don't understand or certainly don't understand the implications that Karson just went over.

So, I'm wondering if there's a way we can introduce something front-end, you said that, but how do we get the folks who don't know what they don't know to understand what the implications are of signing this document?

The thought was maybe if you...so you have a safety and security which are basically tacked maybe you lead and say "why should I be concerned about it" so maybe the leading question is, what happens if there's a breach, you know, who's at fault, what should I do, lead with those kinds of things and you go "well, I get that, I understand that, I see that in the news" that's why I should pay attention up front.

So, I wonder if there's a set of questions for which the client can have their vendor answer up front, you provide...I'm suggesting you provide those questions so that they can already be thinking about that up front when you're talking about even the selection let alone the contracting and start getting more informed about all of these got you or things that happen, downtime, transition all those sorts of things. That maybe some of these things that you have there their interest could be stimulated by questions that they would understand more than the text that they don't know that they need to know up front.

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

Yeah, I think that's a great point and, you know, part of this guide is making sure people read it.

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

Right.

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

Like it doesn't help if no one actually reads the guide so I think that's a good point and that's something we can explore how to kind of draw people in...

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

Right.

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

To actually take a look at it. In addition to that we are also kind of hopeful in working with a number of different organizations to try to get this guide out as a resource through different means and then also having webinars for example like the one Lauren mentioned where we are discussing and walking through the guide. So, I think that's a great point Paul and that's something we can take back and try to figure out how...

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

The questions that people don't know they need to ask but if you tell it to them right away they'll know.

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

Right.

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

Because otherwise they don't think about this until the very end.

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

That's right.

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

So, a lot of questions again. Kathleen? Kathy?

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

So, I want to focus particularly on the EHR safety and security area and maybe it is a reflection of having just spent more than a year negotiating with a well-respected, very widely adopted vendor for some educational programming that we'll be doing at the AMA that has the potential to touch on PHI. And I can tell you that even a year later it is almost impossible for me to recite line and verse how one can assure, as the purchaser, that the system has the necessary privacy and security controls, and that it continues to maintain all of the necessary controls and that there is a reporting cycle, and I should say an audit cycle, that the vendors perform, there is a reporting cycle, there are issues related to timeliness of reporting to the customers when there are problems that arise, and then as you alluded to you really do get into whose primary responsibility is it.

I would argue that no matter what we might say about one party or the other being responsible in the event of a breach it actually does end up being everybody's responsibility and certainly I think that the people who come and see us as patients would regard...because they have no connection to the vendor directly, they do regard it as the obligation of the practice to which they're going for their care.

So, this is one area where I think it would be very helpful to have step-by-step-by-step what are all the different controls, how often do they need to be renewed, how often do there need to be audits so that literally you can turn around and say "respond please to this checklist so I know what you are or are not able to do." Thanks.

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

Arien, I think we're going to have to sort of move along because of time limitations. I'll go Arien and then we'll go back and forth.

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

Thank you. So, there's a lot of really useful content here and a lot of very deep issues that you get into. I'm struck that in some cases you made a decision to provide very...there's a number of issues that have a range of options and the guide very clearly arrays itself on one portion of the spectrum, takes a very specific stand on issues that are usually problematic like limitation of liability, indemnification, I was really struck by the approach to data use rights where the guide takes a very strong position on ownership rights and takes very strong provisions on very strict limitations of data use.

And I worry that the guidance may not be sensitive to different types of technology and different types of technology usage. I generally don't think that ownership is a useful frame for data use rights in any case but there are many technology models that for example facilitate data sharing to the patient, facilitate data sharing between providers. I would note that the Playbook calls out very specific advice on for example patient engagement that was derived by a cloud-based EHR provider who uses de-identified and aggregate data in order to provide generalized conclusions on which kinds of patient engagement tactics are useful or not useful.

And again, if you take the specific approach that's outlined in the contract guide then that kind of value add is inadmissible. So, you know, maybe it's...first of all it's a question, how did you and why did you decide to make very specific recommendations as opposed to, for example, saying "hey, here's some points in a spectrum, here's some things to worry about at this point, here's some things to worry about at that point" so that's question number one.

And then question number two is with regard to the very specific language on data use rights and data ownership, maybe just a reflection back that there are different technology models where that may or may not make sense and again there are some pros and cons to picking one point on a spectrum. But, you know, overall just a lot of detail here that's extraordinarily useful for people who are seeking a background in contract negotiation.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Yeah, you know, I think we appreciate that comment and I think we're very sensitive to that issue and the guide actually doesn't take a position on whether a provider should or shouldn't grant any particular rights to, you know, other vendors, you know, to the partners that they work with, so hopefully I didn't give that impression in my remarks.

You know the approach that the guide takes is that as a custodian of your patient's health information a provider needs to be sort of fundamentally in charge of and able to control its information that its holding on behalf of the patient and then to be in a position to decide how much access it wants to provide to other partners that it's working with.

I agree, I think, you know, there are a lot of different considerations and we certainly are not advocating, the guide does not advocate a particular approach where you should land, you know, on that decision it's more of just a framework for thinking about it. But it's a really good point and I think it's something that, you know, will continue to think about.

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

I can provide more specific content or comments off-line it's, you know, language like "at a minimum you should, you know, your contract should clearly state that all data is your sole and exclusive property" where that stance runs, in many cases, counter to business models, technology models that seek to facilitate data exchange, seek to facilitate HIPAA appropriate data access where honestly that bit is going to be in two or three, or four different places at the same time in that it's actually reflective of the associated HIPAA rights and HIPAA rights to access. So, I'll do the more detailed comment off-line.

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

Okay.

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

Okay, Josh, please? Josh?

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

Sorry, so, first off, thanks for this guide the scope and the depth is really quite impressive and in particular the notion that this is information that will be relevant for organizations sort of up and down the spectrum from large regional health centers to small rural practices.

My sense is though that it's the larger organizations who will really be able to take advantage of the information in this guide and who really will go into EHR contracting as a negotiation and thinking through all these terms in detail, my guess is that many smaller organizations shop for product that they like and then take the terms as they come perhaps without even understanding them.

I wonder if there's an opportunity to develop some complementary guidance maybe an analogy to what's happened with the Model Privacy Notices where a standard set of terms are laid out and a vendor can say "these are the kinds of things I offer" you know for example "I offer contractual terms that allow providers to take screenshots and publish them for the following reasons" and then providers would be able to, you know, in just an opt in kind of way compare terms directly for vendors who are willing to make those kinds of statements.

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

So, I'll say generally that one of the balances we have is my initial comment about providing a resource as opposed to creating the concept for providers. So, I think there is a balance there.

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

Yes.

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

I do think that the guide is helpful across different spectrums, I do get your point in terms of what some might argue is the kind of buying power, you know, per se of a larger system versus a smaller system, but we do think that the guide allows for that conversation to happen and the more, you know, my opinion, as more of these conversations happen the more that there will be an opportunity for information to move where providers need them to move or the more that vendors understand the needs of the provider.

So, I do get your point whether a provider feels the quick to walk in and say "I don't want the standard form contract" but I think that's exactly what we're saying here is that we want you, hopefully as a provider, to take a look at this guide and feel that the standard form contract is not the end-all to be-all that you can go in and say this is a consideration that I would like to talk about as it relates to my technology and then equally so asking questions about that standard form contract that's another kind of approach to this as well.

If I'm a small rural provider and I receive a standard form contract but I don't understand the terms that are in it or I don't understand what you mean by a particular cost that might be associated with exchange asking those questions at the least allows me to understand before I sign. But we hope that they do have this conversation and that the contract demonstrates the shared wants of both the vendor in providing the product and the provider in using the vendor's product.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

And I might add just two points, you know, I think we do say this is a resource for smaller providers. However, I think it's going to be critical that, I think to your point Elise, the medical societies, you know, that groups takes this and build on it and make it, you know, accessible and make sure that it gets into the hands and is actionable because, again, if you don't read it it's not going to be much good.

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

Yes.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

And the reality is the small provider, you know, is pretty busy and doesn't have a lot of time to read through contracts and, you know, it's challenging.

The other piece that I think is also the transparency point that you brought up and I think ONC has been very clear that we believe there needs to be more transparency in this place and that includes the types of contract terms that companies are implementing and so, I mean, I think we would be supportive of that.

The more information that can be out there and contrasted with the sorts of guidance in this guide and the sorts of educational resources that are out there the better a smaller provider is going to be able to comparison shop and decide does this vendor, you know, is this vendor going to meet my needs, are they, you know, sort of accepting sort of these best practices or are they doing something that doesn't work for me.

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

Okay, so we have to get to a number of questions so let's try to keep both the questions please and the responses brief and we'll continue to go back and forth. So, David Kotz?

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

Point taken Paul.

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

David?

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

Yeah, David Kotz, I'm interested also in the section on safety and security and particularly the phrase I'm hearing which you ensure that providers are not unreasonably prevented from reporting and discussing patient safety, security and other issues and I understand from talking to colleagues that a lot of EHR contracts have gag orders, if you will, that prevent EHR users from talking about some of these issues and that concerns me as a technical person interested in the security of these systems. Is there something that you can do or perhaps have done in the report to push on the vendors to be more open about these issues?

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

So, I think, and I can start and Karson can fill in, I think part of that is communication, right, and I think providers play an important role in that in the contracting process. And to Karson's point about transparency that's part of the equation is when am I able to discuss the product or when am I able to share information about the product and we try to lay out in the guide some situations that providers can consider as part of that.

Unrelated, not unrelated, but another part of transparency in terms of what the contract calls for is something that we have in our 2015 edition where you see a lot of elements of transparency creeping in as well through some of the requirements such as the attestation regarding what the technology you can do and the disclosures that we ask vendors to provide about certain requirements associated with the technology.

So, I think it's a shared conversation and particularly providers play an important role through the contracting process to understand where they can speak or disclose information and what that looks like but Karson...

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Yeah, I think, you know, we share the concern that providers are unable to report problems and share information about safety and security of the systems. The guide provides very...this might be an area, you know, Arien where the guide takes a fairly firm stance and recommends that, you know, you really need to have this addressed in your contract, you shouldn't be agreeing to overly broad restrictions on your ability to participate in patient safety improvement activities, cyber threat sharing activities and we've said, in legislative proposals we've officially put forward that, you know, that we believe there is a need for more action from a public policy stand-point on this issue.

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

Thank you that's helpful. I think the communication has often been very clear and the people I talk to say the contract language prevents them from talking about or sharing information about these issues and that's overly restrictive in my opinion.

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

This goes back to the HIT Safety Center discussion we've had in the past...

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

Yes.

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

And would be wonderful if we could re-raise. But I can neither see the person or the card, second from the...there we go, got it, okay, thank you much.

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

Hi, Terry O'Malley, this is really great I'm never going to sign a contract again, all the things I forgot to think about.

And the idea of Paul's comments on not knowing what you don't know and I'm not sure what the limits of your brief are on this project, but there is a whole set of data just prior to the contract and it really is sort of a helpful list of functionality for example, what should I do as a skilled nursing facility or home health agency or small rural practice, or whatever, what should I be looking for in a system given the fact that the ecosystem of health IT is changing so rapidly and the requirements for me to participate in the new payment mechanisms or quality measures, whatever, is continually evolving.

So, it might be helpful to have, you know, kind of an Amazon-like approach for people who are in your situation that have previously bought this. A list of functionalities that's really helpful for a particular type of provider to which they can add their sort of situation specific requirements but that might be helpful because it might also drive this as a learning site, as a teaching site as best practices come in and this functionality becomes more widely available and recognizes it's importance then you've already tee'd people up to have their contract address it.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Great point, yeah.

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

Great, thank you.

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

I'm going to be quick, excellent document and resource, every hospital board should cheer and make sure that their general counsel and CTO has this immediately and as a patient I wish we could go back in a time machine and deliver it to them several years before.

It seems...I want to underscore the point that was just made; it seems like almost an RFP whether to prepare people for putting together and negotiating a contract would be helpful. I simply want to state because it has been addressed but I wanted to just underscore three issues that I think are of utmost importance.

One, the gag rule being against public policy I think is a very important point and so I wanted to underscore David's comments most emphatically.

Understanding the cost of data exchange up front you addressed so I wanted to thank you but I wanted to have that on the record as one of the top, at least from a patient point-of-view, my top three priorities and perhaps sort of my bias prior to this in the justice department.

And continuity of service, which frankly I think as almost a criminal issue as a patient if service and access to my health information and the hospital is crippled and being able to deliver care to me for whatever the circumstances so I thank you for addressing that.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Thank you.

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

Thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Okay, Wanmei?

Wanmei Ou, PhD – Director, Precision Medicine and Data Science – Merck

Thanks for the hard work and the presentation. So, I have one general comment to the guide. So, one consistency fact that I heard over and over again from the EMR or EHR implementation team of cost to providers is that to implement an EHR is not a single vendor or single contract activity and some of them told me that they actually signed like 50+ contracts. So, an example like Karson you mentioned about the clinical decision support and archiving of datasets or order sets, etcetera, etcetera.

So, I think that it would be very useful to stress this point in the guide that it is that many, many contracts have to work together and so the provider can be open minded, think about that when one vendor's responsibility ends and when the other vendor's responsibility starts to pick up so that they can be just more effectively and holistically to tackle the contract negotiation process. Thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thank you and Brent?

