# HIT Policy Committee
# Transcript
# December 4, 2013

## Attendance

Members present:

- Madhulika Agarwal
- Christine Bechtel
- Neil Calman
- Arthur Davidson
- Paul Egerman
- Judith Faulkner
- Thomas Greig
- Scott Gottlieb
- Gayle Harrell
- Charles Kennedy
- David Kotz
- David Lansky
- Devin Mann
- Deven McGraw
- Jacob Reider
- Troy Seagondollar
- Robert Tagalicod
- Paul Tang

Members absent:

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- David Bates
- Patrick Conway
- Aury Nagy
- Marc Probst
- Joshua Sharfstein
- Alicia Staley

## Presentation

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee. This is the 54th Policy Committee meeting. As a reminder today's meeting is being transcribed and recorded so please state your name before speaking. This is a public meeting so there will be time for public comment before lunch and at the end of the meeting.

Also if you're Tweeting the Hashtag for today's meeting is "hashtag hit policy" and today we're going to do roll call just a little bit different. We're going to go around the room and have everyone introduce themselves but before we do that I do want to mention over the summer Paul Egerman was re-appointed and we had never announced that at a meeting, so I just want to welcome Paul Egerman for his second term and he was appointed by Nancy Pelosi's Office. So, we're happy to have you for your second term Paul. And with that we're going to go around and do roll call.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator**
Jodi Daniel, ONC.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
Judy Murphy, ONC.

**Lauren Wu, MHS – Policy Analyst – Office of the National Coordinator**
Lauren Wu, ONC.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
Gayle Harrell, State Representative from Florida member of the committee.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**
David Kotz, Professor of Computer Science at Dartmouth College.

**Robert Tagalicod – Director – eHealth Standards & Services – Centers for Medicare & Medicaid Services**
Robert Tagalicod, CMS.

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

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Deven McGraw, Center for Democracy & Technology.

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

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
Jacob Reider, Acting National Coordinator.

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

**Paul Egerman – Businessman/Software Entrepreneur**
Paul Egerman, Software Entrepreneur.

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

**Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health**
Neil Calman, Institute for Family Health and Mount Sinai Medical Center.

**Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health**
Art Davidson, Denver Public Health, Denver Health.

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

**Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation**
Judy Faulkner, Epic.

**Elise Anthony – Senior Policy Advisor for Meaningful Use – Office of the National Coordinator**
Elise Sweeney Anthony, ONC.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**
Kevin Larsen, ONC.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
And are there any members on the line? Okay and I do want to point out at the last meeting Troy Seagondollar, David Kotz and Devin Mann had attended their first meeting but this is their first meeting in person so we have some new faces in the room which is kind of why we did the roll call the way we did. So, with that I'm going to turn it over to Jacob Reider.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
Thanks Michelle. So the season is one of reflection, right? We meet with our families last week many of us. The days are shorter. The nights are longer. And it's the season that we reflect on what's happened this past year and think a lot about what will happen in the coming 12 months when the New Year starts. And so we've been doing some reflection at ONC and certainly I've been doing some reflection. We had our annual awards, honorary awards session I think yesterday. The days go by so fast, two days ago, it felt like yesterday, where we reflected as an organization, ONC, and honored the folks on our team who we think have helped to change healthcare.

And it was a great time for us to reflect on all the accomplishments and to think forward about what we're doing and I found myself talking about one of my favorite books. See, they're all laughing at me and I will Tweet the link to the YouTube video where the author gives his TED talk. So, the book is a book called Tribal Leadership written by a guy named Dave Logan and some of his colleagues and they look at the cultural behaviors, the cultural themes of different kinds of organizations and I'm going to step through them for you just so that you can witness some of this behavior.

So a Stage 1 organization they're unifying theme might be life sucks. They are unhappy, they are angry, they are angry at each other with each other, they are very dysfunctional and one example that Logan gives in the book is the Postal Service in the 1970s where going postal was literally something that we all understood, it meant going to work and killing your colleagues. So, these are very dysfunctional organizations and very rare that we see these kinds of organizations today.

A Stage 2 organization might be my life sucks as the resounding theme. So my life sucks means you're fine but I don't get the respect I deserve. I don't get the recognition that I should have. My boss doesn't like me. My colleagues don't like me and they should. Again, this is fairly uncommon although about 25 percent of organizations exhibited some Stage 2 behavior.

Stage 3 is I'm great and you're not. Lots of academia is this way. The person who wrote more papers, Paul said surgeons and in the book there are descriptions of surgeons who behave this way. I did more cases than you. I have more residents than you and this is – we don't judge these things, right? See these are accomplished people who do incredible things and yet they're individual contributors. They are shining heroes who don't operate all that we well in teams.

And Stage 4 organizations work really well as teams because their sort of guiding theme is we are great, because they recognize that as teams they can accomplish a whole lot more than extraordinary individuals. And so as a team it stops being about me and how I am great. It starts being about we and how we are great and how we work together collaboratively and we don't individually need to shine or be the shining stars. We can be collaborative teams that work together really closely.

And Stage 5 is life is great and we can see the pinnacle of what we're trying to achieve way off in the distance and the observation and research that was done for the book was that Stage 5 organizations don't get a whole lot done because they're always looking into the future and starry eyed and really happy with the way things are.

And so great really productive organizations vacillate between Stages 4 and 5. They need that vision. They need to see the peak of the mountain way off in the distance but they need to work together to get there and to collaborate and to function in that way.

And so as I reflect on the work that ONC has done and our colleagues at CMS and this group I think about Stage 4. I think about folks from different sectors of the health care delivery continuum working together. So there are folks here who are out in the world competitors but we come together with a common good and I think that's really extraordinary.

My first exposures to this group, way back in the early days, I was struck by how unifying this group has been and now what is it 54? Fifty-four months/meetings later this group continues to be the guiding light for this industry to set the stage for what will happen and as I reflect on this past year and the struggles and I look to Paul because I see the lines on his face that this group has gone through and thinking about how to make Meaningful Use meaningful as we look to Stage 3. And how to make it less prescriptive and more aligned with outcomes so that the providers and the hospitals are not struggling so much to do what we think just makes sense.

Because Meaningful Use should not be the extra thing that we do for the sake of being Meaningful Users. Meaningful Use should be the thing that is just part – as Farzad sometimes said it's the exhaust of the work that we do anyway.

And so we need to find ways to recognize the folks who are leveraging Health Information Technology well and give them credit for that without causing them to jump through additional hoops that are as we sometimes say make work. We tried very hard to avoid the so-called make work.

Now make work to some is core important to others and I think that is the healthy tension that this group has been trying to work through for at least the past nine months. So thank you leaders for your 54 months of dedication and with that I will pass it onto Paul to start to lead the meeting for today.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Great. Thank you for those comments Jacob. And I want to properly attribute the surgeon comment to Paul Egerman so that I don't get in trouble for that one.

**Paul Egerman – Businessman/Software Entrepreneur**
And I did not know that I was going to be quoted. Some of my best friends are surgeons. I'm sorry for that comment.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
I'm just trying to correct the record. Okay, want to welcome the new members to the committee and as you heard from Jacob it really is a committee of very passionate and dedicated folks who really try to do the right thing together despite the tension of where we need to go.

I'll also note that there are now three Davids, two Judys, two Devens and two Pauls on the committee so if your name is Gayle, Art or Christine you might be next because we don't have enough apparently.

Okay, so I want to review the agenda for the meeting and we're face-to-face because there are a number of very good topics. As usual a lot of these policy topics are robust and there have been robust discussions in the Workgroups and Subcommittees and they are being presented today and I want to also say how much work has gone into and how much thought has gone into the recommendations and the findings and updates that you're going to hear.

We're also going to start with the data review from both CMS and ONC. Oftentimes this committee asks for more data and so a couple of topics that are coming up one is on rural health and understanding how this is going in that situation which we want to be sensitive to.

The Office of Civil Rights, Susan McAndrew is going to talk about – we've heard about the need for attention to security from the very first Stage 1 we reemphasized the need for security assessment. We've heard some updates on how it is going and Sue is going to talk about that as well as some of the education materials they've prepared to help people with that assessment.

The Privacy and Security Team is going to talk about their hearing and their findings, and conclusions and recommendations for accounting of disclosures another very hot topic. But they have a very thoughtful response to that that they'll talk to us about. We will need their recommendations approved or the things that come out of the discussion.

The Certification and Adoption Workgroup is going to be talking about framework for certification that's an important program from HITECH, it is one that will continue and there is some look at, how do we make sure we're choosing the right high-priority topics and we're going about it in the right way. They'll also be looking at some of the entities that are not included currently in HITECH like long-term care and post-acute care as well as behavioral health. So that's a hearty discussion as well.

We'll end the morning session with a public comment, have lunch and come back and there's two Workgroups in Privacy and Security, I mean in Policy Committee and Standards Committee on patient generated health data, the really Consumer Empowerment and Consumer Technology Workgroups and they've both deliberated on patient generated health data and they're going to be coming back to us with some of their recommendations for our discussion.

And finally we'll have the Quality Measure Workgroup update us on their work in quality measures particularly looking towards Stage 3 and beyond. There is no action for this month. They are going to be having their final recommendations coming next month but they wanted to update us and get some feedback from us this month.

And then we'll conclude the public comment and that's the agenda which you can see is very full for today. So we look forward to a good discussion and drive towards the consensus that Jacob talked about both in providing feedback to these individual Workgroups as well as discussing some of the recommendations coming forward.

You all received a draft copy of the minutes from last meeting and I'd like to entertain a motion for approval.

**M/W**
So moved.

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

**W**
Second.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
And any further discussions or corrections on the minutes? All approved?

**W/M**
Aye.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Any dissent or abstaining? Okay then those are approved. Thank you very much. So, we'll open it up with a data review from CMS and ONC.

**Robert Tagalicod – Director – eHealth Standards & Services – Centers for Medicare & Medicaid Services**
I'd like to give a few introductory remarks then I'll make my way back. So, I love your take, Jacob, Paul on doing a kind of retrospective of what we've done and what we're getting into in 2014. So, along those lines as we hear the data presented by our respective staffs it would be mindful the context in which we are going into this together into the new season if you will.

So as we are poised to enter 2014 it would be helpful to understand what was trending in 2013 that is not necessarily a predictor of 2014 but it is something that we should be mindful of.

So I think we can not necessarily rest on our laurels, but acknowledge that in 2009 just about 15 percent to 16 percent of US hospitals had an electronic health record system. So five years later in 2013 more than 80 percent of hospitals eligible for Meaningful Use incentives have implemented in fact an EHR that have begun the process of computerizing medical records according to the data that we are going to be talking about.

Arguably, due to Medicare and Medicaid EHR Incentive Programs alongside EHR certification and outreach and education the market is now arguably saturated with EHR vendors small and large. And so as we listen to the data that is presented today it is important to see this among several trends. And again these are not predictors but it behooves us to be mindful of them.

So a bit of context however as we move forward in this new season towards interoperability, population health management, patient engagement and other requirements to move the healthcare industry towards coordinated care.

For us at CMS and arguably throughout HHS HIT is a means to several ends that is really also from a CMS perspective embedded in our mission DNA and that's better affordable care, expanded coverage and improved health outcomes for individuals and populations or communities.

And we understand that EHRs are foundational but yet not an exclusive piece to health delivery and payment reform but nonetheless it is very important to see those trends in the data. So with these in mind in the past year we saw several significant market trends and again I would like to see those trends or see the CMS data or the ONC data, or both of our data vis-à-vis those trends.

So, first of all I think we can acknowledge that not all providers are satisfied with their current system. So, as many as 30 percent especially among providers who chose a smaller or startup vendors are poised to change. So, that's something to be mindful of among physician practices nearly 1 in 3 is considering a new EHR and we are hearing a lot more providers dropping their old systems and moving into a new one.

Secondly, a few EHR vendors now hold a large part of the market share and this is no surprise. Historically it does follow a trajectory of many technology innovations and implementations and the EHR incentive programs and the certification programs have allowed 1000 flowers to bloom.

And to borrow on the theme of seasonality the question remains which of these blooms will be hearty to meet the challenges of summer? And that summer being Stage 2 and prospectively Stage 3. And we expect to see increasing mergers and acquisition activity when the healthcare industry given that payment reform, for example the formation of the accountable care organizations and the like, has encouraged providers, hospitals and health systems to choose vendors that handle business needs that encompass healthcare payments, healthcare delivery and payment reform.

And thirdly, the next big trend that we are seeing is the desire for EHR, the complete solution to support Meaningful Use and payment reform and again this is patient engagement and education anticipated in Meaningful Use 2, decision support, mobile capabilities, interoperability, clinical quality measurement solutions. In short what modules can be added on and successfully integrated as part of the complete solution.

And finally and fourthly, we see this in the context of other programmatic demands and trends. ICD 10 in 2014, no delay. Administrative simplification, HPID in 2014. A lot of pay for quality in 2014 and 2015, coordination of care of benefits from coverage to preventive care, to primary care, to community-based care, etcetera.

And to see the data we need to see these data as they will presented shortly in the context of this and so the question for us is how do we, around the table and our partners in our public and private partnerships, can be successful in managing all of this understanding that EHRs have been seen as the backbone of transformation of healthcare in this country.

So, I wouldn't say that this is what CMS is doing, this is what CMS is doing alone, this is what we are doing with all of you around the table and again we're entering into a new season. So with that –

**Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid Services**
So, we're going to have a little bit of a back and forth this morning as we do data updates. We'll do a CMS and then an ONC data update and then we will come back and we will talk a little bit about rural hospitals some of these things that CMS has been looking at and ONC will talk about some of the things they've been doing with rural hospitals. So, bear with us as we do a little back and forth.

And all due respect to Dr. Reider's favorite book I want to move away from the idea of Stage 1 and life sucks and talk a little bit about where we actually are. We are, as of the end of October, at almost 431,000 eligible professionals and hospitals registered for the program.

The Medicaid totals we tried to break down of course every month and I think the important figure that we like to focus on is the number of eligible professionals that have converted to Meaningful Use. We're watching that figure closely. Of course towards the end of the year I think we've talked in the last couple of months that we are in sort of the slowdown period and December, January, February, March is when we'll really see the hockey stick, the end of that jump off.

But we are at a little over 24,000 Medicaid EPs that have achieved Meaningful Use under the Medicaid Program bringing us just short of about $17 billion paid in incentives and almost 330,000 providers and that's eligible professionals, eligible hospitals and Medicare advantage organization EPs that have been paid incentives under the program.

So that puts us at just shy of 93 percent of all eligible hospitals registered for the program and about 85 percent of eligible hospitals that have actually been paid an incentive payment under either Medicare, Medicaid or both, usually both.

We are seeing a lot of closing of the loop for eligible professionals who are actually registering. So, we are at about 80 percent of the total popularization of eligible professionals who have registered. And we have seen this piece of the pie, the blue piece of the pie, begin to shrink more and more. We are at about 65 percent of eligible professionals actually paid under the program as well.

We've looked at this in the past and we've I think stabilized in this area but this is a breakdown of the Medicare EPs by specialty. We are at a point where 61 percent of all the Medicare EPs who are Meaningful Users are non-primary care and we really haven't seen a shifting of these categories and where they rank but of course encouraging to see that we have a number of specialists who are participating.

As I said at about 85 percent of all eligible hospitals paid we've got more than 8 out of 10 hospitals that have made that financial commitment. We are at about 60 percent or 3 out of every 5 eligible professionals under Medicare who are now Meaningful Users.

We have about three quarters 3 out of every 4 Medicaid EPs that have actually received an incentive payment. Most of those have been for adopt, implement upgrade and as you know the timeline for Medicaid is considerably longer it goes through 2021. So we've been looking at those percentage figures underneath to see how the conversion actually happens and we are at about 17 percent of Medicaid EPs who are Meaningful Users. And that means that overall we have a little over 64 percent 3 out of every 5 eligible professionals who have made that commitment to an EHR and as I said about 330,000 total providers.

These are draft estimates for November and as always with estimates especially this time of year with hospitals I try to put that asterisk in because we don't necessarily have all of the folks in but it looks like we had about 600 hospitals through the end of November and I apologize that column should be November.

This again is still something of a slow month for eligible professionals. It has historically been so and we will expect that obviously there will be some jump in December as we get the very beginning of 90 day New Year professionals in, but of course we'll really take off in January and February.

I want to talk very briefly, we looked at this last time. We are continuing to look at it as we have ended on November 30th the close of the attestation period for hospitals for this previous fiscal year. We are still compiling some of this data but we do have a lot of this from returning hospitals and we've been looking at hospitals in their first, second and third year performance across core and menu objectives.

