



**HIT Standards Committee
HIT Policy Committee
Joint Meeting
Final Transcript
February 10, 2015**

Presentation

Operator

All lines are now bridged.

Michelle Consolazio, MPA – Federal Advisory Committee 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 Standards Committee and Health IT Policy Committee.

This is a public meeting and there will be time for two public comment sessions one before lunch and one after lunch. The public comment is limited to 3 minutes and we ask that you please state your name and your organization when you do public comment. As a reminder, please state your name when speaking as this meeting is being transcribed and recorded. I'll now take roll by going around the room and we'll start with Leslie Kelly Hall.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here, that's it, I'm sorry.

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

Sorry, can you just say your name as we go around the room?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Leslie Kelly Hall, Healthwise, Consumer Advocate.

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

Thank you, Leslie.

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

Dr. Anne LeMaistre, that's a hard act to follow, Ascension Health.

Wes Rishel – Independent Consultant

Wes Rishel.

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

Kim Nolen, Pfizer.

Thomas W. Greig, MD, MPH – Chief Medical Information Officer - Department of Defense

Tom Greig, DoD.

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

Liz Johnson, Tenet Healthcare.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Dixie Baker, Martin, Blanck & Associates.

Charles Kennedy, MD, MBA – Chief Executive Officer – Accountable Care Solutions – Aetna

Charles Kennedy, Aetna.

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

Anne Castro, BlueCross BlueShield South Carolina.

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

Chesley Richards, CDC.

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

Jamie Ferguson, Kaiser Permanente.

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

Andy Wiesenthal, Deloitte Consulting.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Deven McGraw, Manatt, Phelps & Phillips.

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

David Lansky, Pacific Business Group on Health.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

David McCallie, Cerner.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Jodi Daniel, ONC.

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

Paul Tang, Palo Alto Medical Foundation.

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

Jon White, ONC.

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

Steve Posnack, ONC.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Christine Bechtel, Consumer Representative.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC

John Derr, Long-Term Post-Acute Care.

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

Gayle Harrell, State Representative from Florida.

Keith J. Figlioli, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc.

Keith Figlioli, Premier.

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

Kim Schofield, Lupus Foundation.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Stan Huff with Intermountain Healthcare and the University of Utah.

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

Nancy Orvis, DoD.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Arien Malec, RelayHealth.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Marc Probst, Intermountain Healthcare.

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

Kaiser Permanente and Labor Representative.

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Anjum Khurshid, Louisiana Public Health Institute.

Kelly Cronin, MS, MPH – Director, Office of Transformation – Office of the National Coordinator for Health Information Technology – Health & Human Services

Kelly Cronin, ONC.

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

Lucia Savage, ONC.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Erica Galvez, ONC.

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

Neal Patterson?

Neal Patterson, MBA – Chairman of the Board & Chief Executive Officer & President – Cerner Corporation

Cerner.

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

And...

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

Karen DeSalvo.

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

And on the phone we have David Bates.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Here.

M

Let me just take one call.

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

Hi, David. David Kotz?

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Here.

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

Hi, David. Devin Mann?

Devin M. Mann, MD, MS – Assistant Professor – Boston University School of Medicine; Attending Physician – Boston Medical Center

Here.

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

Hi, Devin. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Yes, 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

And John Halamka?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

I am here.

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

Is there anyone else on the phone that we missed?

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

Yeah, Kevin Brady.

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

Lisa Gallagher.

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

I'm sorry; I missed all the Standards Committee on the phone.

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

Lisa Gallagher?

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

Here.

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

Kevin Brady for Charles Romine, NIST.

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

Eric Rose?

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

Yes, Eric is here.

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

Jeremy Delinsky?

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – athenahealth, Inc.

I'm here.

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

Lorraine Doo?

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

Here.

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

Now is there anyone else that we missed? Okay, well thank you everyone for joining us for this joint meeting. I just want to make one quick announcement. We are now accepting applications to the Health IT Standards Committee for a few members that we will be losing shortly. Applications will be open through March 6th for the Health IT Standards Committee. As you can see on the site there is a link on healthit.gov under FACAs for you to go and apply through our database.

We also have some openings on the Health IT Policy Committee and GAO will be accepting applications for folks on Policy Committee. So, they will be accepting them through February 27th and we hope that members of public and those participating in our Workgroup are interested and will be applying. And with that I'm going to turn it over to Karen for any remarks.

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

Thank you, Michelle, good morning everybody here and everybody on the phone it's nice to see your faces and I want to thank you all for making time to come down and get some back-and-forth with us about the Health IT Strategic Plan, excuse me that was this morning, about the roadmap this afternoon. I had chance to listen to some of the discussion this morning and it sounded really productive and helpful so thank you for that piece from the Policy Committee looking forward to digging in more today into the nationwide interoperability roadmap. We've had some nice feedback already and we look forward to you guys helping us put a finer point on it and share how we want to carry forward the FACA's guidance and input. And that's all I have. Thank you, Michelle.

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

Do you want to offer any comments?

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

Sure, I've always got a comment. Hi everybody, this is Jon White, many of you have worked with me in the past at the Agency for Healthcare Research and Quality we're I've been for the past 10 years. I am now the Acting Deputy to ONC. It is a great pleasure to be working with you in that different capacity and I look forward to the discussion. On behalf of the Standards Committee thank you so much for your time and effort as Karen said for coming here. Let us all be grateful that we don't live in Boston except for, Michelle, who is grateful that she made it out of Boston. So, thank you.

You know the only thing that I add to what Karen said is that, you know, you're coming here on the end of a pretty incredible couple of weeks for ONC between the delivery system reform announcements and the release of the roadmap and the President's Precision Medicine Initiative and unbelievable annual meeting and just to have been at ONC for the past two months and watch the incredible work of my colleagues here it really has been a joy to behold and I'm grateful for all their efforts. So, thank you very much, look forward to a great meeting.

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

Okay, thank you. Thanks for everyone joining us, this is a combined meeting with the Standards Committee and the Policy Committee and we're really grateful for everybody making the trip here. Sorry for the folks in Boston. I made some comments to John Halamka when he was not able to make it, but...

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

Loving comments.

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

Loving comments, right, but I'm sure he's on the line. This is a day we've been waiting for a long time and I'm sure it's not going to be...we're not going to be disappointed. This is a tremendous piece of work that's gone through so much iteration and incorporation of public comments and the comments of this committee from the past. It's just really a work of art.

I want to congratulate Karen and Erica for leading the charge on behalf of ONC in putting this together. I think in tandem, as Jon alluded to, the delivery reform announcement on January 26th about the 30% by the end of 2016 and 50% by end of 2018 was very enabling for this work.

We've always talked about, when we talk about Stage 3 and Meaningful Use and all the work that's gone on through ONC and the HIT Policy and Standards Committee, is that we need to pass the baton on to have it pulled and that's probably through different health models and different payment models. And I think the uncertainty around when it is going to come was partly answered by this announcement that the Secretary made on the 26th.

I think 30% is past that tipping point where people start behaving differently. So putting a stake in the ground, a timeline is really helpful. I think the market doesn't like uncertainty. And I'm not talking about the stock market and so having something work towards is really, really helpful and I think the baton now, the receiver is now there and that's going to help this work tremendously.

So, we're going to start off...it's going to go section by section. It's not exactly in the order written but we're trying to present it in a way of sort of setting up what's the rationale, what are the things, the framework around interoperability and then conclude more with the standards and more technical aspects of it.

John was going to lead the standards related pieces we'll still have him on the line. I'll just sort of moderate in his absence but he will be on the phone. So, we're going to walk through each section. Erica is going to present an overview or a summary of that section and then we're going to have time for questions for each part. So, we'll try to manage within the time because we do have to finish by 5:00 p.m., it sounds like a long day but it's 166 pages.

So, any...oh, let me ask about the minutes as well. You've had distribution of minutes beforehand, now we approved in the Policy Committee...

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

Paul, we didn't do minutes.

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

Didn't do minutes? Okay, I read something. Didn't do it for the combined meeting I guess. Okay. Any other questions about the agenda, how we're going to move through it?

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

I have a couple of comments.

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

Yes, please?

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

We might want to let John Halamka say a few thoughts first though.

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

Yes, John.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, thanks very much Michelle and again apologies to everybody. It was the shutdown of the trains and the planes that was the only thing that kept me from Washington today. And so today, as Paul has said, we're going to hear about policy and technology. We're going to hear very important framing of cultural, business and environmental issues that help contribute to standards adoption and he will lead those on more the policy focus and environmental focus and I will do my best, with his assistance, to lead the discussion on technology and standards.

I think if you look at the day overall, and Paul you're right, it's something we all look forward to. I think of Yogi Berra's quote "if you don't know where you're going you might not get there." And so we look today at the interoperability roadmap, the standards advisory these are meant as frameworks that are going to help all of us whether we're in the public or private sector focus our work for the next several years.

And as you've said, Paul, I very much look forward to making sure that jointly the Policy and the Standards Committee have a laser-like focus on achieving the policy outcomes we all want through the interoperability we need. So, let me turn it back to you Michelle.

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

Thank you, John. I just have one final comment. I got word that we may have been taking coffee from another meeting's event. So, if there is coffee outside, please don't take it it's not ours. Sorry about that.

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

So, nothing's changed from our previous rules. All right Erica I'd like to invite you up to the table please. So, Erica's going to start out with the summary and introduction and we'll have some committee discussion before she goes on into the business, clinical, cultural and regulatory environments continuing then with rules of engagement, privacy and security, after lunch that is, more technical standards and we'll end with a summary and next steps. And we all have assignments so don't leave before the end of that.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That's right, thank you, that's an important note.

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

All right Erica thanks.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

You bet. Thank you. Thank you for the opportunity to have this conversation about interoperability today. We spoke about the roadmap you may recall back in mid-October. The document has evolved significantly since then. I think I gave you 60 some odd slides in October. I have given you over 160 pages this time around. It is a beast of a document. We tried to be as comprehensive and streamlined as possible.

A little bit about process just here at the beginning to remind everybody of what we've been up to and how we've gotten to where we are. We have tried to take both an iterative and inclusive approach to developing the roadmap. We have held a number of listening sessions across the country, launched an on-line forum, held a number of federal workgroups, very specific state engagements we know that our state partners have been important role to play in advancing interoperability.

We ask all of you, through the Interoperability and Exchange Workgroup, I think is the title, to give us feedback on the preliminary work that we brought forward in October. We've had contractors, just a tremendous team processing this input, conducting research really thinking about how it is we overcome critical barriers that exist in interoperability and achieve the goals that we put out in the vision paper in June of last year.

So, we are today gathered together to talk about a draft. We have put forward a draft roadmap that relates very explicitly back to the vision paper that we put out last year. It is open for public comment for 60 days. I'll talk a little bit about exact dates at the end of our time together today.

Each Workgroup within both the Standards and Policy Committee will have an assignment. We will be asking for feedback and review. There are some sections that we will actually refrain from asking for review about I'll talk a little bit about those.

And then we will produce an updated version, right, that's kind of the point of iterating, we will come back this summer, we will process all the feedback we get and put out a version 1.0. Right now it's a draft version, version 1.0 in the spring, oh, I'm sorry the summer.

So, a little refresher on why interoperability. Significant progress has been made in digitizing the care experience. We know that consumers are increasingly demanding and expecting their health information to be accessible and useful. We have vastly evolving care delivery and payment models. Paul mentioned the delivery system reform announcement last week really accelerating in that space.

We have a number of successes and promising practices that we can build from, right, we've actually been at this for a while and we know that it can work. We have very good examples of success. We see technology evolving very rapidly both in terms of scale and sophistication. And we have real opportunities to improve care and advance science by using technology and information in appropriate ways. The time is right. Dr. DeSalvo has said this very poetically many times "the time is right for us to take this journey together."

So, a quick refresh on what are we aiming for? Why are we at this? In the vision paper, interoperability vision paper that we put out last year, we described a vision for a learning health system and we said, you know we think it will take about 10 years to get there. I think, personally, that's fairly ambitious but I think it's the right goal and it's the right timeline for us to be thinking about it.

And then we worked back from that 10-year vision to say, what are the important things that we can accomplish along the way both in a 6-year timeframe and a 3-year time frame? Three-year timeframe really focused on building for what we've already started, making aggressive progress. We tried to be as specific as possible because we know we tend to stay on the right track when we're very clear about what we're trying to do. So, we set a target for the next three years around the major of providers and individuals, we used the term determine individuals to refer to what we often call consumers, that they have the ability to send receive, find and use a common clinical dataset. Send, receive, find, use common clinical dataset, next three years.

We also described a framework for getting there. Five building blocks, five fundamental areas where we think critical action needs to occur in order to achieve those goals and you'll notice the roadmap is parsed by building blocks. I'll talk a little bit about some of the subcomponents there within each building block but as a refresh we're talking about core technical standards and functions not just standards but also services.

Certification relates to standards but is an important standalone. Privacy and security protections, all the environmental factors that we know influence interoperability that range from business to cultural, to clinical pieces and rules of engagement and governance.

Quick refresh on principles, guiding principles. We very intentionally set out to focus on what I've been calling principle-based interoperability to be guided by a core set of principles that help us make decisions. Building on existing health IT infrastructure given the progress that we have to date is one important guiding principle; maintaining modularity so that we have flexibility and extensibility over time, particularly, as we start to move into ultra large scale systems, recognizing that one size does not fit all; considering the current environment and supporting multiple levels of advancement.

Empowering individuals, lots of discussion this morning amongst the Policy Committee about this one; simplifying where we can, let's not make this...interoperability is already complex, right, let's not make this any more complex than it needs to be.

Certainly protecting privacy and security in all aspects of interoperability; leveraging the market to the extent that we can this relates a lot to innovation and thinking about how we create an environment where the market can really take off; focusing on value, focusing on aspects of interoperability that really deliver value to users whether those are consumers, providers, researchers or public health officials and focusing on scalability and universal access; this bottom guiding principle is one that you did not see in vision paper it's one that we added through the course of our deliberations on the roadmap and this really is focused on the notion of working toward interoperability that is nationwide not interoperability that just occurs in certain regions, that occurs in certain communities or circles where folks can afford certain technologies, but really thinking about how do we scale services and support for interoperability across the entire nation.

The print on this slide is really small I apologize for that but I wanted to give you a quick overview, because we won't be able to touch on all of these items today, of the different sections you'll find in the interoperability roadmap. So, when we set out to develop the roadmap we asked ourselves what are the core business and functional requirements of a learning health system?

If we want to achieve a learning health system 10 years from now, what are the requirements that we need to meet in order to make that a reality and then we worked backward and what's interesting is most, if not all of these core functional and business requirements apply to our three-year goals as well.

Organized by building block you'll see within technical standards and functions consistent data format and semantics, consistent secure transport techniques in all of these areas. We talked about the minimum number of standards needed to achieve our goals.

Standards secure services, accurate identity matching, historically we've called this patient matching. We've tried to steer clear of that term in the roadmap so we called this identity matching. Reliable resource location for those of you who care a lot about provider directories this is the area where you'll find discussion on provider directories.

Within certification a functional requirement around stakeholders having assurance that their Health IT is in fact interoperable. Under privacy and security, ubiquitous, secure network infrastructure this is where you will find discussion of all of the security aspects that are so critical. Verifiable identity and authentication of all participants, consistent representation of permission to collect, share and use identifiable health information we often call this consent in common vernacular we call it permission in the roadmap and consistent representation of authorization to access health information.

Under our environmental bucket, business and functional requirements relate to a supportive business and regulatory environment that encourages interoperability, individuals being empowered to be active managers of their health not just their healthcare but their health broadly.

Care providers partnering with individuals to deliver high-value care. We do give explicit attention to the care delivery system in this section. And under rules of engagement and governance, certainly, one core requirement around shared governance of policy and standards that enable interoperability. Again, our frame of reference is health broadly and healthcare as one component of that. So, when we think about these core functional and business requirements I would encourage you with the exception of the one that is explicit about the care delivery system to think about these again in the context of health and healthcare as one piece of that.

And with that, we'll go straight into our first building block. I will give you a snapshot of some of the pieces within the building block for each of these sections that we think rise to the top, again, recognizing there is no possible way that I can cover all of the pieces of each building block. That doesn't mean the other stuff isn't important, right, and if you want to entertain a conversation about some of those pieces and we have time to do that I'm glad to do that.

Also a quick note, for each of these building blocks I have the luxury of having someone else around the table on the hook with me to answer questions. So, I'll call them out at the beginning of each segment. For our conversation about the environmental building block we're actually going to focus on the business and regulatory pieces of this. Kelly Cronin from our Office of Care Transformation leads a lot of our work in this area. She is an expert on many of these all policy levers and so as we...I'll give an overview as we go into discussion I will invite her to answer just as many questions as I do.

So, support of business and regulatory environment, the reality is that new models of care are rewarding providers for outcomes and those models of care help create an environment where interoperability makes business sense. This is has been a gap that I think many folks have recognized and pushed on for a very long time.

We've already mentioned the HHS announcement, 30% of Medicare fee-for-service payments targeted to move into alternative payment models by the end of 2016, that's the end of next year, coming up very rapidly, 50% by the end of 2018 and 90% target tied to quality by 2018.

Requirements for participants in these new models can certainly reinforce interoperability. They set...they depend in many ways on interoperability. They also have the opportunity to set requirements that help us advance the technology and the movement of health information that indeed supports the health outcomes that we're aiming toward.

Other topics that I mentioned are addressed in this section of the roadmap relate to individuals being empowered to be active partners in their health, as well as specifically care providers, the care delivery system and what providers need to do to partner with individuals to deliver high-value care.

A couple of examples of critical actions, so each section of roadmap has a background section that describes what is the background, why do we need to take action here, what do we need to think about going forward and what are the critical actions that need to be taken?

There are by the way, I pulled a number just so I could tell you, 139 critical actions for the three year timeframe in the road. Only 48 of those belong to ONC. So, many, many calls to action as you have probably already noted throughout this document.

For federal government within this section there is a pretty robust discussion of linking policy and funding activities beyond the Meaningful Use Program to both the adoption and use of certified health IT and electronic information sharing really striving to do that according to national standards, national technology standards.

One example that we can pull from relates to the DoD EHR RFP, right, so this isn't necessarily a payment policy but it is certainly a federal policy lever. The DoD EHR RFP requires not only ONC certification for their product but robust interface strategy for devices and external data as well as open systems architecture a really fabulous example of a federal policy lever that can be put to good use there.

Another example, several CMS policy levers are discussed in the document, one forward-looking opportunity that we discuss is around conditions of participation really thinking about scalability and ubiquity.

Conditions of participation or in fact survey or certification required for Medicare reimbursement could be updated to include electronic exchange of clinical data for safe transitions in care now there are a lot of other considerations that would have to be taken around this but these are the types of things that we push on thinking about in the roadmap.

For state governments, a number of additional opportunities at the state level to use available levers some of those around Medicaid purchasing power and extending other existing efforts and then thinking about new options given the many ways that states interact with the care delivery system.

And for non-government payers and purchasers, they are also addressed in this section of the roadmap, a very clear call to action to explore financial incentives in other ways to emphasize the interoperable movement of health information between provider networks. So, let me pause there and pass it may be back to you, Paul, or whomever to open it up for discussion.

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

Okay, thanks Erica. Comments or questions on this section for Erica? Arien?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah, thank you very much, so first of all, Erica and the rest of the ONC staff I really want to applaud you for a really well thought out roadmap. I actually did read all the pages.

I want to go back to the outcomes and goals because I think there is a little bit of tension in the overall roadmap with regard to the notion of a nationwide ability to send, receive, find and use. And in some portions of the roadmap there is a clear principled stand on person-centered interoperability and in other sections of the roadmap there is an implication that we're really talking about providers and provider centered or EHR or HIT centered interoperability.

And you're going to come to very different kinds of policy frameworks and different kind of standards if you adopt a person-centered approach from adopting a fragment of record centered approach and we may conclude that certain things are successful if for example we can open up EHRs and go get a fragment of a person's record but conclude that we failed if we don't have the ability to access a person's whole record across the delivery system and across the settings of care that they receive.

And I'd point out that, you know, I like the focus on identity and identity matching. Those are really critical features in addressing, from a standards perspective, are really critical feature is if we're looking at a person-centered approach.

So, one interesting, giant meta comment would be I would appreciate it if the roadmap had a level of clarity about whether our aim and success is a person-centered success and I understand by 2017 we may have a fragment of record success. But I'd encourage us not to stop with "oh, great, we can go look up somebody else's EHR and pull out a fragment of the record." My strong belief is we need to, you know, send, receive, find and use should be relevant to the full person record.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Thank you for that. Wholeheartedly agree, we tried to frame the roadmap not only from a person centered perspective but from a broad health perspective and thinking not only as you pointed out about success being defined by access to a particular provider's EHR but thinking about the movement of health information that supports a person and the decisions that they need to make oftentimes outside the care delivery system, right, in order to achieve health.

Specific thoughts, you don't have to give them now, but, on how we can make sure that carries through the entire roadmap would be tremendous.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Thank you.

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

David Lansky?

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

Thanks, I agree with Arien's comment I think it's really...you've really come a long way and I love the way you've laid out this section in support of business environment. Can you go to slide nine if possible?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Certainly.

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

Yeah, thanks, I think this is a very important point and it's really the first-time we've really strongly stated the link between federal, state and private sector activity to create pull incentives towards Interoperability and information-sharing which I think is exactly right.