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

First I'd like to say I commend you for the guide you put together. I deal with a lot of contracts and I think you did a good job of outlining many of the key issues and giving some good guidance.

A couple of items, one, a contract I think is focused around contracting for an EHR with the focus on the clinical side, most EHRs also come with a revenue cycle and I would encourage being sure that you address key things on that aspect as well such as, you know, okay, what happens at the end, workout the AR which probably needs to occur around there, does it meet all the billing requirements. And also relative to revenue cycle what's required around expecting PCI certification by that vendor if they're running credit card transactions through it and so forth.

On the security it covered a lot, I think one item is now that there is some certification to security frameworks being provided I think giving representation there that, you know, they should be able to depend on a vendor if they are certified with something like HITRUST or something of that nature that they can depend and that a lot of the security issues should be addressed by that vendor if that certification is not only in place but maintained during the duration of the contract.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Thank you, good points.

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

Kyle Meadors – President – Chart Luz Consulting

Thank you, especially for bringing...talking about third-party and fostering interoperability that was well done and one thing along those lines and something kind of in a different way Terry alluded to, but, because you talked about HIEs, ACOs, patient portals, other systems, maybe an idea for the next iteration would be like an appendices that you can add for those scenarios to kind of go a little deeper because you referenced that but each of those have some of their own nuances and things to think about and so as Paul talked about you don't know what you don't know kind of thing. Well, if you know

you're going to be working with an HIE here are things specifically we'd like to have in this contract and so on. So, just an idea but very well done.

I know from an ACB side of things I would also see complaints that came in that were not...they weren't non-compliances they were just kind of black holes in the contract and they were just kind of stuck with that and so...I don't think initially the vendor did anything wrong either necessarily just no one addressed it and made assumptions. So, bringing this to their attention I think will go a long way. So, thank you all for a good job on this.

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

Thank you.

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

Thank you. Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi, so as we go forward into the open API world although we can see that in the future the patient choosing their vendor of choice and attaching it to the API we think much of the initial implementations will come from Apps that are being endorsed by the provider and what we don't want to see happen is everything become an EMR contract because in fact the Apps that would be attached don't have to apply to HIPAA, there's a whole new area of opportunity so that if an API is connected to that App what does the contract look like for a vendor who is choosing to sell to a provider on behalf of the patient so it's an endorsed App by the provider, although it might be purchased by either the provider or the consumer, connected by the consumer to the API, there's huge confusion about all of this right now and I think it would be helpful to get ahead of that and do some model practices or contracts for that particular area. It would be great to get ahead of that curve so we can encourage adoption.

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

Thank you.

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

Thank you. Carolyn?

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

Hello, thank you, I echo the others comments about this really comprehensive and well-drawn out effort and I think it will be very, very useful for healthcare providers and hospitals, and others going forward. It addresses a lot of the issues that I have been involved in discussions in, in the ethics and public policy committees of AMIA and other groups where people talk about some of the problems they've had so I think it's a really, really excellent start.

In looking through the sections that you've highlighted today I noticed I did not see anything related to intellectual property and data rights with regard to patient generated health data. I know that is talked about quite clearly and nicely in the Patient Engagement Playbook but I didn't see anything noted in this particular Playbook. I really strongly recommend that you look at bringing that information into the next iteration to help providers understand how this might come into play, to understand what rights they should be thinking about and what they can do to protect the patient's rights and also to help make it clear to patients what is involved in what they're doing when they start using things like wearables and

sensors and other ways that they can, either at their own or their provider's request, submit information. Otherwise, I think it's an outstanding effort and thank you.

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

Thank you.

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

Thanks, and Aaron you have the last word.

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

Thanks, very much Paul. Aaron Miri, I just want to say thank you, as a hospital CIO for a long time this is very helpful. I think all of us have been in the room with our counsel at some point when they simply say "we really don't know what the right answer is...accept the risk" so thank you for giving some bumpers I appreciate that.

A couple of items, number one, with reference to the NIST framework, excellent, I think the more we can layer in some sort of standards referenceable guide is very helpful for hospital systems as they start navigating this world in detail.

A couple of items though I didn't see identified, one, any undue cost implications especially around interoperability. You'll often hear from respective vendors that "oh, we can be interoperable with other third-party software but it's going to cost you" or "we can only do it via PDF unless you want to pay extra bucks" right, so there's a lot of those bumpers there that I realize this is not a legal document, this is to help you navigate landmines but those are big ones that often come up.

Another one, around M&A there's a lot of consolidation going on right now in the marketplace, I personally have tried to navigate integrating merging two health systems together and EMRs, and records and whatnot and that gets very, very murky very quick. Understanding that up front would be very helpful.

Last but not least, hosted versus on premise EMRs, those are two totally different scenarios for a hospital to have to navigate and understand what those are especially for a hosted model where does that data live, who has it, who has access to it and whatnot that really gets down to a level of granularity for awareness, again, it's not a legal document but it really helps you.

Ultimately, I go back to what Paul said which is we need sort of a Hippocratic oath per se up front that everybody plays by the same rules and does right by the hospital systems, this is not to vilify the vendors but to make sure that everybody plays by the same rules so thank you guys for the work on this.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Yeah, thanks so much. And, you know, again, we've just touched on highlights today but, so a lot of the comments that have been brought up we have addressed in some way in the guide. So, on the cost there's actually, you know, a quite extensive discussion around how you might, in the interoperability context, make sure that ahead of time you're thinking about your interface strategy, your interoperability strategy and agreeing up front with the vendor that, look, you know, if you're going to be developing an interface it's going to be based on the time and labor costs, on your then currently rates for similar services, you know, to other clients, your actual costs, so I just wanted to sort of

mention that, you know, we have tried to address a lot of those issues, obviously haven't been able to dive into them in as much detail as would like today.

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

And...

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

But we appreciate the feedback though.

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

Yeah and I think it's helpful, like Karson said, a number of these pieces are addressed in some way but in terms of how we built out the presentation because we do plan to continue to go out and share this information I think these are good comments so that we can actually build that into the presentation in terms of what is of interest and to Paul's point how to draw people into actually read it further.

So, I thank you for all the comments and I would ask, if possible, if folks can please share this, send it to whomever and everywhere, we want people to read it, we want people to start asking these questions and more importantly having these conversations before the contracting table, so a couple of points that were raised. So, thank you very much I appreciate it, we appreciate it.

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

Well, you can tell by the interest one, outstanding work and two, we really think this is reading material everybody should have access to and read even if you're already under contract, you don't actually know what's coming ahead of you and have a broader community even discuss this and try to problem solve would be worthwhile.

So, it's already in print but maybe as part of the attraction just because you don't want...people don't recognize what you have in here, all of us who have been through this see where you've said this but you need to inform the rest of the folks...

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

Yes.

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

And maybe just probing questions is one of the ways. I also see it's sort of implicit because there's so much baked into here which are actually reactive to things that have already happened and you hear about there's a lot of policy issues that maybe the Policy Committee should look at this and tease out what we haven't done, what we haven't addressed, because it's the public good thing. By definition it's so widespread it has become a public need and a public good.

So, I wonder if there's more we should pay attention to looking at your work as a stimulus I see what's going on here, have we addressed it already and if we haven't...if we have and it's not effective yet we still need to get at it but some of the things we may not have tried to address and yet it's effecting so many people and we're all doing the same work and we're getting involved in the same issues so...

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

That's a great point.

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

Again, expressed by the whole group everybody has one, appreciated yours and the Playbook that came before and want to see it put to good use so thanks so much.

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

Thank you.

Karson Mahler, JD – Policy Analyst, Office of Policy – Office of the National Coordinator for Health Information Technology

Thanks so much.

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

Okay, we are running behind but we're going to continue with the Zika presentation and Vindell's message to delay lunch but we're going to extend lunch a little bit, so we'll try to fit it all in. Part of it is because the work has been so rich and so robust and our interest, based on our experiences, has been so sometimes painful...

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

Actually we're going to make another change.

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

We're going to make another change, okay.

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

We're going to have Vindell go first and then Jim.

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

Okay, great, Vindell you're on.

B. Vindell Washington, MD, MHCM, FACEP – National Coordinator – Office of the National Coordinator for Health Information Technology

Poor Jim now it's between you and lunch now that I've of changed my position. I will make this very brief. I do want to just spend a moment or two and thank people for all the work they've done to support health IT especially coming off of Health IT Week. I think we had a good week and we really just want to recognize the support you've provided for the health IT community.

I just wanted to share just a few thoughts we're particularly happy following the AMA survey last week and sort of even though we know there are still hills to climb and work to be done that 85% number of providers who are enthusiastic and happy about the direction of IT and think that it has a role in improving their quality and safety work that's being done for their patients we think is very good and I'm just enthusiastic and optimistic about that and sort of our digital health future.

I want to underscore again that part of our strategy around the Health IT Playbook and the contract guide was to try to put something in the hands of providers that was empowering and so I would again encourage you to recommend that, help us make it better by continuing to make your comments. It's really this effort to try to level the playing field.

I'll underscore one specific comment about the contract guide both as a former CIO and CMIO to health systems both when we were acquiring practices and just talking with physicians about connecting you'd be surprised at the number of clinicians in the field that don't recognize they're buying an EHR system that's not the same as sort of buying your Microsoft Office Suite where, you know, you get what you get, I mean, sort of just the concept that I should take a list in and have a conversation where there's a negotiation, but even though I may not get all 10 items that they have no clue that the doctor down the street has a different relationship with the same vendor that they're using.

And so I think that what we're just trying to do is to raise the awareness and so both the Playbook, the contract guide and some of our DSR whiteboard work is now available on healthit.gov and if you haven't had a chance I'd just encourage you to take a look and share as we're trying to spread that word. We think we're in a good spot there.

One other thing I want to share is last week I had an opportunity to announce the winners of our HIP and SEA awards, those are our High Impact Pilots and our Standards Exploration Awards, fairly broad in their scope but still aiming at supporting these pilots that are aimed at creating technology and standards-based solutions and so the total award amount was 1.5 million.

Again, what we think we're doing in that space is providing just a little bit of a catalyst, we know that that's not necessarily enough to catalyze the whole marketplace but I was really very encouraged by the number and types of folks who applied and the awardees I think are very impressive in their own right.

And then yesterday, as we were sort of kicking off the National Cybersecurity Awareness Month we did partner with ASPR to offer an award, this cooperative agreement, that was about \$350,000 but that's to strengthen the ability of healthcare and public health institutions to share their information so you can think of it almost as a clearinghouse that would allow folks to submit sort of awful things that have happened in a way that is not just what happens in the press that they might read about and some details that might be sent out broadly across institutions in order for them to address holes in security, etcetera, that they found in their institution, it's a one year sprint that we're hoping to have products delivered from those folks and then perhaps renewing after that for a total of five years but it's really to foster this vibrant cyber information sharing ecosystem so that it's not really lost in a silo or it isn't just a blurb that you read in the newspaper about a horrible thing that happened down the street.

We think really that all of this work that we're pushing toward in this administration is in support of our work around delivery system reform and some of the high-profile projects like Cancer Moonshot and Precision Medicine and we were particularly happy to have President Obama last week in his National Health IT Week message really sort of double down on some of the work and the commitment at least, you know, as we sprint through this administration and I had a quote that I was going to share sort of part of that he said it would help advance...this work would help advance our administration's goal of fostering the seamless and secure flow of electronic health information where and when it's needed most. He did say that there's more work to be done to realize a healthcare system that fits our needs but I think a lot of what we talk about at ONC is in that space, in that direction we're just happy that we have such great support from the President in that effort.

I want to say one last word about both the President and the transition that's coming up, we have been working to make sure that it is a smooth transition as you might expect that we would at least try, myself as a political appointee am particularly interested in that the work here would continue and that there wouldn't be a hiccup and so we have very able folks I'm surrounded by two within elbow's length right now with Elise and Jon, but, you know, we are very happy with the plans as they're coming together we have great faith in Jon and Lisa our sort of Deputies that sort of push this mountain up the hill and we are very happy for that.

And then the last thing I'll say is we really think that it's not that the federal government really could or should, or even would attempt to do this work alone and so I'll go back to my first comment which is that we really thank you for your support and we really rely on your innovation, your input, your insights to help us reach the heights that we need to reach for us to have our best healthcare environment so thank you very much.

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

Thank you, Vindell. All right, Jim, it's all yours, I'm sorry for the delay.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Great, thank you so much, thanks for the opportunity to give you this update on the work that we've been doing to support the Zika virus efforts with health IT. We're just going to do a quick introduction/overview talk about some of the work that's been going on to date and then a little bit about what we're looking towards in the future.

Just as an introduction I do want to really emphasize that this has been a very collaborative effort with the Centers for Disease Control, they have activated the Emergency Operation Center and we are in very close contact with them and I believe Dr. Richards is on the phone from CDC and we would definitely like to thank Dr. Richards for facilitating our interactions with the Zika EOC none of this work would have really been possible without them.

And in addition to putting out the clinical decision support that you'll hear me talk about in a little bit more, they also actually run the US Zika Pregnancy Registry and collecting all the information on the pregnancies with evidence of Zika virus infections as well as the outcomes and just so you have an idea of what's going on right now the latest numbers are around 800 pregnant women in the US with evidence of Zika virus infection and across the US territories we're almost at 1500 and just in the US we've have had 21 birth defects and live births, an additional five in infants who were not born alive.