So, we'd be comparing first-year 90 day performance, second year full year and third year full year. All of this of course is at Stage 1 and making sure that we're continuing to see that same high level of achievement. And in some areas you're actually seeing some jump.

You can see in a few areas like CPOE, problem list, recording vital signs, smoking status where from the first 90 days there was a slight dip into the next year and then a jump back as we see them incorporating that more into workflow and adjusting to a full year Meaningful Use process.

But regardless you can see that these are considerably higher than the required threshold and they continue to be high from year to year and the same is true on the menu side. Of course there is a little bit of fluctuation on the public health objectives but even that is consistently high at this point.

We obviously always have more breakdown of the individual percentages but we're continuing to see high 90 percent in most of those objectives and you can go to the CMS website which is down at the bottom of the data and reports page if anybody is interested in additional information there and I will turn it over to ONC colleagues to discuss data from their side.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**
Okay, good morning everyone. We have a packed agenda this morning so we are going to quickly run through the latest information on progress to 2014 certification. The picture is largely the same as it was last month but we have seen some progress over the past month.

So, on the hospital side we now have 89 percent of hospitals that have attested that used a primary vendor that currently has some sort of 2014 addition product certified and this is 17 vendors that are accounting for that 89 percent of hospitals and we're still at 81 percent of hospitals that have a 2014 edition-based EHR product available by their primary vendor.

So, a caveat on this slide and all the slides that follow, this is looking at vendors that have products certified. So we don't know whether or not the provider has actually purchased and implemented that product yet and we don't have information on the vendor timelines in terms of how they're rolling this out, but it's an indication that the products are available that have been certified.

This slide just shows the snapshot of all the hospitals that have attested so far and the specific vendors that fall into each of these categories of having a 2014 edition-based EHR, having a 2014 edition some type of product but not based EHR and then those vendors that only have 2011 products so far which account for 11 percent of attested hospitals at this point.

And we've listed the specific vendors that account for at least 1 percent of the market share in each of those categories. Then again taking a look at how this looks across different types of hospitals. As we saw last month you can see that the critical access hospitals and other rural hospitals are a little bit less likely to have a vendor with a 2014 edition product certified so just wanted to highlight that here especially given the rural conversation that's going to be coming up next about barriers facing some of the rural hospitals.

And then moving into the professional side, so over the past month there has been 18 vendors that have gotten new products certified to the 2014 edition and that's translated into a small increase in the percent of EPs that are covered by one of these vendors. So, 59 percent of attested EPs have one of the 25 vendors that have a 2014 edition-base product as of mid-November 2013.

And again here is the sort of overall pie of attested professionals and the specific vendors that account for at least 1 percent of market share in each of those categories, I brought this across two slides here, I just want to see if there are bigger numbers.

And then taking a look at how this varies by professional specialty, so you can see that there is some variation and some of the professionals that make up a smaller percent of the overall professional population tend to be less likely to have a vendor with a 2014 edition product at this point. We don't see much variation by specialty among the large physician groups so between surgical, primary care and medical specialist, but we do see some more variation among those other provider types.

And this is the detailed level breakout by specialty for those of you who might be interested. So, that concludes the certification update and just quickly highlighting here some complimentary data to what Rob presented that will be useful perhaps to set the stage for the rural conversation as well.

This takes a look again at progress to Meaningful Use across Medicaid, Medicare and the REC program and up to close to 80 percent of hospitals that have attested to Meaningful Use as of October 2013 and we continue to see variation by hospital size, type and location.

So, critical hospitals continue to lag a bit behind but about 70 percent of them have attested and other rural hospitals and noncritical access hospitals are up over 80 percent that have attested to Meaningful Use and we have the usual slides on the professional progress as well but I'll go ahead and pause here and turn it over to the rural conversation now.

**Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid Services**
Do we want to try and handle any questions about data first and then move onto the rural conversation or – I don't know if anybody had anything pressing immediately?

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

**David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health**
It's not pressing but generally going back to the first part of the data presentation. It struck me as a policy group and going back to Rob's introduction that we're now at a point where we should be asking whether the investment we're making and the penetration we've achieved, which is phenomenal, is making a difference in care outcomes.

So the link between I think at some point tracking the incremental improvements and penetration is probably less important to us than tracking whether our goals are being achieved. And I was wondering if whether CMS across programs has any metrics from PQRS or from hospital reporting that would provide a hint as to whether the investment is – some of these categories like transitions in care you might see reflected in CAHPS scores for example.

And other is medication errors might be reflected by improved medication reconciliation, etcetera. Is there any way we track across other reporting programs whether outcomes are being affected by the broad penetration of the program now?

**Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid Services**
So, I'll take a first stab at this and Rob Tagalicod may want to come behind me and talk about some things as well. But I will say that although at this point I couldn't draw a correlation between a particular objective and a score and the transitions of care is actually an excellent example why that is although we have information there, keep in mind a very, very small number of people are actually doing transitions of care now so we wouldn't have the biggest base comparison.

But what we have started to do within CMS and this is sort of a long-term look at a couple of different areas is to correlate EHR users with either reduction in costs, reduction in billing or reduction in procedure and that is something that is ongoing. I think that it is probably – they're looking at this along an 18 month timeline right now but for exactly the same reasons so that we can begin to draw those correlations.

As we move into Stage 2 and we have more people who move into those areas and we can see more direct transitions of care and certainly, as I think we start thinking about Stage 3 and lining up the idea of outcomes we certainly want to be looking at that so that we can see where the needle moves.

But I think even though we have a sizable number of people participating there are some challenges from a quality metrics at this point in time. Obviously we've been more robust with quality metrics in the 2014 certification. So, we'll have some more reliable data I think there, but we are at the beginning of the process.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Anything else? Paul Egerman?

**Paul Egerman – Businessman/Software Entrepreneur**
First thank you this is a great presentation I always look forward to it and it's impressive to see the progress this is excellent progress. And your presentation is based on – appropriately based on the number of eligible providers and eligible hospitals but there is another way to look at it which is the number of citizens in the country.

In 2004 President Bush set this goal that every American would have an electronic health record and in 2009, in 2004 President Bush said that would happen in 10 years and then in 2009 President Obama reiterated that goal and said in 5 years every American would have an electronic health record. Do you have any sense of or any statistics on what percentage of the population has at least part of their care taken and included in an electronic record?

**Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid Services**
Off the top of my head, no. We did compile some information which obviously we were limited to the information that we're actually collecting through the EHR Incentive Program and that population. And we did collect some information about the total number of patients who had been impacted through EHR Incentive Programs. And I apologize but off the top of my head I cannot remember how many tens of millions of people that was.

We can get that information for you and I can kind of pull some of that out but we looked at number of patients. We looked at a number of lab orders and different things that were facilitated by the use of EHRs that were directly impacted by the incentive programs and I can try and pull that together for the next meeting for you.

**Paul Egerman – Businessman/Software Entrepreneur**
And that would be useful and make the observation that – incentive programs. There are also some people who have electronic health records that are not on the incentive program for various reasons. So, I suspect if you were to look to see what percentage of the population has part of their record computerized it's very high, probably high enough that we would say, yeah, we made the number all even all literally means 100 percent but anyway that's just something that I'm curious about as to whether or not you have any analysis and so if you can analyze that that would be great.

**Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid Services**
And we'll try to pull together some things for a future meeting.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
That's a good point. Why don't we go ahead with your rural health – oh, sorry –

**Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health**
Just one last comment, thank you Rob for the presentation. On the slide where it talks about menu items there are three areas in public health that are off to the right. It might be helpful to just change it to any public health submission rather than each one of those separately. If you leave those on there I think that's valuable, but because really you only have to do one.

**Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid Services**
For hospitals two, but, yes, no we certainly could look at it along those lines. I think the point you're also getting is yeah there are fluctuations from year-to-year and it's based primarily on availability of registries which come and go and their qualifications change. So point well taken.

**Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health**
Thank you.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay, why don't you go ahead with the rural health presentation and then we'll have time for some more questions.

**Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid Services**
Please stand by. So, I'll tee this up by saying before we even get to tee up screen, that as the program matures and as we're getting more and more folks participating one of our concerns is that we've obviously seen the early adopters come into the program and we've seen a shift of the folks that are in the middle especially in 2012 with new EPs, new hospitals and we suspect that we've seen some and we'll see more in 13 with new EPs and new hospitals that have come in.

And the concern now is the focus on people who are on the tail end of that distribution curve. We know in particular that small providers and rural providers face significant challenges in this area and one of the things that we wanted to look at specifically were rural hospitals, critical access hospitals and rural acute care hospitals and see where not only the challenges were but also where the lessons learned could be, what worked and what did not.

So CMS began having some conversations with rural organizations and again really focusing on small rural hospitals. We really focused on hospitals with 25 beds or less. These would be really the most resource challenged whether that was from a financial or a staff or and IT perspective.

And we looked at, as I said, both critical access hospitals and acute care hospitals, but we looked not only and those who had registered for the program but hadn't yet made it to attestation. We also looked at those who had actually been successful with attestation so that we could figure out what the challenges were for them and how they overcame them.

And what we ultimately found is this last bullet here. It's the same problems on a much larger scale and we'll go into some of what those challenges were I think from both an organizational perspective and also from a program perspective and these were really when we talked to them the main barriers to EHR implementation.

High on that list was capital financing for EHR. And I have to say the interesting thing in having these discussions and we had some one-on-one discussions with people who are the decision-makers within these organizations. It wasn't necessarily an issue of the cost of the EHR. It was an issue of finding the resources to afford the system and I think that is an important distinction to make, and I think as we move into talking about some of what's happening on the REC and ONC side the issue of helping people get the grants and financing has been a critical one for us.

Obviously insufficient IT resources, some of this was from a hardware perspective, some of it was obviously from a people perspective when we're talking about a hospital with 25 beds there very often is not a dedicated IT professional, it is an IT professional that is shared among several different hospitals, several different buildings.

In addition a general lack, I think, of personnel was a barrier for workflow implementation. Larger organizations that we have talked to that go into the implementation process go into a fairly lengthy planning process and I think if you talk to those organizations you will see that that planning process is fairly involved with staff at multiple levels whether they are IT, clinical, nursing are all involved in that.

The staffing at critical access and smaller acute care hospitals like these as many of you know are sort of made up of multiple different staff, many of the clinical staff is not necessarily full-time at that particular institution so it was difficult to pull everybody together to do the type of planning they wanted to do.

Without a doubt the number one barrier, I didn't rank these, the number one barrier that got cited by rural hospitals of this size was actually acquiring an EHR system, some of it was certainly the capital or financing aspect of it but nearly everyone we talked to including the hospitals that had been successful and made it to attestation and Meaningful Use cited the fact that they were not able to get on boarded by vendors, that they had difficulty when trying to evaluate which systems would be most appropriate for their hospital, having vendors visit their institution and be able to make an evaluation of the product. So, it was multiple factors that fall under the system acquisition but it was far and away cited as the biggest obstacle.

And then finally and this we had heard from other organizations but I think the circumstances at especially critical access hospitals is unique with internal resistance to EHR implementation and this was very often that they have providers who again are not dedicated full-time staff and they work in multiple locations and being able to get everybody on the same page as to what needs to get done for recording information especially when you have a fairly limited clinical staff to begin with was a major obstacle for those rural hospitals.

We also talked about specific barriers to Meaningful Use from a program perspective. So, beyond the challenges of actual implementation whether they related to workflow or financing, or hardware, or finding a vendor. What those might be and again, some of these are from hospitals that have not yet attested and have not yet achieved Meaningful Use.

But we heard many of the same concerns even from the hospitals that had successfully overcome these obstacles far and away from these rural hospitals and again because there is a limited amount of staff to help with this implementation and help everybody understand what needs to be a done to achieve Meaningful Use was the issue of the program being complicated that there were so many moving parts, that within the objectives and the moving parts there were requirements that needed to be understood across multiple levels.

There were particular challenges for them with meeting thresholds when you have such a small patient population. We tend not to think about that in terms of hospitals but when you have a hospital that has 10 beds and a limited number of actual inpatients missing CPOE on a handful of patients can mean the difference of 10-15 percentage points.

Although this wasn't specifically cited as a barrier to achieving Meaningful Use one of the issues with the program that came up was relevance of quality measures for hospitals. Obviously, there is a set in 2011, a set number of quality measures that hospitals report on and those quality measures were germane to larger institutions but did not necessarily represent the patient population that a critical access or rural acute care hospital would be dealing with.

And then finally, the issue that we had discussed previously about some internal resistance from providers because they are not necessarily full-time staff, this issue of leverage with provider compliance it's very hard when you have somebody who may be at that hospital 15 hours a week to get them on board with recording everything that needs to be recorded and implementing all of these things into workflow.

When we talked to hospitals about what really got them across the finish line now and what really got them to Meaningful Use and attestation these were the four areas that really bubbled up to the top and made the difference between whether they would successful or not in their opinion and this one actually is ranked from left to right.

If this were represented I think on a pie chart the largest part of this pie would be having robust vendor support and that was everything from the support from the vendor in helping to evaluate product but also support from the vendor in implementation and workflow process.

All of those who were successful cited the ability to work with their vendor about not just EHR technical requirements but actual Meaningful Use Program requirements as a major support in helping them achieve Meaningful Use.

Similarly, they cited working with a third-party to be able to help them line up their implementation and understand the different Meaningful Use criteria. Regional extension centers were cited far and above but also working with consultants and we heard over and over again from the folks that we talked to that while there was an expense there and that expense could be large for hospitals in these circumstances it was money so very well spent.

This third one I particularly wanted to draw attention to because it includes a number of different pieces in support. We cited a hospital system support but it involved not just being part of a larger organization which for many critical access hospitals or rural hospitals was key that they were able to secure the attention of a vendor or the support of a vendor because they were one of 12-15 systems that were implementing across a different area, they were all part of a larger hospital system.

But also folks had cited peer-to-peer support. So even if they were not part of a large hospital organization working with an organization that did some lessons learned and helped them, the phrase that came up again and again was not having to reinvent the wheel for them, was critically important in trying to reach Meaningful Use.

And then finally, we were very happy to hear that the program information that we got – that they were getting from CMS had been a major help for them.

So, looking at those lessons learned and what some of those challenges are what we are focusing on in the next 6 to 9 months at CMS is producing some Meaningful Use resources that are focused specifically on rural hospitals and that's something that we heard over and over again was the feeling from those providers that we had a lot of general materials but we didn't have things that were focused specifically on them and their circumstances.

Similarly, we want to work on some webinars and some training modules that are specifically for rural hospitals providing them an opportunity to do some direct Q&A with some program experts so that we can answer some of the questions that they have that are specific about meeting some of these objectives.

But one of the efforts that we are really engaging in, in the next few months is working with some of the partner healthcare organizations because there were a lot of requests for information that were made from hospitals that had not achieved Meaningful Use yet and there were a lot of lessons learned from those who found the information valuable about what they needed and it is not necessarily information that is always best sourced from CMS we are well poised to give people program information. We are not always well poised to give you product information.

So working with partner associations to point people and highlight the resources that are available on how to choose an EHR that is appropriate for your organization. Some of those lessons learned that we talked about so you don't have to reinvent the wheel. If we can find a way to bring small and rural hospitals together to focus on those areas. How to begin implementation planning on a smaller scale for organizations such as those.

And I think Mat and Jennifer will talk a little bit about the financing aspect too but working with those partner associations so that they can point out where some of the grant monies are available and certainly some of the more financing options for critical access hospitals and rural acute care. So, I will pass it off.

**Mat Kendall, MPH – Director, Office of Provider Adoption Support (OPAS) - Office of the National Coordinator for Health Information Technology**

Great, thanks, Rob. So, I'm going to talk a little bit about what we have been doing at ONC to compliment the work that CMS is doing and I really want to commend Rob and his team, a lot of these issues involving small hospitals, small rural hospitals, critical access hospitals are very complicated in terms of their financing, how to get through the program and there has been a lot of initial confusion about this process and Rob and his team have done a fabulous job of helping educate people along the way and I think that's been one of the things that's been very helpful for us as we move along.

I also want to recognize – who is not here today but she is really the rural Health IT coordinator at ONC and she has been doing the heavy lifting in terms of really thinking about this program across the country and tackling it.

And one of the things I want to start off by is that recognizing that despite all the challenges that these small rural hospitals have, these critical access hospitals have in terms of operating on a day-to-day basis and I think we talked about the little bit about the EHR Incentive Program but there are huge challenges to these hospitals that are many hours away from other centers.