When I was looking at the detail I was wondering if you talked about having more applied use cases or mechanisms to...rather than boil the ocean as it were with this vast, complicated, political it's proven to be very difficult to get these players to align on much of anything including payment mechanism for a lot of reasons.

But it may be more attractable if there were some specific mid-term objectives either around population, a condition, something that would draw out the requirements an infrastructure for real interoperability across these players.

So, I'm thinking of patients with complex chronic illness or dual eligible or other groups of people for whom if we could solve that piece of the ocean it would be a teaching process for everybody and begin to pull the mechanisms and standards, and interfaces through for more general applicability. Was that discussed or how do we get this concept into reality?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yeah, I'll give you thoughts and then I'll ask Kelly to chime in because she leads the really gritty work on this. That is absolutely part of the very detailed granular conversation about these policy levers. In fact, most of the policy levers that don't necessarily come through explicitly in roadmap but are part of our internal discussions are related to very explicit things like discharge planning or chronic care management. And so, in fact, the way the policies are often designed really drive toward that type of specificity it's very helpful. Kelly, additional thoughts?

Kelly Cronin, MS, MPH – Director, Office of Transformation – Office of the National Coordinator for Health Information Technology – Health & Human Services

Yeah, I would say we've had a lot of dialogue with states so far about what would the priority use case be and have thought, in the context of policy academies or offering support to them how might we get additional clarity on what are the top, top priorities for the next three years in the context of the overarching goal to send, find and receive across the care continuum.

I think we've also...you know, have a start with the chronic care management fee and Medicare Part B that focuses explicitly on those with two or more Medicare beneficiaries and two or more chronic illnesses and their transitions across the medical neighborhood and the requirement to use certified technology and to exchange with those transitions. So, I think it's an ongoing conversation.

The other venue we think that will be really important to get further clarity and prioritization will be the healthcare payment learning and action network which will bring together a lot of stakeholders particularly a lot of commercial payers and purchasers and really think through in the context of their work streams and their priorities how do we really make sure that financial incentives and the details around interoperability within the context of scaling multi-payer payment reform that this all can happen quickly as we all try to reach these ambitious goals that were sent out by the Secretary.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Maybe one other thing that I would note just on the use case aspect of your question is that when we set the three-year goal for the interoperability roadmap we didn't want to be constrained by a core set of use cases instead wanted to think about what's the core set of data that needs to flow and where does it need to flow in order to support a number of different use cases, right, and so I think we're at the point now, and actually this is one of the charges that we'll be teeing up for one of the FACA Workgroups, is for some of these very specific areas like policy levers, standards, etcetera we need to think about...now we need to think about use cases and what are those priority use cases that again that core set of fluid data can support and in fact if there are gaps in those data elements that type of use case activity will help us identify those.

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

Karen?

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

I have two comments and then I'm going to let Jon borrow my card and ask a question. The comment, Arien, I appreciate you recognizing that the goal is to move to a person-centered model of data that the reality in the short run is we have a lot of fragmented data and the challenge I think and the opportunities to get those systems to begin to talk with a core set of a common clinical dataset and some standards knowing that we need to evolve the policy framework beyond that. So, appreciate you pulling that out and this is where we see that the world needs to go.

My other comment, just...Erica may have mentioned it but I just want to underscore it, predicated on what David's asking, this is a dense document with a number of levers that we point to in there. I want to make sure that we have some clarity for this committee, these committees that the document did go through clearance and everything and there is something that the...our federal partners and anyone else who is mentioned has said, yeah, we're good with this, these are things that we think we can move forward with so there is not...it's not notional it's something that we do believe can be worked out.

On the other hand, you can't do it all in the next six months, as much as we would all like too. So, working out that discrete work plan of what are the most impactful levers that have to be addressed by when in order to see that we can get to goal and because of the Secretary's work around delivery system reform and that learning and action network it's a tremendous opportunity to work with private payers just as we have a tremendous opportunity with the DoD in the short run to make a big difference in actualizing the standards.

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

Thanks, and Arien, I also wanted say I appreciated your comment and I wanted to get to just one slightly lower level of specificity and see if this, you know, sounds right to you.

So, I'm guessing that if I said, you know, Arien I think what you're saying is that, you know, both a person-centered approach to interoperability, as well as a provider centered approach to interoperability both are important because both use the system you know so being able to do deal with both of those needs are important.

That in many cases those needs are, you know, similar and synergistic and can work together in terms of achieving interoperability for both providers and for patients. There are some places where there are tensions and those probably need to be called out and dealt with and with better clarity. Is that...

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

That's part of it, what I was saying though I think is a little different. I'm pointing out that person-centered interoperability really mandates that we have a sense of where a person's records are with the ability to bring them together both for, or all three for purposes of the patient or the person, him or herself, to be able to self-manage and understand what's going on for the purposes of the provider to be able to provide more informed care and then for the purpose of the system to be able to better optimize health and that all of those need to take place with respect to a holistic person-centered record as opposed to what we're merging toward, which is very beneficial, which is the ability to go look up one fragment of that record in the EHR system. So, that's the distinction I'm at least making between person-centered and fragment or patient at site centered record.

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

Perfect, thank you.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Thank you.

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

Gayle?

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

Thank you very much Paul and I think we certainly are on the right track when we start looking at really using the policy levers at the federal level but also down at the state level. People don't realize, as a state representative I can tell you very clearly, that the policies and the laws within each state are very distinct and very different, especially when it comes to things such as consent, things as privacy and what you are allowed to release.

So, making sure that ONC or the federal government really assists the states so that there is some overarching guidance would be very helpful for states to understand what that is and perhaps look to it. That is not to say that it will happen, however, without federal law preempting state law. This is not an easy thing to achieve as we move forward.

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

We'll go to the phone, I think it's Eric?

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

Hello, this is Eric Rose, so I had a quick question about...was intrigued by this reference to identity or excuse me I think it was individual data matching, the phrase that was used as an alternative to patient identity matching, and in the roadmap document it lays out that this includes entities other than patients including providers and devices and so forth.

And I noticed in the section that goes into more detail on this, I think it begins around page 90 of the roadmap document, it seems to focus, as far as I can tell, only on the patient matching. So, I was wondering is there another section of the roadmap document that deals with the other things that you would subsume under that larger paradigm or the larger rubric of, I think it was individual identity matching?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yes that's a good question. And so for folks, the individual identity matching section of the roadmap, currently the comment is correct, deals primarily with the concept of matching data for a person across disparate systems.

We do recognize and we call it explicitly in the roadmap that we need to expand that over time to really contemplate how we match data for devices, different systems, different providers and so there is not another section in the roadmap that deals with those other pieces in detail that's something that we need to evolve and iterate in the roadmap if not for the next version for future versions.

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

Thank you.

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

Great, thanks. Charles?

Charles Kennedy, MD, MBA – Chief Executive Officer – Accountable Care Solutions – Aetna

Yeah, this comment is a follow-up to David Lansky's comment about use cases. You know when we've worked with ACOs one of the things they typically do is to try and identify the patients who are high-cost and have high morbidities and what you typically find is you use the EMR you get one list of patients, you use the claim data you get a totally different list of patients and you ask the doctor and you get yet a third list and it's the doctor's list who is almost always the best. And so many of the ACOs we work with kind of de-emphasize the technology and really double down on training the physicians and making sure they understood the program.

And so the comment I'd like to offer is when we think about interoperability it seems like we talk about it almost like it's a static thing like if I follow these semantics and these tactics then I've achieved interoperability and I think we need to kind of expand the definition to include functionality because interoperability really is a functional state if we're going to get to the point of these systems really supporting physicians in the way we all expect them too.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Great comment.

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

Thanks. David McCallie?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yes, I thought Arien's comment about taking a person centric view to all of these recommendations is a great sort of crosscutting concern and we should rethink it as each one...as we go through each one of these sections.

But I wanted to raise another crosscutting concern, which is to consider the notion that what you've put in the roadmap is a floor and not a ceiling and that we need to be careful not to set sort of lowest common denominator assumptions that actually constrain us and take, you know, person matching for example it's a fairly rudimentary approach to person matching outlined in the document and many of our IDNs have gone far beyond that and implemented biometric systems and we have things like CommonWell that are doing nationwide identity management services and I think that kind of analogy will come up in other areas where the roadmap lays out sort of a minimum necessary but not necessarily a higher barrier or higher bar. And so I just want to bring that point up that...

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yeah.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

We don't want to set anything other than a floor here. We don't want to stop innovation. We don't want to stop expansion of ideas.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

I'm glad you raised that. It's...I think all of you recognize how difficult it is to make sure we strike that balance. The intention is to really think about a floor and the commonality, what's the minimum to achieve something that is functional nationwide, right, that's again not just pockets of success but is establishing a flow of data that can be expansive across nations.

If there are parts of the roadmap, this is a request to all of you, where you think we might be tiptoeing on the wrong side of that balance we may be inadvertently setting a ceiling as opposed to a floor or tiptoeing in the area of constraining innovation, it would be helpful to call those explicitly forward, again, you don't have to do it in the meeting today but at some point during the comment period because we can actually take a step back, right, and revisit those and have a conversation about those and readjust where we strike that balance.

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

Good comment. Paul Egerman on the phone?

Paul Egerman – Businessman/Software Entrepreneur

Great, thank you very much Paul and thank you Erica, great presentation. I also had a comment or a question about slide nine and I think it's great that you are talking about this call to action to get state governments and other entities, players involved.

But my question is, as somebody else had just said, you know, the entire interoperability process is evolving and ONC's certification process changes and there is like a 2014 edition, there is a 2105 edition, there are basically upgrades and versions now to the certifications and is there a concern that some of these entities, a state government or a non-government payer or purchaser will provide, in effect, regulations around a different version of interoperability than the federal government is providing or the states themselves will be different and is that an issue that you've considered and do you think there is any need for coordination of that activity?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yeah, Kelly, do you have thoughts on that?

Kelly Cronin, MS, MPH – Director, Office of Transformation – Office of the National Coordinator for Health Information Technology – Health & Human Services

Yeah, I think part of the rationale around the standards advisory for best available standards and also just the need to coordinate across sectors on these incentives, you know, sort of speaks to this issue. We don't want to be giving mixed signals to providers we want them to know what are sort of the common, widely adopted industry-standards that are working for summary record exchange or are working for ADT alerts and have everyone sort of reinforce the developed, tested, balloted standards that are either recognized already in the certification program or in the standards advisory and have been vetted through that process.

So, we do expect to have a lot of ongoing collaboration with states with Medicaid programs, with the other payers that they work both on a state and regional level in addition to any national players or others that are involved in this learning and action network we alluded to before.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Maybe the only thing I would add is I have not counted the number of times we used the word "align" in this section of the roadmap but it is common, it is a common term in this section and I think really speaks to what Kelly was just talking about and to the question which is, there does have to be some systematic and intentional alignment across these different levelers if, in fact, we're going to...they're going to work in concert.

Paul Egerman – Businessman/Software Entrepreneur

Thank you.

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

Thank you. Wes?

Wes Rishel – Independent Consultant

Thanks, I have two comments; one I was delighted to hear you use term ultra large system today meaning a system that is too big to be managed that somehow has to carry the processes of management within itself as opposed to being externally managed. I went back and did a search in the report though and I didn't find the term or even the concept necessarily discussed there.

I think as you roll forward it will become increasingly clear that the principles that create the governance for the healthcare network will be those that enable use cases to arise out of economic necessity and multiple solutions to develop and some be proven and some not as opposed to being identified and going through a waterfall process. So, I urge that point-of-view going forward.

On a related issue, I carry a card now that says "retired healthcare interoperability nerd" and it allows me to look back on 30 years of working on interoperability and it strikes me that it only ever happens when some non-technical person has a job function that will succeed or fail based on it and then it happens in the fastest and best way possible and if that happens to be idiosyncratic so be it because it became a business imperative rather than a box checking exercise.

We talk about the changes in the health care system and the payment structure and so forth that create that condition where some person who is not a technologist job depends on interoperability, presumably a CEO, a chief medical officer, all of those people who like to believe they have some impact on how physician's practice.

What we will see...what we're seeing now, for example, in gathering data for analytics is imperative driven ad hoc nonstandard solutions that create business value. We somehow need in this plan not to stifle that but to learn from it.

And I believe that like the Internet we will find this ultra large system has some important fundamental processes, principles and standards but for the most part is very Darwinian in terms of how it succeeds. Thanks.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Thanks.

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

Andy?

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

Thanks, Paul. I'm concerned as I read the document and listen to our conversation that we're talking about interoperability as our goal. In fact, for me, at least, it's the means to an end. The goal is not interoperability. The goal is that at any clinical decision whether it's taken by a patient or by a caregiver is taken with full information at hand. And if we don't structure our measures and all our statements about where we're going to that goal then what we'll get is a set of process stuff that doesn't actually get us to that goal. It's the difference in quality, David, between process measures and outcome measures.

The outcome is we make decisions with good information that's what we want. And if we...with Wes if we do it by some nonstandard way it's still the right outcome and then we can learn from that. So, I don't want to wordsmith but I think that if we don't focus people's attention on the ultimate goal by stating it we will not get the non-techies on board.

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

I think that's fair. I think one of the strains of the document though is the background structure and that each one really justifies why we would work on some of these process measures so maybe it could be stated more clearly up front, but I'm sure ONC understands. Anjum?

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Thank you. Thank you for the presentation. So, this is...I want to clarify, you know, the wording that is used here and maybe we need to, you know, clarify it in the document as well. The goal between 2015 and 2017 that refers to, you know, common clinical data, as we all know there is enough evidence to show that if we need to improve population health and the health of patients we would need more than the data that is collected in the clinical or medical settings.

So, is there an assumption that this will include all necessary data that is required for improving an individual's health especially related to social and behavioral health data?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yes. In fact...so we described this explicitly in the vision paper. So, we put forward a vision paper that says "here's what we want to accomplish, here are our goals, here's the end we want to get to with interoperability as a means." The roadmap is intended to be the companion document that says "here's how we think we get there."

So, we describe very clearly that in a three-year timeframe what we think is realistic is probably focused on a pretty narrow set of clinical data again since our site is set on this notion of nationwide interoperability.

But we talk very explicitly about expanding that in this six-year timeframe imagining that starting at the end of 2017, the beginning of 2018 to include many additional data elements, data sources, data users that certainly expand beyond the care delivery system. We talk explicitly about our prison system, about human services, public health, the research community. I think we've also found...so that is absolutely an intention but we want to take digestible chunks or bites.

The other thing that I think we have found as we've gone through this iteration around the roadmap is that, and I don't have a slide unfortunately with a common clinical dataset on it, but it covers basic stuff demographics, vitals, labs, medications, medication allergies, care plan, notes. In fact a lot of the things that are on that list while those won't cover everyone's needs and every use case they actually cover a lot of different needs beyond the care delivery system whether it's, you know, the desire to link genetic data with something around your labs or simply the need to accurately, again going back to accurate identity matching, matching information for people across systems, having a consistent standardized way to share this information so that, again, I don't think I said this explicitly, but I'll say it explicitly now, and we do say this in the roadmap, we really want to drive toward semantic interoperability for that dataset, should help and put us on a path that leads us to a much broader and richer data flow.

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

Okay, Jim, you have a final comment?

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

Thanks, so thank you also for, you know, for both a great presentation and a great document. I want to build on I think a number of the comments that have been made Andy, David, Arien, David and others, but in a particular area where we want to make sure not to set a ceiling instead of a floor and that is that perhaps an unintended focus on requiring transactional movement of data between entities and this is not to say that interoperability is not needed but it's also to allow for cases where the patient centered view or dataset can be created by actually sharing platforms, sharing authoritative sources among entities. And this is certainly accounted for in ACOs and patient centered medical homes, also in organized healthcare arrangements as organized under HIPPA.

And so I think there is an interplay between allowing for shared platforms and allowing for the development of health reform in terms of the delivery system transformation. But I think then separately we're also seeing a number of new cases where new technology platforms can share some of the collect, share and use functions on a single shared platform and so where you would potentially set a requirement for transactional movement of data we just want to make sure that this happens where it's needed but not where it may not be needed.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yeah, that's a great point.

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

Okay. I think we're going to proceed with the next section which is on rules of engagement and governance. The committees will remember that we did have an RFI on governance a few years ago and at the time the public's advice was to sort of stay out of it for a while and like many things EHRs or as Wes was pointing out the interoperability we've been here before there is a time for everything. And I think particularly with the reform coming, the reformed timeline, that time is closing in and we need an organized way of working on these rules and so I think that's what Erica is going to talk about.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yes, yes that's perfect, thanks, Paul, and I think this is the last section we're covering before lunch. I anticipate this will be a juicy discussion.

So, the environment that we see today is an environment where there are a number of different data sharing arrangements they may be technology networks, many of them have what we typically think of as governance structures associated with them, right, there has to be some way of establishing trust between data sharing partners, establishing some ways of operating almost always involves some, even if it's very lightweight, some degree of addressing business practices and common technical ways of moving information, right, particularly around standards.

The challenge is we don't see consistent bridges across all of those different data sharing arrangements so that we can start to scale the movement of information again nationwide thinking again about the frame of reference around nationwide interoperability.

As we've talked about, how do we get to a place where there really is a seamless flow of a common clinical dataset whether individuals need it or care providers need it across the country? It has, I think, become fairly clear that there has to be some organized way, to use Paul's term, of coming to common decisions about three, at least three categories of stuff. We call these policy operations and standards you'll note in the roadmap the governance section addresses each of these explicitly.

Doing that, coming to agreement in an organized way around decisions that relate to policy operations and standards for nationwide interoperability is hard to do without some singular framework for that, some common framework for that and a common process for that.

So we put forward in the interoperability roadmap a few bold actions on ONC's part, a very clear commitment from ONC to establish a common governance framework with rules of the road for interoperability of a common clinical dataset. We suggest starting around purposes using...purposes of treatment, use of that information for treatment and then expanding those uses over time. We do put forward a set of principles, high-level principles in the document that relate to each of the categories that I just talked about.

ONC also commits to identifying a process for recognizing organizations that comply with those rules of the road, those rules that are part of that governance framework. I will say we are evaluating both regulatory and certification options for carrying that out.

And then we put forward a call to action to public and private stakeholders to establish that single coordinated governance process. So we did not say ONC should establish and operate a process but rather a frame and that it really is incumbent upon the community at large to sort out what that process should look like and come together ideally very quickly around that process. And I'll pause there. There is other material in governance section but I think these critical actions give you quite a bit to react to and chew on.

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

Okay. Open for questions and Gayle, please?

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

Thank you very much Paul.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

I'm so sorry, Gayle, just to interrupt really quickly, Jodi Daniel is on point to answer questions with me for this one, thanks.

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

Terrific, okay, well maybe Jodi can help me. To me governance is extremely important because the reason we make laws is because people don't follow the generally accepted rules of the road and you wind up with laws.

As part of governance and if we...and I like the idea of public/private stakeholders working really to help establish that and perhaps implement it in a certification process but there are always those who diverge from that and there are bad players out there. We've just seen an example of some of that. What do you anticipate to do to deal with the bad actors?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yeah, well, I'll give you a few thoughts and then Jodi may have some others. So, the way we've described this in the roadmap I actually think there would probably have to be activities that attempt to address noncompliant actors or bad actors at multiple levels.

Certainly, if ONC launches a process by which it identifies organizations that comply with a framework and comply with rules of the road we would need to have a mechanism for knowing when they don't because we don't want to inadvertently say, yes this organization does and when in fact they don't. So there is something that would have to operate I think at that level.

When we think about a process that is very operational in nature and managed ideally by stakeholders many of the details that would have to be sorted out through that type of process, again, relate to things like business practices, relate to compliance of standards. They would have to have a mechanism for identifying those bad actors and addressing them. What that would look like I think would be up to them.

Your point is I think very well taken that sometimes industry is very good at self-managing and self-regulating and sometimes it's not and that's something I think we'd have to keep a close eye on. Jodi do you have other thoughts?

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Yes, so just a couple of things Gayle that I wanted to add, one, for the very reason you're saying about making sure that folks are not just, you know, all working together to share the information but that there are some rules of the road with regard to consumer protection making sure patient data flows appropriately, privacy, all of that is...that is the reason that if you see the first bullet that we wanted ONC to establish a governance framework and we put forward set of principles for comment for folks to give us feedback on to start flushing out what are the areas where we have to think about consumer protection, what are the areas we have to think about making sure that the data flows appropriately and that there aren't blocks to the data and some people have their data flowing and others don't that kind of thing.

So we thought that there was a really important role for government to play in creating those rules of the road and so that's what you see in the document. And, you know, we're looking forward to people's comments on that.

We do...we are talking about how do we hold people who say they're following the rules of the road accountable for following those rules of the road and we are, as Erica mentioned, exploring options for how we can do that.

You know the one thing I will note because I think it's important to note is that we want to create a process that folks want to be drawn to because it will open up the door for better care for their patients, better access to information in order to improve the health there of communities and of providers, patients and for patients themselves.

But it is...you know the way we have this set up...the reason we have public and private stakeholders coming together is that we don't necessarily...we can't go out and say, you know, there is somebody who is trying to hack into the system and we, ONC, are not going to be able to go after those kinds of bad actors. There are other mechanisms in place to do that.