So, what we're doing currently I think really is building on a lot of the work that we did with Ebola looking back at the things that the health IT developer community found helpful during that and helping build the algorithms that they can understand making sure that our vocabulary sets are standardized and really making sure that we're reaching out to those vendor communities and the health IT developers to make sure that we're answering any questions that they might have that are more specific to the type of work that they're doing.

So, we have ongoing webinars where every time we have updates to the clinical guidance from CDC we present our version of the updated guidance from ONC. We have had additional webinars with them to make sure that we are understanding their needs and really trying to develop some of the things that they're looking for as well.

But, I think really the crux of what we're doing is taking the guidance that comes out of CDC from the Zika EOC what you might see in MMWR and really translating that into something more applicable for health IT developers.

So, if you looked at the MMWR guidance it's great guidance coming out from CDC but it's not really the type of workflow and guidance that our health IT developers are expecting. So, with the help of Dr. Eisenberg we actually take that and then translate it into guidance for health IT developers and what that means is really taking a lot of the information where you might have five or six decision points all in one box in the CDC guidance and really pulling that out and separating that into discrete questions with discrete answers and what the actions are following those answers. So, we take this every time there is updated guidance and create these new algorithms. The health IT developers I think found this very useful during Ebola and they found this very useful during Zika as well.

So, the other part that goes along with this is with each of the processes or actions taken in that there are guidance documents as well as vocabularies that are very important parts of this so we worked closely with the CDC to make sure that we have up-to-date sites with all of the information available for providers and one of the things we heard during Ebola that we're working with CDC here as well is to make sure that these sites don't change so that you can always go to the same site for the most up-to-date information. This has been helpful as well as our health IT developers start to think about how they might implement InfoButton for some of these as well.

We also work with the CDC to make sure that we've got value sets for each of the decision points as well. We want to make sure that everyone is using the same value sets that everyone knows for example the Zika affected areas that we've got the right value sets for those. So we have an entire link, a set of links for value sets that are mostly kept up-to-date on the CDC PHIN VADS or their vocabulary site and just as an example here you can see what you might pull down for current countries at risk for Zika.

We've looked at some other types of guidance that we might be able to offer from ONC based on recommendations from our health IT developers. One of the things that really fits in with our guidance is the order sets that are related to Zika. So, we did a lot of exploration on if there's some guidance that we could put out similar to our health IT version of the clinical guidance around order sets and even though there are few companies that really provide those order sets to most of the health IT developers the local variation and the mapping really I think made it impossible for us to put out sort of a standard order set so it's really the current documentation that we have that allows people to then implement those order sets within their products as either the vendor or the local level.

So, some of the things that we've found moving forward specifically with Zika are really being able to make those clinical decisions support modules more automated. What we know is that we can produce these paper-based versions of the documents that make it easier for health IT developers and large healthcare delivery systems to implement that guidance into their document but it's still really off built at a local level, everyone is still having to take these documents and put this guidance into their own implementation, so that's one of the things that has been a real challenge is with Zika the guidance does change quite frequently there are new transmission routes, new countries that are affected on almost a weekly basis, so that guidance is being constantly updated, so having everyone have to update their guidance every week is a big challenge. So, we're really thinking about ways to potentially automate that.

And another major challenge that we've discovered with Zika especially is the capture of pregnancy status and other data related to the case management of Zika. So, it turns out pregnancy status is a little difficult, current pregnancy status is a little difficult to actually pull from electronic health records and

getting that information to public health has been a challenge as well. So public health would very much like to know at a point that a lab test is ordered what the pregnancy status of that person is because it not only means that they might need to follow that person for outcomes but it also plays a role in how they prioritize the testing of that person as well.

The reagents for Zika testing are very limited in some states right now and they want to make sure that those tests are being given to the right person so knowing the pregnancy status at the time of testing is actually critical. So, we're working very closely with our public health partners and the health IT developers to try to come up with some best practice around how to get that information in a timely fashion to public health and make sure that we have those linkages as well not only to the state and local health departments but to the US Zika Pregnancy Registry which is where all of the information eventually gets to for our surveillance networks.

So, again, you know, the capture of pregnancy status I think is really important that not only are states struggling with the reagents but now more commercial labs are starting to do the test as well and depending on the pregnancy status the health department might want to do the test themselves versus sending it out to a commercial lab. So, all that information is very important from the very first day of the response for an individual.

So, moving into the future one of the things that we've really thought about a lot is as we've done this for Ebola, as we did this for MERS as well, we've realized that we're really doing the same sets of processes over and over and one of the things that we like to do is start building an all hazards approach and one that meets not only infectious disease but other types of public health events as well to make sure that we're thinking about this at a higher level so that we're not starting to scratch every time and that we can start thinking about the standards to make some of this information flow between public health and our health IT developers more automated.

So, thinking about our best practices and what some of the standards might be we actually really kind of started here with the business process and thinking about, from a business process, for the all hazards approach, what is the right type of information that we need to collect? And a lot of it really is that patient profile, the different buckets of the patient profile, the characteristics, the exposure, the symptoms all of those are things that we saw across Ebola, MERS and Zika were things that were important for public health and important for the response at the clinician level as well.

So, trying to come up with a standard way of thinking about that type of information and also what the workflow or the movement of that data might be, there is a trigger where you identify the patients a lot of times that is travel history, with Zika it's also pregnancy status, and what the exposures might be, the symptoms and then what you actually do with those people in the clinical setting as well as how you get that information to the public health department as well.

So, those building blocks for the characteristics and the workflow, you know, we want to make sure that they work across all different potential events and for a given situation the importance of each building block might be a little bit different or the workflow might be in a different order but we still have those building blocks and hopefully the standards that allow for that information to flow seamlessly between our public health partners and clinicians.

So, we've started thinking about actually applying this to our Zika response efforts and how it fits into the all hazards approach and how we can start building something that might work in the future as well.

So, I think you've seen from what we've shown we really start with the intent from CDC, the clinical guidance, that narrative document, the guidance coming out of the EOC and start putting that into semi-structured content with this clarification of the workflow processes, our vocabularies and then really putting that into more of a diagram format where we've got our algorithms with binary decision points where possible, this is still where the vendors and the local organizations have to implement that but now we're moving more into a formalism or structured version of that where we're starting to think about what are the ways that we could do this in a more standardized fashion, what are the standards that could support this like CQL, like CQF on FHIR, CDS Hooks, InfoButton what are the standards that really could support this.

So, these are the things that we're starting to think about so that we can start moving forward and have an infrastructure in place that could help support us to do this in a more automated fashion with Zika and with other infectious diseases and public health responses that come up in the future.

So, we did actually do some work at the HL7 connect-a-thon as well as the Public Health Informatics Conference back in August looking at structured data capture using FHIR to collect some of the information around pregnancy status, looking at CDS Hooks for links to travel history and testing recommendations, as well as CQF for standard terminology and clinical decision support.

So again, we're starting to think about that, a lot of that is very much still in the very early phases but it's where we see our work going forward to, again, support this because having done this for quite a while I think my first day in public health was back when we had West Nile virus so going back to that, you know, it seems like every year there is something so we want to make sure that we're able to support this with our health IT developers in a way that makes it easier for them.

So, I do want to acknowledge the fact that we worked very closely with CDC with Dr. Richards shop at CDC and Sanjeev Tandon there, Floyd Eisenberg who is here with us today luckily to help answer questions has been integral in developing the algorithms for the health IT developers.

We have a whole team here at ONC with Dan Chaput, Rachel Abbey and Michael Baker, and we have great connections again at the Zika Emergency Operations Center with Hilary Wall and Margaret Lampe who have been essential in helping do this, we obviously could not do this work without them as they developed the guidance, they worked very close with us to clarify all of our questions so that we could actually create the documentation that we're able to create.

So, I did not show it on our slide set but at the end of this presentation that is actually out for distribution we do have the full algorithm that's been developed by CDC, by ONC for the health IT developers so that you do have that. So, I'll stop for questions.

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

I just want to thank you Jim this is just a fabulous example of the power of HIT, right, it's really bringing public health to the point of care and vice versa and it's what's required to deal with one health, right, across the globe, it wasn't possible I don't think on paper. So, let me open it up for brief questions. I'll start...is that you Peter? Or who is...Eric, okay...

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

Thank you, fascinating presentation. Did you consider at any point whether...I'm curious whether the electronic directory of services standard or eDOS which is an electronic way for clinical laboratories to provide a list of the tests that they can offer along with the questions that providers might need to

answer when ordering a test, is that potentially a way to address some of the issues you were talking about and if not what are the shortcomings?

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

It is, it definitely is and that is one of the things that we're looking at as one of our potential short-term solutions that we could put into place immediately and that questions actually came up on one of our last webinars so we're very lucky to have Riki Merrick with APHL working with us and so she's actually putting together a best practice document based on eDOS for ask on order entry what the vocabulary standards would be for those questions like pregnancy status.

There are definitely some different options that are available so we're actually going through and cataloging those now, running them by the Zika EOC to make sure we're meeting all of their requirements and we'll have a best practice document for eDOS standards on for ask on order entry.

And then also making sure that we give the guidance back to the public health departments so that they are aware that they might be getting this information as well and are capable of receiving it but that's a great question and that's something that is definitely in the works and will hopefully be one of our next webinars.

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

Thank you.

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

Okay. Floyd?

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

So, I just wanted to add, I think our collaboration with CDC has really been very productive. I actually find what's coming out in MMWR is much closer to what we need in the algorithm with every publication so that does work and our communication with vendors and implementers has actually fed a lot as well because we are providing LOINC codes for the labs but learned that that's not what implementers actually use, maybe for interoperability but not for ordering, so that has been very helpful. Thanks.

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

Thanks, Floyd. Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's very sobering information and great deal of help, thank you and you mentioned the need for the pregnancy registries to have that information what are you doing direct to consumer with so much of our pregnancy testing being done over-the-counter how can patients participate or women participate in registry entries themselves?

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Sure, that's a great question and I think is probably one more for CDC than myself and I don't know if Dr. Richards is on the call. We do provide some guidance for getting information from the EHRs into the pregnancy registry but I think they're really focused on the outreach to consumers there.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's a great example of patient generated health data not only for the registry but also for providers to reach out to their known population of women and ask...

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Get the data back into the EHR and present it back...

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Yeah, that...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And encouragement to continue that cycle would be helpful.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Yeah, that is a great point and some of those questions have definitely come up on our webinars as well and CDC is thinking about the best ways to implement those.

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

That's a great idea. And, oh, Kathy?

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

So, just briefly in thinking ahead and perhaps more optimistically than is currently warranted, but certainly there have been some encouraging reports to suggest that more rapid than usual progress is being made with respect to Zika virus immunization and so I didn't hear anything said about shall we say anticipatory action so that the information being collected here could at some point include information about immunization.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

That's a great point and I was actually at the National Immunization Conference a few weeks ago and we did talk about this and so I put that bug in their ear so that we could all be thinking about that. Luckily, we are very fortunate that immunization information systems across the country are very mature and are moving into a bidirectional world with the standards for 2015 edition certified technology. So I think it will be a real opportunity to make sure that information that is in the immunization information systems can get back to the clinician in a timely manner to help make those decisions.

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

I would just add that it may also be that could be a platform for assessing some of the early clinical experience with immunizations for or really again Zika.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Okay, great, thank you.

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

Larry?

Larry Wolf, MS – Principal – Strategic Health Network

So, actually picking up a little bit on what Kathy was just asking, we've talked a lot over the years about a learning health system and I'm seeing a lot of evidence of sort of learning on the tech side of how to do this better and better coordination with CDC. I wonder though in terms of there's been, at least to the general public, a lot of learning in general about what Zika is, modes of transmission, you know, how it manifests and so it seems like there might be an opportunity here to actually be doing sort of the science, if you will, of an emerging hazard. So, has there been any learnings around that and do you have a sense of how that might be brought forward?

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

So, I think from a technology perspective to address that, I think one of the things that we have looked at are the InfoButton standards and looking at...I mean those are really done for consumers and thinking about how some of that information can get back to the patients and consumers as well.

Larry Wolf, MS – Principal – Strategic Health Network

Yeah, I'm thinking more of the EHR as just like a research tool.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Oh, sure, yeah.

Larry Wolf, MS – Principal – Strategic Health Network

So, it's collecting information...

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Yeah.

Larry Wolf, MS – Principal – Strategic Health Network

We're learning about an emerging threat, emerging hazard...

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Yes.

Larry Wolf, MS – Principal – Strategic Health Network

And so, you know, actually using the systems to better understand what are the aspects of this disease and how does it show up.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

I think we're trying to lay the framework for that to make sure we're all using the same vocabularies...

Larry Wolf, MS – Principal – Strategic Health Network

Probably...

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

So that we can go back and ask those questions but I don't think we've gotten to the point of thinking about what those questions are but we're definitely trying to lay the groundwork so that can happen.

Larry Wolf, MS – Principal – Strategic Health Network

Yeah, it seemed like your slide that talked about the kind of information you want to collect actually begins to look at that broadly that when there's an outbreak of something that there is sort of like the standard epidemiology that gets asked and then could build on that and that becomes an aspect of the EHRs that we actually want to encourage.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Right.

Larry Wolf, MS – Principal – Strategic Health Network

Thanks.

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

So, thanks. Raj?