There is a remarkable amount of success that's going on across the country and I think it's really important that while we recognize that we are nowhere near where we want to be in terms of moving all these things forward that there are some amazing individuals who are working hard every day with limited resources to be successful.

And, you know, as someone who is looking at all the numbers all the time and trying to figure out what's happening across the country I'm constantly amazed by the ingenuity, the resourcefulness of these folks out in rural America. They really are committed to their population. They understand population health more than I think a lot of people because they are the only provider around. So they get the potential for Health IT. They want to use this in the right way and despite the fact that they have all of these challenges they're moving forward.

So, I think, you know, we recognize that there is a lot of big work that needs to be done in this area but we have great partners in the field and they've been making amazing success. We recently did a blog about sort of what we're seeing across the country in terms of this because they are moving forward. They are holding their own despite being out resourced and I think it's amazing.

These are a couple of different other graphs very similar to what we've covered by Jen and Rob in terms of just tracking where these different groups are. And I think it is important to recognize that the critical access hospitals are different from small rural hospitals and that there are different payment models in place, there are different networks and, you know, just because they can attest to Meaningful Use doesn't mean they're necessarily paid.

So, these are all nuances that we've been working very closely with CMS to work through, help people get through the whole process because they do have unique values and as you can see for both the critical access hospitals and the small rural hospitals we're trending upward in the direction we want to go.

But, I do want to emphasize that this is very encouraging but there is a lot of hard work that needs to be done. One of the things that we do is we spend a lot of time not only looking at the national trends but looking at the micro level trends.

So, thinking about what's happening in different states is very important to us because what we find, especially in these rural and critical access hospitals, is local is very important. Different states have different policies, different mechanisms in place to do this. There are different consolidation in the market places in different states, there are different vendor penetration mixes and there are different infrastructure issues.

And I think all of those are very important for us to think about when we think about rural in general because yes there are constraints in general, they're very similar to what are happening in other places but the way to solve rural communities needs is going to have to be very customized and we're really going to have to be working very closely not only with the critical access hospitals and the rural hospitals, the hospital associations in their state with their rural healthcare organizations with the state organizations that are really focusing on rural healthcare.

And to that point I think, you know, we at ONC have a great partner in HRSA, their rural health team is amazing and they have done an incredible job of helping us connect to everybody across the country and through our regional extension centers and others we have really tried to engage every rural critical access hospital and small rural hospital in the nation to really see where they are and to move them ahead. And we couldn't do that without that strong partnership with HRSA as well as the people they have in the states who are working on this and I think that there is a lot of success from that collaboration.

Again, what we've also been doing is we've convened what we call community practice which is basically bringing together folks from our regional extension centers, folks from state rural health boards, folks from HRSA bringing together all their expertise to sort of not only query them about best practices and solutions but also try to figure out how to prioritize how we can get resources out to folks in the field. Because again, these folks have very limited resources and, you know, you have to be very micro-segmented in terms of how you're customizing things across the board.

One of the things that – again this is very similar to what Rob presented so I won't dig into it but I want to highlight this one issue which is involving access to capital, because I think from our perspective we talk a lot of the times about the EHR implementation cost but in rural communities you've got to think much more broadly, because a lot of these communities don't have broadband access. They don't have access to often times facilities that can house these things.

And, you know, we're going out to a lot of these communities, critical access hospitals that are looking at they need to get capital to help get a new boiler because in the winter they just can't get the heat in their facility and, you know, we've got to think of it as there are a lot of other challenges these organizations are operating under and that while the EHR Incentive Program is really important and they agree with it you've got to get everything in the facility working first, you've got to get it all together to be able to get that last step.

So, I think keeping that context of that these facilities are often incredibly under resourced, I mean, Rob is talking about 10 bed hospitals. We have 3 bed hospitals we're working with all the time. It's just the volume is down very slow and you've got to think about how we can get the dollars out to folks.

And while the Meaningful Use Incentive Programs does offer financial benefits we've got to think broader if we're really going to be working with those folks. And so one of the things that we have been doing at ONC is working really closely with USDA because they have a rural development program that is targeting resources for these rural communities.

And I think historically they've been looking at ways in which they can better support the health care safety net and by educating them about the EHR Incentive Program and how the Meaningful Use is viewed as being the first step into being more integrated into healthcare delivery, increasing quality, efficiency of care.

This has really resonated with USDA and allowed us to have a very successful pilot last year where we went out to four targeted states. We went to Iowa, Kansas, Georgia and Mississippi. We went on the ground. We convened all the right people in the states, the critical access hospital people had to drive in. We had to do this in the states because these people can't get out of their states that long they have to go back to their facilities.

And we actually had a sit down session where we worked with our colleagues at USDA who were fabulous, their local folks came and helped us to help these folks apply for the funds that are out there. And as a result of this, just four piloted efforts we got $38 million in additional funding to these critical access hospitals. And I can tell you that these dollars are critically important for getting these folks to Meaningful Use.

I think this is one example of the efforts that we need to be thinking about to help these folks in terms of bringing in other dollars. We've been working very closely with FCC, they have some new pilot programs out there that we really want to extend to really focus on the broadband issue because that's critically important.

And we're also looking at partnering with the VA to think about how we can do care coordination because what we're finding is a lot of Vets are returning to rural communities and are getting some of their care at VA facilities but then getting the critical access hospital and leveraging technologies like Blue Button to facilitate easier exchange of information we've got a great pilot in Iowa right now about that. I think it will really help address some of the other underlying issues.

So, as we move forward in ONC we're trying to think about ways in which we can continue to reach out to these folks and like Rob saying we've been spending a lot of time thinking about the resources we've developed. We have, from our community of practice, a rural resource page and we're working with CMS to compliment the information out there.

But a lot of this is stuff about just the different steps that people should take in implementing and I think it's important to recognize that, you know, as we get folks through Stages 1 and thinking about Stages 2 and beyond these steps are going to change and I think that that change is going to be very hard for some of these organizations because they just don't have a lot of resources.

So, the more that we can deploy tools or to convene groups of providers who can talk the same language to each other. I think the more successful we will be as we move ahead. So, that is it and I think we're ready for any questions that folks might have.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Well, thank you very much this was a very enlightening presentation. I mean, we certainly understand the special challenges I think Mat actually put the context very well in the introductory comments who is – they have special challenges on top of getting the boilers to heat the hospitals they have to install these systems to take care of patients and it's really heartening to hear about the collaboration you talked about CMS, ONC, also HRSA and USDA in bringing the special resources to this group.

We are running seriously behind on our schedule so I'm going to invite some comments but could you keep them very brief please. Judy?

**Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation**
Yeah, listening to Jacob in the beginning talking about how this should be a byproduct of other things we do and then listening to the barriers that are there and the fact that it doesn't at all seem like a byproduct for the small rural hospitals but it seems, as you said, to be that much of what we're asking them to do is better done for the larger hospitals and that the small rural hospitals the measures that we have in there may not be relevant and might be too complicated for them and it may not really be helping them in the way that we deem helping the larger ones better.

So where our energy is going now into having more people help them reach it maybe our energy instead should be going into what do we change? Because are we really in the end harming them by having them concentrate on things that are not relevant to them? Because otherwise they won't get the money or they may get dinged later on and instead should we be finding different ways to help them by having different requirements and by excluding them from things that they think aren't as important.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Do you think we are helping or harming?

**Mat Kendall, MPH – Director, Office of Provider Adoption Support (OPAS) - Office of the National Coordinator for Health Information Technology**
I would say that the providers that I talk to understand the potential for Health IT and the challenges they face are care coordination. They have to send patients to different hospitals in six different states. So some of the things – they get very excited about the future of where we are going.

**Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation**
But how do you separate those things that you think will help from them from those things that you look at and say yes they seem absurd to you but we have to get through to them. Are there both categories?

**Mat Kendall, MPH – Director, Office of Provider Adoption Support (OPAS) - Office of the National Coordinator for Health Information Technology**
I think – I mean, Rob you could talk to maybe more the data you're seeing. I see from our perspective a lot of desire to move in this direction to be more integrated in providing care and how these people feel that they are very important to the healthcare network as a whole and don't want to be bypassed. But it certainly – even getting there, there are a lot more challenges just to even getting to that participation and others but in terms of the criteria I'm sure there are Rob, if you –

**Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation**
Because two of your four barriers relevance and meeting threshold seem to be barriers that say it's not relevant and, well anyway – so that's why I was wondering if you could separate them.

**Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid Services**
So, the interesting thing about talking to these hospitals one-on-one is that it reveals exactly what Matt was saying about some of the implementation circumstances is that it really does come down to individual characteristics of those hospitals even on achieving Meaningful Use thresholds.

Certainly, you know, when we get to the 3 bed hospital you're absolutely in a situation where whatever your numerator or denominator happens to be whatever measure you place on this it really doesn't matter what you do it's just that you have such a limited number of patient visits that by default you're going to have more of a challenge. I don't think there is any way that you alleviate that.

I think that there is a way that what we can try to do is we try and make sure that those institutions are cognizant of that as they are implementing Meaningful Use and how important it is to have that implementation plan and make this a part of a workflow so that they can achieve those percentages.

That said we talked to a number of small institutions that met Meaningful Use and were successful and they too consistently score very high. The ones that are successful with this are doing exactly that and I think that's the role that we can try to serve with those hospitals.

There is certainly an issue with relevance of quality measures and as we shift in 2014 to more of a selection criteria where they are broader hopefully that alleviate some of that. I think too as we develop more electronic quality measures that can be part of that we'll start to realize more quality measures that can fit a particular situation of a hospital. I don't think we're there yet. I think that's where we're all headed.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Gayle, last question.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
I just have one quick question. One of the major problems I have seen in our rural hospitals in Florida is the lack of broadband and I know the FCC had a program several years ago that had grants to states. I know we did get one in the Panhandle area on expansion of broadband to hospitals. Do you see – is there anything – is that a continuing program?

And can you give us some – how impactful has that truly been percentage-wise that broadband is the major handicap one of them. Certainly what Judy was speaking about is significant. But broadband seems to be difficult and then you also have the issue where meeting thresholds and, you know, getting information out to patients electronically when there is no broadband of course is very problematic.

**Mat Kendall, MPH – Director, Office of Provider Adoption Support (OPAS) - Office of the National Coordinator for Health Information Technology**
Broadband clearly is one of the big capital expenditures that we're looking at and we have broken it out by practice. FCC does have a new program that's really targeting to do this. I think historically some of the FCC broadband pilots were very successful and we have regional examples of that. We're now trying to partner with FCC to do the same thing we did with USDA which is to figure out regional approaches to really addressing this.

So, making it easier for the critical access hospitals to actually figure out the best way of getting on into that program, assisting them there so that they can get to it because you're right for a lot of these facilities there is just no telecom.

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

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
You know, I think I'm just going to have to move on the agenda. We can bring back the topic again but we're just out of time. And thank you so much for that update because it was very interesting and we're encouraged by the work.

The next topic is going to be an update from Susan McAndrew in the Office of Civil Rights. The topic is security assessment. As you know security assessment was a provision of HIPAA and so it has been in existence for a long time. The purpose of having it in Stage 1 was to really up the ante.

So people are at risk if they're not going to be doing security assessment. They are at risk in the Meaningful Use Program. So Sue is going to present some of the work that the OCR has been doing and some of the proactive work in helping to educate providers more on this topic.

**Susan McAndrew, JD – Deputy Director for Health Information Privacy & Security - Health & Human Services – Office for Civil Rights**

Thank you Paul. So, I will try my best to get you a little bit back on schedule. So the Office for Civil Rights with regard to the HIPAA Privacy and Security requirements we do policy, we do compliance and enforcement and we also do public awareness and outreach and across each of these areas we have been very active in partnering with ONC and CMS to advance both the adoption of EHRs to improve consumer engagement in that process, as well as to advance Meaningful Use of those and to make sure that what we are doing with the HIPAA Privacy and Security requirements do align to further all of those efforts.

Some of the policy things that we are doing before we get directly to security, just for your awareness, is we are very, very close to finalizing the CLIA changes which would make the test results electronically available through HIPAA access requirements directly from labs to patients and so that rulemaking has been long in process but we are in the very, very final stages of that joint effort.

I will skip – we are also doing very close to a collaboration we've been doing with the Department of Justice and the White House in looking at HIPAA barriers to the reporting of mental health information about those who should not be owning guns or possessing guns into the National Criminal Database and some mental health disclosure policies that have risen from that endeavor.

You will be hearing after me from the Tiger Team who has been very helpful with us in the other remaining policy area that we are doing for electronic information and that is accounting for disclosures that comes out of the HITECH Act and what to do with the rulemaking that we initiated in 2011 and getting updates on industry capacity as well as consumer, where consumers are in terms of these accounting requirements. And we're really looking forward to their recommendations and the recommendations from this Policy Committee in that area.

With regards to security in particular we – it is clearly an emphasis that we have put a major part of our enforcement efforts is to look at – make sure entities are in compliance with the security requirements and clearly we know that a risk assessment is an important and foundational part of that and it is also a much neglected effort within states. I think that is a Meaningful Use criteria.

We are really looking at entities for how they are doing risk assessment and the majority of our compliance efforts have been targeted to failures to adhere to the security rule requirements in a variety of settings but in particular across all of those there was failures with risk assessment and part of the corrective action planning that we got was to bring those entities into compliance and I think to highlight across the industry the importance of risk assessment as well as general security rule requirements.

As many of you know we are also engaged in audit. We had an audit pilot program. We are now at the very bottom of this slide which is evaluating the audit program and preparing for the permanent integration of the audit function into the OCR compliance and enforcement portfolio.

The importance of that is I do think that with regard to security rule compliance and assessment that audit is a very significant tool and is going to be much more valuable for compliance in that area then our complaint driven processes and so while we can follow up with breeches and find security violations that comes far too late in the process and so we think if we can get out in front of this process through an audit function as opposed to just following complaints that we will help everyone get ahead of the curve.

I believe you did have a briefing earlier this year on our audit program so in the interest of time I will skip over some of the findings other than to note that yes security did account for the majority of our audit findings during the pilot. Again, underscoring the importance of security and security assessment in this environment and with regard to the security results themselves the failure to do an accurate and complete risk analysis, risk assessment and risk management program did account for what was a failing across the board.

In general it did rank high and I will get to what we have been doing to address that on the privacy side. The most failings that we found through the audit program were in the privacy notice and access requirements and we have also focused on those in particular the access requirements in order to have people – as the major way that we do engage consumers and the benefits that they can get from having their engagement with electronic health records electronically.

So, that's a new requirement from HITECH is electronic access and we are going to be promoting that through 2014 and we also think that notice, in this case the privacy notice but also notice of what is happening with their information in this electronic environment is going to be very important going forward in 2014.

So where we are in audit again is we're completing our evaluation process. We are going through the assessment of how best to continue to integrate this function and make it a part of our portfolio coming out of the regional offices to assist us in the field in doing these.

And we will also be tackling the integration of business associates as well as a component of the audit program. And so many of the networks and other entities that support the HIT endeavors and the EHR endeavors will be business associates and will be part of our redesigned permanent audit program.

Just briefly in how we have to date tried to address some of the issues that we have found across the board and this again was with great partnership with ONC as well as partnership with CMS is we now have a model notice of privacy practices. We have a version up for health plans. We have a version up for healthcare providers and these come in several shapes. In the consumer focus groups apparently the booklet form was very popular.

Unfortunately the booklet form is also going to be the most complicated form for entities to produce and replicate but nonetheless it was very popular with consumers so we have put it up in both for health plans and for consumers and then we have also versions that present a layered notice so that the front page in very simple terms highlights the important parts of the notice and details to follow and we do have a text only version for entities that cannot cope with graphics.

So, I think this was a very successful collaboration, had a lot of good feedback from the consumer focus groups and we hope that this will solve some of the issues that we found during audit and the notice in particular how to make the notice understandable to the consumer. So I commend you all to our new notice.

We have also a little card that we did on HIPAA for law enforcement. But in terms of access we did have a campaign over the summer directed toward – why, well you don't like my picture – directed towards – we call it the information powerful medicine campaign and it targeted AIDS and HIV populations. It was a very – we also were able to, out of that campaign, have good public awareness materials again in very consumer friendly terms advising people about their rights and we got a very good penetration in trying to introduce this audience to the benefits of electronic sharing of their information and electronic access to their information.

And so we are looking for opportunities to roll a similar type campaign out for other groups for whom interacting with their provider electronically will be important to their care and so if there are suggestions about important groups where consumer engagement would be helpful we are more than happy to work with people on that.