And so I think what we're trying to do is figure out...set the parameters and the principles for health information exchange in governance that address consumer protection, address the appropriate flow of information and try to bring folks together over diverse policies so that we can have that nationwide flow of health information for improvement of health and then a way of holding people accountable who say they're going to follow those rules of the road to do so.

We are also looking also at tying it to other programs so that we have...keep people accountable to complying with those rules of the road. But there could be activities that happen outside of this process that we may not be able to control and I think that that's an important point to make.

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

So, as a follow-up to that then pretty much we don't have a framework yet and we're looking for further comment and advice as to how to hold people accountable.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

So, we started laying that out. If you look at the roadmap there is a comprehensive set of principles that we have laid out that are our proposed set of rules of the road. So, I encourage folks to take a look at that.

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

Enforcement mechanisms at this point it's we're still open.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

We are exploring, how do we hold people accountable to meeting those rules of the road once we have them enforced, yes.

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

Thank you.

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

Good, thanks. David McCallie?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yes, thank you. My comment will piggyback on the comment I made in the previous discussion which is that in thinking in terms of ceilings and floors that we have to be really careful in enumerating these rules of the road to come up with the minimum necessary to achieve the desired outcome without overly constraining the system in what on the surface might seem like a good idea but in fact actually inhibits progress in a variety of ways.

So, I'll just make a bad metaphor, but sometimes metaphors are helpful, if you imagine the designer of the Internet sitting down and saying, we've got this HTTP and this HTML and everybody can connect their web browsers to the web servers let's come up with a shopping cart standard so they can purchase goods at any website and carry them in their electronic virtual shopping cart from website to website. You can imagine that sounds like a great idea but in fact it would have been a terrible idea and it fortunately didn't happen and vendors who sell things on the Internet have competed to make that shopping experience interesting and more flexible than had ever been the case if you tried to standardize it.

So, when we do rules of the road and we deal with things like privacy rules, identity rules that absolutely have to apply to everybody that makes a lot of sense. If we start getting too deep into the standards for exactly how you must interoperate then I think you are on thin ice.

And the JASON Task Force tried to deal with this with this notion of data sharing arrangements that would have bridging amongst them so that you could have independent entities building collaborative networks that would achieve ever higher capabilities but would be able to bridge to the other networks in whatever minimum ways as defined as part of the rules of the road. So, just again, caution, don't overdo it, set the floor but don't set the ceiling.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That's a really good cautionary note. The other thing that's not on the slide that I will mention is we need some measurement to know, right...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yes.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

When we're treading in the wrong space and we do call for specific measurement activities around the governance activities that there is a check and a balance and an opportunity to of course correct. So that's a really good point.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

And I would just agree with your point. I think if you look at the rules of the road that we have put forward I think at a sufficiently high-level that they're not sort of crossing that line, although, would love feedback on that. And I do think we probably have to get a level down below that as well and think about how you operationalize them.

But I think our expectation was that we were sort of setting the guardrails, the parameters we weren't necessarily telling people how...like, you know, if the speed limit is 55 we're not saying you have to drive 55 we're saying that that's the speed limit and there is some variation within that, you can drive 54, you can drive 52. So, I think what we're trying to do is set the...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

How about 60?

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

You can probably drive...well, that's a different question.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Maybe 64.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

That's 64...

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

Sixty-four.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

But the goal is to set the guardrails not to tell...not all of the operating rules. Now that said I think what we have put forth, and Erica you can jump in as well, with this a public/private stakeholder governance process is that there may be some more detailed operating rules that are important in order to bridge between different governance entities or different health information exchange organizations, or health information exchange activities and so we would expect that this coordinating governance process would help identify what those are and the level of detail that we need to get at in order to get that interoperation between the networks.

But what we tried to do from a federal government stand-point is set forward principles that would endure and that would kind of set those guardrails even as the technology changes as there is more information flowing so that the principles would endure and maybe some of the operating details may need to change over time. So that was... we tried to make it kind of future proof so that it can stay at a principal level and then there can be more details that are necessary.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And thanks for that and I agree I think as soon as...the part that is likely to change the fastest is the part you should be most careful not to...

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Over constrained and that's going to be the technology and the functionality.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Yes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So, privacy rules are going to be pretty slow changing, you know, what's the minimum identification requirements to join the network and to participate in the network, what are the expected DURSA-like constraints on parties, those things would change very slowly and make good candidates for well understood articulated rules of the road.

The technology, the capabilities, I mean, I hope that five years from now we're not still doing document-based exchange as our only way to do interoperability. But if we were to standardize it today that would be what you'd pick.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

That would be right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And that would be a mistake.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

That's a good point, thank you.

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

Thanks. Arien?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

I'll follow-up on David's comments. The HIT Policy Committee's Tiger Team has published through the Policy Committee really, really helpful clarification and guidance in areas of policy that have remained a mystery to many practitioners that's the kind of governance that done well can increase flow of information.

You know I was reminded in Gayle's comments about the recent breach issues. It's important that we not treat the target of a sophisticated state actor as being themselves a bad actor. It is though important that if there are well recognized standards for security, security risk assessment and defense against known patterns of attack that promulgating a framework and guidance for those kinds of things is incredibly useful.

To David's point where it gets very concerning is where...and I was just involved in a conversation today with a counterpart from Carequality and were talking about a notion of doing XDS-based identity queries and there is a simplicity in believing that if only everybody does just this then we'll get interoperability.

And what we discovered when we engaged in the conversation is that there are different problems that CommonWell is trying to solve from this problem that eHealth Exchange is trying to solve and a broad brush kind of brute force approach would get us to a point where, to David's point, we're stuck at the floor and, you know, not the ceiling.

So, this is an area where there are areas in governance that I would absolutely applaud where it involves clearing up areas of mystery, addressing well-known bad actors or addressing activities that people have pointed to in the past as being potentially on the side of bad actors like use of de-identified data and providing appropriate frameworks for those kinds of things.

I do worry that governance poorly done, and particularly in the area of standards because that's one of the areas that's explicitly called out, would have a negative consequence of either driving us towards a least common denominator approaches or almost as bad just getting us in a morass of not actually addressing the real issues. So I think the summary is it all depends.

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

Wes was your card left over or a new one?

Wes Rishel – Independent Consultant

No.

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

Okay. Anne?

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

Hi, I don't know what near-term is on here but we're solving this problem one at a time today. So, I would go back to an earlier comment and reiterate how we need to bring in what's actually going on and not what we want to go on and, you know, feed the process from that as well because your timeline is not helping at all. It's another layer of pain and money, and waste right after ICD-10, right after health reform, right after, you know, implementing EMRs and if...we're doing connectivity today, we're working it out. We need to talk before we get a governance posture. We need to look at what's gone on in the industry and see if we can model after some of that.

We can't sustain the hits we're getting if our overall goal was to actually reduce the cost curve and to improve quality and gain satisfaction because we're just going to hit the providers again, we're going to hit the payers again and we're going to give vendors and opportunity to make your money.

So, I'm just saying that this is all great and good and it sounds wonderful and you're moving forward and there is a blank slate but there is not a blank slate here and I just want to make sure that we bring to the table some of the things that we're already learning from. So, thanks.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yeah, I would just reiterate one of our guiding principles, right, where this about principle-based interoperability, one of our guiding principles is to build from what's working, build from our existing successes. So your point is well taken and that's absolutely the intention.

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

Thank you. Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, I would like to echo some of these comments but when we think about governance fundamentally we have to protect those that we serve which is the patient all of us. And we also want to make sure that the patient's entry into this world come with consumer innovation, come with things we don't know about yet.

And so perhaps as we think of this infrastructure and the rules of the road we emphasize the on-ramps and the off-ramps as a place for governance because it might be one on-ramp has a Jiffy Lube and the other one has a hospital but we've got to have something that would accommodate that we don't know what we don't know. There will be all kinds of things coming up to support consumers as they enter.

But if the governance and the structure emphasizes the on and off-ramps without mandating the world beyond we have a secure environment with significant flexibility beyond that would sit around the patient.

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

Good, thank you. Okay, I think that may clear out the comments from the committee and I think we are...at this point we could go to public comment if that's appropriate.

Public Comment

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

Operator, can you please open the lines and if there is anyone in the room who would like to make a public comment please come up to the table. And if you are making a public comment please state your name and the organization that you represent and public comment is limited to three minutes.

Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute

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

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

While we're waiting for public comment I overlooked John Derr.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC

Yeah, I'm sorry I thought was going to be more, I was going to make it a little bit later, I represent, as you know, long-term post-acute care, I haven't read it entirely, oh, she left, oh, I haven't read it entirely but I haven't seen anything on there on timeliness of the interoperability and, you know, in a nursing home or a home care agency we get people at 4:30 on Friday afternoon and sometimes we're getting the electronic record on Monday or Tuesday which is irrelevant.

So, I'm just saying in...there should be something about it in the transitions of care documentation that it has to be timely too. If they're just going home and they have no more care in a longitudinal person centric care plan that might be one thing but somewhere there has to be timeliness because it's really not helping us when we get the electronic thing, record, on a Monday or Tuesday when we have to start medications on Friday afternoon.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That's a very good point. We talk broadly in the roadmap about making sure that information is accessible when and where it's needed and timeliness is a fundamental piece of that. It's something...the notion of timeliness though is something I don't know that we call out explicitly in other parts of the roadmap and so that's a great point and something we can look back at.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC

Thanks.

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

Thank you. Are there any public comments?

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

No public comment.

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

Okay, this is a long day so we're going to move up the schedule for lunch. Lunch is allocated for one hour so that would be 1:25 and we'll try to keep that to make sure we get out on time. Thank you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Thank you, Paul.

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

If you all could take your seats we're going to get started in a moment. If everyone could take their seats we're going to get started. I think we're ready to get started we're just waiting for our key speaker but I don't know if Karen or Paul, or anywhere else has any comments beforehand.

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

Karen wanted to make some introductions.

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

We lost Erica at the break. If we lose Erica we're all in really big trouble...

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

...

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

That's what I'm saying. Thank you, Michelle, we just wanted to take a minute, we've been adding some new members to the team at the Office of the National Coordinator for Health IT and wanted to make certain that the committees had a chance to know them by not only name but by face.

Someone who is not here with us today is Chartese Day she has been on the team now for a few weeks. Some of you all might know Nora Super she and her folks are part of that so she's in that role of the Director of the Office of Public Affairs and Communications, Chartese Day. So, you'll probably see or have already seen her e-mails, her name and e-mail in other places. So, that's one person.

Dr. Mike McCoy, if you could stand up Mike, joined us a couple of weeks ago as the Chief Health Information Officer who has a...I think a lot of you may know him he's been in the Health IT space for quite a number of years, trained in OB/GYN and is really going to be technically helping us with rules and standards but also in the interoperability space, note the name, Chief Health Information Officer not Chief Medical Information Officer, thinking that this is about health and a broader view. So, thank you Mike for joining the team.

And then Andy Gettinger who, stand up please Andy, joined us a couple of months ago, I'm losing track a little bit but I think this is the first meeting we've had since you've been on the team, who actually was in Washington as a Health Policy Fellow with RWJ for a couple of years is based up in Vermont at Dartmouth, I have the wrong state, New Hampshire at Dartmouth, and is an anesthesiologist by training but is down now doing the clinical and quality shop, he's Acting Director of the Office of Clinical Quality so things about safety and quality and usability in that portfolio so I wanted to make sure I called you out too. Oh, and look and our speaker is back, perfect timing.

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

Andy is also, is the Chief Medical Information Officer.

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

Thank you.

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

No problem, in contrast to the Chief Health Information Officer.

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

Thank you, thank you so much...yes ma'am.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Hopefully, everybody had a hearty lunch we've got a little bit of a marathon afternoon I think ahead of us. So, to pick up where we left off, we'll dig back in with privacy and security protections for health information. A number of different topics are addressed in the roadmap under this building block. We thought for purposes of today's conversation we would focus on privacy and privacy aspects of what we've put forward.

So we know that the legal requirements for health information sharing are philosophically aligned across our different state boundaries but in content actually differ quite a bit. In order to effectively and seamlessly communicate decisions about information sharing permissions and to get to a place where we can actually start automating that, so the collection, transmission and persistence of information about permission carries forward we need to think about some alignment across these different boundaries and these different policies that relate to privacy and permission to collect, share and use identifiable health information.

Other topics that we address in this section, just to call to your attention, we won't talk about them today again unless there is time and there is appetite for it, are ubiquitous secure network infrastructure, verifiable identity and authentication of all participants and consistent representation of authorization to access data or services.

So what do we say in the roadmap, near-term critical actions, for OCR and ONC we really call out the need to educate stakeholders about the current federal framework for health information, privacy health information sharing. We know that there is a lot of misinterpretation of HIPAA. Sometimes HIPAA is used as an excuse to not interoperate other times there really is just a genuine misunderstanding of the parameters of the privacy rule and so we think there is a lot of good to be done by educating the broad array of stakeholders about what in fact the current federal framework is, what are the permissible uses.

For both federal and state government we call forward, excuse me, a call to action to reach consensus on what is permissible to exchange using disclosure for treatment, payment and operations without consent for information that is regulated by HIPAA, I was just mentioning this, you'll hear Lucia refer to this often times as background rules so what happens to information when someone doesn't make a written statement or give a written permission.

Not for the three-year timeframe but moving into more of the six year timeframe we do talk about standardizing existing laws pertaining to sensitive health information so not just the basic stuff but what's characterized as or deemed sensitive so that laws mean the same thing in all US jurisdictions without undermining the privacy protections that individuals have to date, so this is more about alignment and streamlining not reducing privacy protections. And again, this is because we really need the permissions that relate to sensitive health information, the definitions first of all for sensitive health information and then permissions related to that to be able to transmit across our technologies in a pretty seamless way.

And then there's a call to action to stakeholders broadly. This is not just for states but also for the vast array of data trading partners, organizations that establish policies for example, to align their policies for information sharing regulated by HIPAA with HIPAA permitted uses and disclosures for TPO and to then actively share health information in accordance with the law.

And I'll pause there, Paul, see if there's an opportunity for discussion. Lucia Savage, hopefully all of you know, is our Chief Privacy Officer she is on point to answer questions with me and has lots of insight to share on this.

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

Good, thank you. Comments, questions about privacy? Arien?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

So, first of all I applaud this work, clearly reaching consensus on background rules or contextual integrity with regard to information sharing between state and federal jurisdictions would be incredibly useful it's a pain point. I wonder...so, heavily encourage that and heavily applaud foregrounding this notion of the background rule.

I have two pieces of comment here, one is, is this the place where we discuss the notion of basic choice and I was a little confused by the notion of basic choice because in some senses it was or in some language it was implying that there had to be some basic level of choice before permitted use could be...information for permitted use could be exchange. So, I'd love some clarification of the thought process behind basic choice.

And then as a scope framework operations is such a huge space that I'm wondering whether it would be more profitable to focus on treatment first. I think payment is relatively noncontroversial and then carving out areas for operations use like quality improvement that have a significant impact on the framework and on the achievement of accountable care and other kinds of value-based arrangements that don't require us to wade too far into the morass of operations use.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Sure, Lucia do you want to talk a little bit about basic choice?

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

Sure, so here's the thing about basic...let me start with the background rule. So, in HIPAA are already rules that support the interoperable exchange of information without getting writings from patients unless state law or other federal laws apply and some of those actually reach directly to, let's just call it provider to provider movement of data with certain types of operations but not others so there's actually already in the laws and regulations a pretty narrow scope and that's what the education is going to focus on.

However, where we find ourselves, sort of six years into HITECH and with this rapid cycle sort of dynamic environment where the technology is changing is we find two things, one is a lot of organizations trying to sort this out for themselves, and as Anne referenced, you know, coming up with governance that works for them have actually manifested choice but we don't have any standards for what that looks like and how you capture it, and what is fair to the consumer, and how it's persisted so that's part of what basic choice is as described in the roadmap which is we have a manifestation.

You guys have all been around long enough to have heard opt in/opt out whatever you want to call it, we have this manifestation of consumers being offered some type of choice relative to the activity of electronic exchange versus paper exchange, versus their physicians talking to each other on the phone and we need to bring some standards to that space and we need to bring standards to that space that facilitate where we need to get in 10 years for the learning health system because if we do it wrong we won't have evenly spread data that reflects the demographics of the population for purposes of learning so that's what basic choice is and I don't want to belabor the point today.

And then the last thing I'd say is also know that because we've been asking patients and consumers, and their antennae are up in a really good way they're paying attention, they actually want to be asked. They want to be asked about what their data is being used for and they want to know where it's going and so that tells us philosophically that there is a desire on the one hand of consumers to access this for themselves and on the other hand they actually want to have some respect for their autonomy.

And the last thing I'll say is, that access is a really key part of it and it's something we all forget but individuals have a right to access their health information even in an electronic environment and we need to really capitalize on that as we empower the consumer and those patient centered or individual centered environment.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Okay, can I follow up on that with maybe one follow on question? Is the notion that HIPAA is insufficient or is the notion that for organizations that want to do a little to explain HIPAA better, HIPAA permitted uses better, there needs to be a framework for those organizations to better explain that framework?

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

I wasn't even thinking about it that way. I was thinking observing that we have dozens and dozens of organizations whether their state designated entities or, you know, private organizations that have sort of struggled with how to respect individual autonomy, get data available for exchange, respect people's fears, some founded some unfounded, about the dangers of electronic exchange and that we don't have standards for them.

I mean we literally looked at whether there was some kind of choice standards we could put in the standards advisory that Steve will talk about later and we could not identify a good one. So, I wasn't even thinking about it at that level.

I would hope that through education and standards we would be able to provide tools so that people can do what's right in their populations with these governance minimums that Jodi is talking of.

And then your second question is HIPAA it adequate. HIPAA is what we have. I do not have an opinion about adequacy or inadequacy my job is kind of to diagnose the landscape we have HIPAA, we have other federal laws, we have state laws and that's the landscape that we have and we need to advance interoperability with the landscape we have.

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

Thank you. Gayle?

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

Thank you, Paul. And I think the Privacy and Security Tiger Team several years ago really addressed meaningful choice and I think that perhaps going back and revisiting some of that could help set...move this discussion forward and I'm sure Deven's going to jump in on that, but I really want to talk about states and the difficulty that there is among states and the different laws very much related to consent, very much related to privacy and security.

So, I think...I remember several years ago I sat on the National Governor's Association, had a committee that addressed...that started to address a variety of things, this is back in the early 2000s, and really at least started a conversation, unfortunately that no longer exists but I think this is a discussion that needs to happen across the country and my suggestion would be that a place to start is the National Governor's Association and it takes...then it takes legislators because governors don't make laws, legislators make laws

So, it takes a concerted effort to at least level the playing field across states and it's not without contention. So, this is not something that's going to easily happen and it's a conversation that needs to start as soon as possible if we want to meet this timeframe and you've got a three-year time window that you're establishing here.

So, my question is, is this unrealistic to think that within the next two years you can align state laws to be able to allow this kind of interoperability specifically on behavioral health information. You've got federal statutes, federal laws, you know, in 42 looking at laws, federal restrictions. You also then have...every state has their own set of that dealing with substance abuse and mental health. You then add to that such things as STDs, HIV, abortion, you name it every state has their own perspective on those kinds of things. So, it's not an easy task but it is certainly something that must happen in order to have true interoperability across state lines.

When I get hit in DC by a bus I want to make sure they get my records from Florida, you know, so we all have to work together to make this happen.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

I think we're in violent agreement. Lucia may have some specific thoughts. I'll just share a few general reactions. So the trajectory that we've kind of plotted out around this notion of alignment across states and the roadmap starts in the three-year timeframe really focused on this notion of basic choice and thinking about HIPAA then moving in the six-year timeframe toward common definitions for sensitive health information and alignment of policies and laws around those. We did that in part because we recognize, to your point, it's highly unlikely that all of that progress would be made by the end of 2017 and we would all sing kumbaya it's just...it's not realistic and so we've tried to kind of stage that sequentially in the roadmap.

The other thing I want to draw your attention to is there is a specific critical action included in that section around what we're calling a state policy academy and Lucia can talk in a little more detail about that but it's a very aggressive approach that we're teeing up to bring states together and engage in that type of dialogue. Lucia do you want to add anything?

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

Yeah, two things, so I think Erica is right that we do have a focus on articulating standards for what are the known background rules under HIPAA, what is basic choice but we're going to be doing a lot of things in parallel at the Chief Privacy Officer's Office and our activity to develop this policy academy is underway already. We're hoping to get feedback from you guys hopefully you'll validate what we observe and what we've drawn from our conversations with not only you but many other stakeholders out in the field and if we're wrong we have the opportunity to of course correct but we think we're right in we're charging ahead.

That being said, it is a very complicated environment, there are legislative calendars some states don't meet every year, there is, you know, a general election in 2016 not just federally but in most states as well and to your point earlier Gayle a state has to want to do something about the environment it finds itself in and that it created for itself. Our job is to help bring some expertise to that goal and hopefully get all the states headed in the same direction.

And the last thing I wanted to address was Part 2 42 CFR Part 2. So, here's the interesting thing about that, very restrictive rule you're all really familiar with it. It's the same in every state. So, what we know from that is if we can, you know, use for example our data segmentation for privacy to help move data where it needs to move for people who are being treated in Part 2 regulated facilities we can do that because all those facilities are the same. We don't have a different Part 2 rule for Maryland, you know, than for Pennsylvania.