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

Yeah, no, I very much appreciated the presentation especially your comments about your other experiences for example with West Nile and applying what you've learned and now leveraging healthcare IT to offer Zika and I'm very glad that we're thinking along these lines but I wonder a little bit if the ONC is properly equipped given I think reduction in some of its activities relative to the laboratory IT for LOI for example, now eDOS was mentioned, you know, I think that if there's opportunity to take the lessons learned as you apply health IT or try to apply it for managing the Zika threat to all of the other diseases potentially and all of the other needs across the laboratory space that are not well addressed today, I mean, simple things like having a common order name, having common result names doesn't exist in this country yet. So, you know, machine interoperability through LOINC is kind of an attempt at that but it's a far cry from actually being successful.

So, I let me ask you the question, do you think ONC has what it needs in order to address this threat and apply it to all the other needs that healthcare IT can potentially address following a similar model?

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

So, fortunately we have been very fortunate to have some people detailed to help with the Zika response and it really is not just us at ONC working on this but we have our great partners at CDC who have brought in their health IT team as well to try to help as well. And as I mentioned we do have some people from the laboratory side and we actually have a laboratory technical assistance request through the CDC team to make sure that they are providing those resources to us. So, we are doing definitely the best that we can and people are definitely willing to step in and help whenever possible.

And, you know, to your point about some of the lab interoperability issues those have been some questions that have been raised on our webinars as well and some of the other things that have been requested that we do is actually to help develop a set of order names for Zika tests that are going to be provided by the commercial lab so that's something that we'll be working with Riki Merrick and APHL on as well and again they've been very supportive of this work and through their CDC funding have been able to help out where possible as well so it is not just ONC addressing this.

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

Thank you and finally, Andy.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Great, Andy gets to say what I didn't say.

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

Yeah, I'll be quick; this is actually a plug for something that Jim is...

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

I was aware of.

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

Well aware of.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Yes.

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

There is...

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

I saved this for you.

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

You saved it for me? So, there's an effort being funded by the Robert Wood Johnson Foundation called The Digital Bridge US which is actually trying to address the governance and infrastructure for the routine bidirectional exchange of data between electronic health records and public health setting governance and data standards for all this and actually setting up proof of the concept within the next several months. There's a lot of work that's already gone on and it's not ignoring that it's building on that. If you're interested look at DigitalBridge.us, all one word, for the website and a lot of progress is being made, has been made.

Jim participated in an important meeting between the vendors public health and delivery systems that was held during the summer and so...and Vindell I know has stepped out of the room but he's been

briefed, I'm hoping that there will be more to say about this over the next several months but it's actually, for me personally, quite exciting and if anybody has any questions about it I would be happy to answer them.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Thanks, Dr. Wiesenthal, I would add to that one of the things that we definitely realized in our all hazards approach is building frameworks and technology like that work best when they're put in use in everyday and the types of reporting and the use case reporting that this project is looking at through the Digital Bridge are the every day work between public health and the clinical world so we're definitely aligning those as we move forward because I really do strongly feel that we can't do something in an emergency situation that is not happening on a day-to-day basis as well so that's a real opportunity to put some of this in our daily work as well.

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

Very good, thank you.

Chesley Richards, MD, MPH, FACP – Director, Office of Public Health Scientific Services – Centers for Disease Control and Prevention

This is Chesley Richards...

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

Is it...Floyd?

Chesley Richards, MD, MPH, FACP – Director, Office of Public Health Scientific Services – Centers for Disease Control and Prevention

And I...

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

Who is that?

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

I'm sorry, who is that?

Chesley Richards, MD, MPH, FACP – Director, Office of Public Health Scientific Services – Centers for Disease Control and Prevention

This is Chesley Richards.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

It's Dr. Richards from CDC...

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

Oh, yes, go ahead, thank you.

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

Yes, please?

Chesley Richards, MD, MPH, FACP – Director, Office of Public Health Scientific Services – Centers for Disease Control and Prevention

I want to thank the participation with Jim and I just would second everything he said I think the collaboration has certainly been terrific and...Most of the comments people had are things that are interested in working on, but one thing I would bring us back to is we still are interested in getting pregnancy status in the EHRs and so anything the committee can do to help recommend pathways for being able to do that I think would really be appreciated.

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

Okay. Just real quick, Floyd?

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

And this is just a comment on the standards work. I know there was a slide about the HL7 connect-a-thon what that actually enabled was people from CDS Hooks and the clinical quality framework and structure data capture, and actually some DAF folks all to talk to each other about trying to, from the ground up, not just because it's government-sponsored but, pull those together to see how they work together. So there's actually work going on in that to coordinate and I think that will be really helpful.

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

Great. I want to thank Jim again and for the CDC's work with this and ONC, just a tremendous job and it's gratifying and heartwarming to see the kinds of work that we can now do as a result of the HIT that's been put in place, thanks very much.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology

Thank you.

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

And when we talked...I talked to Elise earlier about the agenda for today and she talked about how much work to share from ONC and this has been extremely impressive what we've heard this morning both the content and just the activities, and we're just happy to hear about it and would like to participate in any way that we could be helpful, thanks very much. And open it up to public comment?

Public Comment

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

Okay, operator can you please open the lines? And if there is anyone in the room who would like to make a public comment if you could please come up to the table. As a reminder, public comment is limited to three minutes.

Jim Wetherill – Technical Specialist – Altarum Institute

If you would like to make a public comment and you are listening through your computer speakers please dial 1-877-705-6006 and press *1 or if you are listening from your telephone you may press *1 at this time to be entered into the queue.

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

Well, there's no one in the room and there's no one on the line so they'll be another opportunity at the end of today's meeting as well though. So, I think we're going to go for a quick lunch. I apologize to everyone, if you ordered food there is a room over here just outside on the other side of the wall where the food has been delivered and we will reconvene at 1:15. So, thank you.

All right, folks, we're going to get started if you could take your seats. All right, well, welcome back from lunch thank you everyone. We're going to get started and so the lines are open so I'm going to turn it over to Kathy to introduce our next agenda item.

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

Great, thank you so much Michelle and we're looking forward to hearing from the combined committees Consumer Task Force and they'll be talking with us in specifics about the Model Privacy Notice update. Joining us are Margeaux Akazawa, Donna Cryer and Patty Sengstack and I'll turn it over to the three of you to present to the committees.

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

Thank you, great, okay, so I'm Patty and this is Donna, this is Margeaux. All right, so I just have up the slide here of the members of our Task Force and if you take a look at it you can see that we have a diverse group representing many sectors of healthcare so whenever we have meetings it's a really great...everybody brings such great perspective to the table.

So, the Consumer Task Force, as Michelle has told me several times, is a different sort of group than some of the other teams I like the word "special" we like to think of ourselves as special...

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

Special teams, that's right.

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

Because we're convened as an on...sort of like an ad hoc or as needed and so we are tasked to come together to provide advice, insight, our thoughts, ideas to ONC on various projects and initiatives from the consumer perspective so that's been our task.

We've been...we've looked at the Blue Button Connector, we have looked at the Patient Engagement Playbook and then most recently we've been asked to look at the Model Privacy Notice. So, I thought, ah, it's after lunch we've all got post prandial fatigue I'm going to tell a little story. So...and it's related don't worry, it's related to this topic.

So, about a year ago I started having some heart palpitations, I could feel them and I thought what in the world is going on here? And as an ex-ICU nurse and someone who trained nurses how to read telemetry I needed to know what was happening to me, inside of me, was it a trial, was it ventricular, was it a first-degree heart block, second-degree, third-degree some of you are probably thinking yeah, yeah, I'd to need to know too.

So, I went and bought this App that has these sensors and you put your two fingers on this App and you can see across your phone, your cell phone, you can actually see your EKG and that gave me peace of mind. Now I'm happy to say that I no longer am having that issue but I sure do wonder what this company is doing with my EKG data as well as all of my friend's EKG readings when we pass it around at parties.

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

Didn't you read your contract?

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

So, just the other day...just the other day I thought, after we've been doing this exercise, I thought, well, gee I'd better go and look I know I probably clicked the button that said "agree to terms" I'd better go look at it after this, so I did, I went and looked at this vendor's privacy notice and it was, I'm not kidding you, 50 screens of scrolling and scrolling, and scrolling and nothing like what ONC is proposing for this Model Privacy Notice, so there's my story.

M

...

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

I think that, yes, I looked at it, yes, they can, it made me a little nervous, it will be interesting. So, the Model Privacy Notice for those who don't know exactly what it is I'll just kind of lay the foundation and the background and Margeaux will help me, it's a voluntary openly available resource and is designed to help developers provide transparent notice to consumers about what happens to their data. And so its approach is to provide a standardized, easy-to-use framework to help developers clearly convey information about privacy and security to their users.

Even I think in one of the ONC documents it talks about that it's an engaging document, and that might be a little stretch, but it's sort of like the analogy that they've given me that makes sense is that nutrition facts label that you see on the can of soup so you know how many calories, how much sodium, how many grams of fiber are all...so it's very similar.

So, in 2011 there was a 2011 version of the Model Privacy Notice in collaboration...that ONC developed in collaboration with the Federal Trade Commission and it focus primarily on personal health records because in 2011 that was really the emerging technology that needed a focus around this. And so this is essentially what it looked like. You can see it's, you know, small, concise, it gives developers a place to sort of insert your name and made it really easy for them to do that.

And so then in 2016 now the ONC realized that, you know, hey there's a lot more devices out there that are collecting clinical data on patients and we probably need to broaden the scope of the Model Privacy Notice so the need for 2016 is to modernize the notice to be more of a useful resource for consumers and developers in a market with more varied products, so, you know, fitness devices, you know, the healthcare Apps there are thousands out there now, all of these are collecting some kind of digital or electronic health information.

So ONC put out a request for information back in March, March 1st, sought comment on what information practices health technology developers should disclose to consumers and what language should be used to describe those practices, you know, is the language that is, you know, in the Model

Privacy Notice appropriate, you know, do consumers really understand it, you know, if you go out and ask your uncle or aunt, your brother, your sister would they be able to understand it?

So, this public comment period closed on April 15th, there were 13 submissions total with really broad stakeholder...I know that doesn't sound like a lot but they represent developer organizations of around 5000 members and provider organizations that represent over 200,000 providers, consumer organizations representing patients, consumers across the country and they're all available online too, you can go to the website there's actually...from the slides, if you have those open you can click and you can actually see all of the different links to PDFs of all the comments that were submitted.

And so in that request for information in the Federal Register they asked to focus comments in these areas and I'm going to...I know that Margeaux can probably explain a little bit better than I can on the questions that were being asked in that request from the public.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Sure, so we did put out that Federal Register notice, and it was very broad, of just really trying to generate sort of what things should we be including in the updated MPN and really ask commenters to provide feedback on these eight areas.

So, the first one is user scope, what types of health technology developers, including non-covered entities and potential HIPAA covered entities, should be using and included in an updated voluntary MPN.

Also information type, what information types should be considered in an out of scope of the MPN?

Information practices, what type of practices involving those information types should be included.

Sharing and storage, so what are the privacy and security concerns that consumers are concerned about when it comes to privacy like the storage and sharing of their data.

Security and encryption, so, you know, what is it to...what should the MPN convey around encryption practices.

Access to other device information, again kind of wanting to update this notice knowing that many mobile health Apps and wearable devices do connect to other device information such as other things in the device such as your camera or your contacts, so what information around that should be disclosed in the MPN.

Also the format, really how should this be presented to consumers?

And then finally, information portability, how should the MPN describe to consumers whether an application enables the consumer to download or transmit their health information?

So, this is kind of this broad sort of request for information and we received those 13 submissions from that broad stakeholder group and we pulled that together with those comments to create a draft content and we have that draft content, I think we shared it out as a Word document as part of this meeting today, and this is the content that we pulled together from the comments and presented to the Consumer Task Force for their review. I don't know if we will be able to bring that up on the slides or not

but if not you can, again, go to I believe it might be in your packets and it also is online with the meeting today.

And we really wanted to, again, while we got comments and submissions from the Federal Register notice that helped us to kind of create this draft content, we really wanted to turn back to the Consumer Task Force for their help because we realized that privacy and security policies are really complex, really hard for consumers to understand and so we really wanted the Consumer Task Force to provide feedback from a consumer perspective to really make sure that this is really speaking to consumers, that it's really clear and simple, and understandable, and that it's also addressing kind of the topline concerns that consumers have when it comes to privacy and security.

I think one thing I would like to just kind of add in as additional background before we jump into what the Consumer Task Force provided in their feedback, is that this is in no way supposed to replace the existing privacy policies this is really those longer policies will still be in place, this is solely to be kind of providing that snapshot, you know, pulling from that privacy policy what are those really topline concerns things that kind of can be summarized in a very clear way so that consumers can really look at that and have a clear, quick view of it and then be able to make more informed decisions about the types of technologies that they are deciding to use based on their own privacy and security concerns and considerations. So, with that I will turn it back over to Donna and Patty.

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

So, we were given homework and, as we are with all of our tasks, so our homework this time was to take the updated proposed version of the MPN and answer the following questions, they asked us, okay take a look at it for us and ask yourself is the language clear and are the terms understandable to consumers?

They even asked us to take it out and ask some of our peers, colleagues, friends, relatives and if not, what suggestions do you have to make the content more consumer-friendly and easier to understand?

So, I'm hoping that you're pulling up that Word document because you too can give us feedback on this.