We have a number of YouTube videos and I will say our HIPAA Security Rule video has just gone off – is that me? But anyway, so we have experimented with YouTube as a way of reaching consumers as well as entities. We share the concerns that have been expressed earlier about the difficulty of reaching small providers and rural hospitals and other entities that don't frequent the Beltway and so we are using YouTube.

We have a range of videos out there. We are almost close to 2 million views of our various YouTube videos and the security rule is a very popular one. So we are getting the word out through that mechanism.

We also have been attempting to reach this population, the smaller providers we have partnered with Medscape to do a variety of videos and learning modules on Medscape. And we did, again, a lot of those do concentrate on the security rule and security rule compliance. But we have also ventured into other areas.

There was the Leon and Farzad show which is now our number two video on Medscape where they do a dialogue on mobile device security and how do you use mobile devices effectively while maintaining privacy and security? And I understand there is an awesome fist pump at the end of that which may account for its popularity.

But in addition Leon has done at least three videos that focus on the culture of compliance, compliance with the privacy rights as well as understanding risk analysis and risk management as a way of trying to get these concepts out there to smaller providers and in an understandable manner.

We are also going to be partnering with CMS for another video to put up on Medscape, another training module that will look at privacy and security and Meaningful Use. So that is in production. And we are looking to that. So, with that I will try to – I don't know where the video went, but –

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Sorry.

**Susan McAndrew, JD – Deputy Director for Health Information Privacy & Security - Health & Human Services – Office for Civil Rights**
Okay.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
One of the reasons we're having her to present is also to highlight some of the results from their initial audit pilot and I think – so you went quickly through that but one of your findings was the majority of folks the audits were not in compliance or full compliance with the security risk assessment.

**Susan McAndrew, JD – Deputy Director for Health Information Privacy & Security - Health & Human Services – Office for Civil Rights**
That's right.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
And that's something we want the community to be of where of that that is part of the audit it's part of Meaningful Use and that's something that everyone should be encouraged to address or potentially face the consequences of not meeting that requirement. Other questions? Neil please?

**Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health**
So, a question and a comment. The question is, in terms of people self-reporting problems as they go through internal audits what is the process that is expected as people discover security problems in their own organizations either through, you know, internal complaints that could come or through, you know, an internal audit that they are doing? Are there external reporting requirements for that?

And my second question is, you know, is there likely to be other issues? In New York the issue of the Affinity copy machine memory sort of spread like wildfire through the state not so much I think because of the fine but because every single person that heard that said "oh my God I would have never thought of that."

**Susan McAndrew, JD – Deputy Director for Health Information Privacy & Security - Health & Human Services – Office for Civil Rights**
Right.

**Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health**
And so what's the list of – who's got the list of "oh my God I would have never thought of that?" Because honestly if people get dinged on that kind of stuff that is going to be such a huge problem for us as a community.

I mean, this is new technology. Doctors in the community don't know how their fax machines work. They do not know how their copy machines work and if people start getting million dollar fines for this stuff you might as well just shut down half of the work that we've done over the last year.

So, you know, I think those things send a shock wave through not because they're that kinds of things that we all know that we should be doing but because there could be a lot of things out there that people just don't know about in terms of where their information resides and what those kinds of security problems could potentially be.

**Susan McAndrew, JD – Deputy Director for Health Information Privacy & Security - Health & Human Services – Office for Civil Rights**
Okay a couple of responses. To your first question about self-reporting. You know one of the benefits that we wanted out of the pilot audit program was to be able to put a protocol out there not only so that when our auditors went in it was essentially an open book test for covered entities but then they could also take it and do their own internal assessments and internal audits and that is really where we will really get the exponential benefit from the whole audit program.

There is no – but all of that is for the entities own self learning and self-correction. So, right now the only obligation the entities have to self-report is when there is an actual breach.

And so if there is a security risk that they uncover and they do discover that in fact that did lead to a disclosure, an impermissible disclosure of information then that needs to be reported to the department under our breach notification requirements as well as notifying individuals that that impermissible disclosure occurred.

**Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health**
A follow on to that?

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

**Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health**
So, just to make the point again, I think, you know, in the issue of medical liability we've created protected places for people even when they recognize errors to have discussions about those within their organizations that are not subject to being fined or disciplined or whatever but are ways that we all learn from each other.

And, I mean, I'm not a pilot but I understand that, you know, that issue in the airline industry is similar. And it seems to me like we've skipped over that piece here. We've skipped over the ability for people to report on things that have happened that are unintentional kinds of disclosures without fear of penalty but with the opportunity to share those with the larger community so that we can all learn about what the risks are.

And, you know, as we've gone through this in our own organization, you know, people keep, there are "ah ha's" almost every day about things that people are doing that people just haven't thought about.

And so I just think that it's important that as these issues come up that we create a mechanism and if all of them are, you know, related to huge monetary fines, you know, I think that serves – it serves the opposite purpose of what we're trying to do which is at the early stage of this technology to learn from each other, learn what the vulnerabilities are and to be able to improve our systems.

**Susan McAndrew, JD – Deputy Director for Health Information Privacy & Security - Health & Human Services – Office for Civil Rights**
Right and I think there is plenty of opportunity to do that. I think by and large the vast number of breaches that have occurred, by and large the vast number of complaints that we investigate, we do – they do not result in resolution agreements, they do not result in CMPs and they do not result in settlement agreements with fines. So there is plenty of room still for that type of learning environment and learning from mistakes.

So – but on the other side there is, you know, the security rules are flexible and scalable. They have been in place since 2005. There is a lot – I think, you know, there is time for people to get serious about risk assessment.

And I think the other thing to keep in mind particularly with cases like Affinity this is an opportunity to learn, but in many of the breach cases the resulting fines and settlement agreement, and corrective actions that are asked for – the incident that occurred, the breach that occurred is rarely the sole or even the most prominent aspect of that whole compliance effort.

It was the event that got us into the entity to look at what they were doing and I think most of what we do and most of the efforts that we do work with these entities is not – is not just to – this is punishment for that act it's that – there was a range of management and other failures that then contributed to this event and we are more interested in getting the entity to focus on their overall management and structure, and how they approach security.

So, it's not just this one little thing will not happen again but that everyone becomes more generally aware. But it does serve a purpose of spreading the word across a broader segment of the industry. Think about this because your information can be on that computer.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Joy, I think you had a comment about this.

**Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator**
Just very quickly, we do, we at ONC do provide a mechanism for people to share information about privacy and security within the Regional Extension Center Program there is a community of practice that focuses on privacy and security.

OCR often participates and gives information on that session and they also get off the phone so that people can very freely discuss what is happening on the ground and how they are addressing their own issues. So there is a forum that does have a very large impact on many of the smaller providers at least.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
For the people with the cards please keep it very, very brief. So, I have Deven, Gayle and then Judy.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yeah, in my own self-interest since I'm one of the presentations that's now a bit behind. So, I just want to say I'm glad to hear that the CLIA rule is close to being issued and I just wanted to get some assurance that the right that we're providing with respect to ability for patients to get lab data is the same as the one that's granted in HIPAA which is in the former format that the patient wants subject to of course the capability of the entity to provide it in that form or format.

I worry a little bit that the PDF becomes the ceiling rather than the floor, because we ultimately want patients to be able to have data in a usable format that they can share and plug into Apps, etcetera, etcetera.

**Susan McAndrew, JD – Deputy Director for Health Information Privacy & Security - Health & Human Services – Office for Civil Rights**
**Yeah, so the labs would be subject to the same requirements of any other entity now. Where the individual has access rights.**
**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Thanks, Gayle?

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
I just want to make a brief comment that I think for small providers when I look at the analysis that you've presented on your pilot on the privacy and security issues this is frightening from a small provider's point-of-view. When you look at, you know, what people are being tagged on and it's very, very problematic and I'm glad to hear that the RECs are reaching out, but they really – one of the issues with the RECs is that is geared principally towards primary care providers and we have a lot of physicians in our communities in small groups, you know, 3-10 that are not part of the RECs, they're not primary care and this is the number one issue I hear from small groups is getting tagged by OCR on the privacy and security things.

There needs to be much more outreach, much more – as Neil says that community of sharing information and whatever you can do, whatever ONC can do to make sure providers are getting the information out there. You hit the nail on the head Neil in what you said exactly. We need to make sure that we have a safe environment where people can help each other achieve this because it's the most frightening thing out there for our small providers right now.

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

**Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation**
I agree strongly with Neil too because when I hear the – see the examples up there and I heard your explanation that it really was a whole lot more than that. But for those who don't understand that it might be a lot more than that the word that kept coming through my mind was its mean. Because we are trying to work with sharing when there are mistakes and a mistake such as some of the examples on there were things that others can do without really being intentional.

The other problem too is that when you have a large number of employees even if you have your rules – I heard Warren Buffett once said that he's sure that on any given day several of his employees are doing things that are wrong. How do you stop that? Does that mean that it is in the best interest of the organization to harm them when you can't figure out which of your thousands of employees might do something wrong?

So I think you have got both the intentional and the unintentional wrong that isn't really the fault of the healthcare organization and by dinging them rather than helping them I am worried that it is a: the wrong message and b: it's harmful to them.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay, well thank you Sue for that update and I think this remains to be an area we all want to be aware of. Some of the things that are in place it sounds like from what Joy said is that there are these areas, there are these forums for sharing and another thing that Sue mentioned is the open book test, in other words, I guess they're going to publish sort of the templates for the audits that help people prepare by doing their self-assessment. But anyway I think the discussion has been good both in raising awareness but also how do we help everybody, share and help everybody improve. Thanks Sue.

Next we're going to hear from the Privacy and Security Tiger Team on accounting of disclosures and this is the Deven and Paul Egerman Show. And as Paul walks up I want to thank him. He is stepping down as Co-Chair after this topic and want to thank him for – it always has been the Deven and Paul Egerman Show and it's always been a very well thought out process that they've led and we've very much appreciated the outcomes of all of the recommendations that come through this Tiger Team.

*Applause*
And for people on the phone and the web Paul has been presented with a plaque to acknowledge his years of service. Thank you.

**Paul Egerman – Businessman/Software Entrepreneur**
Well, thank you very much. After hearing all those nice comments I almost feel like I should say absolutely nothing because I might mess it up after all of those kind comments but it's been terrific to work with Deven, we've got a great Tiger Team and Joy Pritts and ONC and Linda Sanches in OCR have all been great to work with and a lot of fun. And we've got a great topic.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
We do.

**Paul Egerman – Businessman/Software Entrepreneur**
That Deven is going to –

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
We do.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Sorry, obviously we have some projector issues, but –

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yes.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
There are paper copies for committee members and hopefully it will be up soon.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yes.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Apologies.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
We will work with –

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
The web is fine?

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
The web is fine.

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

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
So we'll work with what we have, again, our slides are in your paper deck and as always it begins with a list of the Tiger Team members. I want to give you a little bit of a roadmap, I'm already up to slide three if you're following along, about what we're going to do today.

So, our recommendations are on this issue called accounting of disclosures. And in order for the recommendations to really make sense we need to go through a little bit of background for all of you to make sure people understand what HIPAA says about accounting of disclosures today, what congress did with respect to this accounting of disclosure right in HITECH and then the efforts done today by HHS to try to implement this, because our recommendations essentially are suggesting that HHS move in a slightly different direction in order to facilitate what happened in HITECH.

And so I think you really sort of need to understand as much of the background as possible. So forgive us that the presentation is lengthier than our usual ones and we tend to be on the lengthy side anyway. So, bear with us so we can get through that piece.

Also part of the presentation is sort of updating you on what we learned from the hearing that we had as well as the comments that we – public comments that were submitted as part of a blog post that we put up on this issue so tried to gather as much public feedback as possible.

My role today will be to bring you through all of that background and then I'm going to hand it over to Paul to deliver our recommendations to you and then we'll take your questions. So, I'm all the way up to slide four and that's where we discuss sort of what's in the current HIPAA rule on this concept called accounting of disclosure.

This is part of the HIPAA Privacy Rule and what it says is that covered entities which are generally hospitals, healthcare providers and health plans are required to make available to patients when they ask for it an accounting of certain disclosures of their identifiable health information made up to six years prior to the point of that request. So, it's six-year look back.

And what a patient would get if they asked for one of these is the date, the name of the recipient and the address, if it's known, and a brief description of what was disclosed and the purpose of the disclosure. And this applies to whether or not that disclosure was made on paper or whether or not it is an electronic disclosure.

Skipping ahead to slide five, however there are in the privacy rule a number of exceptions to this right to an accounting of disclosures and probably most important for our discussion today is that there is an exemption for disclosures that are made to carry out treatment, payment or operations otherwise known in HIPAA language as TPO. Those are the most common routine disclosures of a patient's health information that occur on a daily basis. Those are not required to be included.

There are a number of other disclosures that are not required to be included. In fact, the way the rule is worded today is that there is an accounting of disclosure right but there is a laundry list of things that do not have to be included. It's actually a little bit difficult to understand because it's the exception, you know, it's the things you have to carve out.

At any rate, that's the rule that existed prior to 2009 that still is actually, if you pull up the privacy rule on line, that is what you'll see, that is the rule that still exists today. I'm on slide six.

HITECH made a change to that. Congress said that the exception for disclosures to carry out treatment, payment and operations is no longer going to apply to disclosures that are made through an electronic health record.

They also changed the look back period for the accounting of disclosure provisions, changed it from six years to three. They also stated that with respect to disclosures to business associates and disclosures from business associates to their subcontractors and so on said that it's the responsibility of the covered entity to either provide in fact the disclosures that the business associates has made or to give patients a list of business associates so that then the patients can go to them and request an accounting of disclosures from them, you know, keeping in mind that the other thing that HITECH did was make business associates directly accountable to certain provisions of the rule.

HITECH also said there needs to be a technical standard here and it requires the adoption of an initial set of standards, implementation, specifications and certification criteria for accounting disclosures in EHR technology. So, that in a nutshell is what HITECH dictated be done with the accounting of disclosure provisions that have customarily been in the rule.

Slide seven now, so, in order to implement this, the first thing that HHS and the Office for Civil Rights where Sue works did was to issue a request for information and upon getting feedback from the public on the issue they issued a Notice of Proposed Rulemaking to implement HITECH and make some changes to accounting of disclosure.

And essentially what the Notice of Proposed Rulemaking provides is two rights for an individual an accounting of disclosures and an access report. And the access report is really the response that HHS made to congress's mandate that treatment, payment and operations disclosures would have to be available to patients if they asked for it when they are made through an EHR. I'm on slide eight.

I am going to discuss for a minute what they said about the accounting of disclosures. So, keep in mind two reports here, accounting of disclosures and access report. I'm going to first describe what's been proposed for the accounting of disclosures.

In many ways much more understandable, rather than a right that says patients can get an accounting of disclosures but it doesn't include the following things instead there is an affirmative statement that patients have a right to certain disclosures from the records, an affirmative list of the disclosures that have to occur.

Again, it still applies to disclosures both paper and electronically and it is still also very focused on – I call them extraordinary disclosures. They're not necessarily unexpected but they're not the routine treatment, payment and operations disclosures.

Next slide, page nine or slide nine. There are still exceptions though, but at least this time you're starting with here's an affirmative list of disclosures that have to be in included but there still are some disclosures that for public policy reasons will not be put in this report and there is a list of them here.

Moving onto slide 10, there is a description of what is required to be included in the report about those disclosures that are to be included, the date of the disclosure, either the name of the entity or the natural person which is a real human being who received the report but, you know, an optionality there, a description of the type of information disclosed and a description of the purpose for the disclosure. So, very similar to where the privacy rule is currently.

Slide 11, the access report. Again, here is how HHS proposed to implement those congressional provisions regarding inclusion of, you know, being able to give patients the right to see TPO disclosures through an EHR.

They've proposed the right to access report that indicates whose accessed a patient's protected health information which is identifiable health information that's maintained in an electronic designated record set that's a HIPAA term of art that refers to the type of information in a patient record that's used to make decisions about patients. So, it's your typical EMR information in a provider context and its billing records and health plan context and that's essentially what a designated record set means.

The right to an access report as proposed would – that report would include the date and time of access, the name of the actual person, the human, if it's available, who received the information, otherwise the name of the entity, a description of the information that is disclosed and the particular user action, so remember this is an access report. So, what happened to the information was it created, was it modified, was a deleted, again if that's available.

There are several provisions with respect to how access is to be included when you're talking about intrasystem, transfers of information and how that would be included. There obviously you would have to – what they've proposed is that the access is identified by the name of the covered entity, because essentially it's reflecting the fact that an individual's information was accessed by one of the covered entities own systems.