So, there are actually a lot of learnings we've done on this going back to HISPC and since then, it's not just the Tiger Team, it's HISPC, NGA there is a bibliography in the roadmap you can read all about it.

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

All right, thank you. Deven did you want to add on?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, I don't think I was next in the queue though, but...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay, so I mean, I just wanted to maybe reinforce the thread that Arien started that Gayle picked up on and that is the sort of concept of basic consent and what you're trying to say in this roadmap about when it would be required versus saying when you get it either because you have, as a matter of institutional or HIE or other policy, decided that you're going to extend that choice to patients or when it's legally required ideally we would have both standardization with respect to policy and as I think you and Gayle both pointed out that's a tough thing to get for at least the state law piece. But from a standards perspective we ultimately want that to be conveyed ideally in a standardized way.

But I just want to ask to articulate once again are you actually saying in the report that you're calling for people to have basic choice about any exchange of their data for any purposes or are you suggesting that when choice is present either because it's imposed as a matter of, you know, sort voluntarily this is what we want to do for patients or it's required by law there ought to be ideally some consistency both from a policy and a standard's stand-point?

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

We tried to draft a roadmap to state the later which if you're going to do this let's do it in a standard way.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay.

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

We know that in fact, you know, among...across ACO settings, in other...in many other settings people are taking advantage of the permitted uses which do not necessarily automatically and as matter right offer people choices and there are other settings where people have been offered choices. If you're going to do it do it in a way that's standard so that all the actors in the system understand what that offers and the patient's response to it entails in terms of what data would be available, how that data is going to show up when it moves or doesn't move, etcetera.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay, thank you, that's what I thought but I just wanted to make sure.

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

Good, thanks. David McCallie?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yes, thank you, I think that...first off I liked the clarity that the roadmap brought to this problem in the early pages of the section and then it got more and more complicated as you layered on more and more of the complexities and potential inconsistencies and what you're left with, when you start you get an optimistic view that HIPAA is actually going to help us enable some of the data sharing that we want and you end up with confusion again that, gee I'm not sure what we can do at all. So, it's going to be this messy problem that we've wrestled with for so long.

What I think might be a useful approach would be to identify some very simple focus sort of unambiguously straight up use cases and then work through the privacy issues to enable those use cases almost in the form of guidance and I know that word guidance has technical meaning and legal meanings and I'm just hinting that it would be powerful guidance that would allow participants who want to exchange on that fundamental basic level to do so without some of the complexity that we go through today and it would be in the context of a very specific and narrow use case.

So, you know, my hypothetical, most common use case is the patient with their provider giving that provider permission to go get the rest of their record and bring it to the point of care because they want a complete record to guide their provider. That use case ought to be straightforward, well enumerated, all the details lined up and any ambiguities addressed to the degree that the law allows us to address them and then pick off another couple of simple use cases that may layer on top of that perhaps around the 42 CFR Part 2 data that's more complicated where you have to have written permission and things like that.

But laying out all the rules leaves us with the same confused mess that we started with, laying out a few simple use cases that we all agree are valuable, noncontroversial and make it a smooth path for those of us that have to implement systems would be a really helpful part of the roadmap.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That's a great suggestion for the educational piece that we've got on here. Thank you.

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

Thanks. Dixie.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I wanted to make two points and thank you I think you've done a good job. Two points I wanted to make, first is as we move toward the learning health system the use and sharing of health information for clinical care and for research purposes are beginning to converge and that convergence will continue to blur this distinction before it just goes away, the PCORI Initiative is one example, the precision medicine's initiative as another example.

I'd like to see a recommendation for harmonization between HIPAA and the Common Rule and also a recommendation to address privacy on autonomy along the whole continuum of data use not just here's for clinical, here's for research because that distinction is going to go away.

The section...the second comment I wanted to make, I'd like to encourage thinking about consent as an ongoing process and not as a signed piece of paper. I think in the future computable consent, which you use in your slide and in the roadmap, will be the standard for consent and not the signed piece of paper so harkening back to David McCallie's comments that he has made several times I don't think we should constrain innovation by continuing to think of individual permissions as this signed piece of paper that you file in a drawer.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yes, that's a mindset I think is what you're pointing to.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yes.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

And the conclusions that we arrive at may actually be very different if we think about permission or consent as something that's ongoing and not aesthetic, not just a piece of paper but something that happens at one point in time. Great feedback. I don't know if Lucia has the Common Rule has been a common phrase in our conversations so I don't know if you have anything to add on that?

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

So, almost everyone in the room will probably know that OHRP...there was an RFI about the Common Rule, I don't know about a year and a half ago...

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Right.

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

So, the agency responsible for that is in the process of figuring out exactly what it wants to put out next and I'm sure that you will all be involved in seeing that and commenting on it and we will provide whatever expertise that agency asks for so that we can do our job of coordinating. So, that's very much in our minds but it's not within our agency's purview.

Also, I wanted to talk just briefly about computable privacy. I completely have this vision of getting rid of the paper. I know a particular state where an authorization to release data requires a witnessed signature and we don't manage our 401K plans that way and we don't pay our credit card bills that way and we need to sort of open our minds to how the modern American adult or even teenager makes choices in their life which is electronically and we need to figure out...that's why we need standards is so that we can have user interfaces that make sense everywhere and we can say to a patient, you chose this before and this is what it meant and you can make a new choice about that anytime you want through whatever the appropriate portal is if that's their PHR, if that's their physician's portal, if that's their health plan portal, I am agnostic on that, but we have to...I'm with you got to move away from the paper it's not computable.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Good, thank you.

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

Good. Karen?

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

Just want to thank Dixie and some others for raising this issue that there is a today world and then there is a future world where we're quickly evolving and we don't want to get in the way of what is good in that we want to protect people thought about what might be bad in that to be very simplistic about it.

And that as Lucia said the today world is HIPAA and so there's been a lot of conversation in a lot of corners about whether that's sufficient for a future system where data is more blurred, the lines are more blurred and we do need to work with what's at hand and I think back to Gayle's point the states...certainly the conversations that I've had with state leadership has been very much like what Gayle has said is that we would like some assistance with harmonizing and seeing that the data can move and do that sort of in today's world.

But what I'm trying to say is work with today's world, built upon what works. The administration is already been engaged in this space of big data and privacy and trying to understand where HIPAA helps and where we might need to be more thoughtful about the future. Thank you.

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

Troy your card is still up?

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

Yeah, I'm okay.

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

Okay, great, thanks. Wes?

Wes Rishel – Independent Consultant

I think the term used in the document is computational privacy is that right?

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

Well, so here's a true confession, computational privacy actually means it has a meaning it's the opposite of what we want. So, computational privacy actually has a market meaning of being able to undo people's privacy choices that is so not what we want to do.

So, we're trying to coin the phrase computable privacy we want people's privacy choices to be able to be captured and persistent under standards in electronic forms. However you guys want to call that but that's the phrase I came up with.

Wes Rishel – Independent Consultant

Yeah, okay, just to try not to do this I read the document and computational is at least somewhere in the document, but my concern is that this notion runs along sort of at the level of supply and then crashes into the level of ridiculous at about the point where people say, we should be able to determine through the use of some service whether this particular bit of information can be released according to the person's current privacy preferences that there are systems that do that for research data, there are systems that have been described to do that but the reality of trying to implement that in an ultra large system is just unthinkable.

The reason that we have this sort of sudden shift is that all of the preparatory work that is rationalizing and normalizing the views of privacy and consent and things like that are absolutely necessary in order to achieve lesser goals of just letting the health information management department have a defensible rationale for knowing what to release so just putting together some kind of data sharing arrangement with specific rules and things like that. But I just want to specifically express the concern that this notion that there will be a national arbiter of privacy decisions is over the top.

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

So, I can only give you my personal diagnosis about that which definitely there is in the universe of the nation at large a wide variety of opinions about what kind of information should be able to be refrained from being shared. My perspective is we actually have laws that tell us that and those laws whether it is HIPAA or Florida State Law or Connecticut State Law, or New York State Law, or any state, my home State of California those laws have been developed in response to open and democratic processes and public policy debates and they definitely fall into particular philosophical categories and that's what we'll be working on at OCPO.

So, there are...but there are definitely differences of opinion about this and there are definitely...people have differences of opinion about how that relates to the Internet of things and mHealth and all the ways that we capture information about health that fall outside the specific jurisdiction of HIPAA. So I'm sure that all of those comments will come out as we are now in the public comment period for the roadmap.

Wes Rishel – Independent Consultant

I couldn't tell if you were violently agreeing or violently disagreeing, the violent I was pretty sure of. But the fact that there are laws that are not rapidly mutable if not totally immutable the fact that those are the laws of the land we need to work with it that's absolutely true.

The need to be able to express those laws in a way, some of my old math buddies would have said a calculus of expressions of consent and so forth, is work that's arguably been done for some simple environments arguably not proven for bigger, all of that I think is incredibly useful and important and is holding up progress until we get there.

What concerns me is just a vision that having a calculus, therefore having a computational algorithm implies automatically we can employ that nationwide for all the patients for every individual decision that's made about releasing information. I think that's a vision that is frightening.

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

Frightening because it's unachievable...

Wes Rishel – Independent Consultant

Yes.

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

Or frightening because you don't think it can be achieved?

Wes Rishel – Independent Consultant

Right, I mean, I may end up discovering my secret inner republican and saying it's frightening for other reasons, but I definitely think it's unachievable.

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

So, and I guess my final comment would be, you know, if you look at the roadmap and you look at what we've done on privacy we've really tried to stage it carefully over time and we have a very acute understanding that getting to complexity of what in the roadmap is called granular choice but might be reflected in these sort of eight or so clinical categories that are philosophically aligned, behavioral, STDs, Gayle ticked a few of them off, there is so much work to be done there in order to get to the place where for example, a law can be related back to, dare I say it, clinical codes so you actually know, you know, which version of acyclovir is for chickenpox and which one is for HIV and you protect the HIV if you're required to but the chickenpox is just acyclovir for chickenpox to give a real example. Lots of work and that's why that falls starting in year six.

Wes Rishel – Independent Consultant

Yeah, no, I think on that part we're in violent agreement.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Can I ask just one quick follow up question, Wes?

Wes Rishel – Independent Consultant

Sure.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

I want to make sure I'm tracking with you. Is your concern related to the capability of technology or is it related more to the variation that we see around policies and laws and that kind of policy backdrop?

Wes Rishel – Independent Consultant

My...I'm a propeller beanie guy so I'm concerned about the technology.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Okay.

Wes Rishel – Independent Consultant

I think that we have learned over the years that things that we thought were technologically impossible at one point become technologically possible as technology advances. But the closest I can come to trying to put an ability to predict that is to relate it to the statistical combination, statistical concept of degrees of freedom or for the mathematicians how many different axes of infinity do you have at the same time.

And each sort of major 10-year progression in technology maybe adds one more degree of freedom of things that were intimately uncomputable now become computable but that's so many of those together all at the same time that it seems to be not computable in this timeframe of the roadmap for sure.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Okay.

Wes Rishel – Independent Consultant

So...

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That's helpful, thank you.

Wes Rishel – Independent Consultant

Yeah, all right, thanks.

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

I think David McCallie has an add on there.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, just a friendly add on to Wes's point. I think the enemy is complexity and it's what's the difference between enterprise scale systems a national scale systems or what Wes called ultra large scale systems is fundamentally the degree of pre-coordination that's required before the system can work.

And within an enterprise where you have top-down control you can pre-coordinate enough to make computable consent models work but at national scale you have to have an incredible amount of pre-coordination and pre-agreement on taxonomies, on rules, on locations of consent stores which requires the knowledge of identity of patients and providers, you have to essentially solve every single problem we've ever surfaced in these meetings in order to have computable consent work at a national scale and I just think that the complexity there is the enemy.

So you have to come up with some subset that's workable without all that intense pre-coordination hopefully better than just a written document that's been scanned in but keep that in your back pocket.

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

And actually I agree because I think that's where the background rules come in, right, we have to think about how much...how far can we advance interoperable exchange for health using background rules because we know what those are already and they're not dependent upon people's personal choices.

So, there's going to be a lot of discussion about that and the analogy I give to non-lawyers is, you know, many of us have wills but if we all...if some disaster happened and we didn't have wills there are rules that operate even if we do nothing and that's where we need to get with privacy rules that operate if people do nothing that we can explain to people and to the people we need to have move the data.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I think that's a useful distinction but it's still pretty hard because even those background rules assume that you can codify all the data in such a way that you know which parts of the data are affected by what background rule and unless you've got more sophisticated natural language parsing than I've ever seen you're not going to be able to do that with textual notes in the record. So, you're going to immediately run into...

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

That's right we need to get rid of paper.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Execution possibilities.

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

We need to get rid of paper.

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

Okay, I have Leslie and then Andy.

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

...

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

Oh, okay, sure.

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

David, if somebody could assert that they had followed all the rules in obtaining consent and that fact was transmitted rather than all of the data that supported the consent just "I did it and I did it right" do you think that would be as difficult as what you are describing?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

No, I mean, I think that's the use case I was calling for in my first comment...

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Of a very simple notion that the patient says, I want my record available to my provider, I give them permission to go get it, I'm going to do simple choice, I'm not going to try to subset it or manage...

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

What's exposed. That ought to be straightforward and we ought to make that one optimal because it's basically permission granted to go get the record.

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

Right, so, but let's just say I then assert this to a secondary request or I've done it and I've done it correctly that should be enough for them.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I think so.

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

Not to get all of the data underlying all of the consent.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Right, right.

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

Okay.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So, that's an easy use case that probably hits 85% of people's opinions as long as they get to pick the physician that they're enabling to do that. It gets much more complicated when you start getting, you know, more control than that and at some point it becomes so complicated that we'll be in the morass that we've been in for the last decade with XACML and other things where small demos have demonstrated that it's technically feasible but it's just scalable.

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

And something for us also to remember is the most recent amendment to the HIPAA rule actually says if you're standing right there and your patient is telling you right, you know, right in front of you that they want the data sent somewhere you can send it...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Right.

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

And it's not a violation of HIPAA and people forgot that...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Right.

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

And we'll be talking about that.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yes, I think that's a great one.

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

Okay. Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would just going to actually comment and say that if we start with the problem of how do we solve what the patient wants instead of how do we align all of the laws, rules, potential things we can get to David's point 85% of something. Yes, I want you to share my data here are the people I'd like you to share it with. Yes, I have...I acknowledge that sensitive data will be passed. We look at it from a computable privacy using the patient at the center and the patient's majority of their use case as the top five use cases rather than a bottom up approach of trying to align so much complexity.

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

David Bates on the phone or Kotz, I can't read that?

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

David Kotz.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Yes, David Kotz. I had an observation, as we look ahead 10 years this plan is forecasting that far ahead and as had been mentioned several times today the learning health system will be more than just EHRs and medical information that's expanding and blurring to include other kinds of health information, how does this model for privacy and security and consent address the data that is collected and handled, and manipulated beyond the current health or sort of HIPAA covered entities as is starting to happen in the booming mHealth space?

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

So, I have two responses and I think Deven sort of hit on it earlier today. There is actually a lot of work being done by ONC as well as other experts on the executive side of the government to try and develop where we should go next with that in a way that looks around the corner.

So our office has been engaged in a lot of work talking about mHealth, collaborating with other agencies like FTC and OCR and we have to think about that in terms of the personal health records and we're also working on big health data and there's a point at which there may be conceptual overlap about what are the needs in those spaces that strike the right balance to give us the data we need to produce information and learning in the learning health system while respecting individual privacy and autonomy and maintaining security so three legs of that stool.

So, I don't have an answer for you. I can't give you a check list but I can tell you we're all thinking about it pretty much every day.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Thanks.

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

Good, thank you, everyone. Okay, so now we're going into the final section getting down brass tacks going down to the technical standards and certification and John Halamka are you on the line?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

I am indeed. And so just a brief...well, certainly thank you Paul for yeoman's work and I really also want to thank the whole group for such valuable policy discussion because we know policy and technology are two sides of the same coin and influence each other.

So, as Erica goes through this I think everyone on the Standards Committee will find the material familiar in that we have long said that standards are vocabulary, content and transport with as little optionality as possible. What I think she adds, which we've all had discussions over the last year, is there is some additions to that usual construct.

We need to understand provenance, where provenance means what was the source of the data and can I trust it, can I ensure it was not altered from the point of source to the point of use?

And I think as we have further discussions with Steve Posnack and talk about the standards advisory we'll also look at standards are enumerated. What is their level of maturity per the Dixie Baker criteria and are there test harnesses available so we can ensure that as standards are in the field implemented that they can truly bring us the interoperability.

I think we've heard many discuss such things as Postel's principle or the notion that standards on the sender and the receiver may over time have asynchronous versioning and how do we deal with such issues. So, the construct that we'll see from Erica I think does incorporate many of these important ideas. So, Erica, go ahead?

M

Maybe we continue to...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yes, Erica, please?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

All right, thank you. So, these are two separate building blocks. They are distinct in the roadmap. We've combined them for purposes of discussion this afternoon. I don't think I have to say much to this group about the fact that health information has to be properly standardized, packaged, securely transported in order for meaning to be retained across the systems and to be parsed in systematic ways so that it's useful, right, so people can put it to good work.

A number of topics are addressed in both of these categories in the roadmap. I've mentioned these already. We have a section around data format and semantics, transport, standard services, identity data, individual data matching, reliable resource location.

Maybe just as a gestalt for this conversation I want to point out that we talk about identifying the minimum set of standards in each of these areas to support the various needs of a learning health system and to achieve our goals both at the three-year and six-year mark. We do not suggest that there will be one magical standard to achieve all of those needs. I'm highly confident it will not be just one standard. But we need as few as possible.

So, getting down to core technical standards and functions critical actions that we've put forward that are particularly relevant for the three-year timeframe. We call ONC to action to publish a list of best available technical standards for core interoperability functions so that there is a single resource for everyone to consult around about what's best available in the standard space and use that as a resource and focus implementation around that.

And then we call stakeholders to action broadly around some core topics that John mentioned we think need very aggressive work in order to achieve this notion of send, receive, find and use a common clinical dataset both on a provider side and an individual side over the next three years.

The first is tightly defining that common clinical data set those data elements where there are gaps to facilitate semantic interoperability.

The second is around constraining implementation of the Consolidated CDA, I don't need to recount the pain points that you're all familiar with around Consolidated CDA particularly as a result of what we've seen through Stage 2 Meaningful Use, absolute need to constrain implementation there.

Standard's work needs to proceed around data provenance so that the recipients of information understand where it originated from and can trust it. Folks are not going to use health information if they don't understand where it came from. We call in the roadmap for data provenance both at a document level and data element level.

And then the notion of really advancing aggressively RESTful APIs to support a more nimble and scalable approach to nationwide interoperability. Hopefully nothing is surprising to any of you on that list.

The other piece I wanted to call out for purposes of this discussion, we've talked about this a little bit already, is individual data matching. We recognize any time we're talking but interoperability we're talking about a core function of needing to accurately match information for a particular person moving into the future for other things like providers and devices and so on.

We put forward a set of individual attributes that were put forward actually in a report that ONC commissioned around patient matching. We asked...inquiry to work with a number of folks who are doing matching very well with high degrees of success, high degrees of confidence across industry and give us a sense of what are the attributes, the core attributes that should be used consistently. If we don't have a national identifier what's the next best thing and so we've put forward that list of attributes in the roadmap as a starting point and we call for some standardization around those and consistent use of those.

I think one of the other pieces of feedback we've particularly heard from federal partners like the VA and others is that, it's great if you standardize these attributes but in an exchange of transactions with a patient or individual health information if those aren't present we actually can't use them to match and so we need some consistency not just in standardizing the attributes but in the actual use of them and the transmission of them.

So, I'll pause there and I will point out that Steve Posnack is my colleague on point to field questions and discussion on this topic.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so Michelle Consolazio since I can't see the individuals do you want to create a list or how would you like to deal with discussion?

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

If you don't mind I'll go ahead and call out names is that okay John?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

That sounds great, thank you, Paul.

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

Of which there are none right at the moment but David McCallie is going to be first.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I didn't want to disappoint and not have a comment. I've got to bat 1000 here. I think the list is a good start and the approach is sound. I think that the only major concern I have is that it's, you know, standards of the recent past. It's probably not an adequate set even for some of the simplest things that we need to do in the next couple of years mostly around moving past document or aggregated documents as the medium for interoperability, the core medium for interoperability pushing 50 and 60 page CDAs around has not proven to be very workable and for many use cases that come up when clinicians need, you know, quick access to a specific data element to facilitate a decision.

So, back to the floor not ceiling conversations and the notion of emerging networks that will go beyond these standards let's make sure that we don't prevent that from happening by structuring incentives or certification requirements such that you're disincentivized to do better than the minimum because I think we will be working really hard to do better than the minimum.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That's a great point. One other thing I didn't mention but I should probably call out related to what I think you're pointing out David is that we suggest in the roadmap that the trajectory does need to work toward this notion of specific data element queries, right, the ability to find and retrieve the precise data that you're looking for which means moving beyond document, a document centric world.

The other...related to that though we also recognize that we probably for some time will exist in a space where both are required and needed to support the use cases that we have at hand, right, so, as we advance some of our RESTful APIs...

Technical Problems

W

Ladies and gentlemen, please stand-by your conference will resume momentarily.

Technical Problems

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

The concern you raise...so you raised a concern around computable privacy about the ability to...