And what are...a second question, what are consumer's primary concerns with privacy and security of their data when using health Apps or devices and are there any concerns that are missing from this draft notice template, you know, and was anything missed?

How can...I love this question, how can we simplify the notice? Okay.

And then the last question they asked us to give input on, does the draft content provide enough detail on privacy and security terms for consumers to understand, enough detail for them to understand it and if not, what additional details or definitions should be included?

So that was a task we were given this time and so we all sent our homework in and I will turn it over to Donna to go over that.

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

Excellent. Okay, thank you so much and I will be brief and summarize the...I never need a microphone...I will summarize the feedback that the Consumer Task Force made and I do want to underscore the fact that the public comments were quite detailed, extensive, very thoughtful, very informative so the committee did take into consideration the public comment and many or most of the areas that were

provided for recommendations are consistent with those comments and so we focused on areas in answering the questions that were put before us that would add additional value or clarity to what was already provided in the public comment since they were of such great quality.

The other point I would like to mention just in terms of overall feedback is having us all be mindful that the Model Privacy Notice really has a dual audience with that primarily being that of developers so that...and I do hope and I share that I believe I can speak to that, make that thought with the rest of the committee that it will actually change practice having come fresh from Health 2.0 and talking with developers and hearing first-hand from them the value that they do find in OCR and other ONC guidance as they are in the process of building their companies and working with their legal counsel, I do hope that instead of 50 page scrolling documents we will have things that are based more on the Model Privacy Notice as it will be revised based on recommendations.

And then the third point just in terms of overall feedback is that the most important take away that the committee felt was a recommendation that the Model Privacy Notice seek to be in plain language more conversational in tone and that definitions for words not in common use by the average person really was a form of importance and so I will get to that point of language clarity.

I think overall, because we loved the brevity of the document and the simplicity of the structure we focused a lot on the language clarity. Overall impression of the members was that, although of course it's clear to us who live in this space that when we would put it through readability health literacy, literacy tools it's at a very high level and so we gave feedback back to staff again about making the tone as well as the terms and the word choice more conversational.

There were specific words, aggregate, de-identified, even privacy and security that would benefit from perhaps hyperlink definitions where the...so as not to clutter the document but to make those words as if they are carried over into the document and certainly ones like privacy and security must be, but things like aggregate and others, that there are ways to make sure that people who are using the document whether they're developers or end users, providers or consumers would be able to have access to definitions.

So, languages and having the information available in multiple languages and accessible for people with disabilities were some of the other suggestions from the committee based on...to increase language clarity, understandability both for developers frankly and the increasing diverse ecosystem of developers as well as for consumers.

And in terms of the structure of the document recommendations were for several headings.

For privacy and security the main point I wanted to get across from the committee was that they're different we know that and we want to make that clear to the consumer. Several items are...several items are noted and I'll allow you to read that in the fullness of your time, but an area of privacy and security that the committee spent or Task Force spent a lot of time on was what happens when a company is acquired, goes out of business or the user terminates the relationship, so what happens and what is your recourse in those circumstances?

The majority of the time that we spent was in making recommendations for tweaks really because we did think that was a really fantastic start that the ONC staff put together for us to respond to, that really tweaking in the following areas, less often in what's missing but just being thoughtful from a consumer perspective or sort of a reasonable person's perspective using an App of what prompts, just as we were

talking about in the EHR guide, what things or situations you might not have contemplated before, what things you could contemplate.

So even the information used for the App itself within that own company we felt needed to be included not just for what happens when that data may go outside the company and then we added or made suggestions or recommendations for additional types of use and categories that could be added to the pull down menu and we thought the structure of having the basic categories and a pull down menu of options for you to understand the different ways that your data may be used, shared, stored and the like was very useful and we added different categories such as under privacy that it connects to my camera, my photos, geo-located, contacts all of those things making sure people were aware of...and this is of course pertaining to...it would be different depending on the App or PHR that it was connected to but those were the types of level of detail or suggestions that were made by the committee to improve this already really excellent document.

And finally, and I told you I would speed this up, I think the bottom line for the committee was that this Model Privacy Notice would have incredible value not only to the developers but to the consumers, the last consideration that we had was about, you know, how would this be rolled out is it just sort of given to you under the typical scrolling and you click it and you never have...you never think about it again or would it be used in a more modular, granular fashion so a consumer had the opportunity to consider their choices at appropriate places and time or, you know, repeatedly as appropriate with their use with that particular application. Thank you.

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

David?

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

Thank you that was very helpful, I'm encouraged by the production of a Model Privacy Notice or update of this because I share your concerns that the privacy notices, when they exist, are often too long and too complicated to read.

I had a couple of comments and questions and one was about something you mentioned in which this would not necessarily replace the long privacy notice and if that is true then as a consumer how would I know which one actually applies? Do I need to still read and understand the long notice in order to know what is going to happen with my data? Maybe there's some detail in the fine print that's not exposed in the simpler notice.

And the second question I had was one of the last things you mentioned was that the committee discussed this notion of what I think some call progressive consent sort of providing to the user over time notice about what might happen and giving them the opportunity to think again about what would be shared so that they don't have to digest this all at the first moment of installing an App or using a device, so those are two comments and questions.

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

It is actually the recommendation of the committee that this...it is voluntary so, but it is our recommendation, and our hope, as we talk through dissemination strategies and socializing this with not only developers but the developer ecosystem of attorneys, VCs and others that they go to for advice that privacy, policies and notices do more closely resemble this model but it is voluntary.

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

Meaning...

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

I think...

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

Resemble this progressive model is that what you're saying?

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

No, no, I mean, yes, I'm just answering the first question about...

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

Oh, sorry.

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

Would this replace...it's voluntary.

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

Okay.

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

So...

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

Yes.

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

There may be some that still scroll 50 pages, but we hope that they will all evolve to look more like this simpler version.

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

Good.

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

So, to your second question...

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

Can I make a comment on the first one?

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

Yes, absolutely.

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

And I know you...

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

I...

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

I should have done it progressively one at a time.

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

I'm going to progress down the line here.

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

We're going to progress down the line.

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

I believe there was conversation about the short of short and sweet version like the nutrition facts label, but then is there a way the developers could then have links to the more detailed part, you know, how, you know how websites are set up like that.

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

That would help.

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

You know here's the nutshell version but click on this for the details and it will take you down.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Yeah and just to echo that, Patty, and if you can see in the draft that we did share, the draft content that we did share with the Consumer Task Force to review, you know, we do have some...we're wanting to include say a link to the longer privacy policy would still be included for those who want to gain more information and go through that policy, you know, so I think that we want to really...the Model Privacy Notice to really kind of capture that topline for what are the quick snapshots that people want in it but then still provide additional details and granularity for those consumers that want to know more.

And so I think that we really turned to the Consumer Task Force and are taking all of their feedback, really valuable feedback, on sort of how we find that nice line between having a simple, easy to understand notice with also sort of balancing out the granularity that is involved with privacy policies.

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

But it wouldn't be a separate longer more complicated different notice.

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

Okay.

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

It would simply be additional details...

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

Yeah.

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

If you wanted to know them on a very...a much simpler privacy notice.

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

Yeah, I'm not a lawyer but I can imagine as a consumer I'd be concerned that the lawyers would pay attention to the long one but I'm making my decisions based on the short one.

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

Right, no, no, no I think there needs to be one so I'll...

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

Yes.

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

Put a little bit of my lawyer hat on, but also having just talked with developers and talking about what they...how their conversations go with their counsel, so there needs to be one, we hope it looks more like this simpler version, supplemented though with definitions...

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

Right.

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

To add additional nuance or clarity if need be. And to your second question about progressive consent, the vast majority of the committee feels that that's a very helpful technique both for understanding and for truly informed consent.

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

Yeah, I think studies have shown that actually.

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

Yes, yes.

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

I just want to note that Mike Lipinski is on the phone from ONC and I think he has a comment to make as well.

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

Excellent.

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Hi, good afternoon everyone, and I want to thank you especially to the Consumer Task Force for taking on this project and providing feedback under a very tight time schedule so I wanted to start there and just extend my gratitude for that and give you a little more background about the intent of the notice and obviously we're still in the process of, you know, taking stakeholder feedback and considering that in how we form a potential final version of this.

So, the notice itself is...and I think, you know, it was good to hear that folks are thinking that yeah this isn't...it's starting to get to place where people would actually, you know, consumers would actually look at this and that was our goal.

So we're still working and we're taking feedback from other, you know, stakeholders like developers to say like "when would you present this" so that's one key, right, like when...so like say if you download an App would this comes up first and we're hoping that it gets to a point where like it comes up and it has the information that's there that somebody...a consumer would actually take the time to look at because, I mean, personally even I'll say that how many of us actually go through the entire long extended privacy practice privacy agreement before we make a decision whether or not to download that App usually we're downloading the App based on functionality.

So, that's the key here and as you heard from like Margeaux and others there would be links to the more, we'll call them "legal" privacy practices, you know, all the disclaimers and that and the reason why I want to...I jumped in to mention this is because we still have...or is under consideration and I think we have a goal for this to be able to be used even by a covered entity. So they could link to their notice of privacy practices, which are required by HIPAA, but this could still be a way of putting some of that information in front of them in a way that is more understandable plain language as we're hearing from the Task Force.

So, I just wanted to get some of that out that, you know, this process is involving, you know, other stakeholders as well and that the goal isn't to replace, as I think has been said, but, you know, the other privacy practice notices and also to clarify that we are still considering and hoping, I think as our goal, that this could be used by a covered entity as well.

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

Arien?

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

Thank you, great work. The last round of this with regard to PHRs, you know, one of the things that we saw was that it was the active and engaged companies that adopted this and then a bunch of folks who just ignored it.

So the question really is, you know, if we have malicious intent this isn't going to affect malicious intent but if we have good intent how do we get this into the hands both of counsel and usability experts who are developing such Apps who may not have thought about these issues and categorized their privacy policies in this way, you know, how do we get this in the hands of more folks to spur the conversations?

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

I think one of the reasons that this Task Force was purposefully constructed to be very diverse was that one, so that our feedback was reflective of patients and consumers but also could be sort of tested in the confines of the Task Force itself for usability and workflow, and relevance to the ecosystem. So, we often discussed dissemination and a lot of out-of-the-box sort of dissemination strategies and so your point is very well taken.

I think one of the things that...and this is...I'll make this statement outside of the scope of the committee conversation, but just recently through Health IT Week and having some ONC and other staff being a fly on the wall, talking to developers and doing that outreach, one of the "aha" moment's I think I referenced was a way of socializing this with where developers go to receive their legal counsel and information.

I think that there was...what was exposed was sort of a divide between the sort of DC legal culture that feels, you know, very comfortable and knows about us and our work and is able to access it and recommend it to their clients, and sort of more of a Silicon Valley...legal culture that perhaps would benefit from a greater and more targeted outreach so that they see the value and have a greater comfort level with the tools that are being created so some things like that I think would achieve the objectives that you set out.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

And just to...

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

Just...

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Oh, sorry...

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

Yes?

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Just to jump in from the ONC's side is for the...I think Mike on the line, and Mike please jump in as well, kind of hinted to it but I think as part of...as we are updating this content we are also outreaching to various stakeholders from different organizations really trying to make sure that this really, once developed, becomes a useful resource and that it actually is put in the hands of people that actually need to use it.

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

Also, the breadth of the organizations that provided public comment and their expressed willingness to help spread the word about this I think does give potential for quite a broad reach.

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

As a comment, if the major App store stakeholders incorporated this as at least guidance in their App store submission process for health and fitness applications that would go a long way to making sure that it gets into the hands of developers.

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

So...

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

Yeah, I think what...

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

This is Mike, I was just going to say, yes, I think that was Arien, you know, we...if you're familiar with the PHR notice, you know, Healthkit actually points to that currently, Apple Healthkit, and so obviously that's a, you know, a stakeholder that we're interested in hearing from as well as, you know, the App developers that use their store and the associations that represent them like ACT, so we agree with your sentiment that we need to reach out and we have been in that process of reaching out to all, you know, relevant stakeholders.

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

Thank you.

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

Okay, I think the vendors are needing to figure the "what's in it for me" concept and I think, you know, we've started to do that with some of the vendors that we're familiar with and ONC is working on that but I think that that's, you know, I think that's going to help drive it, you know, the what's in it for me, right?

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

Great, thank you, Paul?

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

Thanks for this great work because it's so necessary. I draw a little bit to the contract guide that we talked about and Donna alluded to that, it's the consumer may not know what they do not know and one of the things is whether we need to stimulate the questions in their mind that they haven't thought about. So, as with the...

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

But there's a long list and I wanted to be respectful of the time allotted to us, but there was a long and very specific list that the committee generated and added to the ONC's suggestions that address...that are prompts for a variety of scenarios that may or may not be contemplated by consumer...by the developers and the consumers at the time.

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

Well, it's almost like the contract guide if we could put a short list, not a long one at front and say "hey, have you thought about what happens if they get acquired" or what if they...

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

Right.

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

So, on and so forth...

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

And that's where the headings come in.

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

Okay.

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

So there's a short list of headings and then, you know, I think that's to the ONC to edit, you know, what they like to include, we wanted to provide sort of a blue sky exercise for them to have many options to choose from and to offer as possible examples perhaps in the hyperlinked supplementary area.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Yeah, and I think to that point as well, one of the things the ONC team when thinking about the Model Privacy Notice in addition to it just being really our ideal of a goal of having it as a transparency tool we also kind of see it as playing an additional role as potentially an education tool as well, getting consumers to start thinking about things that they might not have previously thought about when it comes to privacy and security in a very clear way.