There is however an exception, which is on slide 12, which is for access where the purpose of the access is for patient safety work product generation that information is supposed to be confidential so the fact that the information was accessed for that purpose needs to be excluded from the proposed access report.

That rule was never finalized. That's one of the reasons why we are coming to you today because we have been asked to provide input to assist HHS in implementing the HITECH provisions and helping them generally with this task.

On the certification stand-point, remember that HITECH had both a policy piece and a technical piece for this. For certification, ONC has made accounting of disclosures an optional certification criteria for EHRs in both the original certification criteria as well as the 2014 criteria and the rationale for this is to allow EHR developers the flexibility to innovate in this area and to develop new solutions to address the needs of customers. So, this is not a required capability today and so consequently, we don't have a good match where there is, you know, a policy mandate that's matched with the technical capability to implement it.

I'm on slide 14. I want to talk to you about what we heard in the hearing that we held on September 30th where we heard from patient representatives, provider representatives, vendors, business associates and health plans about this issue, the HITECH requirements, the current rule, the proposed rule. We got feedback on all of it. And here are sort of the key points.

Transparency to individuals about uses and disclosures of their health information is very important for building trust in Health IT. Transparency should be done in a way that individuals can understand including those who have disabilities and those for whom English is not their primary language. The patient representatives at the hearing did testify that they thought that patients would want the kind of transparency that the access report would provide them.

They also took the opportunity though to emphasize to us the importance of patients being able to get copies of their own data in addition to having some indication of who accesses their records and where their records go. Next slide, slide 15.

However, no testimony supported that the proposed access report was doable at least with current technologies. Audit trail technologies are frequently mentioned and probably envisioned in a lot of minds as the tool for offering greater transparency to individuals but audit logs are not deployed for the purpose of reporting to individuals they are deployed for security compliance within an organization and they're not designed – they're designed to track security relevant events for a system and not necessarily individual user activity and they don't easily produce the kind of reports that the access report proposal would require.

Nobody at the hearing, including the technologists, the patient representatives offered a specific technical path forward to being able to accomplish the scope of what was proposed in the access reports and a lot of questions were raised about the potentially significant cost of building in the capability that would be required in order to do the access report. Next slide.

Also it wasn't clear to us that patients would want or find value in the deluge of information that was likely to be produced by the access report. Certainly, the patient representatives at the hearing said "yes, we think patients would want this" but given that this is not the report that is produced today and given it's certainly on the provider side looking at the huge volume of information that would be produced from an access report, a lot of questions raised about whether in fact patients, if we went ahead and said go ahead and implement this would actually find value in it.

Today, patients rarely ask for the HIPAA Privacy Rule Accounting Report. The patient advocate said to us this is because those reports today don't have very much in them. There is not very many disclosures that have to be reported. Patients are generally not even aware of their right to have this notwithstanding that it's typically included in – it has to be included in the notice of privacy practices.

Providers and payers told us they very rarely, if ever, receive requests for this and they feel strongly that past behavior is a strong indication that patients would probably not find very much value in these. Given those thing together it seemed unwise to us to impose a new access report mandate given the potential cost of building in that new capability and how little evidence we have about patients who would actually ask for them. So, potentially high cost of implementation with a lot of uncertainty of demand and value.

Next slide 17. All seemed to agree that patients should have the right to a full investigation of complaints about inappropriate access. Because, generally folks thought that the potential for inappropriate access or concerns about inappropriate access was what would be likely to drive somebody to ask for something like an access report.

Such an episodic response could be more effective frankly at addressing patient concerns versus trying to build in the expensive technology to produce the report because it's an investigation that is targeted to the patient's complaint versus the handing over of a voluminous report and saying, well let's you and I or the patient figure it out, or let's you and I sit down together and try to figure out what is.

Lots of concerns were raised about providing patients with the names of individual users who had accessed their reports and questions were raised about whether other laws that provide patients with some transparency about record access such as the OECD Fair Information Practice Principles and the Fair Credit Reporting Act and the Privacy Act of 1974 provide this kind of access, we have investigated that and none of them do not at the level of the individual name.

For example, if you ask under the Fair Credit Reporting Act for a list of who has accessed your credit report what you get is a list of the entities who have accessed you credit report not the list of the person at the bank who asked for your credit report. Slide 18 I'm on, we're almost there.

Testifiers also noted to us that the technology today does not distinguish between an internal access and a disclosure and part of the reason for that is the way that HIPAA currently defines a disclosure which is in essence when a community physician who is not employed by a hospital system accesses that hospital's record that's considered to be a disclosure even though they are a credentialed user of the hospital system and I think, you know, from a sort of common sense perspective we might think, well why isn't that an access, it's not and essentially the way the system would track it would be they couldn't tell whether it was an access or a disclosure frankly.

There were also a lot of questions about what the heck did congress mean by disclosures through an EHR. What is through an EHR, does it have to pass through the EHR, can it come from the EHR, what does it mean? So we had a lot of questions about that.

On pages 19 and 20 we summarized the comments that we got from our posts on the Health IT Buzz Blog and they largely tracked very closely the testimony that we received at the hearing. So, there is a fair degree of consistency of views out there. Lots of concerns about the proposed access report, you know, desire from patients though to increase transparency and to have ways to address the very real potential for inappropriate access.

And so with that I'm going to turn it over to my Co-Chair Paul to take us through the recommendations. We are on slide 21.

**Paul Egerman – Businessman/Software Entrepreneur**
Yes, thanks Deven, we are on slide 21. We have about 100 more slides to do and not to worry. And I did want to make a comment first about the public comments. Public comments are always helpful. In this situation we got a lot of public comments on the ONC Blog and they were extremely helpful to us, because as we're going through everything to help us gain essential confidence that we're headed in the right direction in the recommendations. So, those public comments were terrific.

And we had a hearing, Deven made reference to our hearing, we had over 200 people attend or participate in our hearing which we believe is record setting for an ONC hearing. We believe that because we discovered that 200 is the maximum number of people that can sign on and so we had to ask other kind people at ONC and OCR, the staff members to sign off so members of the public would have room, which we of course was sort of like a family hold back or something they did.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
And some of us got kicked off.

**Paul Egerman – Businessman/Software Entrepreneur**
And some of the presenters, it was an interesting challenge. But, so we have this situation where fundamentally there's a clear desire to do the right thing for the patients and to provide information that they need.

We have this law, and it is a law, about patients have a right to get an accounting of disclosures. And then we also have a very complicated description of what is a disclosure, you know, this whole idea that a disclosure of a physician, if the physician is employed by an institution it's not a disclosure but if the physician isn't employed then it is a disclosure.

We actually had to go through that like three times during the hearing, in fact I asked Joy about that, I said “are you really sure that’s how it works” and she said “yeah that’s how it works.” So, that’s the challenge and so we have a series of recommendations here and we figured it out in terms of how to deal with this.

And basically in that overview slide to just give you a sense, it was very simple is, we’re saying, well we’re not going to look at like every disclosure we’re only going to look at the types of disclosures, the kinds of disclosures that occur outside of the entity or outside of the OHCA and I’m assuming everyone still remembers what an OHCA is, Organized Health Care Arrangement. There is a definition at the very last slide of what an OHCA is but it’s basically maybe multiple provider entities that appear to be public as it’s one. But there is a better description in the text.

So, the idea is to report disclosures to go outside not necessarily to report all disclosures and then for things that occur inside that involves employees to sort of reiterate and reinforce the patient’s right to an investigation. So, that’s like the summary of the slides and the recommendations.

So to walk you through it, the first one that’s on – and these are important recommendations, which is why they’re on the screen in a format you cannot read. But, the basic concept here is there are three points here to this summary and first of all in some sense it’s sort of a comical part of the summary, we say we should do this in a stepwise basis and we should start with something that is workable and this gives a clear description that what was presented was not workable and the second bullet is to explain that the part that wasn’t workable is the whole business about this internal access report of every single employee and every internal access. To understand that that’s the part that wasn’t workable.

And so as a result we took the approach that sort of says, well let’s make something that’s workable, let’s approach the access report differently and we have this concept of quality over quantity. And what that means is, you know, basically we want to focus again on disclosures outside of the covered entity or the OHCA. It also means that we want to make sure this is a document that’s usable and realistic for patients.

We do not want to have like some 5 or 10 page document you throw at a patient and most patients will never read it and if they read it they probably wouldn’t understand it. We don’t think that’s what was intended. We want to try to come up with something that sort of says to a patient where their data is located, what has happened to their data. So, that’s the concept of external and going quality over quantity.

And so the way we addressed this is we sort of said, well let’s take a minute and let’s forget a moment about all these like HIPAA definitions of what is a disclosure. So, let’s essentially just stop thinking about it that way and instead focus on the data and follow the data and that was the concept that we had.

And then we established a concept of saying, well if you follow the data the real issue is going to be, well who has control over the data and if the healthcare organization keeps control of the data then we say that’s internal but if they somehow transfer control, if somebody else gets control of the data then we’re saying, well that’s, you know, that’s the type of disclosure that triggers something that should appear on the report.

And then when we discussed that we came up with this description of it that a lot of people liked. We said it’s the compliance environment so if it’s within your compliance environment you’re all set. If it leaves your compliance environment than that triggers being on the report.

One person in our – we had a conference call on Monday, said, well, you know, compliance environment that’s a lot of big words. Why don’t you just say that, you know, if you have a username and password and you got it from your covered entity then you’re internal, but if you got it from somebody else than that’s outside and they said they thought that was a simpler way to describe it and maybe that is a simpler way, but that’s the basic concept of control of the data.

And to make sure people understand that then we have a series of examples of what that looks like and so in just going through the series of examples you see the first one is, if the data is moved from a provider to a health information exchange organization to where that organization is able to then further disclose the data that would trigger being on the report.

Data sent to a facility for ePrescribing is another example. Another is payment that send a claim form to an insurance company and another one is registries, you send data to a registry for quality improvement that would be included and also included here, we wanted to link our recommendations to Stage 2 of Meaningful Use is really the Stage 2 Meaningful Use information exchange requirements. So for example if you use Direct and you sent say a CCD to some other facility that would be a triggering event.

And on the next screen is also just a few other examples. If the recipient is able to do any of these things, that is also triggering on the report. So, if the recipient can resell or monetize the data, further disclose the data to other organizations, use it for internal purposes other than quality review of the covered entity or create limited data sets or de-identify the data for purposes unrelated to the covered entity. Those are also things that would trigger being on this report.

So we have a couple of examples also of what's not on the report just to be clear on that. And so first is that if you – if anybody, but in particular if a community physician is able to access the EHR using his or her security credentials, which might be like a user name and password, it might be other credentials and again we're using credentials in the context of security not in the context of physician credentials, but if they're able to access the EHR system that way that is not triggering on the report even if it's a community physician regardless of employment status.

And the second bullet talks about automatic or manual transfers of information from an EHR to other electronic systems. Basically, we're saying that if you move the data around internally to different computer systems that also does not trigger being on the accounting of disclosures report. So that's a description of how we tried to decide what types of disclosures not every disclosure, what types of disclosures would be included.

Next what we said is to accomplish this we also recommend that this whole thing be piloted by ONC. So, you know, there enough excitement about this and you are talking a report that every citizen in this country, every patient should have the right to get and it's hard to figure out how to design that. So, there ought to be a pilot.

We also need to pilot the technologies to make sure that this is a feasible approach and need a pilot to make sure that the approach we're taking is not administratively burdensome to the providers. So, the idea was to suggest several pilots.

We also made some very broad recommendations about the content of the report and in making these recommendations, you know, we tried not to be specific. We tried to be very general. We just sort of said, well, you know, you should have the name of the entity but not necessarily the name of the employee involved in the disclosure.

And besides testing the pilot we said – the report in the pilot, we said that similar – you should include the concept of grouping which I guess is already included in HIPAA but the idea being that if possible even having like blanket disclosures.

And so that way that would work is – the discussion is, you know, you could do a disclosure and you could sort of say like, you know, October 1st we sent the LDL to the HIE and October 2nd we sent the triglycerides and you can list out every single thing that got sent as it got sent or possibly you could simply say, for the past three years we've sent all of your tests results to this HIE organization or similarly you could list the date every single claim form was produced or you could simply say, for the past three years we've sent all of your claim forms to your insurance company and that that disclosure might be more meaningful and useful to the patients then the detail. So, that's the concept on the report.

So, far I've, as rapidly as I could, have told you a little bit about what the accounting of disclosures report will look like but then there is the other side about, you know, the internal things and the accesses and the rights of the patient there. So, I'm going to turn to that for a moment and basically what we did here is we reinforced the importance of the right of an individual to an investigation of an alleged inappropriate access.

So, if a patient or individual thinks that something perhaps happened inappropriately the organization has a responsibility to do an investigation. Now this is not like a new recommendation that we're making this exists already in the security rule. We are simply repeating it here because we think it's very important. We think it's important first to make sure that the people at the hearing, the people in the public who made comments about these issues understand that we heard what they had to say and that we agree that this is an important issue.

And we also wanted to give a few examples. So, there is an example listed in the middle on that screen and what that example basically says that you can have the right to request an examination if you have a reason to suspect a specific person might be involved or might be concerned so that's a suggestion I think Gayle Harrell made, but an excellent suggestion.

So, the way I might imagine that working is you go to your health care organization and say, well gee, you know, I've been divorced and I'm worried my former husband, my former wife might be looking at my records. Can you tell me if that is occurring and so that would be a reasonable kind of request and the organization would need to investigate it.

The other thing is it says here an investigation of circumstances. So a circumstance could be like maybe say, well gee I had this like really embarrassing thing happened and then I had to go to the emergency room and I'm really embarrassed by it all but then I was at work like two days later and people seemed to know about it and I don't know how that happened can you tell me if people were looking at that visit and so that would be another example. So, this is a right that patients have to get an investigation of what happens like internal within the organization.

Now also this slide also leads to our next slide, it's a very important recommendation. Basically, a little bit difficult to read and we made it that way because it is so important. But, this is a recommendation that's very exciting because it's a recommendation specifically to the Office of Civil Rights and it relates to their audit control standard and a specific reference to that audit control standard.

And we wanted to recommend in support of what we just presented on the previous screen that that audit control standard be strengthened. And so we have two very specific recommendations for the implementation specification for the audit control standard which are addressable recommendations and basically say that the audit control must record the access activities to a level of granularity that includes the – identifies the individual user, which we put in parenthesis (human) and the individual whose PHI is accessed. So, that's really needed to do what was on the previous screen.

And the second one is little bit broader basically because you have to record in the audit control information necessary to perform investigations. So we think that's an important recommendation.

And then we have here the rationale for our recommendations. So, if you look at our recommendations in total what we've sort of done is say, you know, we had this large thing that seemed unworkable, we've defined not all disclosures, but certain types of disclosures that need to be listed and we've sort of limited it and so the next question is, well there is a law here how do we have the right to do this and so this is an explanation as to why we're doing this and how we can do this.

First is we want to simply provide a solid place for HHS to start and we think that we've done that in terms of narrowing the kinds of things that have to be done. We think that this will provide better information for patients and this concept of quality over quantity. If we give them a sense of where their data is and I think that that's an important thing to know, but it is still consistent with the statutory language which is what you see on the third bullet here.

Because we are addressing disclosures for treatment being in operations through an EHR but there is also part of the statute that says we're supposed to balance the interests of the individuals with the administrative burden and what was originally created in the NPRM based on very significant and enthusiastic feedback was that it was administratively burdensome at best. So, we think that's all consistent.

The next slide, which is mercifully the last one. This recommendation we also want to point out is consistent with prior Tiger Team work and when we showed this to the Tiger Team a lot of people were confused by this. So, what we're trying to say here is we did some work, actually I think a couple of years ago on meaningful choice which is a similarly controversial topic and we took the same approach of looking at control of the data.

And so what we're trying to say is the approach is the same it's not that we're trying to link these two recommendations. This is an independent recommendations we're saying, but looking at control of data is an approach that we have taken and the approach is also the same in the sense that when we did that recommendation we similarly presented a ton of slides to you with a lot of words and not one single picture and so that's also similar in our approach.

But anyway this is our series of recommendations and we offer them to you for discussion and ask for your approval.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Well, thank you very much to both of you and to the Tiger Team, really excellently discussed and deliberated and I think excellently presented. The context is very helpful from the HIPAA to the HITECH to how you are reacting to the NPRM. And I think the feedback you got from the public was vocal and a lot of it was consistent in that you've come up with a balanced approach. Just for clarification, you talked about external disclosure, internal investigation. And when you said pilot, the pilot proceeds putting those recommendations into force?