Wes Rishel – Independent Consultant

Well my specific concern here is the phrase deep provenance.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Deep provenance.

Wes Rishel – Independent Consultant

Which I take to imply that data comes in in some kind of a bundle either it's a nice computable lab test or it's a one of these aggregate documents that happens to have the common dataset included in it or things like that and it gets stored as a document, can be retrieved as a document and that's very valuable. It also gets...the technical people tend to call it shredded meaning the individual data elements are pulled out and stored as discrete data in the database.

And while it is theoretically very easy to store the provenance of each of those individual data elements and when one data element is passed from one place to the next maybe shredded and synthesized in another document and shredded again it's possible to get the deep provenance going all the way back to where it started. The reality is setting that as a tangible tested required goal any time in the near future is enough to frighten away what would otherwise be a cooperative environment around provenance.

I did remember the other topic which is...has to do with the bottom part of this slide. I think that this is an area where the definition of the area is created based on the limitations of what the government can do about a national health ID. So, the definition of this area assumes patient matching based on demographic data okay? I think that it can be helpful to standardize the way that's done to do a number of things but it's equally important not to preclude industry from finding better ways to do it and in particular, beyond all of the fuzzy wuzzies about matching a common name with a common birthdate and things like that this approach assumes excellent process on the part of the healthcare providers that are storing the data in the first place that are capturing the identity and that's not a valid assumption.

And some of the industry approach is bundle in with the technology agree to improve processes for capturing identifying information. So, it's very important that, you know, this is one area where the law is the law maybe you can't help but you can sure get out of the way.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yes, thank you for...I'm glad you remembered your second comment that was a good one. And thank you also for clarifying the first piece I want to make sure that I actually am tracking with you on that.

On the matching piece that section of the roadmap continued to evolve until very, very recently. I believe that we have some material in there that talks at least about data quality which is intended to speak to exactly what I think you're getting at around provider processes and data source processes in fact wherever the data is originating recognizing that there...the quality of the data and the accuracy is dependent largely on those human processes. Maybe over a beer some time I'll tell you about some of the other stuff that was in there that isn't any more.

Wes Rishel – Independent Consultant

It sounds like a two beer topic.

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Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That's right.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, Michelle Consolazio I think is a highly important suggestion that the minutes should record.

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

Marc Probst?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

I'd hate to let an opportunity to talk about standards go by without saying something. You know the whole concept of standards isn't painless and I sometimes worry that we want to take a let's try and make it the easiest way possible for what exists today approach versus sometimes you know it makes sense to rip and replace and to do things that are just going to be smarter in the long run but a little bit painful today.

As we look at standards and particularly this report where's the concept of priority even in provenance, Wes, you know, my hair color really doesn't matter, the provenance of that piece of data, but there are pieces of data that I think we can if we prioritize them that are incredibly important to understand the provenance of that data and we probably, if we focused on it in a more incremental approach and prioritize what's going to be most important for the care of our patients we might be able to get things done a little bit quicker. So, I just think that whole concept of priority and looking at that and what should we really be tackling first is important.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

It's an excellent point. The list that you see today is our best attempt based on input to actually prioritize so as the Workgroups takes a look at the standard sections of the roadmap and you guys do that off-line, if you can help give us advice on further constraining those priorities and really driving toward an even shorter list that kind of input would be welcome because that's...what you see now is a first attempt.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And Erica, just to add to that comment, wow, I sound like God I'm echoing, the notion of what this Argonaut initiative is all about is trying to constrain scope, it's to recognize that there are finite resources and fixed time and therefore what we have to do is set scope to that which is highest and most useful.

And so for example, what we said to the comments you've made earlier today, for the Meaningful Use common dataset with its problems and medications, and allergies, and labs, and care plans has so many uses that if you created a RESTful API around that strictly enumerated set of elements and then a RESTful API for document exchange, which we know is imperfect but still going to be used for many years to come, that's a pretty good start.

Now in parallel exactly as your slide says, C-CDA is in use today, millions of transactions are being sent we simply need to reduce the optionality there, constrain it so it's easier to generate and parse to the comments others have made 60 pages of auto generated unreadable material is not a meaningful transition of care.

So, you know, I hope the spirit, which is in the slide and everyone in the room would agree, is clean up C-CDA to make it as useful and meaningful as possible, get the smallest number of RESTful APIs available as soon as possible and think of course about the issues of provenance which help us understand the utility of the data we're exchanging.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That's right, well said.

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

Great, John, and do you have anything more before the summary? Do you have another section or...

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

I have just briefly certification and I'll be short.

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

Okay. Okay, is that okay, John for us to move on?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Oh, Paul, you never have to ask my permission and so of course certification very important, many of us who have gone through the certification process for 2011 and 2014 edition knows that it can be very important and useful to foster interoperability. It can also be burdensome. So we need to think about how to structure future certification so that it much more tightly ensures interoperability while also at the same time not creating an undue burden. So, Erica, please go ahead.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Great, thank you. So, this is actually probably the...oddly enough ONC coordinating this roadmap and having certification authority this is perhaps the lightest section in the interoperability roadmap. We approached thinking about certification, again remember from the perspective of those functional and business requirements, for the learning health system and so we thought about for stakeholders who are purchasing technology or using technology and need some degree of confidence in its ability or its interoperability with other systems then how should we think about certification and along with certification testing. So we addressed both concepts in this section of the roadmap both certification, ONC certification, and ongoing testing.

In terms of near-term critical actions there is certainly room to improve the rigor of ONC certification to reach Health IT so not only from an interoperability perspective but also the Health IT that is used in a number of different settings, right, and we've been pretty explicit in conversations with these groups about our desire to do that.

We find ourselves in a little bit of an awkward situation with active rulemaking happening around the certification program and drafting content for the roadmap. So, there are lots of things that may be contemplated from a rulemaking perspective that we simply cannot talk about here and we simply can't talk about in the roadmap.

Certainly, a call to action both to ONC and federal partners to continue to develop and provide testing tools that support the certification program. And a call to action to stakeholders broadly to accelerate a suite of testing tools some of which exist but certainly opportunities to improve on those and expand them that can be used both pre-technology implementation and post technology implementation to help advance interoperability. This is the notion that testing isn't something that should just be done before implementation or for certification but should be part of the full lifecycle of technology and is something that should be ongoing.

Also a call to action to the field to help identify gaps and provide feedback particularly to ONC but really across the industry about what certification criteria need to address for interoperability, we've put forward some, we know that there may be gaps, a clear call for feedback on that. And I'll pause there.

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

Okay. Comments, questions John?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, just...was that another John by the way Paul?

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

That was you and there are no other cards up.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, so just as a comment, the importance of testing tools that are robust and easily used cannot be overstated because as we experienced with previous editions sometimes getting us to interoperability was a function of getting the tools to be robust and stable first.

So, I think, you know, as Steve Posnack and I have talked about and he will go through his section, as the advisory is circulated and updated ensuring that there is a column added to the advisory about the availability of the suite of testing tools would be important.

And making sure, as you have said in the slide Erica, that there is rigor to certification, that it isn't just a check box, that as we think of certification that it's really testing the workflow as it might exist in a true clinical setting and the sense that there is going to be meaningful data exchange that's tested from the point at which a clinician enters it to the point at which a clinician consumes it in a somewhat continuous kind of script or fashion as opposed to it just a test of an individual point function because I think we find that if you just check the boxes it doesn't necessarily equate to the sum being greater than the parts and achieving interoperability. But happy to hear other comments.

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

Well, you're talking stimulated some cards to go us so we'll start with Wes.

Wes Rishel – Independent Consultant

So, I'm going to make some ugly comments here, if you thought the old ones were ugly...

M

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Wes Rishel – Independent Consultant

We are in an environment where it appears to an outsider that we're attempting to substitute certification testing for compliance where we have a lot of backlash from Meaningful Use compliance and it's not going to work that well.

First off, the only thing that motivates a developer to go through the expense of certification testing is an absolute economic need to do it in order to use or sell their product according to whether they're self-developers.

The level, we talked already about in the area of patient ID data where interoperability problems are as much in the implementation as they are in the product and we know that certification testing mandated by the government has economic limitations, the amount that a certifying body can charge for certification necessarily limits the amount of testing they can do to the point where it's not...we're not able to test the functionality that thoroughly much less look for functionality that assures it works well in implementation.

So, I think that as we go through this process we need to find ways that make the buyer of the equipment actually require certification not because it's a checkmark that they have to mark but because they have processes internally that will hurt them economically if they fail and we have long way to go to reach that new parameter where it's based on the basis that the payment system is changing but it's up until then I think certification is good it ought to be done, it ought to be not too expensive but we ought not to expect too much of it until it is demanded by the users independent of the government program.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And Wes I think that's actually a friendly amendment to what I said not an ugly comment. And so we absolutely, you know, know that when economic incentives are aligned...and that's really how Erica began some of her discussion today on business, clinical, cultural and regulatory environments, that then you will get customers pulling the vendors as opposed to the vendors pushing the customer so that's absolutely true.

I always think of certification as in some ways...well the certification is a floor that says that the product must be at least capable of certain actions. So, if a customer buys that product and it is not capable of certain actions you can point back and say "wait is the product you certified the product you're shipping, there seems to be a disconnect." So, totally agree that the reality of economics will drive true interoperability. I just see certification as one of the steps that supports it.

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

Okay, thank you. Anne?

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

So, I totally agree with everything that's been said and would like to add what I think is a true value proposition to certification and that is the collection of what interoperable systems have been tested for that system being certified.

The thing that physicians can't do or hospitals is you can't trust that you can be interoperable with your physician base. There is no tool to tell you whether the Allscripts certification covered the 50 versions of Allscripts that are out there and that the one version your physicians have cost \$30,000 a piece because they weren't in the certified body because we're bringing a lot of stuff with us through Meaningful Use.

So, all of this is good and fine but it's not the true thing that will help a person on the ground pick a product, you know, the certification doesn't mean anything I'm still going to have to budget \$30,000 a pop to interface with my network that I just put together because the certified product doesn't interoperate with those tools. So I think something along those lines would be more helpful faster in a near-term than practically everything else. I say it that broadly because, you know, as payer we actually own some physicians and just the shopping event is painful.

The marketing folks just market the tool "it's certified" you give them this false sense of security and they find out that they've assembled a network of physicians because they're all being acquired, I say broad stroke things but it's true to a large degree, and then they find out they can't even interoperate with their own employed physicians. So, I think a little bit of time and energy on that topic would be a good faith thing for the people who are trying to help. Thanks.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Well, the functional requirement that we tried to capture within this building block which is certification...in fact in some ways it's maybe a little bit controversial we actually didn't think about certification in the context of a learning health system as a tool for a Meaningful Use program. I don't think we had a single discussion really about that but it was really focused on if our functional requirement long-term and even near-term is giving buyer's confidence that a product or service can do something then how do we work backward and think about both certification and broader testing that facilitates that I think your point is very well taken.

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

I would...if you couldn't test it to certify that you approved it, I would still like to have a list of what they said they could do so that I could hold them accountable to it, you know, without having a \$15,000, \$30,000 price tag for that interoperable ability.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And to Anne's point, which is an excellent one, is that a number of us who oversee health information exchange in Massachusetts have yet to connect major certified vendor products with a generic direct compliant HISP and you scratch your head and say "but wait a minute you're certified, how could that be?"

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Amplify some of these comments and give a little bit of a taste for what this looked like in the last round of certification. I'd observe that in other areas of information technology people test that their products work and because they have a goal of their products working and working reliably there are testing bodies like for Wi-Fi for example where consumers have an expectation that when they buy a Wi-Fi enabled device that works.

What happened in the last round of certification was not testing to make sure the product worked it was, as Wes said, checking the compliance box.

We found in our practical experience that the actual certification tests were markedly unhelpful and what I mean by unhelpful is that they neither helped us develop interoperable technology nor were they a reliable barometer having been certified that our product could actually handle real-world variation nor was it a great example of other products being certified and their ability to handle real-world verification or situations. So as examples, we've interoperated with certified EHR technology that will admit CCD, C32 template IDs in the context of a Consolidated CDA which should just be a never happen.

We have...we got certified for Direct very early on and then we went through a very, very long process of interoperating with everybody else and it was actually that experience of interoperating through everybody else that we got our technology to a level of production level or reliability where it just works. It was through the experience of consuming everybody's in the wild Consolidated CDAs that we were able to get some level of interoperability testing.

So, there's a huge disconnect right now between the tools that are being used and what I think the outcome is and I think what you're trying to do is get the outcome that Anne is looking for, the outcome being that, if I got certified the thing should work in production. I just want a word of reality that that's not the world that we live in, number one.

And number two, that the definition of madness is trying the same thing over again and expecting a different result. The same certification cycle and approach in policy that we applied last time I very much believe will lead to the same situation that we had for Meaningful Use Stage 1 and Meaningful Use Stage 2.

So, the words sound good on paper but I'd actually issue a call to action to ONC to relook at the policy, the certification framework, the testing bodies, the process of standards development because what we have right now is not leading to where we need to be.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Thank you for that statement. Steve anything you want to add?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

It's all your fault.

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

Conveniently you were off mic for that. So, you know, this is Steven Posnack from ONC. You know one element here that may be should more clearly be called out as well is that ONC is but one player. Wi-Fi is a great example, not government run. So...and there is a business interest for the, you know, Wi-Fi manufacturers to make sure that their products work because when I roll in here and I type in the code I know my phone just works, right, plug it in, type in the code.

So, there are a number of issues related to I think the engagement in some of these and I don't mean this with any offense but feedback at an advisory committee meeting is not the type of feedback that we need from the community at large.

We need day in and day out implementation experience that comes to us or it comes to NIST, or it comes to some other place that may need to exist that doesn't yet exist where people can talk about this, that it goes to the standards development organizations because they are also I think, based on my limited experience now having been in this role and more intimately engaged with them, not getting in the field feedback as well as how their standards are being implemented and, you know, to the point that David made and we've talked, you know, before about the length of an XML document.

That's not necessarily I'm hearing an issue with the standard it's how it's implemented and how it's put in practice, right, so it's not necessarily a flaw with the standard itself. Maybe there is optionality and things to disagree about those things, but, you know, how much data is getting pushed into that and the decision not to use one of the other document templates in the C-CDA versus something that auto-gens a CCD is not necessarily a standard's issue on its own.

The other thing is, we have, at a, you know, federal program level we're running a service, you know, we're administering a service and we have as many resources as we can bring to bear to that service, right, so the tools that we worked with our colleagues at NIST are as best as we can get them with the resources that we have available to us to get them to.

Part of your point is, and part of I think Anne's point as well is, well that's not really good enough for some of the things that you'd like to see or some of the assurance for which certification could provide that you'd also like to see. So the challenge there is, is there some other way for people to step up and not necessarily with ONC, you know, relying on ONC solely to do this and accomplish that on your behalf.

So, you know, we'd certainly be interested in collaborative approaches and that's one thing that we'd love to see out of testing in general, relying on ONC just to be the ones to develop testing is a challenge and a scale issue as well for us.

So, I think, you know, and don't want to steal any thunder from presentation that we give a little bit later on certification and the certification program, there are areas where we are certainly making improvements, you know, in the day to day kind of blocking and tackling of how the program is administered.

Testing is a broader challenge for how detailed testing can be and that's going to be an iterative and cyclical approach where we can take on more things or where we've built in and got some feedback that, hey, you know, your header example about C32 or something that...first time I've ever heard it, you know, and not everyone talks to me about it but I'd be willing to bet that other people that are neck deep in some of this that's the first time that they may have heard it and there are other instances where we've identified or stakeholders have brought to our attention that the product doesn't seem to be performing correctly and it's generating a C32 and there was some other configuration requirement that they needed to put in place to actually generate a, you know, C-CDA 1.1.

So, you know, that's also experience in the field as well that is starting to shake out as you said people are using it. DirectTrust is a great example of, you know, another non-government run, you know, program where a lot of testing is going on. Other models like that where, you know, testing could occur is certainly an area where we're interested.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Can I follow-up on that because first of all I really thank you so much for those comments and obviously my on mic/off mic was meant as a joke I think very highly of Steve.

The timeframes that we had for certification caused the situation that we're in and the...so you mentioned DirectTrust I think DirectTrust would be a wonderful mechanism for certifying direct interoperability because I actually know more about it than the testing bodies do. But there is no great regulatory mechanism for having DirectTrust certify direct exchange or having HL7 certify or some consortium of EHR vendors who have an interest in making interoperability work certify Consolidated CDA-based document exchange.

So, what I mean by, if we do the same thing again, and we're lining up for kind of the same timeframe, if you just look at the calendar and read the tea leaves that we had last time, if you look at the way that process played out we're going to get the same outcome which I think will be disappointing.

So, again, it's not a blame ONC, I understand the limitations of the tools but it is a call to look for different policy levers and different tools to enable the outcome that we're trying to get to because if you try the same policy levers and the same tools the outcome is going to be the same.

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

Okay. Wes?

Wes Rishel – Independent Consultant

I put my card up twice but I got away with it. The...I just had a thought that actually maybe positive. One of the fundamental economic mismatches that drives so much interoperability problems in healthcare is that standards groups aren't incented to have their standards work. They're incented to produce standards.

When I was on the board of HL7 every time we produced a new standard membership and attendance went up. And every year we didn't it went down and as a result the board, which sort of creates the most widely aggregate focus in an organization, was focused on producing standards, all right?

For years I kept trying to think of how could we actually get paid for the use of standards as opposed to producing them? And at the time, you know, we thought about licensing the standard and people had to pay a licensing fee to use it and that didn't work for a lot of reasons, but we probably have the technology today to easily track volumes of usages of standards. We need some type of regulatory framework to require it. I mean, there is an idea it's got all kinds of use but if fundamentally the board of HL7 went to their retreat and said, why is the volume of this standard down this year or why did it not come up like we expected or something like that then the focus within the organization would be on solving the interoperability problem rather than producing a new standard. So, I think the technology is there whether it's regulatory possible or not I don't know but it's certainly worth considering.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Again, a friendly comment, Wes, that the Dixie Baker paper on standards maturity actually breaks standards evaluation into two chunks their maturity and a measure of adoption. So, I completely concur with you it's very interesting to ask how many live transactions across real clinical systems involving payers, providers and patients have occurred and even if it's not quantitative if it's qualitative that's a very important assessment of a standard's success.

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

So we could have meaningful standards. Okay. David McCallie?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I'm going to reference the JASON Task Force again because I think we had some things to say about the certification in the context of this notion of data sharing arrangements or data sharing networks. And our assumption was that these...that the standards that we have, even the very best standards, still require a fair amount of implementation guidance and constraints to particular legal and trust frameworks to actually be implementable that it makes sense, at least as a supplement, to whatever ONC level certification there is, that you get certified by the data sharing networks that you intend your product to be able to participate in and that this testing will go deeper and be more of a guarantee that it's going to actually do something that you expect it to do. So, that if you've certified against eHealth Exchange or CommonWell, or Surescripts ePrescribing your...the little sticker on the box says, you know, we've tested it and it works in those networks.

And I think in the long run for interoperability that will become more meaningful validation than whatever you could do certifying against an abstract standard that hasn't actually been constrained to a specific implementation.

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

So, John, I think the discussion around meaningful certification and standards use leads into the summary for Erica in terms of measuring how we achieve success with interoperability.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, thank you, Paul and I certainly turn it back to you and I will pick up again after the break.

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

All right, thanks. Go ahead, Erica?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

We're near the end of this piece folks, thanks for hanging on. In October we had a really robust discussion about measurement, a lot of commentary about the need for measurement around interoperability and the challenges that we face adequately and effectively measuring.

I just wanted to leave you with a couple of notes. We won't have a robust discussion about this today but there is an entire section in the roadmap dedicated to measuring progress and success. What we've put forward is a measurement framework. We think it's probably unlikely that a single measure adequately answers all the questions that we have about how we're doing, how successful we've been.

The answer to one question tends to beg five other questions and so what we've put forward is a framework that looks at different aspects of interoperability and we think a set of measures in each of these areas with pretty solid data sources will help us track progress and measure success over the long-term.

The categories in the framework relate to capability, technical capability, the actual usage of technology, the usage of standards things like transactions, etcetera. And then impacts and you'll note in the roadmap we talk about impacts both from a process perspective and an outcomes perspective.

In the near-term our plan is to take a measurement approach that focuses on what we have, right, uses Meaningful Use data, uses data from surveys that we have access to, American Hospital Association, NAMCS surveys many of the data points that you all are familiar with today because that at least tells us something and in the meantime working with several subject matter experts to really curate measures and data sources for this framework. So that's something we're working aggressively on and something I think we'll continue to discuss with you in future meetings but wanted to put it on your radar.

Quick notes about logistics, so, we opened the public comment period for the road on January 30th it will remain open until 5:00 p.m. Eastern on April 3rd that's about 60 days. Public comments can be submitted through the healthit.gov website where the roadmap is posted.

And we will be asking, I mentioned at the beginning of the meeting, a number of the Workgroups under both the Policy Committee and the Standards Committee to give us very targeted feedback on specific sections of the roadmap.

I want to review just really quickly what those assignments look like. And I don't think the slide I have on my piece of paper matches exactly with this so I'm going to try to read the small print that's on the screen.