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

Yeah, just...so the suggestion for the contractor was to give that to the vendors and say vendors "how do you answer these questions" similarly maybe there could be a voluntary checklist to the App owners and say "how do you answer these questions the consumer would like" and that's a voluntary thing but at least they would have the answers instead of asking the consumer to go have to reach out and there's other...

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

No, that's...it is actually in that format, I wish we could have shown it to you, but that is actually the format it's in.

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

But, I think you're right Paul, I think it is not mainstream yet, you know, we're all used to going into the grocery store and picking up the can and looking at the label, you know, we're all concerned about what's in there but we're not there yet for this, you know, I mean take my example, I just said clicked on it and said "oh, sure, yeah."

I think that, you know, we need to get there and I think it's happening I just think it's happening slowly that we're asking those questions and people are, you know, concerned about what they're doing with

their data because I think that people don't really understand at this point the potential...things that could potentially happen.

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

Just briefly to add to that I would say that also...so you're really talking about this as an iterative process of learning from experience and then being able to update the notice. I think a piece of that will be being able to get a strong sense of at what point does the notice have so much information in it that it loses its usefulness and that consumers once again might start to ignore it, that we don't...we want it to have a lot may be behind the curtain that can be accessed if people want it but not so much that their afraid to even look at or don't have the time to look at what's right in front of them.

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

Agree.

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

Yes, don't make it scary.

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

Yeah. Terrence?

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

Terry O'Malley, thinking of your example Pat of your EKG machine, what might be nice for you to know before you pick that up and put it on just what information specifically that device was collecting so if it was just collecting your EKG recording, you know, no big deal, but maybe it's the date stamp and the time and a geolocation and your IP address, so would it be helpful to have actually a specific list of the data that the App is actually going to record including a box that says other/yes/no so that you'd close it so if there was other stuff that you haven't listed and they click "yes" for collecting other than you can have your drop-down menu so what else, but if they say "no" this is it, this is the list we're collecting your EKG recording and your geolocation and the date and time your just...might be different if that's the limited data set.

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

I know it was an intent of staff to circulate the draft model template so it is...the good news is as much as we're all aspiring to and describing so...the first category in fact is information uses, how we use your information within the company, so understanding just the functionality of the device.

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

No, it's not so much how we use your information it's what information...

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

Right, what is the...

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

Are we collecting.

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

Exactly, what...

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

And then what we do with it.

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

Information is collected.

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

Yeah.

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

So, we agree that just understanding the basic functionality even though you download a device and plan to use it doesn’t mean that you understand what it does or what it’s collecting. So, that should be the first thing, we agree.

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

Are there any questions on the phone? With no questions on the phone I’ll thank our three presenters and turn things over to Arien for the next discussion.

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

Thank you.

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

Excellent, so the issue of cybersecurity in general has been in the air both with respect to healthcare in general and obviously with respect to our broader political conversation. Of course we’ve all learned now to talk about cybersecurity as the “cyber” and, you know, we know that the security aspect of cyber is very, very hard and perhaps not even doable.

But we, in healthcare, hope to actually do something about it and encourage broader adoption of the basics of cybersecurity better adherence to, for example, the HIPAA safeguards on privacy and security, adherence to risk assessment and remediation, and importantly adherence to what we might call as the learning health system of cybersecurity to share threat information and share response information. This is something that’s been proven in general industry and something that we hope to get better adherence to in the healthcare sector. So, with that as an introduction I’ll turn it over to you.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Good afternoon. Thank you everyone for giving us the opportunity to provide a good update on our information sharing and analysis organization initiative at ONC in collaboration with ASPR, the Assistant Secretary for Preparedness and Response Agency, at HHS.

We have some background slides, but before we get started I would like to extend a couple of thank yous, thank you to our FACA members that participated in the evaluation of the applicants Dale Nordenberg and Lisa Gallagher were extremely helpful in participating in the review of our applicants

that took a lot of time and effort and Dale was the chair on that review, it was a very objective review and they provided good recommendations and we moved ahead with their recommendations.

We also want to thank ONC leadership, the former National Coordinator, Dr. DeSalvo, for this initiative and Dr. Vindell Washington for moving it forward, our colleagues at ASPR, Steve Curren, Dr. Lurie as well as members of OCPO staff and ONC leadership in general. From what I understood, I've been at ONC over a year and a half, it's been over three years that this discussion started so a lot went into thinking about engaging information sharing.

So, our overview today will include some of the purpose of the information sharing initiative, the expected outcomes from an ASPR perspective as well as ONC, the current state, Nickol from ASPR will be providing an overview of the planning grant which her office put out some the results and summary of the planning grant. We will wrap up by providing an update of the awardee which was announced yesterday and we'll have some time for Q&A.

So, again, I will be skipping over a lot of the background information that was provided for some more knowledge and just some general information to share in case everyone was not familiar with ONC's mission and vision in this space.

But I would like to reiterate two key guiding principles which is to protect privacy and security in all aspects of interoperability that's ONC's principle number three and with that principle in mind we had to look at the health IT ecosystem and look at what measures can we take, aside from regulation, aside from telling health systems to implement software technology and robust IT infrastructure, we have to figure out a way for them to beef up to enhance their security posture and with information sharing they can do that with minimal technical capability. They have to be engaged, they have to be prepared to share and receive actionable threat information and they have to be willing to learn from all the other stakeholders that are participating in information sharing.

And part of the commitment in ONC's roadmap had to do with coordinating with ASPR on priority issues regarding critical infrastructure, critical cybersecurity infrastructure, and I would like to make a comment on that, it includes not just critical infrastructure but health IT infrastructure in general.

So, the background of health IT information sharing, some of the key drivers have to do with the recent healthcare breaches. We've heard of ransomware how it could essentially shut down a health system really creating a patient safety issue.

We've heard of incidences where patients are turned away from receiving care when an organization is not informed of sort of the attacks that are happening or is not aware. We do know health systems sort of struggle to maintain effective security of staff to have the right tools and techniques to mitigate risk so information sharing would sort of bring that knowledge to the table without heavy investments.

So, another key driver are Executive Orders from President Obama and some of them date back as far as President Clinton in 1998 with the ISAC, Information Sharing and Analysis Council Act, our roadmap is a key driver, the Federal IT Strategic Plan, as well as our 2015 edition certification rule.

In our certification rule we put security provisions, again, the idea is to improve the security posture of our constituents and really for them to be more resilient to cyber threats, we're trying to minimize the threat environment and so whatever we can do at ONC to ensure that information flows, to ensure we can leverage APIs, we can promote the use of Apps, mitigating threats is going to be a big one.

Building trust in the community as well as advancing knowledge and just the ability for people to feel comfortable that they can allow an App that has already been authenticated to all the right mechanisms to collect information will be very important.

And so part of this information sharing will have a ripple effect in terms of bringing security to the forefront of many of the board members at every single organization level. It will be more of a cyber hygiene process. Back in healthcare days we called it handwashing hygiene, so we can make this a cyber hygiene, what a lot of people have called, it would mean the information is always present we know, we think about security, we pay more attention to security and we allow health information exchanges to happen so that our consumers, our patients have the right information where and when they want it and we'll progress into a learning health nation by engaging in those efforts.

So, I want to go over why it's really important for us to share information. We sort of talked about the breaches, we talked about the fact that we really have to build resilience with our healthcare community, health and public health sector, but one thing I would like to mention is this is a joint collaborative effort in HHS we're working with not just ASPR but with the Assistant Secretary for Administration, ASA, the Office of the Chief Information Officer, OCIO, as well as OSSI, the Office of Security and Strategic Information they participated in reviewing this initiative and sort of guiding us as we were drafting the proposal to put forward an Information Sharing Analysis Organization that will be targeted to improve the health and public health sector cyber resilience processes.

And with that I would like to mention the CONOPS, I think Lucia had mentioned the CONOPS, which is the concept of operations that HHS has put forward. We will be working alongside the internal HHS process to disseminate cyber incidents and threats so HHS can respond internally as well as externally and so some of this initiative is well aligned with some of the regulatory and executive orders that Nickol Todd from ASPR will be discussing. With that I'll turn it over to Nickol.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

Thanks, Rose-Marie. And so keeping in line with sort of going over background and identifying the key drivers for this initiative, obviously one of the key drivers is the Cybersecurity Information Sharing Act of 2015 also known as CISA. It outlined new requirements for cyber threat information sharing; it required HHS to establish a healthcare industry Cybersecurity Task Force, ASPR has taken the lead in basically convening and supporting the Task Force under its critical infrastructure mission.

Section 405 of CISA outlines the Task Force duties which also include, and I'll just summarize, recommendations for a cyber threat information dissemination plan for the federal government health and public health sector, stakeholders to share actionable cyber threat indicators and defensive measures.

The Task Force is actually required to submit a report to Congress in the spring of 2017 with their findings and recommendations so that will be coming soon.

As Rose-Marie mentioned there were several executive orders that were put forth that were also drivers for this effort. Executive Order 13636 calls for the federal government to closely coordinate with critical infrastructure owners and operators to improve cyber information sharing to develop a technology neutral cybersecurity network and promote incentivized adoption of strong cybersecurity practices.

Executive Order 13691 calls for the federal government, again, to just closely align their efforts as it relates to critical infrastructure owners operating under cybersecurity information sharing. A lot of the work that continues under this relates to the formulation of the ISAOs, Information Sharing and Analysis

Organizations, and how they are to be the focal points for collaborating with the private sector and the federal government engagement.

So, I wanted to also just provide some clarification in terms of the difference between the ISACs and the ISAOs. So we put together this table, I'm not going to go through everything but I did want to highlight just kind of where the key differences are.

So, all ISACs are considered ISAOs but not vice versa and so something to take note of. Also, the ISACs usually are aligned with one or more of the 16 critical infrastructure sector but ISAOs don't necessarily have to be aligned in that way. They have a broader sort of reach and they can cross sectors, they can, you know, sort of work within a geography or type of threat so it's a lot broader and diverse in terms of their reach.

And then also just wanted to highlight the fact that under the National Cybersecurity and Communications Integration Center, the NCCIC, the ISAOs can enter into agreements and increase collaboration between the ISAO and the federal government through the NCCIC and we'll talk a little bit more about that later as well. And so I'll turn it back over to Rose-Marie.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Thanks, Nickol. So, the purpose of the award is to expand the capacity of an existing ISAO or ISAC to share cyber threat information bidirectionally between HHS and the HPH sector and to provide outreach and education and it's not really just to share cyber threat information ISAOs do a little bit more than that as well as ISACs if they're serving the role of an ISAO, you're sharing best practices, you're sharing information and you're building resilience. What happens technically is you're essentially augmenting the IT capabilities of organizations. They have the benefit of learning from experiences of other stakeholders and bringing that knowledge to the table.

The other thing that works extremely well is I watch investigation discovery quite a bit and without knowing what should exist in the neighborhood, without knowing what to look for you get bombarded by a lot of information. So, ONC our core purpose was really to provide education and outreach. If you don't know what you don't know that's okay but, again, we need to provide that information so it's actionable, it's measurable, it's timely and that would really help mitigate some of the risks we're having in healthcare since we still have a long way to go in the sectors to improve our security.

Another goal was to improve cybersecurity awareness similar to what I mentioned handwashing hygiene, I used to serve as an HR Director in health systems and one thing we had to do was promote handwashing hygiene as a way to reduce hospital infections. In this case we're talking cyber hygiene ensuring we think about security on the day-to-day basis to reduce the harm and to minimize the impact that a cyber threat will have to our system and environment. It could be a very, very...it could be an operational burden, it could shut down your system and again it's a concern that a lot of organizations their CEOs, CFOs, CIOs they have a lot of concerns over that. So, that's sort of the purpose of the award.

I won't read through this but it was for \$350,000, it's a cooperative agreement and the number is set out on the screen, it was awarded 9/26 and more to come. The press release was done yesterday.

So, the overarching goals of the ONC's award provide cybersecurity information and education on cyber threats affecting the health care and public health sector. What we have heard is the indicators of compromise, the incidents and vulnerabilities that are shared did not have a lot of context. The health

systems that have come to us have said “well, we get a lot of information we don’t know what to do with it, it’s not actionable, it’s not meaningful.”

So, this organization, the whole purpose is to bring that knowledge in better context. Don’t tell me an

IP address is infected or that the JavaScript that has not been done, that has not been updated. You need to provide a little more context because the health systems and our core constituents’ small and medium providers they do not have very technical expertise to understand some of those threat indicators they are receiving or they don’t want to receive information that they do not understand.

So, the purpose of this is to expand outreach by providing more context by providing more analysis and not just disseminating cyber threat information we’re hoping to engage the health system organizations to this information sharing environment, sort of this paradigm shift to creating communities of trust to share information.

We’d like to equip stakeholders to take action in response to cyber threat information. When we think about ransomware, and it affected a health system that I actually have records in and the first thing I thought was this happened a few days ago in another state, the exact same threat of the ransomware...the exact same method through phishing, the exact same e-mail communication, so again if they were part of an information sharing analysis organization the risk would have been reduced, you minimize your risk quite a bit engaging in active, proactive information sharing communities.