**Paul Egerman – Businessman/Software Entrepreneur**
Yeah, the pilot would proceed any further effort at certification.

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

**Paul Egerman – Businessman/Software Entrepreneur**
In other words, I'm glad you asked the question, we did not make a recommendation about certification of this accounting of disclosures report based on part of the learning experience that this is a hard thing to do. We thought that there needed to be some operational model and some experience before you could go to that step.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yeah, we also – the pilot is directed at figuring out a way to accommodate the accounting for the external disclosures through an EHR. We did not specifically say, well you should also pilot the additional recommendations we made on the audit trail specification.

So, the pilot is really – again, technically enabling providers to be able to do this easily is really pretty key, because if there is a whole lot of work that has to be done manually in order to produce this report that's when the sort of balance test gets off, because even with a very much improved right I think it's still probably the case that there is not going to be a huge demand for these, right?

So, there absolutely has to be a technical component to this and congress definitely foresaw that, technical standard, policy change. The idea was that press button produced an accounting of disclosure report and we don't have that technology today. Can we develop that technology?

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So, just to be explicit, unlike what the NPRM suggests you would say to not only not put that into a final rule but before even producing the final rule you should do this pilot so that you – to inform the final rule. Is that a correct way of interpreting what you said?

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yes.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay, very good. Christine?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Thanks, I just have a question, a couple of questions actually. This is really thoughtful so I really appreciate it and I know this has been a sticky issue for a long time and you guys have really done some good work.

So, my question is, probably not about the recommendations you're making but about the law itself. So, when you talk about the individual's right to have an investigation can you tell me more about that right, who does the investigation.

I know that when I asked for a copy of my records HIPAA put some constraints around it like 30 days and, you know, these formats and da, da, da. Are there any, you know, constraints or requirements around the investigation like how timely it has to be?

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
There's not a lot of detail about that, you know, certainly, you know, so this is in response essentially to a patient complaint, right?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Right.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
I think there's been an inappropriate access to my records, the complaint goes, you know, at least for this investigation to the provider or to the health plan where the patient has a suspicion that something funky with their information is going on.

There aren't sort of parameters around that. Time limit for investigation, parameters of it, you know, generally the providers who testified to us took their obligations for this very seriously. What the patient has as a recourse, if they don't think they're getting a good response, is to complain to the regulators but there are not any more details around it other than that.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Is there any way to collect some more evidence from the field about what the experiences of patients and providers a little more broadly than just our folks who testified in the hearing?

I just want to make sure – I really like this idea but I'm a little bit worried that an organization could stonewall a patient or they could give a report that's not at all helpful or they could just decide not to give a report or it's not done in a timely way or it's like the, you know, fox in the hen house.

So, my instinct is to encourage maybe in these recommendations OCR to think through some of those issues or at least explore them more, but I don't want to create a set of recommendations to solve a problem that's not out there.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Right, right.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So, I don't know if there is a way to figure out if that is a problem or not, but that's my immediate instinct.

**Paul Egerman – Businessman/Software Entrepreneur**
And I don't know whether or not it's a problem. I mean, there was certainly indications in the hearings and our discussions that that these investigations are going on now. So people would talk about that, you know, it's like the emergency room example was one that somebody had mentioned.

And we also heard another example where an employee of an organization who was concerned that she was treated in behavior health and her fellow employees knew that and so perhaps there was some employee snooping going on in the record.

And so the sense was that this is going on and the other thing that we talked about a little bit is many health care organization are sort of doing a lot of things proactively to avoid problems and especially proactive if they have like a celebrity or VIP involved. So, they will, you know, watch the record carefully, just give that record additional scrutiny if a VIP is say an inpatient to make sure that, you know, nobody is trying to look at it and if they are they'll take action before there is a complaint.

So, I got the sense that organizations are treating it seriously but there is no – I don't think that we have any data about that.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So maybe we could just –

**Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator**
Could I jump in for just a second?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Oh, perfect, Joy, yes.

**Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator**
I think that there might be a potential to collect some information on that if we went to OCR and asked if when they – they receive a lot of complaints, you can see the number, they receive a lot, whether they are able to identify complaints where people say, I complained about a breach and nothing was done about it.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Right.

**Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator**
I don't know if they can sort it that way, but we can certainly ask if they have that data available.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
I would love to just make part of the recommendations that we need to explore it and potentially, you know, put into place some, you know, safeguards based on what is found out there.

I remember when we did our Consumer Health IT Survey two years ago I think it was about 2 percent of respondents had experienced a breach so it's obviously some, you know, smaller subset so it's not a huge number necessarily out there, but I still think that if this is going to be a major, you know, path of recourse for patients we need to make sure it's actually working well.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Good point.

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

**Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health**
So, I wanted to get back to one of the points you made about sort of things that happened through the EHR, sorry.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
That's okay.

**Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health**
But, so a lot of the security concerns that I have and about where potential breaches could take place is around the work that we do around quality reporting follow-ups, recalls and all of those things which usually generate reports on paper and those reports get passed around. And so as long as they're within the organization I guess maybe that's no problem.

But there's no way, you know, the only thing that shows up in the electronic health record in terms of the audit is the person who actually printed the report. There's nothing about who else saw it, who else saw the names on it or anything else.

So I guess just as long as we're clear that there is still a lot of interplay between the electronic health record and paper that goes on within organizations and that stuff is not subject to this kind of review.

**Paul Egerman – Businessman/Software Entrepreneur**
Yeah and there's a number of aspects to what you said Neil. There is – it is the case that was in the hearing that a lot of people gain access to PHI without signing on to the system. So therefore they're not in an access log and it's because they get printed documents and that's a valid point.

And the issue is if they're given a printed document presumably they're authorized to receive it, there was a reason why you gave it to them and they may subsequently give that printed document to somebody else who really isn't – shouldn't receive it but that sort of like in a different category, it's like it's called inappropriate use as opposed to inappropriate access and so it's a challenge.

And the main concept to understand is when we look at the access report and inappropriate access we're only looking at like one potential breach or one potential problem. There's a lot of other things that can also go wrong.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
I think just for point of clarification, so we think we've addressed or given HHS a pathway for addressing, giving patients the right to accounting of disclosures through an EHR and we did that in a couple of ways. One we said real disclosures, outside the entity or OHCA it goes somewhere else, the control of the data.

Number two we said pilot this with EHRs, right, because one of the things that I didn't emphasize in the explanation I gave is that, you know, HIPAA tends to apply equally to all covered entities health plans, pharmacies, health care providers.

Here we said we have the capacity through ONC and potentially maybe a certification requirement to see whether this actually works in EHRs and then we'll have better knowledge about how to expand it from there.

So, I guess one could argue, what does through mean versus from and we decided that from was sufficient.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Can I follow-up on Neil's question which was reduced to paper but came "from an EHR" if it goes from an EHR to some warehouse and most of the reports and disclosures occur from that warehouse are you saying that would not be covered in this disclosure?

**Paul Egerman – Businessman/Software Entrepreneur**
Well, I'm not sure I know what you mean by warehouse, but –

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Well, let's say, so you were extracting information into a data warehouse and it's from there that the reports either for quality or for disclosures occur is that –

**Paul Egerman – Businessman/Software Entrepreneur**
No a data warehouse is one of the internal electronic systems that is for producing quality reports and different things, it's a great example because in theory I think it's a technicality that might be considered a disclosure because it's not in an EHR anymore, but at that the same time as long as your entity has control over the access, has control of compliance of that we're saying that's not listed on the disclosure report.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Correct, I'm saying if all of the accesses to external organizations occur through that computer. Is that considered an extension of the EHR and hence "through" the EHR or is that excluded? I mean, that's the electronic counterpart to what Neil is talking about.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
So, yeah, so we did the best we could to scope out conceptually where we think HHS ought to head with this and to provide some examples of what we mean. It is their job to figure out the intricacies through the pilot.

Because ultimately we could sit here for another three hours and come up with what about this scenario, what about that scenario, you know, in my view a data warehouse that's not a universally defined term. I want to know where that data warehouse is. Is it within your compliance environment of your covered entity even though it's not part of your EHR.

Under our follow the data approach if it's within your environment that's not the kind of disclosure that we are trying to – we are suggesting that HHS try to capture. It's if you think about it conceptually, follow the data, did the data go somewhere else where you don't control it anymore.

And so if that data warehouse is – you're describing an HIE model where other people can disclose it and the data warehouse is actually an external entity and not part of your system and you don't have control over who discloses it then "yeah" from our follow the data approach you would get there.

So, it's – you can't tell me data warehouse and ask me how to explain it without explaining to us I think a little bit more detail is it within. I mean, I like the term compliance environment but I can see how that's confusing to folks. Is it part of you or are you sending it out somewhere else or if you're sending it somewhere and then it's going to go externally further from there.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Actually we might be able to apply your follow the data methods to this. So, if you did not call it a disclosure to go from traditional EHR to a "data warehouse" then it's incumbent on you to, if it goes somewhere else, to disclose it. Do you see what I'm saying?

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yes.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So, it may be applying your rule to that question.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yes.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
And the same thing would be happening although with paper you can't, you know, it's already excluded.

**Paul Egerman – Businessman/Software Entrepreneur**
Ultimately, the concept of what we're trying to do is the patient should know where their data is. In some sense it's a simple thing. And we're saying, well if it's somewhere within say the organization, the organization could be large, it could be like Sutter, that's okay and you don't have to say specifically where all the different like nooks and crannies within Sutter where that data might be because there might be a lot, but if it goes someplace else then the patient should know and you should be able to produce a report that says that. Now it may continue to – there might be a cascading thing and it may go other places but you have to at least say where you sent the data.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yeah.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Yeah. Troy?

**Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Kaiser Permanente**
Thank you, you touched a little bit on my struggles with this. I didn't hear anything mentioned about public comment on consent. One of the provisions for HIPAA is, you know, if they consent to have their information shared then they can do so.

And the other thing I was wondering is the triggering of the report. Is the proposal to make this an automated process? Is the proposal to say that only under the event that there is a request made to reveal the disclosure? I'm not sure where that goes.

**Paul Egerman – Businessman/Software Entrepreneur**
Let me try to do the last part first. I mean, the concept of the accounting of disclosures report it's a report the patient has the right to get it so that's what that is. In terms of whether or not it's automated, the answer is probably yes. Again, this will come from the pilot.

One vision of how it might work is organizations might be able to have like a single page that handles like 90 percent of what normally happens like the insurance stuff and they might then attach to that perhaps another page or something or things that I would call one offs so that, you know, happened based on something else, some information exchange but that's exactly the kind of issue we have to work out.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yeah.

**Paul Egerman – Businessman/Software Entrepreneur**
It probably has to be automated to avoid an administrative burden.

**Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Kaiser Permanente**
So that leads to another question, who would receive the report and, you know, patients typically when they present to a provider they know that their information will be shared with their insurance company for example. Would that necessarily say that it needs to be automated or triggered?

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Okay, okay.

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

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
First a couple of things here, we are not – the report is produced only if a patient asks for one.

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

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Only.

**Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Kaiser Permanente**
That helps me.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Only if a patient asks for one, this is not an automatic, you know, like your explanation of benefits that you get in the mail every time you get treated. It is not an affirmative right to be told. It is, I am interested to know where my data goes so I'm going to ask for one of these and that's why, because that is not likely to happen very often even with a much improved right. It really should be something that can be automatically tracked in some way so that if the provider is asked to produce it it's easy to do so.

The other thing is we are not messing at all with the traditional rules about when you can share information without consent where authorization is required. All of the data flows that are currently permitted under HIPAA we are not messing with those at all.

We're just trying to help HHS figure out how to implement the ability to give a patient a report when they ask for it of disclosures through an EHR. We're confining disclosures and we're asking for a testing of automated capabilities to produce it.

**Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Kaiser Permanente**
Okay, thank you.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Very good. Okay, so we're going to get ready to vote on the recommendations. Thanks again to the Tiger Team for really thinking this through and producing I think very actionable recommendations. So entertain a motion to approve their recommendations. Christine?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
And would include the change I was suggesting before about gathering some information on investigations, etcetera?

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Yeah, so what we can do is add a recommendation for the Office for Civil Rights to further explore whether these investigations are occurring.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Okay and how they're going that would be great. So, I'll move to approve.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay. Second? And all in favor?

**W/M**
Aye.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Any opposed or abstained? Great, well thanks again. Okay and thank you again Paul for serving as Co-Chair. All right our final morning topic is from the Certification and Adoption Workgroup to talk about alternative certification framework for approval and some work to come on the currently ineligible providers and how we might help interoperability related to that, their receipt of information. And Larry Wolf and is Marc on the line? Okay, so Larry Wolf is going to kick us off.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
So it's good to be here this morning. This is again sort of a look backwards and a look forwards, seems to be a theme for today. Things we've done, things we're going to be doing.

Specifically, we were asked to take a look at what would it be to extend certification program, last year, actually earlier this year, there was a request for information put out by CMS and ONC, this is a little background I'm giving, CMS and ONC looking for insight, input into extending adoption of interoperability among all healthcare providers not just those in the incentive programs and so that in some ways is a driving force behind this.

And then that RFI and the request to the Workgroup was specifically looking at long-term post-acute care and behavioral health as two areas, two sets of providers who are not covered by HITECH but where there is some interest in having certified software.

So, we have a very pretty robust Workgroup. We've expanded this a little bit to get a couple of experts in long-term post-acute care on the Workgroup as well behavioral health. We've also brought in two members from the Standards Committee so that we have better insight into what's currently available on the standards side and we have a couple of federal representatives as ex-officio members of the Workgroup as well and again those folks have background on behavioral health and long-term post-acute care.

So, certification is not a new thing. It seems like this is our day for reviewing where we've come from. So, before HITECH, going back into 2006, there were regulations, legislation, regulations around EHR safe harbors so that a provider or hospital for example could make EHRs available to physician groups or to nursing facilities and not be in violation of any kick back or referral law requirements.

And in order to do that, ONC was asked to create a certification program that was part of that safe harbor provision. So if you're using software that's been certified and that's an allowable thing to be provided then the safe harbor would apply. So, that was in place pre-HITECH and I bring it forward as an example of certification, it doesn't need to be about Meaningful Use.

Then beginning in 2009 we had a pretty broad program put together for certification that began with a temporary certification program and then the current program which dropped temporary or permanent from its name it just is the certification program and that's been in place now for a couple of years.

And in the regulations ONC has pretty broad authority beyond Meaningful Use for certification programs and these are voluntary and we've had some discussion in the Workgroup about what voluntary meant, you know, sometimes voluntary means if you want to get paid and you want to be a healthcare provider then you could do something. So, pretty strong voluntary and other times it really is completely optional.

And so because of that we don't specifically talk about voluntary or non-voluntary in our discussion unless presented beyond this other than to say that there is an inference that this really is all a voluntary program.

Okay, so now talking a little bit about the RFI that was put out from – it was a joint ONC and CMS Request for Information on advancing interoperability in health information exchange. So, this went out in March, there was a comment period and then over the summer there were principles and a strategy put forward again jointly by ONC and CMS that said they're interested in broadly expanding interoperability, expanding health information exchange and that they would be exploring lots of policy levers to do that with and that there were many payment channels of different kinds, grants and regulatory requirements that might need certification and so they asked the Workgroup starting in October to take a look at this.

So, we have a two-part charge to the Workgroup, one is looking at how do we think about a certification program? So, given that we're now looking beyond Meaningful Use what would be the criteria to have one of these and demonstrate that there is value in having a certification program.

And then specifically to look at what ought to be done with some ineligible providers. And so, If you will, what we're presenting today here is some draft to give you some insight into our thinking and where we are with our process.

We have some factors that we'll be presenting that would create a framework for doing certification and then we'll be sort of testing that by hearing from long term post-acute healthcare providers and hearing from behavioral health providers and then assessing that framework given what we're going to learn from them and then going on with some specific recommendations about those care settings.

So, timeline. So, we started in October, we've had a few meetings and then all the italicized dates are things in the future. We've put together this framework and we'll be hearing from the providers.

So, a reminder for context, so the existing certification program we've brought recommendations forward in 2009, it seems like an eternity ago right now, that were specifically around Meaningful Use and that looked to build on what had already been done with certification at the time there was the CCHIT Certification related to the Stark exceptions.