So, for Advance Health Models and Meaningful Use Workgroup we'll be asking those folks to take a look at appendix H which comprises use cases, remember we asked for public feedback through a number of different venues over the last several months. Appendix H contains the "priority" use cases that folks submitted we'll be asking you for some input on how a process around further prioritizing those recognizing that 50 some odd use cases is not really a priority list.

For the Consumer Workgroup we will be asking you to take a look at the individuals are empowered to be active managers in their health section of the roadmap. There is a standard set of questions that we've tee'd up for most of the Workgroups that relate to, you know, did we get it right, what actions are right, where are there gaps, how can we improve? As well as, the Consumer Group will also be taking a look at the care provider's partner with individuals to deliver high-value care section.

Interoperability and HIE Workgroup will be taking a look at the accurate identity matching section of the roadmap as well as reliable resource location.

Privacy and Security Workgroup, a lot of juicy work for you all to take on, you'll be taking a look at consistent representation of permission, part of the conversation that we started today. As well as consistent representation of authorization to access health information.

Under the Standards Committee Architecture, Services and API's Workgroup will take a look at standard secure services. We didn't dive into that in detail today but that's actually where we deal with APIs in some detail in the roadmap. That Workgroup will also be looking at consistent secure transport techniques.

Implementation, Certification and Testing Workgroup will be taking a look at stakeholder assurance that technology can interoperate, this is basically part of the certification conversation that we just had but particularly narrowing in on this notion of semantic interoperability. We have some very specific questions about that.

Content Standards Workgroup will take a look at the format section of the consistent data formats and semantics portion of the roadmap. The Semantics Standards Workgroup will take a look at the semantic side of that section.

And the Transport and Security Standards Workgroup has a pretty heavy lift with ubiquitous secure network infrastructure, remember this is where we deal with security, verifiable identity and authentication of all participants, consistent representation. I think there are some specific questions around consistent representation of permission, the consent topic, that are not being tee'd up to Privacy and Security that will be instead tee'd up to the Transport and Security Standards Workgroup. So, those charges are on the horizon and I think that's all I've got.

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

Great, any questions from the Workgroups on their assignments? Deven?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So, this looks great Erica. Are we just limited to those two sections or do you say anything else that's relevant to your Workgroup but you have to do these two for us for sure?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

So, you're going to have a pretty tight timeline...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

To address what we're teeing up. If you guys are really efficient and can plow through...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

The charges that we tee up and there are other relevant sections that you feel really compelled to comment on I don't see why we would stop you. I would just caution that...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

In looking at the work plans for the Workgroups the timelines that you all will have will be pretty aggressive.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes, understood, thanks, Erica.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Sure.

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

You haven't seen the Privacy and Security Team work.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

I have actually, pretty impressive.

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

Any other comments?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I have a question.

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

Yeah, David?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

You may have said this I was...I stepped out for a second, but could you parse K standard, secure services, is that standard services that are secure or is it secure services that are standardized and how they're secured or...I'm going to interpret that it's standard services that happen to be secure.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That's correct.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Okay.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

That is correct and I mentioned, David, you may not have caught this but this is the part of the roadmap where we have an explicit discussion about APIs.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yes, okay.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

And so we wanted to tee that up to this Workgroup.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Excellent, we will do it with gusto.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Great.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And I didn't use the F word at all.

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

Which was?

W

FHIR I'm thinking.

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

Yes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

FHIR.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo ALTO MEDICAL FOUNDATION

FHIR, yes, it's still four letters.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Four letters.

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

Christine?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Quick question in terms of the Workgroups here are you going to give us any particular issues or questions within those sections or just over...

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

We will.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yes we will. So, we've got a core set of questions that every Workgroup will receive that relate...

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Yeah.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

To the basic stuff that you would expect us to ask around what did we get right, where are there gaps, how can we resolve those? For some of the Workgroups we do have additional specific questions that we'd like you guys to address. For some Workgroups it's more just that basic core set of questions but regardless each Workgroup will get a specific set of questions.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

And the core set of questions you're thinking applies to the assigned sections not to the whole...

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Correct.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

It's not core about the whole thing.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Thank you, yes, correct.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Yes we'd like you to address those questions for the particular section that the Workgroup is assigned.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Terrific, thank you.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

You bet.

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

I have just some general comments and a request for the FACAs about the work going forward. One is to...it might be worthwhile having the guiding principles available all the time when you're talking to help us remember that we're building upon what's working and, you know, the existing framework all of the things that we have laid out there so we don't...we tried really hard not to drift from it because those were built with you all, as you'll recall, over the course of the last many months we've been going back and forth on those and with the community.

Secondly, to what was discussed several times today, the goal here is to create a floor not a ceiling. And, I'm going to tease David McCallie, maybe now not later, that at different times today he was asking us to lower the ceiling and raise the floor or lower the floor and raise the ceiling. I think the point is we want everybody in the policy goal as we move everyone along but that we allow plenty of space for innovation.

So, as you're thinking about this it is true that we want to create room to advance this field because it's advancing quickly and on behalf of the people of this country but we don't want to get in the way but we do need to make sure that we've got a strong solid foundation that can meet expectations in the short run.

Back to our earlier comment, be thinking about creating a flexible and nimble enough system that allows data to move around a person and it's all their data not just their point in time electronic health record information so long data as I write about in the blog that went with this not just the opportunity for big data or for the small data of the encounter.

And to be thoughtful about the fact that we tried really hard, after working many months with you all and others, to be as parsimonious as possible. I know it doesn't particularly feel that way in the document but this is our charge is to do...to bite off what we can chew right now particularly in the next two years so that we want a learning health system that allowed us to do plenty more and have lots of, you know, ways...lot of dimensionality on some of the variables that would allow us to do the kinds of research we want, etcetera. We know we can get there but we need to create a pathway going forward, so just keep remembering that this is about what we can get done in the short run and in the next iteration and then the next. We won't get everything done in the short run.

And it's the same thing with sort of feedback on this document. I would say...by calling it version 1.0 I hope it's been clear to you all that we have an expectation. This is going to continue to iterate in partnership with this FACA and others. So, this is not the last time anyone will see it, it's what we think we ought to be focused on now to get done let's then, you know, act upon those things just like we have by putting out our standards advisory and then keep moving forward. So, I guess I want to give some expectation that this is the beginning of a journey that we have together and let's be thoughtful about what we know we can get done.

Last thing, if there is stuff in here that, you know...we again, the federal government have been working with our...ONC has been working with our partners to say this is a place where OCR can lead and they want to lead. This is a place where FTC has interest and they want to lead and they can lead. This is also an opportunity where we can give a nod to...this is a place the Argonauts can lead and we want them to lead, private sector that is, and beyond.

So, if there are clear places where, we've had some discussion even today, it would make a lot of sense for states or private sector to really be at the forefront we are very open and welcome that because as was also noted, as is known to you all, there is only so much that we can do nor should we do this alone, we the federal government, we should do it in partnership with others.

So, those are just some general asks that I would have, I probably should make sure they're written down some place, to make sure that we're as crisp on all this as possible in advance. Thank you all for your time and for accommodating a short timeline.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...

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

Sure, Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Back to measurement, I guess it was two slides ago. I think there is a wonderful opportunity. ONC has identified the definition of interoperability that I think it can be a guide toward measurement. All individuals and their families and their healthcare providers have appropriate access to health information. It facilitates informed decision making. It supports coordinated healthcare and management and allows patients to be active in their health and improves the overall health of our population. Those are five distinct items that have been stated are the outcomes of interoperability and yet largely silent in our measurement going forward. And it gets back to Andy's comment it's not about transactions that we count it's about relationships and connectivity that we establish to co-produce health. So, I would like us to go back to that definition and see how it can be used to inform our success.

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

I do appreciate that and the little bit of pushback I might give you on it is, trust me we've been having this conversation internally, is to say that interoperability as a means to an end, particularly in the context of Secretary Burwell's work on delivery system reform is the means to the ends of better care, smarter spending and healthier people. So there are a set of outcomes and goals associated with that broader frame and inside of that a sub-goal about, how do we know that we actually have an interoperable system, somewhat technically, but also people and process.

And what we find is that there are so many inputs to better quality of care. It's hard to completely link that as well to some of the piece about interoperability which everybody seems to keep agreeing is one of these key elements to be brought to the equation.

So there are some metrics that speak to the broader piece, it's one and I think the technical piece, the information piece is an element of that, it's one of the inputs, it's not the only one and so it's kind of hard to tightly link those.

And I guess I'm just...I'm personally very hungry to have some way to know that this system is technically doing what we're expecting in the ways that were described today, you know, sort of is the standard operational, is it not just interoperable but operational when it gets out there. Does that make sense?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think it does. I would caution us to be...

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

So, there are two things that we need to measure.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah.

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

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Caution us not to focus only on transactions...

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

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But the outcomes they perform...

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

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

In the definition we've already stated.

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

Right when they arrive what is it like and what are you able to do with the information at the point of care or beyond, yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, thank you.

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

Thank you.

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

All right, thank you. I want to really thank Erica and the whole team at ONC for producing really an outstanding report and thanks for the summary and we will collectively provide feedback. Due when?

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

I think it varies by Workgroup.

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

So, the report out will be at the April committee meeting.

Erica Galvez, MA – Interoperability Portfolio Manager – Office of the National Coordinator for Health Information Technology

Okay.

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

Okay, great, thank you. Okay, we are going to take brief 10 minute break so that we can finish on time. So, if we could re-assemble at 3:35 please thanks.

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

If everyone could take their seats we're going to get started. If everyone could take their seats we're going to get started. If everyone could take their seats we're going to get started. Please.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Michelle, I'm here anytime you are ready.

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

I think we're ready.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, very good, well so folks welcome back from the break. For the next 50 minutes or so Steve Posnack will talk about two important topics. As you read the interoperability roadmap you'll notice it was accompanied by another document, the standards advisory, something new for ONC. So, we'll hear from him what it is, how the federal advisory committees can have input to it it's scheduled for yearly revision and so I think our federal advisory committees always want to be involved in the publication of such things as candidate standards or the standards which are deemed most appropriate for the time and I think that there will be probably several helpful comments from the group about again things like standards maturity, adoptability measures and testing tools to supplement the fine work that Steve has already done.

He will also lead us in a discussion on the certification program highlighting some of the ways in which it will be improved which builds upon the discussion Erica already gave us. So, Steve, let us turn to you.

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

All right, take it away. So, I guess I'm the end of the day right? So, I'm going to first talk about the interoperability standards advisory which we published in concert with the interoperability roadmap draft and one thing that I think this embodies which is a mantra that I like to follow in terms of good process making good policy. So, this is a process oriented approach for standards identification that we think will add additional value to our discussions as well as clarity going forward with respect to the interoperability roadmap.

So, where did this come from which is probably the first question. It did get published the same day, it has a longer comment period which I'll get to at the end, but this came out of the vision paper, you know, first got published last year, last June. There were subsequent conversations, stakeholder engagement, lots of feedback that we gathered throughout the process of developing the interoperability roadmap and one of the common themes that came out of those conversations was, an easier, simpler way to identify the standards that were available to meet specific purposes, could ONC provide that type of document or that type of, you know, presence on the Internet for folks to go to and we took a look at what we could do, what we've already gotten in our regulatory arsenal, so to speak, we've already adopted a lot of standards in our rules as part of the 2011 edition and 2014 edition and, you know, folks don't necessarily think to look to that section of our, you know, rulemaking as the place to look for standards for particular purposes.

So, we thought, you know, packaging it a little bit differently, applying a slightly different process to this and the one thing that I would note that interoperability standards advisory includes a brief kind of section of history and context. So, if you're not familiar with all of the past approaches that ONC and our federal colleagues have taken related to standards identification, recognition, adoption there is about a page or so there for you as well to catch up to current time.

So, why do this? Again, to keep it simple and to create common ground. So there are a lot of standards that exist today many of which we've talked about already. We should identify that in a single place, memorialize those and, you know, have discussions around those standards that we think are best available for particular purposes.

The other, which is a common refrain that I have now echoed a lot of times, is to get specific. The "for what" which I usually interject in a lot of conversations, what do we want interoperability for and why we want it for that particular purpose is really important and to get specific about what we want helps to add value to the conversation and to make our deliberations and our discussions more actionable out of those discussions as well.

So, there are kind of two purposes that are identified in the interoperability standards advisory, you know, one is to provide a single public list of the standards and implementation specifications for particular clinical health information technology and interoperability purposes. We've tried to narrow the scope. So the scope does not focus on administrative or billing related transactions. We've identified that this is generally covered by our colleagues at CMS. There is, you know, a large body of both regulatory and policy work in that area as well and we did not feel that it was necessary for us to duplicate that work.

The other is, which I think is, you know, important to be process point that I identified earlier, we need to have dialogue, debate and ultimately consensus on standards for particular interoperability purposes and what we...as we were looking at the environment in which we're working now with the interoperability roadmap with the feedback that we received, up to the point where we produced the interoperability roadmap there wasn't this sense of urgency to have dialogue in a kind of venue and a process that could elicit the type of feedback and debate around certain standards that is really necessary to move forward.

So, what, as I'm kind of following my questions here, what is it? It's a non-regulatory approach. It's meant to be straightforward. It's meant to be interactive and ultimately one of the things that we've heard and maybe I've included this in the process just based on the war wounds and scars from going through the regulatory cycles, having this be predictable. People know that on an annual basis there will be a process and an opportunity to update the interoperability standards advisory and that it will allow for this kind of rapid iteration which we've also heard that the regulatory process can't keep pace with.

So, the one other thing to emphasize here is that this reflects the "best" available standards and implementation specifications as of December 2014 and we included some characteristics by which we put in a lot of the standards and implementation specifications in this first advisory. We, you know, indicate that it is not yet as comprehensive or exhaustive as we think it can and should be. But it's a good starting point and I think it covers a lot of the areas that we've already covered ground on with respect to our rules and the other work that we've done. So, it's an acknowledgment and it's an honest assessment of where we are in the world today with standards.

How is it supposed to be used? So, our hope and our vision is that it will be a widely vetted resource this gets to the predictability and utility of the document. It would be in one place and done right before or without regulation. So not all of the standards that would be represented in interoperability standards advisory would necessarily make their way into a regulation but it's important from the perspective of consensus and agreement, and understanding that people know that if you're going to do something, you know, one particular purpose you're going to do "x" here's the standard to use to do "x."

And the last important point here in terms of how we also expect this to translate into the future is if we invest the time up front to determine what the best available standards are than it can enable a look for philosophy for government programs, for procurement, for testing and certification programs, for standards development organizations to infuse into all of those processes looking to the interoperability standards advisory as the first source and common ground.

So, I...you know, Arien had to leave to take a plane flight but I mentioned to him, this is really meant to be informational to ground you in what the interoperability standards advisory is. There will be other opportunities for comment and debate especially among the Standards Committee folks so we don't need to get into a sustained discussion about each particular standard that's in the advisory right now.

My intent here is to run through and make sure that you all understand the kind of structure and content of the advisory as well. So, the scope, again, is focused on clinical Health IT interoperability right now, and John Halamka stole much of my thunder now at this point, I had three columns the purpose, the standards associated with that purpose and the implementation specifications associated, you know, with those columns.

So, we could also add more columns as added value or as perceive, you know, value to stakeholders. One of the things that, you know, immediately came up is, you know, if there are testing tools available for those standards we should identify those and we can hyperlink them. And the one thing that I would note is that we painstakingly hyperlinked every single standard that's in the advisory so that people can click on them and get access to those standards directly.

So, the advisory is broken into four categories for standards, vocabulary, code set, terminology is one, content and structure is another, transport and then services. And what we know is that just one of those isn't necessarily going to solve an interoperability use case or an interoperability problem for what we are trying to achieve and that they will likely need to be cumulatively paired together in order to meet a specific use case and achieving interoperability.

These are more for your reference. I did these as kind of background handout slides. So, there are over 20 purposes in the vocabulary section for which we have identified in some cases an exclusive standard for those particular purposes. For content and structured similarly, again, over I think 20 purposes where we've identified standards and implementation specifications for each of those. They, as you may know, as you start to get up a little bit higher in the levels, the content standards reference vocabulary and terminology standards. So, again that's an opportunity where in discussions as we start to narrow or identify a single vocabulary if that's not reflected say upstream in a content standard then a subsequent discussion in the industry needs to occur to start reconciling that and mirroring some of the exclusivity that we've included in the interoperability standards advisory.

For transport, the purposes are really narrow. There are not really too many purposes at least that we identified and we identified three specific transport standards that are in use by the industry today relative to transport.

And then for services, which is another area where I think, you know, I would expect this area and the purposes for which we are looking for standards to be identified to expand as well. Some of the usual suspects related to Direct and IT profiles, etcetera.

So, how's this going to work in terms of the interactive process? If you had assumed as we had been doing this in the past then we would have put out an advisory in December of the preceding calendar year. So we would have put out an advisory December of 2014 that would have been applicable to the calendar year of 2015.

What's going to happen now since we put this out a little bit late, we have a 90 day comment period that's going to expire May 1st and upon that time the ONC staff will compile all of the comments on the interoperability standards advisory and we will bring a synopsis to the Standards Committee at which point the Standards Committee will have an isolated period of time to do its thing with the interoperability standards advisory go through all this and make recommendations at which point the public at large would have an opportunity to comment on those recommendations and provide additional feedback and commentary to any of the areas that the Standards Committee has indicated its agreement or proposal for something to be added or taken away from the interoperability standards advisory.

And then we would go forward and distill all of those together and publish another interoperability standards advisory in December so starting to create this annual process, iterative process in a way in which everybody can be engaged as part of the interoperability standards advisory process.

So, again, it's posted on healthit.gov it got posted the same day as the interoperability roadmap. Public comment, to give people a little more time in terms of all of the activities that we've asked for public comment on, the public comment period will close on May 1st again at which point we will then take all that information to the Standards Committee for it to do its process.

I think I'll break now, is that right, for the...before I go onto my next. So, I won't blaze right into the certification program updates yet in case there are just some general questions.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, thanks so much, excellent work and Paul of course would rely on you to be the arbiter of comments. One question though I would like to raise Steve and that is, if we believe that a column should be added for maturity and level of adoption and we determine collectively as a federal advisory committee that the standard, although it may be the best we have, is really not fit for purpose, should we even leave the column blank?

And so, you know, in the interest of being controversial I could suggest that some of the standards today for quality measurement, although they exist, aren't widely used and may not be something we want to see widely implemented because we have work to do to make them better. But, Paul, let me turn it over to you for cards that may be raised.

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

All right and the first card that was up was Jon White.

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

Wow, Steve, I don't know if you want to respond to Dr. Halamka but in the interest of being noncontroversial I want to say thank you to you and your team, and your office for a job well done. As one of your federal partners for a number of years, and as still the Project Officer of the US Health Information Knowledge Base, I'm really appreciative of the clarity and simplicity so thank you.

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

Yeah and I'll just...you know, to respond to John Halamka's point. We want this to be valuable to you all and this is something that we as part of the roadmap committed to stewarding but it needs your input and it needs the dialogue and debate and as John mentioned, this is a document that will be reflective of the industry at large.

And so if there is an indication that a, you know, cell of the table or a row should remain blank for particular purposes than that to me indicates that we have a lot of work to do and that's also some of the feedback that we need to know and how high we want to prioritize those things as well.

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

Thank you. Nancy we'll start with you?

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

Again, Steve this is great work in terms of...from the charts for Meaningful Use Stage 1 where it was a little bit simpler to Stage 2 to now having something that we can hand out.

One of the things that I would comment on right now though having...in my organization I field questions all the time like, well, when do I use this and what do I use this for?

So, the section 1 is best available vocabulary, terminology set standards and it's even...it's the trade-off between using this list for those who need a primer on what are content vocabulary standards for certain areas...you may or may not wish to have something like under procedures medical where there is both the ICD and the CPT HCPCS some simple thing that says this is for outpatient medical procedures versus inpatient procedures that's an example of what I'm talking about because I constantly am having to explain to several developer types when to use certain things. Okay, that's all.

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

No that's helpful feedback and, you know, clarification like that is certainly welcome as part of the process, obviously you're also part of the federal family so we can take into account too.

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

Since I'll be asked to comment on this, yes, okay, thanks.

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

Good. Gayle?

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

Thank you, Paul, as a non-member of the Standards Committee for obvious reasons I'm on the policy side, I do have a question and I would like to know, what is the long-term goal of this? Is this the precursor of guidance and what kind of implications does it have in the policy framework?

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

I would like to answer policy with policy and I'll play a little bit of our hand here Gayle. This was actually a technique that was used in the Bush administration by the Office of the National Coordinator under Secretary Leavitt, it was prior to HITECH and the certification program that we had internally so just to give you some context that we're borrowing best practices even from ourselves to publish a standards advisory it wasn't quite like Steve and his team have made it but that notion. And then federal programs whether they were grant programs, procurement programs, technology programs could point to that and that would be the mandated standards for those federal entities.

So, the example would be that we might point using our certification program would point to that list for some of the appropriate standards that were there. So that would be the Meaningful Use and the certification program there or the Department of Defense has said that they would point to that list if they were looking at their procurement and their implementation of standards. It's the kind of thing that other...that grant programs and SAMHSA and others might do as well or the Medicaid program.

And so it's a great question and I think the idea is that, just as Steve said, it gives us a playbook. It gives us kind of a dictionary, data dictionary that we can begin to work from and all have the same foundation that we're moving forward on and it gives us a set of expectations federally that we know our systems will start to talk something critically important to the VA and DoD folks.