Another goal is to facilitate information sharing widely regardless of the size of the organization. We’re really hoping that the awardee would reach out, build a method to engage small and medium providers. There is a benefit through your supply chain small, medium and large. We all participate in physician networks, provider organization networks who would like to share information and so making sure the entire supply chain is secured is extremely important.

And we would like to fulfill the commitment in the roadmap which indicates we would work on cybersecurity in collaboration with ASPR and the broader HHS agencies to build a better cybersecurity posture for the health and public health sector.

So some of our objectives that are expected of the recipient is to build internal resources to serve as a single ISAO and by a single ISAO we’re not talking about eliminating all the ISAOs that may or may not function in the healthcare space. We need a point of contact where we can better engage our stakeholders that are not as engaged, statistics show less than 15% are actively engaged and about 6 or 7% of the larger providers that are engaged are not as actively engaged as they should be. They do not understand the value. So our value proposition is to provide meaningful information in a timely manner and we’re hoping the awardee will be able to do that.

Expand current membership base, again, I talked about including small and medium providers to the mix ensuring there’s a broader, large-scale dissemination of information with a lot of knowledge sharing, best practices what works and what doesn’t work, building trust, again, would foster all ONC’s goals of large scale health information exchange, the iteration of Apps, you know, motivating patients to be more engaged so we feel that really engaging small and medium providers of varying sizes will be important.

And we’re also hoping the cost of entry, since most ISAOs and ISACs operate on a membership model the cost of entry will be revisited, we’re hoping to create a lower cost of entry and again the awardee

will sort of provide the plan of action to engage in the smaller providers to participate information sharing.

And the last sort of core objective is to provide some level of free information sharing services. The information is already available how can we disseminate it and provide free cyber threat information sharing to the entire HPH sector. With that I'll turn it over to the Nickol to talk about ASPR's purpose, thanks.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

And so Rose-Marie shared sort of ONC's goals behind their award and the way I like to look at the two awards and the differentiation is that ONC's award is to really promote and expand the education and outreach of the cybersecurity information sharing but ASPR's award is really about the mechanism and infrastructure that needs to basically be built or built upon in order to make sure that this information gets disseminated widely.

And so the purpose of the award, as you can see, is cyber information sharing having an awardee that can really use whatever they currently have and expand it and broaden it. That broadened access we hope will reach to those smaller sized organizations.

In a former life I used to be the Director of Operations for a multispecialty medical group of small practices throughout Southern Maryland and I can tell you it's very hard to be able to collect information from various sources when you have to do your day job. So, it's better to have a consolidated point of contact to be able to get information and push out to you that's actionable as Rose-Marie already mentioned. And of course we hope to have economies of scale by having one organization to reach to so we can reduce the cost to those organizations.

Again, overarching goals as Rose-Marie mentioned we did put out a planning grant that Harris Health actually was able to carry forth and present to us some gaps that are already inherent in the system. I'll share a little bit more about that later on in another slide, but using and leveraging those gaps will help our awardee to be able to move forward with basically shortening those gaps and filling them.

Like Rose-Marie mentioned also, you know, we're looking to the awardees to develop a concept of operations for multidirectional sharing of cyber information. Again, expanding reach for the communications is critical and also gathering and analyzing the cyber information from the private sectors is key. It is not a small lift to be able to gather the information. There's a lot of information that gets propagated throughout the system and so it is quite labor-intensive. We have information that says it can be upwards of seven FTEs that actually touch the information that comes in, any one incident of information that comes in, to be able to digest it and make it something that's actionable and that's a lot of effort.

So, here's some information in terms of who is eligible to apply. Nothing new there in terms of the nonprofit organizations whether they're 501(c)(3) or 503(b). Organizations that currently provide CTI sharing services were obviously a lot of the folks that did apply and obviously those folks would hopefully be in a well-positioned or a good position to be able to expand the reach that they may already have in the sector.

A little bit more about the planning grant, you know, we did have some initial findings. We do have a final report that we'll push out soon but we do have some of the findings here. There was some perception that cyber threat information sharing, the effectiveness of it, was pretty low.

In addition automation is key, it was preferred to have sort of an automated way for information to come to, you know, the respondents and that makes sense. Obviously, again, that labor-intensive piece is a lot especially for smaller sized organizations, so having something that's more automated was preferable.

And I wanted highlight the last or the second to last bullet, respondents said they would like an active ISAO and we preface by saying "an active" so it's that single point of contact where, you know, there's that consolidation of information is very important and key to the folks out in the field because at the end of the day if you're just getting bombarded with information coming from various sources and then who knows for those folks that are actually in a situation where there is some cyber threat that has occurred well who do they share to, right, so that bidirectional, multidirectional exchange needs to happen and we need an organization to coordinate all of that. And I'll turn it back over to Rose-Marie to tell us some more about our awardee, we're very excited.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yes, yes, yes, thanks again to those who reviewed the application it was really independently carried out, ASPR had its own panel, ONC did, we arrived at the exact same grantee which was awesome because that would really help our collaboration efforts to be more consistent and to have a better impact on the public health sector.

So, the grantee was announced yesterday it's National Health Information Sharing and Analysis Center, NH-ISAC, again, part of our grant had to do with an existing ISAO that has the capabilities and has the infrastructure to share information so it's not surprising that we gave it to one of the best out in the industry. They participate in a lot of activities some of which are listed on the slide and I would read through them.

They have a lot of experience in the field and they look at information sharing as just not information sharing but, you know, disseminating best practices, looking at it from the educational perspective, ensuring that those threats are mitigated before they happen. A lot of times they have referred to...they have called organizations and prevented a major impact within 15 minutes of the attack so we do know they have a lot of expertise in the field and they are well connected in the cyber environment as I will relay real quick.

So, the grantee membership is here. They have about 22.6 providers and payers 34.7 so this is sort of their membership mix at the moment. We're hoping to definitely increase the provider/payer mix, definitely the providers need a lot of guidance but in general we're hoping that a grantee can improve the member mix to include diverse small, medium providers.

So, types of information shared, just to quickly wrap up, they share diverse information from malicious sites, threat indicators, software, incident response, e-mails, you know, courses of action, exploited targets, but the grantee also provides a lot of education and outreach. They worked alongside the FBI to do ransomware outreach education and from what I heard they have several road shows ongoing just promoting security awareness, promoting cybersecurity training and also promoting information sharing as a mechanism to facilitate large-scale information exchange.

And the last slide has to do with just a general overview of how they're connected. They're already well connected in the federal space. The work with NCCIC, which Nickol mentioned, the National Cybersecurity Communication and Integration Center, they're well connected to HHS, Sector Coordinating Council, the governmental coordinating council, they have a seat at the NCCIC floor.

So, they're already well connected so we're not reinventing the wheels here we're taking an organization that already has so much capacity and experience in the field to help us promote information sharing in healthcare so a lot of what we're promoting in terms of a learning health system can be achieved with a better threat environment minimizing risk through information sharing and really just promoting best practices as we move forward in the national health IT landscape.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

And one more quick thing with regard to this particular organization as well, they do have reach into other sectors so they're able to leverage information that is being shared within other sectors that, you know, potentially, for instance the financial sector, that could potentially help in the health and public health sector with regard to threat information sharing.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Thanks, Nickol, that's a good point. So, for additional information we have a link on healthit.gov and finally thank you so much members of the FACA for the opportunity to present this initiative and we'll open it up for questions.

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

Great, so, we're running a little behind, that being said I actually do have a couple of questions that I'll start off with and we'll go to Larry and to David, is that right? So, first question is, you know, the GAO Report to HHS recently critiqued HHS on a number of points regarding cybersecurity.

One point I thought was interesting they critiqued OCR for not sharing information with CMS with regard to the Meaningful Use Program and my comment back to that, to the GAO Report, is that actually is desirable that in cases where you've got an organization that's helping to improve information security mixing that mission with the mission of penalizing actors is in fact inappropriate.

So the question is, you know, with regard to the variety of kind of regulatory levers that HHS has, the Meaningful Use Program and MACRA disincentives, obligations under OCR and the wall of shame and those kinds of things, is there an approach to segregating the information that's shared in the threat sharing so that we can encourage a learning health system without having people sort of think about, is this information going to be used against me?

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

So, I'll take that question, so the threat information that is shared is not protected health information, it's not PII, it's really information that's already been anonymized, aggregated, it doesn't have who and why in all the known factors, however, because of that notion that OCR will be involved and OCR is a partner in a lot of the privacy and security discussions we have, we decided to sort of not have OCR to the table because there were concerns if we shared information we'll get regulated. However, they are still our partners in terms of promoting patient access, security principles, etcetera, but, again, the information shared are threat indicators they really do not have any sort of protected health information or any information that would lead to that.

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

Understood on the outbound side but if I voluntarily share information about, for example, an attack do I have assurance that the sharing of information that I'm giving back to the ISAO or SEC is not going to be used against me in other context?

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

That's a good question. There were legislations that indicated there will be some protections with ISAOs, however, I would have to defer that to Nickol. So, the...in terms of the actual implementation it's fairly new. I don't know if that has been put in place which is sort of a protection.

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

Yes.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Again, sharing the right information.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

Yeah, we can certainly take that back to the organization. Actually since they're already doing it I'm sure they have something in place we're just not aware of the specifics of it.

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

And the second question is, you know, we've got a number of federal actors who are also in the healthcare space as very large providers and often have very substantial information security offices are the DoD, VA, IHS, CMS participating with regard to their information security activities and are they kind of a vector for threat sharing?

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

Yeah, definitely from an ASPR perspective we do coordinate a lot with DoD and DoD for sure, FBI for sure they have reached into the other operating divisions, yes.

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

Awesome, thank you.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

Sure.

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

Larry?

Larry Wolf, MS – Principal – Strategic Health Network

So, it's great to see this happening. Clearly there is a great need and, you know, we're sort of seeing in the news almost daily the level of cyber threat activity is like a shocking reminder of how vulnerable collectively we are. So, I want to pick up on your comments about small and medium providers and encourage you to look at ways to connect to those providers.

The RECs come to mind as examples of organizations that actually actively reached out to small providers and in many cases were very helpful. I know there's a lot of funding that made that happen at the beginning, but some of those organizations have figured out what their sustainable model is and I think the need to have human beings engaged with those small providers is really critical because, you know, as I'm guessing from your experience running a small practice the cyber threat in response is not at the top of your list of things to do every day, worry about every day.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

Right.

Larry Wolf, MS – Principal – Strategic Health Network

And mapping a threat to action often requires a very sophisticated understanding of what your systems are actually doing. So, a huge area I think to really focus on to actually protect the whole of the healthcare establishment because of the huge numbers of small providers.

And to that end it might be interesting to have the ISAC take their lovely pie chart and not just show sectors but also show organizational size because I think it would really highlight the fact that it's large providers, large organizations that are engaged in doing something but we need to call attention to the folks who aren't at the table. Thanks.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

Thank you.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Thanks.

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

So, we're going to go to David, Dale and Aaron.

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

David Kotz, Dartmouth College, thank you for this, I agree with Larry, this is badly needed, we need more information sharing as much as possible.

My question is about distinguishing this from an organization I just learned about the Cyber Health Working Group. I just in fact just joined that today at the invitation of the FBI which I understand helps to coordinate that working group and it seems to serve a similar purpose so maybe you can help me understand how this relates to the new ISA0?

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Sure, we are working with the FBI Cyber Health Working Group it's a new initiative it sort of started a few months ago, back in June, and they coordinated efforts with us. It's the same idea, again, having people who would just have automated processes would help spread the message and build membership and so the Cyber Health Working Group consists of members. We did provide a lot of contacts to the FBI since they are not directly operating the health space and I'm glad you will be joining.

It is to sort of bring members together to share concerns that effect their health environment. So, it's the same concept, however, the Cyber Working Group is very informal, they're really trying to build how it's formulated and we will be working directly with them on that initiative as well and getting them plugged into our ISA0 infrastructure.

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

Thank you.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Thank you.

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

Dale?

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

Thanks, so one of the issues, I guess this is along similar lines is, what do you see the opportunity for this FACA to be involved with the other related, you know, and ongoing and expanding activities including the new ISAO and then there's the ASPR response or Cyber Security Task Force.

So, it feels like it's very important for us to start to make it clear that cyber is not just a technical problem it's a healthcare challenge and that increasingly we're seeing the communication around this being actually a public health challenge and that it's really necessary to have, just like we had Meaningful Use, we should have meaningful security and it feels as the ISAO Standards Group that was funded by...I forgot which group it was funded.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

DHS.

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

Pardon?

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

Department of Homeland Security.

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

Oh, DHS funded them. As they start to produce their documents they're starting to recommend standards for data exchange and it feels like there's an opportunity here where we have HIT experts and healthcare experts, and public health experts to have an opportunity to help synthesize these activities especially since some of them are termed activities and presumably will expire, you know, in the next, you know, several months.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yes, thanks, Dale for that comment. I think that's a very great comment. They had a meeting in Reston not too long ago, the second working meeting, to create standards around information sharing and having health IT experts at the table will be extremely helpful.

I'm hoping...is listening to your comment because they'll be sort of our organization that would help bring the health IT knowledge within that environment of standards organization that DHS is running which is a big initiative by DHS.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

I think as there are opportunities for moving forward and expanding the work that we're doing for this year we'll be certainly be seeking comment and we'll come back and really reach out to the group to seek further comment on any products that we produce.