And we wanted to make sure that the new processes were objective and transparent. And that we wanted to make sure that they covered a broad range of software. It was interesting in the collective memory of the Workgroup we also thought we'd address modularity but that actually came later as we went back through much of our notes in the process, but I think that's also an important concept and in fact I think our go forward work is going to very heavily rely on the modular certification that's been done and that there be a transition plan. So, I think as general guidelines these still hold up and let's talk about where we are.

So, we've done step one, we have some draft materials here I'll be presenting. We're about to do step two diving into long-term post-acute care and behavioral health and then we'll be back with recommendations in March.

Okay, so there is a five factor framework we came up, I guess we were into – and you can think of these really as gates to get through not necessarily sequential but the thought was that any certification program would need to fit all of these and address all of these.

And the first one was that there actually is some national priority or legislative mandate that, you know, this shouldn't be just some capricious thing that, you know, hey, wouldn't it be fun if, it's like no there really should be some driving reason for doing this.

Very much we wanted to align with existing federal and state programs. Healthcare is a heavily regulated space with the particular providers that we'll be looking at is ineligible providers, you know, everyone thinks that they are the most, right, so they think they're the most heavily regulated and so whatever we do here around certification ought to be directly in support of those programs as well and not creating additional burden.

That we should look at the existing technology pipeline. So, what is already in place and for example would certification help move things forward or not and there was some sense for example that if the pipeline is really robust and think the marketplace is meeting the need then that's great. But if perhaps there is demonstrated presence in the marketplace but not widespread there is actually something to build on here. Similarly with standards of that knowledge it would be using.

Is there existing stakeholder support? So, you know, is there any evidence that people want this. Do they see value in this and what does that support look like. And then finally, if you will, sort of summing all of this up, what's the balance of cost and benefit to the program because there have been a lot of questions about that.

Certainly the current program, Meaningful Use Program, has provided a lot of funding for providers to acquire systems to through those acquisitions provide a lot of funds to technology companies that have created the software to get it certified. So, that's certainly one of the open questions.

Okay, so, looking into the framework, so for those following I'm on slide 9, factor one of the framework. So, what we've tried to do with each of these is provide some sample questions to further expand on what should be done.

And I guess I should reiterate that there was consistent sense in the Workgroup that information exchange, interoperability is a place where people feel there is value today and where extending systems to the ineligible providers would extend that value, it's part of patient flow as patients transition out of acute care hospitals.

One third of the Medicare recipients get some kind of post-acute care so we'd like their information to go with them. And some of the patients in those care settings go to acute care hospitals or transition to their community physicians when they're done at those settings and we'd like to continue that information flow to them as well.

So two areas we put forward as some examples, so care coordination and also potentially safety and we're not saying that there are problems in this we're just saying that these are areas that should to be assessed.

Moving on to the next slide, slide 10, factor two of the framework existing federal programs. So, in particular these areas have mandated assessments and other mandated reporting requirements and so anything that's done ought to acknowledge and address those.

For example one of the dissimilarities with the acute care settings is they don't have similar mandated assessment and if you said, well just use the requirements that are there for the existing EHRs they're not going to include anything about these mandated assessments.

And we already know that we've got differences in the certification program between eligible hospitals and eligible providers so there is a common core that applies to both and then there are variations and so as we look at variations to recognize that we'll probably be trying to understand better that common core as well as the needed variations for each of the care settings.

There is a long list of considers here as examples of some of the things that we know are in place in these different care settings and some of the various drivers. Particularly this notion of collect once and reuse data. So there is a concern that some of the requirements for current mandated assessments are in fact creating data collection burdens and we'd like to see EHR technology as a way to address those burdens rather than add to them.

Using existing technology pipelines, so looking at the maturity of what's currently in place and also considering certification alternatives. So, are there other ways to achieve a similar endpoint without a certification program or in fact there is some value in having certification.

Moving onto factor four, so where are we with existing stakeholder support? So, in some ways there has been a continuing discussion about this ever since HITECH first passed. Some people were in and some people were out and to completely over simplify, I think there is concern about the people who are out that they are part of the health system and they are using health technology and they would like that to be recognized and they would like there to be, if you will, some parity in how they're seen with how others are seen.

And that there is also a desire to actually be on an even playing field with the other providers and that it be very clear about what information can be passed to them, what information they can produce and that the extent to which certification provides a floor of capability it becomes a target that says, you know, we can meet this floor and we can participate to that level.

We'll also be looking at what's currently in place with the stakeholders. The kinds of the systems they've already put in and where there is value of information within an organization and across organizations. So, as we know with Meaningful Use there is a pretty broad set of criteria or broad set of outcomes, objectives that drive certification criteria.

So, I think, you know, maybe I should have said this at the very beginning, there is a need to be nuanced in what we do here. This is not a time to bring out a big sledgehammer and say we're going to require everything be certified but in fact where is there value for certification and what can we learn from the existing certification program.

I think we – through the request for information there is a lot of comment that was received by ONC and CMS and in general it asks us to be nuanced, to pay attention to details that while there is a lot of support from the stakeholders for having systems be certified that it also needs to be done in context that the certification needs to be, if you will, achievable and not create huge burdens for folks.

And finally, factor five and there was lot of discussion in the Workgroup about really what are the costs and the unintended consequences that we've had with the certification program and so embedded in that first bullet is a long list of considerations impact on innovation, cost for development and testing, the varying functional needs of specialist and settings, changes in workflow and surrounding processes, changes in usability and so, you know, sometimes that can be over simplified into we're asking providers to click more than they used have to click and they don't necessarily see the value in all those clicks. So, let's make sure this is in fact valuable to the patient care process and to delivery of good care.

And perhaps some of the things we learned in the usability hearings we need enough runway for implementation development to happen and implementation to happen so that we are not just slapping on additional functions that are in many ways redundant to existing capabilities but actually give a chance for them to shake out and be, if you will, optimized early in the process both as a way to manage usability and reduce the burden on the providers.

Potentially, you know, we are looking at financial and nonfinancial cost in benefits so also to think about. So, are there any risks of software that are not certified. And again, these would be examples of where we would be looking for evidence to support this or asking ONC to do that as part of developing a certification program. And again are there other ways to achieve the same means, the same ends with less burden.

So that's sort of round one of what we've done this first step and we just began to learn about long-term post-acute care. We had an hour and a half presentation on Monday talking about what is currently happening in this space and we'll be having a half-day hearing in a couple of weeks and then continuing on.

So, this sort of restates that, that we have a hearing on the 12th and that from December through January we'll be continuing work with long-term post-acute care and then in January we'll pick up behavioral health and then we'll revisit this and come back with recommendations to the Workgroup. And for those who want there are some references to some of the National Quality Strategy information. Okay.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Great, thanks Larry.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
I'd like to get some discussion here.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So you're looking for feedback on the five factor framework?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
So, I'm looking for feedback on the framework, I'm looking for any guidance that the Policy Committee has on looking at the needs of these care settings and I guess a reminder that we are really looking to focus on interoperability as the driver, but recognize that there are other requirements and we know that at least one State, Minnesota, that's looking to require all healthcare providers have certified EHRs.

So, the states are beginning to take some actions in this area and so there may be reason to look at certification that's beyond just interoperability but really focusing primarily on inoperability recognizing again that in order to have something to exchange you need some systems that are generating the information that you are exchanging. So, it may drive us to revisit for example, what's in the base EHR and is that really appropriate in all the care settings as we expand those care settings.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Thank you. Paul Egerman?

**Paul Egerman – Businessman/Software Entrepreneur**
Great, thanks and thank you Larry for the presentation and you've done a lot of work in this area and I really appreciate what you've done.

My view of this is people talk about certification and sometimes I think they conflict certification with our entire program that includes Meaningful Use and an incentive program and that basically in some of the Workgroup discussions some people think, well, gee if we can just certify that will increase adoption.

But certification alone did not cause the adoption it was I think for example the incentive program was like really important and I think also the entire concept of using Meaningful Use to drive what was in certification was important and we don't have – we're talking now about ineligible providers, we do not have any incentive program for them and we do not have any Meaningful Use Program for them.

So the question becomes how do you drive what's going to be in this sort of voluntary/optional certification process. And I guess my view – over the Thanksgiving weekend we managed to have one of these e-mail blizzards that was a lot of fun, unfortunately it was only e-mail and not a real blizzard, but basically, my view is that basically ONC should be limiting itself to information exchange for this process and it should be information exchange that exists already in the EHR program. That that would be useful to allow these organizations to interact, interoperate with EHR systems and that would be a reasonable stand-point.

I think also that it would be useful to do some of the security aspects that also exist. I think that those are transformed or can be transformed. But my view there is that that's what the focus should be. It really shouldn't be more and in particular it should not be any functionality in these areas and, you know, in your presentation today Larry you've talked about – you used the word like predominantly inoperability but in the Workgroups there has been clear discussion about all kinds of functionality that could be included for LTPAC and behavioral health and I think that is a mistake to do for a lot of reasons, one is I have a fear that there is no guidepost, there is no Meaningful Use as to how you're going to decide what to include.

But also, in a program that is like extremely optional the harder you make it for vendors to adopt the certification they just won't do it. And it's especially true when you look at LTPAC and behavioral health where there is such a range of potential users, you know, the potential customers for this, the provider organizations are just very, very different. There is an amazing range in terms of their functions, it would be very hard to get one size that fits all.

So, my feedback is very simple is limit it to information exchange, limit it to information exchange and standards that already exist and exist in the EHR certification program and also security.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Thank you Paul.

**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**
Thank you Paul and Larry thank you I think that was a really good report from really good work and it raised – I come out somewhere where Paul Egerman comes out. For me the entry point though is what's the public policy opportunity and requirement here that this process helps to address and I think coming through that lens I come out somewhere Paul did that the public policy interest is in interoperability and creating an opportunity for these other providers to be knit together with the rest of the system in a good flow of electronic information.

So, I think your factors one and two are the places I would put the most emphasis and then within that I would also tailor – I would sort of revisit those factors for the specific applications like long-term care, post-acute care, behavioral health what are the federal programs and requirements that are specific to those domains and especially as those domains interact with one others.

So, you know, episode of payment or some of those kinds of programs clearly tie these new provider categories into the traditional ones and ACO formation, etcetera. So, going through that lens it narrows the requirements that certification might want to speak to, to facilitate a broader ecosystem that is capable of sharing information.

And then the second kind of complimentary point is that from my constituency the purchaser point-of-view they would really want to be at the table for some of these discussions because they are the uses of the data that is abstracted from or extracted from these systems as they interoperate.

So, not only the – you know, patient care interoperability to move a message back and forth between two providers but if I want to look at the performance of an ACO or an episode or any of these constructs I want to extract data from multiple EHR systems to create a longitudinal record and do some performance analysis or that sort of thing with it.

So, I was thinking specifically with the first task the LTPAC group there is some application, my purchaser members have great interest in about the revolving door situation that they sometimes see, but I think especially when you get to the behavioral health that is a huge issue for the purchaser community, the disconnection between behavioral health and other medical service providers, that they really are very interested in helping to address. So, as you get to that I hope you'll invite some purchaser participation in the planning.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Thank you.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Larry, do you want to comment on the theme about limitation and scope?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
So, I'm hearing the concern of without structure like Meaningful Use provides that, you know, this could become a Wild West of throwing things out there. But also, there are existing regulations that do provide some, if you will, minimum requirements for these care settings. So, I think it would be useful to bring those into review.

There also is all the questions about the information that is generated in these care settings that would be passed on and is that well represented. So, for example, I know in the last two rounds of HL7 updates to Consolidated CDA that there were some specific things that address information related to these care settings and so we may be looking at extending document types beyond care summaries for example as documents that are useful to exchange.

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

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
Thank you so much. I think we have an opportunity here I don't want us to think too narrowly. We have an opportunity here to really delve into two areas that have a tremendous impact on the overall continuum of care of a patient and having my mother spend most the summer in and out of long-term care, out of nursing homes and the information that was lost back and forth between the hospital and the input back into her record was unfortunate.

And I think if you look at certification you need to look at what is that primary care at doctor's record looking like, what does that hospital record look like?

So I really feel that the patient record needs to be able to ingest the information coming from other settings even though those settings are not eligible providers. So, if you look at it from that point-of-view yes there is the ability to control some things under Meaningful Use.

The exchange component is key you've got to be able to exchange this data electronically from one care setting to another care setting and you have – there is a Wild West out there and it's not – I know from the hospice perspective there's really no system that works perfectly in a setting, in that setting, I sit on the board of a hospice, a large hospice so it's difficult to find appropriate things.

I think we have an opportunity here to give, if we can't use Meaningful Use, we can at least give a good housekeeping seal of approval kind of thing that there is a way to do certification that does than give vendors the ability to go out and say yes I'm certified in this environment and the market will follow.

So, perhaps there is the ability to help the market move in a certain way. So, I would go first with exchange of data that's the key thing being able to follow that continuum of care.

Secondly, I would look at making sure that all EHRs can ingest the information coming from other settings whether they're behavioral health settings and now under the ACA behavioral health is a covered expense through your insurance policy. So, there is going to be more information coming into that record.

And thirdly, I would make sure that we include specifically and look to see how in the behavioral health arena, how you deal with the privacy and security that's key and we have lots of different state laws that impact privacy and security not just at the federal level but there are also state laws that impact that. The records need to be able to ingest those records as well. Thank you.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Thanks, Gayle.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Thanks. Jacob?

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
Thank you Larry, thank you Paul and Gayle these are great comments. I wanted to provide a little bit of context for some of what Larry and team were commissioned to do and I wanted to make sure that everybody knew that this group did work because ONC asked it to do this work and part of the reason that ONC asked this group to do this work is because in the RFI that we put out last spring we had an overwhelming call for certification for these care delivery settings.

So, this is in response to a market that said to us, and we have heard over and over again from these sectors of that care delivery market place that they want the, as Gayle described, seal of approval. As recently as a couple of weeks ago, not saying that this is the next item, but the pharmacist said to us, hey our systems can't be certified and we want our systems to be certified and it for, as Paul was describing, the context of interoperability. We want our systems to do that and if our vendors say they do it, we don't know that they're tested in order to do these sorts of things.

So, it's the certification, which as Gayle described, is the seal of approval which gives them that confidence to buy products that do the things that the vendors say that they do and so there's been a question that I think has been raised is, does ONC have the authority to do this and the answer is absolutely we do.

And I think, you know, as Paul described there has been a conflation of Meaningful Use and certification historically, as Larry put in his initial slide, there has been this deliberate alignment of certification and Meaningful Use. And yet that historical alignment need not be what happens forever and Meaningful Use is one program but it's not the only program that could leverage a Health IT certification program.

And so we explicitly have the authority and I'm going to read what our lawyers wrote for me. The Office of the National Coordinator has the authority to develop programs "for the voluntary certification of health information technology." So that is not constrained to that would be leveraged by the Meaningful Use Incentive Program. It is an explicit program so that we can certify health information technology for the use in many programs.

And there are many programs for example the Accountable Care Program or the State Innovation Model Program, or as Larry described other states that may want to take advantage of certification that go beyond the Meaningful Use Incentive Program.

And so that's just a little bit of context I wanted to clarify that these things are not forever conflated. They are in fact autonomous, interdependent and yet could take different complimentary paths going forward.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Thanks Jacob. Paul Egerman did you have a –

**Paul Egerman – Businessman/Software Entrepreneur**
Yeah, before –

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Yeah, Judy, go ahead.

**Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation**
The overlap where they're not autonomous and independent is could be who is doing the development and I think as we talk about new areas of work and I was just thinking as Christine had mentioned, the reports have to be – that go out to the patient have to be readable, understandable, being able to see them in different ways and I was thinking how many programmers that takes just for that one comment.

And then when we add this I think if you have – if you're looking at the standalone long-term care vendors then they will have free programmers to do this but my worry is watching the number of vendors who've dropped off from Stage 1 to Stage 2 and then if we add this I think there needs to be some consideration of how big a task is it because that is where you have the overlap and will you then get poor results, poor quality or just many more vendors dropping out can it really be done. I'm not against doing it I'm thinking that the timing on doing it is very important.

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

**Paul Egerman – Businessman/Software Entrepreneur**
Yes, I wanted to briefly respond about the comments that both Gayle and Jacob made about certification being a good housekeeping seal of approval. I mean, that's not what ONC certification is right now. ONC certification, if you buy a certified product it just means the purchaser has software that enables it to meet the Meaningful Use requirements and also to do information exchange.

It doesn't mean anything at all about the quality of the product and it was like never intended to do that. I mean, Larry showed the 2009 slides, I did that presentation and we were very clear in that presentation this is not a good housekeeping seal of approval it is sort of a minimalist approach to make sure that the software will be able to meet these requirements.