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

But does not have or as it moves forward will it have the implications of guidance?

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

So, it has the sub-regulatory value of being able to be done with the private sector and to iterate and not have to also have to do in closed rulemaking framework though we could point to it in rulemaking that we might do in other avenues.

So, I think the benefit is that it's guidance in the sense of it would be a list that we could point to and we could use it for other purposes within government and the private sector can use it also. So, the private payers and others could point to that or to David's point earlier interoperability networks could point to it and say these standards expectations that we would have and it just puts it all in one central place.

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

This is the type of thing that has the potential to be used in the arena of states developing privacy and security and consent rules. And as they go down the pathway this has potential in other arenas as well.

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

Yes, Ma'am that's right.

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

Good, David McCallie?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Two comments, one is just a picky technical term to caution you about is when I think some people see the notion of service oriented architecture they may read into that phrase perhaps more than you intended and it's...you know, it's a point of debate as to what that actually means but a lot of people are going to hear a certain subset of technical approaches and that's probably not what you meant, you meant a broader range of things. So, just be sensitive around to that phrase.

The second thought is less clear but over time I think that the architectural patterns and use cases that actually leverage these standards will be the more important reference point than the standards themselves. Most of these things...some of them are profiles that are actually detailed descriptions of a use case but as we move towards API-based and RESTful approaches the things that will matter are the higher level architectural patterns on how you use those lower level standards like the APIs and profiles to achieve some particular use case like say close loop referral management or appropriate screening of a radiologic procedure, or plug in Apps all of those would be use cases on top of something like FHIR.

So, be thinking about, you know, kind of the next iteration of this maybe having a higher level construct to describe some of those architectural patterns or orchestrations, or use cases whatever phrase we come up with.

The API Workgroup is thinking about that, we're going to get sidetracked by doing all our commentary on the roadmap but once we get that done we'll come back to trying to enumerate some of those use cases that can be, you know, patterns that people in the future can say "there must be a pattern that's close to what I need, oh, there it is, let me go and customize for my particular use case that's not covered." I don't know if that made any sense.

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

Yeah, that's helpful feedback and I think, you know, your engagement and participating on how to improve this in real-time is, you know, indicative to me that people see the value and potential in something like this and that's why we want this to be an interactive process if the Standards Committee suggests other approaches or a different way to construct the way in which, you know, what it is that we're trying to accomplish is married with particular standards, all for it, and other columns, you know, as John mentioned as well, again, you know, at the end of the day it's meant to be a public resource for the industry to look to for others to look to, to take the guesswork quite frankly out of some of the stuff that other, you know, people are generally guessing if there's an accessibility issue with individuals accessing, you know, regulations and understanding, you know, kind of the legal structure of how regulations are structured this is meant to, you know, overcome some of those, you know, barriers to access too.

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

You went and used that F word so you didn't make it David.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

But in fact, Paul, to that point, when I read Steve's very fine work I saw that service oriented architecture comment and David I thought the same thing is that service oriented architecture to some might imply SOAP at a time when we're thinking REST is more appropriate. So, it's a term of art issue.

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

And Dixie, please?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I'm a bit curious, which might be an understatement, as to why there is no category for security standards anywhere in this entire advisory. The only reference I see to security at all is a tiny font reference following transport and obviously security is way more than just secure transport. Health data is now the leading target for malicious intruders and we have multiple standards around security ranging from, you know, authentication, authorization, digital certificates, data integrity, audits. So, I really am puzzled by this omission.

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

So we have a section in the advisory that explains why we did not include a security section and to kind of put it succinctly is because the data is the data and it's not unique to healthcare. A lot of the security standards there is not necessarily unique healthcare security standards for protecting information.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

There are no transport healthcare specific transport other than Direct but it uses standard securities.

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

Right, so, you know, that is one area where we felt it was necessary to call out the particular, you know, transport standards that are applicable in the industry today from a healthcare interoperability perspective but, you know, encryption is encryption regardless of the data that it is encrypting.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

What about the implementation guide, your third column?

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

Well, I think that's an opportunity as well where, you know, as we identified for the transport standards we didn't want to just throw out SMTP so that's where we added in S/MIME as well to recognize...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Neither of which are healthcare specific I might point out.

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

Exactly, so I know that there is an inconsistency in the transport side and, you know, that was an area where we felt, again, it was particularly important to call that out given that we do have a specific healthcare oriented standard in Direct.

For the security section we did...we said, you know, this isn't necessarily a place where ONC needs to lead because there is NIST who offers, you know, a tremendous amount of security guidance as well as our colleagues at OCR that provide security requirements as well.

So, I think there is certainly an opportunity if folks think that there's value to call out specific security standards for particular purposes we can do that. The original purpose of this document, you know, was to focus more on the clinical aspects of standards that needed to be determined and to identify areas where there is still I think a lack of consensus on or "competing" standards for clinical health information interoperability purposes.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

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

That's certainly the sort of place for feedback from the Standards Committee that would be helpful, thank you, Dixie.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Thank you.

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

So, Wes, I'm not going to fall for it again, so if you want to say something you'd better wave your card.

Wes Rishel – Independent Consultant

Sorry, asleep at the switch there...

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

Steve, John anything more before Steve closes?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

No, I just...I have been asked by several folks e-mailing me about Dixie Baker's paper on standards maturity and I have given that to Michelle so she can circulate it to anyone who is interested.

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

All right.

Wes Rishel – Independent Consultant

I have a comment if that's okay.

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

You do.

Wes Rishel – Independent Consultant

When I was with Gartner I had to help a colleague answer question of whether a certain product by a large IT vendor would meet the criteria for...HIPAA criteria for data at REST after the last publication of HIPAA regulations and the single issue that sent us around in circles was figuring out which NIST specification applied. One talked about one thing, one talked about another thing nothing...it would have been wonderful if NIST had produced a document like this that not only did the cross-references but did the blank implications where there was no cross-reference. People don't like to do cross-references in documents that go through a long consensus process because they get out of date. Something like this can be very helpful that way.

However, I do...one of the things I've seen is that when you have a consensus group if you change the group you change the consensus. And in standards, you know, somebody doesn't show up at one meeting and the consensus changes you try to stabilize that.

I'm trying to figure out who the consensus group is for this document. That is to say in a world where everybody's got more to do than they have time who puts the time into providing comments on the document that you can reconcile?

I think the users of it clearly are people in government programs who need to do regulations or need to do procurements, consultants, analysts.

What I am concerned about is that this not the broadest consensus group for this. It doesn't sort of carry the industry side or the implementation on the private side. Maybe that's okay. Maybe it's good to just have this document be kind of governing environment document but if there's anything that can be done to make this document more impactful on private industry that generates the priority for people to write the comments to get a broader consensus view. Thanks.

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

So, we can certainly follow up with you Wes on what you think might be more impactful, what will make it more impactful.

Wes Rishel – Independent Consultant

Sure, sure.

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

But, I just, maybe my comments were confusing a little bit earlier, Wes, it would be designed to be used by the private sector not just the...so when we say that we would use it as a reference list to point our certification program for Meaningful Use to it those are private developers and the team worked to see that we were looking at what was widely available in the marketplace right now but leaving room for there to be continued advancement so we should talk more about that.

Wes Rishel – Independent Consultant

Okay.

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

Thank you.

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

Okay, Steve onto certification.

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

Moving on, all right.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Don't worry, Paul, the certification section won't be controversial it will be fast.

W

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

All right so next up is the ONC Health Certification Program update and my partner in crime, Alicia Morton, who is the Director of the Certification Program could not join me she has other duties which I think stem from duties that I've assigned her. So I excused her from attending the presentation with me but I will carry on alone and give you all an update on kind of what's going on with our certification program.

As many of you know there was a hearing kind of joint activity that the Standards and Policy Committees went through, I believe Paul you Chaired that group, right? And there were some, you know, feedback and recommendations that came out of that as well and so I wanted to cover many of the kind of forward progress themes that without, you know, regulation, this is program administration type of work we can do and that we are doing to improve the certification program overall.

And so, you know, those themes include continuous quality improvement, I'm going to touch on these in more detail, greater transparency, greater collaboration, improved customer service and one of the recommendations last year coming out of that group was to have a Kaizen and, oh, by the way we have...it's starting tomorrow. So you can check that box. And, you know, we're very much looking forward to having this conversation kind of end-to-end on the program itself as the scope of the work.

So, in the area continuous quality improvement we have tackled a number of different activities, spring cleaning which is a little bit early, but never too early to clean, as far as my wife is concerned, and so the certified HIT products was one of the feedback points that we had gotten is that, you know, there's a lot of products on the product list not all of those necessarily have ever been used for attestation, not all of those were ever intended by a developer per se as they were going through kind of accumulative process of getting their products certified to be the final version that they would market or make available to particular customers.

And so, you know, we started this process to clean out some of the rows of the database so to speak that don't really have any applicability and that will hopefully reduce the number of products that providers will have to comb through as they go to select their own that they use for attestation.

The current CHPL user interface is going to be in the process of being updated. One of the things also that was a point of feedback is piloting test tools prior to finalizing them. Right now as part of the 2014 release 2, you know, regulation and the process there we have a test tool that's available for edge protocol testing that's in its pilot phase. So, we're following through on this recommendation making available the test tool that is kind of the one that came out of that regulatory cycle available for piloting. I know that folks have kicked the tires on it already based on what my team has said so thank you for those of you that are participating in the pilot.

One things that's more internal to our processes is to have, I think I'm responsible for coining this phrase, testing jamborees where, you know, we walk through here's what we're thinking of proposing, how are we going to test it and that's kind of the bottom line of the process and that's led to I think a lot of iterative feedback on how we would actually specify certification criterion going forward knowing the outcome of how we expect it to be tested, what tools we have available, where we need to invest resources, etcetera.

Future test procedures we expect to be streamlined. Many of the test procedures today are quite long and verbose. Our proposal and idea is to focus on the technical outcomes that need to be achieved and set those forth in the test procedure that directly aligns with the obligations and kind of compliance responsibility's associated with the certification criterion, provide that little bit of extra detail that will be necessary for accredited testing labs to understand what exactly needs to be proven when a product goes forward to get tested. And so, you know, this hopefully will significantly reduce kind of the cognitive burden and load on developers as they comb through the current, you know, slate of test procedures that we've got right now.

And then the last thing also is our plan to release draft test procedures at near same time as the 2015 edition NPRM. So, for the past few regulatory cycles, you know, the NPRM has come out and there haven't been test procedures associated with the certification criterion it's I think made it difficult for developers to have a full sense and a bigger picture of both what the criterion says and how it's expected to be tested so that's another continuous kind of process improvement that we've added in as well in terms of our commitment to get those out. Obviously, making the test procedures more concise and succinct and shorter makes this more possible.

From a transparency perspective many of you know and I presented before that we engaged last summer in an open test method pilot development process. We also, as part of that 2014 edition release 2 to test procedures, solicited public comment and had the dispositions of those test procedures so one of the, you know, points of feedback earlier was that developers and other stakeholders would comment on the test procedures and how those comments were adjudicated and triaged wasn't made publicly available we've since done that now as part of the, you know, new process and we expect to follow that going forward in terms of building out that infrastructure.

We're continuing to publish, you know, FAQs and guidance on our website. We're also exploring a way to migrate the current certified HIT products list in an open data CHPL as we call it so an open data file. There's a lot of product information that's currently locked in PDFs so there is just disclosure and transparency requirements that exist today but it's not computable and so, you know, we've heard from people that want to dig into a lot of that data especially on user centered design and it's tough and so, you know, one of the things that we're going to be doing, you know, in looking forward as we mature the program and looking at the CHPL overall is how can we make more information available for research and analytics about products, there are disclosures that we already include. So, you know, that's one thing that we're actively exploring how to best accomplish.

And then there's other, you know, this may seem like a small thing, but it's actually a big thing to the developers and those that experience the program, as we provide guidance to the testing labs and the certification bodies making sure that this guidance also closes the loop with developers as well so that either they know if they're coming in for the purposes of certification that there is new guidance available to the certification bodies or that if their product is subject to surveillance, which does occur, that the, you know, surveillance parameters may have been influenced by new guidance that we've provided to the certification bodies that may be post, you know, the time that the product had been certified that's something that we intend to discuss as well at the certification Kaizen is how we can best, you know, disseminate that information.

So, in terms of collaboration we're going to be kicking off a kind of federal collaborator, which I'm sure is a government bureaucratic invented word and, you know, we continue to work closely with the accreditors so there is an accreditor for the testing lab which NIST administers which is NVLAP and then ANSI serves as the ONC approved accreditor as well as strengthening kind of the compliance to the ISO standards that both the testing labs and certification bodies need to fulfill.

Last point here, one of the feedback points that came out of that certification hearing was that, and I think this came mostly from the testing labs and certification bodies, you know, ONC engagement and witnessing of testing and how is that occurring, so we've stepped up our game so to speak in terms of engagement and shadowing, and witnessing testing as it's occurring to see what the ATLS and ACBs are seeing as well and that's been quite informative especially to, I would say, Alicia, to single her out because she's been new to the program, and this is something that we committed to doing as well.

In terms of customer service we've attempted numerous different approaches what we've landed on at this point is, you know, we have an e-mail inbox that's always existed but now we're using that as a single point of inquiries so we have response metrics around this, three days to get a response, 10 days for resolution that's what we're striving toward, you know, hold us accountable if we're not meeting your expectations.

Another reminder, and I think this probably goes unsaid or often unsaid, or under indicated, the certification bodies are the ones that obviously issue the certification and, you know, they are also held accountable by ONC to follow through on complaints or concerns relative to product compliance with certification criteria. All of them without any collusion created equally uncreative e-mail addresses for their...and you know, I've chastised them about their creativity here, so I don't mean any offense to them, you know, they can be e-mailed, they have people that monitor these e-mail boxes so if you work with provider groups, if you're a consultant, if you work at a regional extension center and there is a provider that has a problem with a particular product e-mail the certification body and if you're having trouble locating what certification body it is you can certainly e-mail the ONC mailbox staff is certainly helpful, happy to help you find the specific certification body. You can also go to the certified HIT product's list and look it up yourself.

But all of the authorized certification bodies are ready and willing to dig into any of the concerns that may be raised. We also have a tool which is JIRA that some of you may be familiar with for some of the public and accrediting management that's how we've been ticketing and managing these increases as they've come in and then we also have a collaboration space that we've created for joint accredited testing labs, certification body, ANSI, NIST, ONC all the kind of program administration stakeholders that are involved.

And so that is the end of my kind of certification program updates but I wanted to give you a sense that we aren't sitting on our hands, lots going on that, you know, I've described as little things that make a big difference throughout the process for a lot of people including ourselves as engaged participants and very much looking forward to working with you all as the program goes forward, as the, you know, regulatory updates come out and the...obviously you have a session in the next two days relative to the certification program and I expect more will come out of that which we can do better at but that's clearly our focus and, you know, our passion to improve the program.

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

Thank you, Steve that was very responsive to the hearing feedback you got as well. I wonder if I can ask you one question about your open data CHPL. I think that was to address...so there was a request that people have more access to understanding the workflow that following the certification or passing the certification introduces into the products and have some visibility into that. Is that what was intended by that section or...

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

I don't think...I don't know that would necessarily get that level of detail. So what was intended is, you know, we live in a world where the federal government gets a lot of data reported to it. We have data that's reported to us that we've made publicly available but not really necessarily publicly accessible in the most optimal way.

And, you know, as we looked kind of across the board as we were doing our own, you know, program improvement assessment one of the things that we included in the 2014 edition rulemaking was additional disclosure information related specifically to user centered design and the summative usability testing that developers, you know, went through as part of their products and there is detail, you know, in each of those files but it's locked in a PDF.

And so, you know, to use all the phrases that we used before our intent here is to unlock that data, make it available on its own, you know, XML segment and then, you know, make...ultimately make that data available for others to use for whatever purpose that they, you know, deem appropriate or are interested in for analysis. And, you know, that this could ultimately, you know, help initiate a broader kind of market comparison aspect based on the data that may be reported to us. So, you know, other things that have a cross-section with some of the FDASIA work which you are intimately familiar with, some of the other, you know, work that we've been engaged in terms of just, you know, product transparency and what about the products.

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

So I...just a little bit more, the spirit of the recommendation was to give ordinary users or perspective users a look into the workflow implications of the way the products complied with certification because it seemed to be that's where it was the way the products were tested had implicit workflows baked in and that was where the pain and suffering came to the user. Is there any thought about to make that more visible which not only informs the prospective either user or customer but also makes it more accessible so that the market can induce more competition around usability?

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

So, this is probably like one of those, like we've got to take this off-line.

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

Right.

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

So, as not to, you know, put anyone else asleep around the table here. I think that's helpful feedback and, you know, that would be an area where we're interested in how we can best provide that type of information. I would say at this point we've looked at it from a different angle and vantage point in that the test procedures as they are currently written and, you know, kind of our perspective is that they've been interpreted as the way and thus has resulted in particular instantiations of workflows to meet "the way" that testing would occur.

You know our intent to going forward is to say "here's the outcome, the technical outcome that the product needs to demonstrate" if it can deliver on that technical outcome then it has met the...it has met the requirement of the certification criterion as opposed to, you know, laying out very, you know, discrete steps which, you know, some may have argued in the past would "stifle innovation" so not dialing back necessarily the rigor or expectation on what the product needs to deliver but where we don't need to specify every single step not going to that level of detail in the future.

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

Okay. Any other questions or comments?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, Paul, I told you it wouldn't be controversial.

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

No it wasn't.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well done Steve, thanks so much, very responsive as everyone has said.

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

Thank you, Steve.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, well Paul, I turn the meeting back to you to close it up.

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

All right we're going to hear from Dawn and Beth on data updates.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis - Office of the National Coordinator for Health Information Technology

Okay, do I just go ahead and go? You guys are laughing at me.

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

No we're laughing at the...

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

Yes.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis - Office of the National Coordinator for Health Information Technology

Okay. All right, Dawn Heisey-Grove I am going to be giving the ONC portion of the data update and then Beth will be going second and then I guess we'll answer questions after that is that right? All right let's see if I can get this right.

All right, so briefly I'm going to be going over hospital Meaningful Use achievement for the true fiscal year 2014, describe the attrition and return rate or basically skipping rates for hospitals and then talk a little bit about uptake of certified EHR products and the Meaningful Use definitions for those hospitals.

So first I'm going to start with Meaningful Use achievement, the easier one, this is a graph of progress for all hospitals over...through 2014, through fiscal year 2014. The bar at the top is all eligible hospitals which is 4993 hospitals you'll see that 90% of them have achieved Meaningful Use and 95% of them have received at least one payment. Only about 3 or 4% have actually not registered or participated in the program at all.

The next bars below are portions of those eligible hospitals. Children's hospitals got a little bit of a late start because of some of the nuances with the Meaningful Use program so that's probably is why you see the difference in their Meaningful Use achievement rate compared to the all eligible hospitals. And you also see here that critical access hospitals aren't...there isn't a huge difference in their Meaningful Use achievement rate compared to all of the other hospitals that we're talking about.

This is breaking down the characteristics of the hospitals associated with achieving Meaningful Use a little bit further. The critical access bar at the top is the same one that you saw in the previous slide and then the bars below it are other hospitals within that eligible hospital grouping exclusive of the critical access hospitals.

Small hospitals here are classified as hospitals that have less than 100 beds, medium have between 100 and 399 and the large hospitals have more than 400 or 400 and more and what we see here is that small rural hospitals, those that have fewer than 100 beds are achieving Meaningful Use at about the same rate as the larger hospitals that have more than 400 beds.

The smaller urban hospitals have a lower Meaningful Use achievement rate and when we've dived into that before it looks like those are more specialty hospitals that may not be making that leap forward but it's definitely something that we need to look into a little bit further.

So in summary, the vast majority of our eligible hospitals have achieved Meaningful Use or are making progress towards Meaningful Use and now we're going to go into whether they come back after they've attested just for one year.

So before I go into returning and coming back just a general sense of what we're talking about when we talk about the hospitals. We have different...and this would apply for eligible professionals as well, but we have different times when the hospitals could start. They could start in the very first year of Meaningful Use which was 2011. Then they could also have started in 2012, 2013 or 2014. So, the percentages in that first...the second column there indicate the proportion of hospitals, among those that have attested, where they fall in that grouping.

The hospitals that started in 2011 and 2012, marked by those green arrows, are the ones who are scheduled for Stage 2 in 2014. So, when we're talking about the next few slides just keep those in mind, there are different groupings and different proportions of hospitals that are at different stages of the Meaningful Use pathway.

So for the hospitals that first attested in the very first year of the Meaningful Use program we're talking about those hospitals in 2011, they could have come back for as many as four years at this point, 2011, 2012, 2013 and 2014 and what we see is that more than 8 in 10 of them actually have come back for all four years. Another 12% skipped only one year which means they skipped a year and then they came back in a subsequent year, 3% have skipped two of those years and only 2% attested in 2011 and didn't come back any time after that.

In 2012 the number, and again 2012 we're only talking about three years here but we can see that again, 97% of them have participated in all or most of the years since they have started the program. In 2013 we're only talking two years but you can see that there 91% of them came back to attest in 2014 after attesting for the first time in 2013.