So, for instance, the ISAO planning grant award, again, we are producing a report from that and so we will be putting that out. We'd love to hear feedback certainly disseminate it as widely as you would like as we, you know, put that out, but we would love to hear feedback on some of the gaps that were identified, are there gaps that we're missing that were not identified and certainly products that come out of this award we would love to hear feedback from you all as well. So, definitely providing comment and feedback on the products that come out of this is as important as well.

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

So, is there a need or an opportunity for something like a working group or a task force within this body of people like we do for interoperability or we do for consumerism and things like that?

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

I think that would be great.

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

Yeah we do have...we have had a Cybersecurity Task Force that looked at this and actually made recommendations relative to CISA and relative to information sharing.

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

Pardon?

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

We did in the past have a Cybersecurity Task Force convened for CISA that made recommendations relative to information sharing for example. So, it's just...so we've had that focus in the past, if there's something more specific for a task force to focus on that could be something that's appropriate, but just want to reflect that we actually have had that level of deliberation in the past. All right. Aaron?

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

Thank you, Aaron Miri, great job, this is very good work, credit to you guys, credit to Lisa Gallagher and others that all participated in this.

Two questions for you and this is putting on my provider CIO hat. First question is, as more information is shared and more providers particularly become part of a cyber threat sharing information network is there any consideration for safe harbor or some sort of considerations to give air cover to the hospital systems and whatnot that maybe potentially using devices that potentially have a risk on them and those sorts of things?

I think there's a lot of fear within the...especially in the provider community of airing your dirty laundry so those types of things would go a long way to encourage people to share information rapidly.

Number two, is there any consideration for who or what body will take point on any questions or issues, or things that need to be worked through, I don't want to use the term Cyber Czar, but maybe the Office of the Chief Information Security Officer or something at HHS being appointed as that point of contact because, as you know, now it's going to be multiple agencies with the FDA, FTC and others that have to intersect and there's going to be that gray area of who's on first and it would be good to have somebody or office, or something identified as, okay, you make the final shot to help drive this thing forward otherwise there could be a stalemate there.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

I'll take the second one.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Okay, I'll touch on the first one. So, in terms of the first one when the ISAO legislation executive order was put out there, again, there were talks about having liability protection when you share sort of airing your dirty laundry.

However, in terms of the actual implementation and that's actually a question I sent to the Chief Privacy Officer, Lucia Savage before I came to this meeting I'm like "has it ever been implemented, do we have those provisions in place" sort of the safe harbor provision where they can share and there sort of protected. I don't see where it's been implemented but there were a lot of discussions during the initial ISAO kickoff that talked about liability protections, but then there were also concerns that if you're just not doing the right thing and you're opening up yourself to a lot of threats and you have a lot of incidences, do we want to provide liability protection? And so at that point we took that back as a follow-up and we'll be emailing you, I have Aaron your e-mail, so I can follow up with an e-mail to you to address that question.

But, again, if you're sharing, you would try to improve your security posture and I'm hoping that would happen because a lot of times when you engage in sharing you tend to pay more attention to your systems and how you do things then you tend to learn from others and implement best security practices.

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

You're right and being a long-time member of CHIME and others 99% of hospital CIOs want to do the right thing it's that they just simply don't know...

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Right.

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

If a vulnerability exists that they can't identify which this will help tremendously. So, I agree with your point.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Okay.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

Yeah.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Great, thank you.

Nickol Todd, MPH, PMP – Assistant Secretary for Preparedness and Response (ASPR)

And in terms of the question of who's on first that is the big question. So, we're encouraging with this grant to have a coordinator of the information, right, so but who's going to coordinate on behalf of the government in terms of making sure that when there are certain big sort of issues that pop-up how is that going to get handled?

And we've talked about this quite a few times and it's really about who can make sort of the best case, with new administration coming in, as to, you know, who's best, I guess, positioned from, you know, whatever perspective the case is made to be able to take that on. I'm sure any one of our organizations could potentially do it it's just about who can get the authority to do that.

So, I agree with you that we do need sort of to centralize amongst ourselves from a federal government perspective in terms of moving the ball forward when things pop up.

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

And could I mention really quickly to Nicole's point, the concept of operation started as an HHS internal organizational structure to organize how information sharing gets in HHS and gets disseminated within HHS and out of HHS so they are building a process, the OCIOs office is the lead for the concept of operation so they are building a mechanism where when information gets disseminated there will be a primary point of contact and I believe actually, Nickol's ASPR, but we designated ASPR to be sort of the point of contact for disseminating information out of HHS, but that whole framework with the CISA Task Force, the automated information sharing none of that has been have been solidified yet and it's not really operationalized but they are still working through that.

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

Thank you.

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

All right, thanks for this super important update and now...

Rose-Marie O. Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Thank you.

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

We are very behind schedule but we have one more in a long list of incredible updates from HHS. No Joint Committee would be remiss without discussion of HIT SEA so Steve is going to give us a HIT SEA update.

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

He's going to be super-fast though.

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

Super-fast.

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

I am I'm not even going to go over to the dais or whatever we want to call it today. Thanks a lot for having me and so for those of you that may remember Arien has led a Workgroup, a Task Force in 2015 that made a number of recommendations to ONC which we have jokingly referred to in different agile ways have been implemented along government timelines but one of those was to support the production use of health IT standards through a number of different means including facilitating through funding pilots and the production implementation and adoption of those standards, feeding learnings

back to SDOs, evaluating the success of the standards and implementation guidance and achieving national priorities all of the things that I take to heart and read before I go to bed every night.

So, one of the things that we launched this year was a new cooperative agreement program to help advance the use of standards and the implementation experience as well as the feedback that we could bring to the community and so we launched two different cooperative agreement opportunities, one called High-Impact Pilots and the other called Standards Exploration Awards and so they have the HIP and the SEA.

And so the notion behind both of them was that cooperative agreement awardees would have 12 months, they'd have to hit the ground running, they'd have to be able to produce, generate evidence and things that would work, things that don't work and provide that experience back out to the field to help kind of in a rapid cycle way, help advance a lot of the implementation experience and understanding that we have from a feedback perspective.

The approach that we took was to identify four, sorry, three priority categories and one self-identified category so for this HIP round one we identified comprehensive medication management, laboratory data exchange and care coordination as three categories that we wanted awardees to submit proposals for And then we also, in a humble style way, allowed for a self-identified category as well.

And so for the HIP and the SEA cooperative agreement announcements people submitting applications had to address one of those four categories in their submissions and also identify particular impact dimensions we refer to so that includes practice efficiency, clinical quality, cost efficiency, patient experience, safety, privacy and security and interoperable exchange.

And for HIP they had to take on three out of those seven impact dimensions, for SEA it was really focused on one of them and also the scope and size of the financial awards available to each of those cooperative agreements was similarly scoped relative to the amount of impact dimensions that they need to take on.

And as Michele and I were joking earlier, Vindell stole a little bit of...he used a rumble to my thunder here about the announcement that he got to make last week about the awards and we wound up being able to award four HIP Cooperative Agreements, one went to a company called RxREVU who is going to be focusing on comprehensive medication management and point of care price transparency.

The next one was the Health Collaborative focusing on care coordination. The University of Utah, which is also focusing on care coordination, closed loop surgical referrals and then Lantana Consulting Group as well to do care coordination related to pharmacists care plans.

The one thing that I would note, and I should have mentioned up front, all of the proposals that we got submitted and ultimately awarded reflected I think collaborative efforts so while I may name a particular group that got the award they have a big team behind them in most cases to facilitate the type of pilot experience that they're going to try and orchestrate.

The other thing that I do want to thank, and they know who they are, everyone that participated in the objective review process, which is not lengthy but quite an investment of time for folks outside of government to contribute your time to reviewing applications, as these come up in the future I would very much encourage people to continue to do so and volunteer your time to help review these proposals. So, all of these really reflect kind of a peer ranking and rating of the applications that have been referred to the government to kind of ultimately fund.

And then with respect to the standards exploration awards, the first one went to the Cincinnati Children's Hospital Medical Center. They got awarded a self-identified project which is focusing on cost efficiency looking at electronic case report forms and the focus on children, adolescents with inflammatory bowel disease.

The next one went to Arkansas Office of Health Information Technology which is going to be looking at interoperable exchange with behavioral health providers in their area and then a third one from Sysbiochem who is again a big partnership with Boston Children's, Intermountain, Mass General, Dana Farber collaborating on using predictive models for breast cancer using FHIR and SMART on FHIR Apps.

So, lots of cool projects, they will be here in about a year probably to present to all of you, but there's a lot on the horizon and I think, you know, judging by the number of submissions that we got this round, we're looking to do, you know, another round in the future provided, you know, the funding and support is there. So, that's hopefully brief enough.

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

Awesome, thank you, Steve. Okay, we're going to now open for public comment. If there is anyone in the room who would like to make a public comments please come up to the table and, again, as a reminder public comment is limited to three minutes. During the last presentation from Nickol and Rose-Marie we did get a few comments from the awardee that we will share with the group that helped answer some of the questions that were asked. And operator can you please open the lines.

Public Comment

Jim Wetherill – Technical Specialist – Altarum Institute

If you would like to make a public comment and you are listening through your computer speakers please dial 1-877-705-6006 and press *1 or if you are listening through your telephone you may press *1 at this time to be entered into the queue.

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

So, while we wait to see if there is anyone on the phone with a public comment, we are looking to reschedule the November meeting it will be a joint meeting and it will be virtual we just haven't found a date yet with Thanksgiving and holidays things are starting to get pretty busy. Hopefully, you did note that we did adjust the December meeting. The December meeting will be in person and I want to say it is December 6th but I'm not positive and that will be at the Omni, the hotel that we've been at a lot lately.

W

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

Yes, it's December 6th, thank you, and we have no public comment at this time. So, thank you all and thank you for your patience as we went way over the agenda, so, thank you. See you in December in person.

Public Comments received during the meeting

1. **Denise Anderson:** This is Denise Anderson of the NH-ISAC. We are plugged in with the FBI healthcare group already. Also to clarify we have an embedded presence on the NCCIC floor as well as the NICC. I also serve as Chair of WG2 of the ISAO Standards Organization so we are plugged in there as well and the ISACs are providing a lot of input into the SO. Finally I also serve as Chair of the National Council of ISACs so we are very plugged in to all of the other ISACs.
2. **Denise Anderson:** As far as the concern with sharing, ISACs provide anonymity for the organizations that share. CISA provides liability protections to those who share via an ISAO or ISAC.

Joint Committee Attendance

Name	10/05/16	09/13/16	07/27/16	06/23/16	06/08/16	05/17/16	04/19/16	03/10/16	01/20/16
Aaron Miri	X	X	X	X					
Andrew M. Wiesenthal	X	X	X	X	X	X		X	X
Angela Kennedy		X	X		X	X			X
Anjum Khurshid	X	X	X	X	X	X	X	X	X
Anne LeMaistre		X	X	X	X	X	X	X	X
Arien Malec	X	X	X	X	X	X	X	X	X
Aury Nagy									
Brent Snyder	X		X	X	X		X		
Carolyn Petersen	X	X	X	X	X	X			
Chesley Richards	X			X					
Christoph U. Lehmann	X	X		X	X	X		X	X
Dale Nordenberg	X	X	X	X		X	X	X	
David F. Kotz	X		X			X		X	X
Devin M. Mann		X							
Donna Cryer	X	X	X			X	X	X	X
Eric Rose	X	X	X	X	X	X			X
Floyd Eisenberg	X	X	X	X	X	X	X	X	X
Gayle B. Harrell		X	X	X	X	X	X	X	
James Ferguson	X	X	X	X	X				
Jitin Asnaani		X	X	X	X	X		X	X
John Scott	X	X		X	X	X		X	X
Jon White		X		X	X	X		X	X
Jonathan Nebeker		X	X	X					
Josh C. Mandel	X	X		X	X	X	X	X	X
Karen van Caulil	X	X	X	X	X	X			

Name	10/05/16	09/13/16	07/27/16	06/23/16	06/08/16	05/17/16	04/19/16	03/10/16	01/20/16
Kathleen Blake	X	X	X	X	X	X	X	X	X
Kay Eron		X	X						
Kevin B. Johnson	X						X	X	
Kim Nolen			X	X		X	X	X	
Kim Schofield		X	X	X	X			X	X
Kyle Meadors		X	X	X					
Larry Wolf	X	X	X	X					
Leslie Kelly Hall	X	X	X	X		X	X	X	X
Lisa Gallagher	X	X	X	X	X		X	X	X
Lorraine Doo	X		X	X	X	X	X	X	X
Nancy J. Orvis			X	X	X		X	X	X
Neal Patterson			X	X			X	X	
Patricia P. Sengstack	X	X		X	X		X	X	X
Paul Egerman	X	X			X	X	X	X	X
Paul Tang	X	X	X	X	X	X	X	X	X
Peter Johnson	X	X	X	X					
Rajesh Dash	X	X	X						
Ram Sriram		X	X						
Richard Elmore	X	X	X	X	X			X	X
Scott Gottlieb	X	X	X	X		X		X	X
Steve H. Brown	X	X	X						
Terrence O'Malley	X	X	X	X					
Troy Seagondollar		X	X	X	X		X	X	X
Wanmei Ou	X	X	X	X					