This is a very simple graphic but it is to make an important point, the hospitals that were scheduled for Stage 2 that's the hospitals that started in 2011 and 2012 their return rate for 2014 is about 89%. The hospitals that were scheduled to return and do Stage 1 their return rate was 91% and that's just the hospitals that started in 2013. So, the return rate for those two groups, regardless of whether they're...which stage their coming back for, is fairly similar.

And again 98% of our 2011 hospitals, those are the ones that were doing Meaningful Use right out the gate, have come back and attested in multiple years, 97% of the 12 cohort hospitals have attested in subsequent years. So when they skip a year it's usually just the skipping year it's not that they're dropping out of the program entirely.

So now I'm going to talk a little bit about uptake of the 2014 edition for the hospitals through FY14. This graph shows you by the cohorts again when they started...they first attested to Meaningful Use, which version of certified technology they're using and you can see that across all four cohorts most of the hospitals attested using 2014 certified products. A very small portion used the combination, which is that lighter bar, and then the blue bars are the proportion of hospitals that just used 2011 CEHRT.

Now this is a revisit of the previous slide but this is just to show you that now for 2015 when we're talking attestations we add in the 2013 cohort, so those hospitals around 1500 of them are now scheduled to attest to Stage 2 in addition to the 2011 and 2012 hospitals that were scheduled for this year.

So, when we look at those three cohorts its around 4000 hospitals you can see that this is the use of certified technology, the version that they're using as well as which stage of Meaningful Use that they're actually using and the definition, if they're doing Stage 1 2014 definition or if they're doing 2013 definition.

The hospitals that came into attest for Stage 2 the vast majority of them are using 2014 CEHRT and the ones that are doing 2014 definition of Meaningful Use also using the majority of 2014 CEHRT and Stage 1 2014 definitions.

The number of hospitals that are doing 2013 definition of Stage 1 is pretty small it's only 350 hospitals. So, the point of this slide is to show that those hospitals that are supposed to be doing Stage 2 or scheduled to do Stage 2 in 2015 are mostly already on 2014 CEHRT and are mostly already doing 2014 definitions and this slide just re-emphasizes what I've said. Most of our hospitals are already on 2014 CEHRT and they're already using the 2014 definitions for Meaningful Use.

There is one last slide back here that is all of the methodology if you really, really, really want to dive into it's there in very small print and I think we'll now go to Beth.

Elisabeth Myers, MBA - Office of E-Health Standards and Services - Centers for Medicare & Medicaid Services

Thanks, Dawn. So, I have a couple of different things I'm going to be covering today. I have way more slides than we can possibly get through in the time allotted but hopefully they'll at least be a resource for you to review on your own on your time as well and feel free to follow-up with questions at the end and also separately by e-mail if necessary.

First things first, next slide, please, I just want to get this out of the way, we did do an announcement, Patrick Conway has authored a blog to go into it in a little more detail so I won't do too much here, that we intend to engage in rulemaking to do a couple of things for the program beginning in 2015, the first is to shorten the 2015 reporting period to 90 days. The second item that we intend to do is to realign hospitals to reporting on the calendar year rather than the fiscal year. And the third item would be to modify some other aspects of the program to match our ongoing identified program goals, potentially reduce complexity and potentially reduce the reporting burden on providers.

As you all know since this is rule writing I can't really go into further detail on those items except to state that most people know by now that the Stage 3 rule is under review with OMB. We are not looking to do these items in that particular rule. That rule will deal exclusively with the scope of Stage 3 which begins in 2017 or is intended to begin in 2017. This would be pursued through a separate rulemaking vehicle that we intend to engage in in the spring. So, next slide, please.

So now onto some other items, I think the theme of my presentation today is probably by request. Almost everything that's in here today are items that have been requested in our prior meetings that you all were interested in hearing more about or that we've been working on analyzing the data and getting our information together for you so there's a couple of disparate items but largely it's based on your request, one of them was to do a breakdown of the actual number of providers by the amounts that they are being adjusted in the payment adjustment for the providers who are subject to 2015 Medicare payment adjustments.

So, this is specific to EPs, we thought this would be the most useful, there is a lot of variance within hospitals of how this can apply and so for that reason we really focused on EPs here. I do want to make it very, very clear that these are estimates, which is why they are very pretty round numbers. The reason that these are estimates is the payment adjustment is not a flat amount it is a percentage and there is a percentage of the claims that are submitted for Medicare services during 2015. So, obviously there have not been very many days in 2015 yet so the claims have not been submitted.

So what we did is, took a look at historical claim's volume for each of the providers and tried to segment it to try and give a better perspective on what...if that similar claim volume happens in 2015 what the actual payment amount the provider would be assessed would look like and how many providers would sort of fall into that bucket.

So in general about 35% of providers, eligible professionals, can expect to receive in the neighborhood of \$100 to \$250 payment adjustment, about 21% are between \$250 and \$1000, about 14% are between \$1000 and \$2000 and about 31% are over \$2000. So that is just a quick snapshot of it.

The question that I'm sure will generally be asked is what is the total amount based on these numbers and these estimates. Again, a caveat that this is an estimate, we do not know until the end of 2015 what the total claim volume is for any given provider and so for the total that variance gets compounded, however, we do have our actuary report providing some estimates and projections for us which we use both for purposes of budgeting working with OMB and for rule writing purposes. And our current estimate is about 200 million dollars in payment adjustments will be assessed over the course of 2015. Next slide, please.

And next topic, so this is just a quick update we're not going to go into this too much, these are active registrations through the end of December, just wanted to let you know we are well over 500,000 active registrations for providers across the board in the EHR incentive program. Next slide, please.

And our payments we are now totaled over 28 billion dollars in payments through the end of December 2014. Next slide, please.

So onto attestation data, next topic, so our 2014 attestations, this is through the 1st of February so this does...the hospital numbers obviously haven't changed since the last month so that was the end of the year for them and the close of their reporting period and their attestation period. So, this is how many eligible professionals have come in and you can see there's a really big uptake here. Our last number was significantly lower than this and this is because this is the first number where we're reporting that has come after the close of the reporting year.

You see that we have about 25,000 new providers so this is their new program year, who have entered the program at this point in time as of February 1st. Sorry, one second my screen just froze on me, there we go. We have had 91,000 providers so far who have attested to Stage 1 and 36,782 as of February 1st providers who have attested to Stage 2.

Now this last bullet is based again on your requests of what the denominator is. So, I want to make it very clear when...Dawn's presentation last month was talking about the end, the number, the total denominator or potential attesters to Stage 2 that is the eligible professionals across the board who are scheduled to be in Stage 2, this number, this 71,000 is the number of people who have attested so far who were scheduled to be in Stage 2. So you can see that a little over half of the providers who were scheduled to do Stage 2 so far, who have attested so far, have actually come in and demonstrated Stage 2 of Meaningful Use. The other portion of that number is people who have also attested to Stage 1 using the flexibility rule that's an indicator of those providers having come in and attested using one of the flexibility options.

Again, all of these numbers will continue to go up drastically over the next few weeks. Again, as Dawn has shown in a couple of different presentations, we do historically have the largest volume of attestations come in quite literally in the last week of the open attestation period. So providers do have until February 28th to attest. Next slide, please.

So, these are the final hospital numbers, not going to go into them in detail they haven't really changed but again you can see the total schedule to attest to Stage 2 and those who did attest to Stage 2, perhaps that percentage is pretty good. We are encouraged by this and as Dawn covered in her earlier presentation we're also encouraged by the depth of the full implementation and use of 2014 edition software going into 2015. Next slide, please.

So, for this, this shows hospital attestation data but what I'm really going to talk about a bit is performance data that we get through the attestation process. So, this is self-reported data of the performance numbers that providers are scoring on individual measures. So, before we dig in on this sample slide here I want to just go through why we're doing this and why we're presenting this in this way.

We have, since the program's inception, provided the data for attestation data on an individual basis on our website on a quarterly basis in what we call public use files. So that data is accessible and it can be analyzed but as Steve mentioned in his presentation earlier sometimes the issue with transparency is that we're providing too much data and sometimes the issue with transparency is that we're not providing it in a way that's easily accessible.

So, we've tried to take a stab at presenting the performance for it in a way that is a bit easier for people to understand because when we look at it from a program stand-point we actually take a number of different ways of analyzing the data. We look at it on a broad scale. We look at things like averages. We track the change over time but we also do actual statistical analysis on the data.

For those of you who are interested in statistical analysis largely we do a lot of normal distribution curves and then determine standard deviation in variance I'm not going to dive in on these things for everyone today but those are the types of things that we look at to try and get indicators of how performance is really going and this is actually an approach that we take across the board of CMS programs, the quality measurement programs are similarly good examples.

So we look at performance data and look at a normal distribution curve and standard deviation to understand not only how providers are doing in the general sense but how close providers are performing to each other, what the actual relationship is between what provider performance is at top and bottom, different indicator points along that and it also helps to give you an idea of a predictor. So, you can sort of use that distribution and statistical analysis to predict what a provider might perform on the measure in the future. This is done in things like IQR, hospital-based value modifier and actually the National Quality Forum does this in their endorsement process of quality measures. So we take a similar approach with Meaningful Use.

So, the graphic you see on this slide is a way of describing best that I think will be a little more approachable and familiar to everyone. We all remember getting standardized test scores in school or having your children have their standardized test scores and there are sort of a couple of different common factors. There is your overall score, in other words, did you pass or fail and how far above the passing mark were you as an individual.

So, looking at this slide we can see that the measure threshold here is 30%. So for...that would be the passing mark and my individual score, if I scored for example 79%, would be 49 points above that passing score.

But the other thing that you get in standardized testing is your ranking in comparison to your peers which include comparison to the others who have participated in the same test. So, if imagine that all of the providers who have attested to Meaningful Use for a given measure are lined up from lowest score to highest score that's the visual representation that we're doing here.

Point A, provider at the far left, would be the provider who scored the lowest on the measure across the board among their peers. The highest score would be the provider at Point B on the far right who achieved the maximum score that was scored. Now I want to point out the maximum score doesn't necessarily mean the maximum score possible it's simply the maximum score that any provider achieves.

And then there are points in between that provide us with some useful information on how performance is actually going and how to compare it across the program. These are really similar for the use statistician to standards deviations, you should recognize it, but this visual representation we take this first point at the first quartile, so what that first quartile means that is the provider who is at the top of the bottom 25%, so in other words, that provider is at the top of what you might call the lower end of performance.

Now we look at the median provider also designated here as the second quartile that's the provider who is scoring exactly in the middle, above 50% of their peers and below 50% of their peers. The third quartile is the 75% providers that's the individual score that is higher than 75% of their peers and lower than 25% of their peers. And then of course the maximum scores at the end there.

All of these things we can look at to determine a range of how providers are performing and then we can also look at how providers at different key points are performing in relationship to actual measure thresholds. So, let's go to the next slide.

And you can see some examples of the actual measures. Now in this presentation I do have all of the Stage 2 hospital measures included so you can take a look at each of those but we're only going to touch on a few today.

So, for these two, these are record demographics and record vital signs. These are objectives that have been in the program since the beginning. This is providers who are within that cohort that is engaged in Stage 2 for 2014 and you can see that the first quartile provider for record demographics, so person who is ahead of 25% of the class and below 75% of the class is scoring about 98% on this. The median provider is scoring 99%. The third quartile, that's the person that's 75% of the peers, is scoring at 100% and the maximum score was 100% for this particular measure.

So, what this tells us is that generally speaking providers are performing on this measure extremely high, generally speaking providers are outperforming the threshold by that 20% and that the variance between these quartiles gives us a pretty good indicator that future providers in Stage 2 will perform in a similar fashion. Next slide, please.

Again, you can see some more examples of measures. So, what I want to point out CPOE for medication orders. So, there is a bit more variance between the three points that we're looking at in this one and this gives us an idea of room for growth in a particular measure. So, in addition to being able to identify, on the previous one, that most of the providers are performing scores very, very close together that are very, very high. This particular spread shows us there is some variance, there is about a 20 point variance between the 25th and 75th percentile which gives us an idea of the integrity of the measure threshold and the overall predictors of performance on that scale. I will also point out that the maximum score on this particular measure is 94% not 100 which does give us an idea that there may be room for growth there for the entire group. Next slide, please.

And you can see these are the CPOE items that are specific to Stage 2. You can see that they are a little bit lower. We anticipate that this is largely because the medication order item is also a Stage 1 measure so providers have a little bit more experience and practice with it by the time they get to Stage 2. So, this also shows us that there is some room for growth here and that our thresholds are pretty stable and that the variance shows that providers do have some variance within these performance measures. Next slide, please.

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

We have just maybe another minute and we want to save a little bit time for questions okay?

Elisabeth Myers, MBA - Office of E-Health Standards and Services - Centers for Medicare & Medicaid Services

Absolutely, so I really just want to touch on the bottom one on this one and we'll then go to the top one on the next slide. So, this is the patient electronic access measure, this is the 50% threshold for providing access and so I did want to point this one out because I think that this is one that has been a pretty big concern we think is very, very important. We also think that there have been some concerns over the ability to meet this measure. The performance here is pretty strong and it is significantly above the threshold. We do see a little room for growth if you look at the first and third quartiles together but I did want to point that one out. And the next slide, please.

We also see quite a bit of room for growth in the second measure for patient electronic access. It is a positive sign that the median is performing at about twice the measure threshold so that providers are clearly succeeding on this measure but there is obviously room for growth here and we...this is an identifier to us that we need to continue to work with providers on getting closer to meeting this measure to outperforming this measure at a larger degree.

If we can go one more down, I'm sorry one more. So, I'm going to leave it here when we get to questions but I did want to bring up the two summary of care objectives or measures for the objectives. The first one is the 50% by any means so that's the not electronic and you can see pretty good performance on that as well.

And the second one is our summary of care measures, number two, which is a 10% threshold and you can see that the median performance is about 30% there so that's a really good sign that the health information exchange to electronic means is progressing.

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

Okay, is that it Beth, ready for questions?

Elisabeth Myers, MBA - Office of E-Health Standards and Services - Centers for Medicare & Medicaid Services

Yes.

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

Okay. Okay, so let me open up the floor for questions on either of the data presentations. Well, good. Well a lot of encouraging data on the attesting at least for the hospitals who have already completed their fiscal year and good information from Patrick Conway about some of the changes and addition of flexibility. Okay, well, thank you very much Dawn and thank you very much Beth.

Elisabeth Myers, MBA - Office of E-Health Standards and Services - Centers for Medicare & Medicaid Services

Thank you.

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

So, we're going to move onto public comment please.

Public Comment

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

If there's anyone in the room that has a public comment if you could please come up to the table and operator could you please open the lines.

Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute

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

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

If you could just state your name and your organization and you have three minutes.

Mark Roche – Independent Consultant

Sure, Mark Roche, I'm an Independent Consultant, I've seen a slide where we were discussing about identifying core attributes, core patient attributes for patient matching. I've had a discussion with several EHR vendors and in many instances even if you have identical patient attributes that you're looking at if the algorithm of evaluating them is different you may again have one EHR vendor will say, well I do have a patient match those two patient records that actually belong to the same patient and the other algorithm will tell you, no they actually belong to the different patients.

My point is should we...do you think we should be thinking about also setting up some kind of a framework for common algorithms on how...the weights are assigned to specific patient attributes.

Thank you.

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

Thank you. And we have no comments on the phone.

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

Okay, well thank you for the combined committees for your perseverance over a really long day today but I think you'll all agree that the discussion, both the reports and the discussion were really productive and constructive and we have work ahead of us the next few months to get feedback back to ONC and the federal agencies from a strategic plan point-of-view. So, thank you so much and happy travels. So, I guess the people from Boston aren't here so they don't have to go back.

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

Well, Michelle.

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

I'm running, bye.

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

Bye, bye Michelle that's right, she came a day early.

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

Is it going to snow again tomorrow?

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

Yes.

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

What's going on up there, y'all have been living in snow globes and y'all...

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

All right, thank you, everyone.

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

Thanks for coming everyone.

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

Thanks, everybody.

M

Thank you.

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

Thank you, all.

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

Thanks.

Public Comment Received During the Meeting

1. I was impressed with Karen DeSalvo's language during the ONC Annual meeting, we need a digital health infrastructure that is person centric, rather than institutional centric. I do not see this idea well reflected in the principles. I am wondering if one or more of these can be amplified: leveraging the market, empowering individuals, or scalability. Thank you.
2. Slide 6. # 13 requirements...Care providers partner with individuals to delivery high value care. What about a corollary, Individuals partner with providers to co-produce high value health and care. I would to see this requirement be more bi-directional.
3. What would an example of a financial incentive for non-government payers?
4. There are a lot of Joint Commission Patient Safety Goals but not terminology content to support it. Are you evaluating external standards like this?
5. Will there be a write up or the captioning posted following the meeting?
6. Thank you! Last question; is there a way to rewind to the beginning of captioning before it's posted? So to go back to the opening remarks now?
7. Who is a good email contact for follow up questions and comments after the meeting?
8. Regarding the discussion on Privacy: Patients would like to have the notion to decide whom reads their data and whom should not read their data. Data = any PHI.
9. Data = Any PHI or PGHD
10. I want to review a statement that I heard from this morning and saw in the Caption window ... how can I go back and locate that captioned statement?
11. Please elaborate on consumer mediated models for dynamic digital (computable) consent and preference management
12. Will that be "soon" after meeting conclusion or in days, weeks, etc.? (have a WG call tomorrow morning)
13. Yeah.. Glad to hear REST Apis
14. What is the position on the use of Operating Rules for clinical transactions, much like is being used to facilitate interoperability of administrative transactions
15. Thank you Caitlin.....to build upon my earlier comment...for the electronic exchange of healthcare administrative transactions, operating rules build upon standards to optimize multi-stakeholder exchange. They are helpful in clarifying how/when non-healthcare security or transport standards are used (addresses one of the speakers concerns). Operating Rules for administrative transactions were mandated by the ACA Section 1104.

16. Please forward this public comment (part 1 of 2) to the HITSC: Regarding the Interoperability Roadmap and Standards Advisory presentations, it's good that there's a blend of emerging standards such as FHIR RESTful APIs and Data Provenance, along with improvements to existing standards such as CCD. FYI, just last week there was a new Project Proposal called "Pertinent and Relevant" in the HL7 Structured Documents workgroup. Specifically it aims to address, through clinical stakeholder guidance, the problem that Steve Posnack mentioned -- excessively large auto generated CCD documents. I agree with Steve that this problem isn't primarily with the standard itself but with how it's implemented. Hopefully the project will help EHRs and providers to produce pertinent, relevant, and usable documents instead. I hope that members of the FACAs will encourage their organizations -- especially clinicians -- to be aware of that project and possibly to participate.
17. (part 2 of 2) If ONC or the Standards Committee are already working on the same problem, on planning to work on it, I hope they will collaborate with HL7 Structured Documents to avoid redundant or conflicting efforts.

HIT Joint Committee Meeting Attendance – "Standards Committee"							
Name	2/10/15	01/27/15	12/10/14	11/18/14	10/15/14	09/10/14	08/20/14
Andrew Wiesenthal	X	X	X				X
Anne Castro	X	X	X	X		X	
Anne LeMaistre	X	X	X	X			X
Arien Malec	X	X	X	X		X	X
C. Martin Harris		X	X	X		X	
Charles H. Romine	Alternate	X					
Christopher Ross		X				X	X
David McCallie, Jr.	X	X	X	X		X	X
Dixie B. Baker	X	X	X	X		X	X
Elizabeth Johnson	X	X	X	X		X	X
Eric Rose	X	X	X	X		X	X
Floyd Eisenberg		X	X	X			
James Ferguson	X	X	X			X	X
Jeremy Delinsky	X	X		X			
John Halamka	X	X	X	X		X	X

John F. Derr	X	X	X	X		X	X
Jon White	X	X	X				
Jonathan B. Perlin							X
Keith J. Figlioli	X		X			X	
Kim Nolen	X	X	X	X		X	X
Leslie Kelly Hall	X	X	X	X		X	X
Lisa Gallagher	X	X	X	X		X	X
Lorraine Doo	X	X	X	X		X	X
Nancy J. Orvis	X	X				X	
Rebecca D. Kush		X		X		X	X
Sharon F. Terry						X	X
Stanley M. Huff	X	X	X	X		X	X
Steve Brown			X			X	
Wes Rishel	X	X	X	X			X
Total Attendees	22	25	22	20	1	22	21

HIT Joint Committee Meeting Attendance – “Policy Committee”					
Name	02/10/15	02/10/15	01/13/15	12/09/14	11/04/14
Alicia Staley				X	
Anjum Khurshid	X	X	X	X	
Aury Nagy				X	
Charles Kennedy	X	X	X		
Chesley Richards			X		
Christine Bechtel	X	X	X	X	
Christoph U. Lehmann			X		
David Kotz	X	X	X		
David Lansky	X	X	X	X	
David W Bates	X	X			
Deven McGraw	X	X	X	X	
Devin Mann	X	X	X	X	
Gayle B. Harrell	X	X	X	X	
Karen Desalvo	X	X	X	X	
Kim Schofield	X	X	X	X	
Madhulika Agarwal	Alternate				
Marc Probst	X	X	X	X	
Neal Patterson	X	X		X	
Patrick Conway					
Paul Egerman	X	X	X		
Paul Tang	X	X	X	X	
Scott Gottlieb	X	X			
Thomas W. Greig			X		
Troy Seagondollar	X	X	X	X	
Total Attendees	17	17	17	14	0