And I think it's a big leap to change the certification program or to create a new one that has that capability and I even question whether or not the government is capable of doing it. And the reason why I question it is the certification process by the government has to be completely objective. You have to have a process that's like published if you pass this test your certified.

It's got to be completely objective and if you're going to be doing good housekeeping seal of approval you've got to have some subjective quality where people have some sense of things, you know, customer satisfaction, vendor stability. There will be a whole series of things that one would have to have and that's not what this certification program, government certification program should be all about.

This should not be a good housekeeping seal of approval. That should not be the expectation. We should even be clear in not labeling that purchasers should not expect ONC certification to mean anything other than very specific minimal things.

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

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
So, I completely agree Paul and I think the concept of good housekeeping seal of approval might have been a translation, you know, it's a vernacular it's not what we meant. So, when I talk to my mom about the Meaningful Use Incentive Program I actually use the metaphor for the inspection of a car before we go our driver's test we have to have our car inspected, there are very explicit, very concrete tests that the car needs to meet, we take it to a service station and we get these things tested that is what we're talking about here.

We're not talking about the quality, we're not talking about necessarily the usability or the look and feel. All of those things are potentially subjective. So, I am agreeing with you and perhaps we misspoke in using that term good housekeeping seal of approval for this program.

And so if it were to be extended beyond the Meaningful Use Incentive Program it would, as you described earlier, be very focused on very specific, very objective, very important components that systems that are not currently used by so-called Meaningful Use eligibles look for in the capabilities of their tools, right?

They want to, as Judy was saying, somebody who uses the system that they are not currently an eligible provider in the Meaningful Use Incentive Program still want to be able to send and receive data and I think that's all we're talking about here.

**Paul Egerman – Businessman/Software Entrepreneur**
And that's great. I agree with that. The only part that has me concerned is I agree with what you say but it's not the same thing I see in those slides or what I'm hearing in the Workgroup discussions. But what you say is what I agree with. If it's limited and focused that's what it should be.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay, so I'll go Gayle, Troy, David, Judy.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
Thank you, I wanted to jump in also Paul because I think when I use the term good housekeeping seal of approval, it's exactly what you're saying, it is not that term it is saying that this meets a standard. We need a new term other than that, but it meets the standards that are set by ONC and that the information that is coming from those records is then consumable within a certified EHR.

And that you have those interoperability standards that are there and that it's usable information. I think the long-term care people would very much like that to be part of what they are buying and they want to know that the information that they have in their records can be used by that primary care doctor, and that they can also get the information from the primary care doctor and have it within their record in a usable way.

So, perhaps using an inappropriate term that has other connotations but what it does when you do that kind of certification for people who are not eligible under the Meaningful Use Program what you're doing is saying this is a product that I know is going to work and it has the seal, the ONC seal of approval or ONC seal of interoperability, or whatever kind of seal you want to call it but it has the same kind of things in that when people who are not going to get money as an incentive to use it they're going to go and look for it.

And I think this is going to create a market out there and let the market, let the private market go out and sell it and they're going to want to be certified. They're going to look – because the purchaser is going to want to see that certification.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So it sounds like an ONC HIE compliance certification rather than a goodness. Judy?

**Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation**
Just real quick, I think that we can't – that one of the things that we have to narrow on is, what is the definition of long-term care and behavioral health because it's just simply too big?

And we had asked Larry once to come present at Epic just because we didn't understand it and Larry you had I don't know maybe 10-12 different words up there, I'm not going to get them all long-term acute care, long-term care, skilled nursing, transitional care, nursing homes, rehab it's all the ones I can remember right now, but I think that they each have differences and I think that the importance of either having a short amount of information that consistent across all or more for one and pick ones is going to be important because I agree as it was written up there and as we're talking about it seems to be two different things.

And I appreciate the whole concept that wow if it's all of those things it's huge. Does that make sense?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Thank you.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
It sounds like there's agreement with what you were saying Jacob with certain modifications. Is that fair around the table? That the certification would be not of goodness or of the product functionality but really you're focused on exchange of information in a way that can be consumed by EHRs who are certified under the Meaningful Use Program not that it has to – I mean because there's this – there is a cast of vendors who are certified as Meaningful Use certified not that this other certification has to be tied to that, but the purpose is to join this crowd.

**Paul Egerman – Businessman/Software Entrepreneur**
Along with security standards that are also in the EHR I think –

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

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
I would agree Paul. I think a key piece that I want to make sure that we don't gloss over is that there are markets that have expressed to ONC that they need confidence, and I think this is what Gayle was getting at, they need confidence that the products that they purchasing can do the things that must be done.

Exchange is one thing as Paul described, privacy and security is another and I would just say there may, over the course of the next number of months, weeks, years or decades be things that go beyond interoperability that may become in scope.

So, I want to just go on record as saying, today there seems to be consensus that interoperability and security are two important components of that, but as we have thought about – say for example accountable care I mentioned earlier, there are Accountable Care Organizations that need capabilities that, as we are discovering with our friends at CMS, they have expectations of their health information technology that are not being met by the tools that they've purchased and this is a surprise to them when they purchased these tools and they say, gosh my tool can't do population health the way that my vendor said it should or the way that my vendor salesperson told me it would. And so –

**Paul Egerman – Businessman/Software Entrepreneur**
That's a different problem.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
This is again back to confidence, right? So, is there a market failure here and is there a need for someone and we know that there is another organization that, outside of the ONC's certified ACB Program that other organization has created a certification program that describes certain functionality that one would require in an accountable care setting.

Is there a market need and I raise that just because I want to make sure that folks understand that we have been asked to look at those potential market failures and that certification beyond the Meaningful Use Incentive Program may be an option there and I just want to be explicit that we've been asked that and not skate over that as we all nod our heads about interoperability and security being the scope.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So that's good and your charge to Certification and Adoption Workgroup includes just the limited scope or the broader?

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
Yeah, I can interject, we spent – this is Judy Murphy. So, we spent a lot of time here talking about what this group thinks, but I feel like we didn't hear what the Certification and Adoption Workgroup actually thought initially.

You know, Larry spent a fair amount time talking about framework and how the work was going to get done, but not really about the content. So, I am kind of curious Larry, exactly where the Workgroup came down on this. Again, limited versus broad?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
There was a blizzard of e-mails. So, I would say the Workgroup represents both ends of that spectrum. I also want to bring forward that I've heard from some of the behavioral health agencies inside of HHS that they're looking for certification as part of a grant process so that they provide a lot of grant supports to behavioral health and they're saying that if those systems are using – I'm a little bit putting words in their mouth, they haven't said it quite this bluntly, but if they're putting requirements into their grants that we expect you to have electronic records they would like a certification program to go with those records so that they can say, okay we know at least to some degree, some minimum bar that you're spending your money, you're spending our money on systems that will meet some minimum.

And, you know, it could be in the end we say the minimum is interoperability and security but I don't know yet we haven't had input from behavioral health yet. But, you know, we're very focused on the things we've done which is great, which was mostly Meaningful Use, but it's not the only way in which the federal government spends money and it's not the only requirements, there are federal and state requirements that are increasingly looking at encouraging all healthcare providers to use EHRs with the belief that it improves patient safety, that it helps manage cost, that it improves coordination of care.

And so I think there is going to be this balance of – I think there is pretty broad agreement on interoperability. There is not broad agreement on the other areas.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
So you are going to continue to vet that out?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Yes.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
With the group –

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Yes.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
And try to achieve consensus on some limited number potentially?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
So, yes.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
I think Elise is staff to that group and has something to say.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Yes.

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

**Elise Anthony – Senior Policy Advisor for Meaningful Use – Office of the National Coordinator**
Yeah, I was actually just going to reiterate the point that Judy just made. So, the charge was twofold. So, we're at this point just having finished the five factor framework and Larry jump in if I have this incorrect in terms of how you see it, but the goal now is to examine the specific settings of LTPAC and BH, and behavioral health, and I think that's where we'll get into the specific areas of what is truly needed, how small of the bucket, how small the bucket should be and what it should contain and that would take into account the views of the settings themselves.

The way the Workgroup has set it up is that there will be a hearing next week, as mentioned, but also a number of different presenters will talk about what they're seeing in the LTPAC and in the behavioral health field and I think to Judy's point as well one of the things that we've tried to do with the Workgroup and they've been really good about doing is looking at the different areas of LTPAC so not just from one perspective in terms of post-acute care or rehabilitation centers, but also looking at what clinicians specifically are saying, what the patient groups are saying and so forth and we look forward to hearing more, from ONC's perspective, look forward to hearing more from that at the hearing.

And I know the Workgroup will be considering that going forward. So, hopefully that provides a little bit of clarification on where we are in this process.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay, thanks and Paul Egerman?

**Paul Egerman – Businessman/Software Entrepreneur**
Yes, thanks, I just wanted to comment briefly on something that Jacob said and also perhaps something that you said, Elise, when you think about what the needs of users are, I mean, it's great that we listen to their needs but certification in my opinion should only be about certifying things that are ready operational someplace. It's not a tool, certification should be viewed as a tool to design the computer system of our dreams.

In other words this is not a tool to say, we're going to listen to users and now we're going to create certification and that will somehow cause that to be built, it's got to be – certification has to be around things that are already operational.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Any other comments or questions? Michelle?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
I just want to confirm for today's presentation I think part of the goal was to confirm the five factor framework and make sure that that's a good path forward. So, Larry could you go to slide eight and just see if there is consensus at least to move forward with that framework as the Workgroup moves forward with LTPAC and behavioral health.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
I have – can someone else flip the slides?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Slide eight.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Wrong slide deck.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
That's fine.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
No we're on a different slide deck.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So the only thing that I think Jacob brought up that's not, maybe not on this unless you read in under national priority, is Jacob was saying the market is driving this. The needs that are expressed by the market which are attempting to serve the needs of patients are driving this. I suppose you could put that under national priority.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Or stakeholder support.

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

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
We're hearing from stakeholders in the marketplace that there is value here for this.

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

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
And I think, you know, I didn't include some of the things we heard during the first LTPAC sessions because I wanted to bring that together as a bundle. But I thought it was telling that of the vendors selling into that space some of them have gotten modular certification, a couple are more broadly selling their products and have complete certification.

But I think there's a lot to be learned from which criteria people have certified against and which ones they haven't and where they're doing information exchange using products that aren't certified and to understand how that's played out.

You know we created a program that was really crafted around eligible hospitals and eligible professionals and identified a core set of common requirements and I would like us to consider, as we go forward, that those common requirements maybe get modified in small ways as we look at needs in other settings or differences and use in other settings that might say, you know, for example, to pick on one thing that's of high-value to pediatrics growth charts not a lot of value in nursing centers because people are not growing anymore they're actually shrinking in general.

And growth charts are a complex thing. So, I could see where people could say, you know, I can report all the vital signs, I do report that today, I collect them from people, I can graph them and do all kinds of things but not on a growth chart.

So, there may be some very specific things, so there is feedback on this criteria have changed a little bit wouldn't require additional programmers to create it because they already do it and would allow me to say "yes I do that" and perhaps we would actually be able to have a core set of criteria that could be used in many care settings and would be a base for building on for future programs as well.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay. Devin?

**Devin M. Mann, MD, MS – Assistant Professor; Attending Physician – Boston University School of Medicine; Boston Medical Center**
The five factors the Chevron diagram is meant to be non-hierarchal?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Yes.

**Devin M. Mann, MD, MS – Assistant Professor; Attending Physician – Boston University School of Medicine; Boston Medical Center**
Okay. So, you want to make sure that's really clear because the way it was presented sort of gave a feeling that there was a kind of sequence to this and it could be very well, for a lot of these behavioral health providers and other areas, that any of these could be first priority and so then if your reasoning process goes forward, you know, do you stop the moment it doesn't hit one of these factors or you do keep going and average them out? I mean, what's the kind of process you think will happen? I mean, it's good to have these five.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Right.

**Devin M. Mann, MD, MS – Assistant Professor; Attending Physician – Boston University School of Medicine; Boston Medical Center**
But what's the algorithm?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
So, I don't think got as tight as an algorithm. I think we were looking to say how do we get ONC to look at the landscape of things that ought to be considered and when it presents future certification programs that it be able to justify them broadly and say that there's a broad reason for doing this and that these sort of cover that. So, it was more that sense rather than, you know, some scoring methodology that might say you're above a threshold so go forward and create the program or you're not.

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

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Gayle, final question?

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
Yeah, I just want to make one more comment and ask Larry, when you're talking about privacy and security and the interoperability I'm assuming that would fall within the aligned – .with existing federal/state programs.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Yes.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
To make sure that they would be covered under the certification process as well. And also relative to your comment on growth charts. We do have many children with very critically complex medical issues in nursing homes. There are long-term care settings for many children and they're just not elderly people.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Well, I think this has been a very helpful and clarifying discussion. One, just to make clear that ONC does have the authority clearly to have a certification program it can be independent of Meaningful Use. It's interesting that I think some of the market clamoring forward is motivated by some of the success in Meaningful Use despite the challenges of certification.

And that the scope for the Workgroup is actually not limited and part of your recommendation is how should you, if at all, limit the certification program as you look into these "MU ineligible" groups. But hopefully that's clarified at least what we're talking, the topic even and we look forward to your recommendations. Thanks, Larry.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**
Thanks.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
And thank you everyone for helping us to get close to schedule. So we have – we have time for public comment.

## Public Comment

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Yes, so quickly, operator if you could please open the lines and while the operator opens the line if there is anyone in the room that has a public comment please make sure that you keep your public comment to 3 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.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
And so we have public comment in the room. Why don't you go first?

**Gary L. Dickinson – Director, Healthcare Standards – CentriHealth**
Okay, I'm Gary Dickinson Director of Healthcare Standards at CentriHealth. I'm also Co-Chair of the HL7 EHR Workgroup and I would point out that we've had an EHR system functional model in place since we got a request from the VA, ASPE, HIMSS and our Robert Wood Johnson Foundation actually in 2003 to develop such a thing.

And the certification program that was put in place by CCHIT starting in 2004/2005 on through 2009 was actually based substantially, in terms of the conformance – in terms of certification criteria on the conformance criteria of the HL7 EHR system functional model.

And since 2009 of course with the Meaningful Use Stages 1 and 2 coming into play the certification has been or US-based certification, in any case, has been based largely around what is required for Meaningful Use certification and no longer references the HL7 EHR system functional model as the basis for that certification criteria.

Meanwhile, HL7 has continued to work on the model. There is now release 2 which is just completing ballot with HL7 and five international partners are jointly balloting that particular standard. It is known in that space as ISO 10781, it's the same system functional model that we had in place previously but in fact has added a number of additional functions and criteria since the earlier version release 1 and release 1.1 which go back to 19, I'm sorry, go back to 2006/2008 timeframe.

I would point out that we have functional profiles in place although they're not updated to the most recent version for behavioral health, for long-term care, for pharmacy and for child health which are four of the subject areas or care settings that were mentioned in the previous discussion.

So, I would invite you to take a look at the work that has been done, again it needs to be brought up to the current release of the functional model but in fact a significant amount of work has been focused on these particular areas of practice and care settings that might be useful to the discussion you are considering at this point. Thank you.

**Mari Savickis – Assistant Director, Medical Affairs - American Medical Association**
Hi, I'm Mari Savickis of the American Medical Association and have an awful cold, but I'm going to power through. You guys covered a lot of ground today and I have a few comments I'll try to limit them to 2 minutes.

Let me start first the risk analysis. We know that that's a problem for our physicians and we know that they're missing the mark on this. And we want to continue to work with you to come up with ways that they can meet this.

The AMA has a free toolkit on our website on the privacy and security requirements for the Omnibus Rule and we also link to all of your YouTube videos and the games and we're promoting this very widely but one thing that would be really helpful, and I know there is a lot of reluctance to do this, is a checklist.

I know it's sort of like the third rail but at least as a starting point with maybe a big fat disclaimer that would say this is the be-all end-all but physicians need more black and white guidelines as to how they're going to meet the risk assessment because they're going to continue to fail it if they don't know what they're being held to, especially the small practitioners.

So, I would just re-urge and plead to HHS, ONC, OCR, CMS to help work with us. I'm a little reluctant to do that because I want to make sure that it meets the HHS standard, but I'm happy to do that together with you, so that is one thing.

The second thing is I would like to thank CMS and ONC for being such good listeners. I appreciate all the listening you've been doing recently with respect to what we would consider constructive feedback on Meaningful Use.

One of the things we talked about today was a certification and I just want to mention something that I mentioned at the last meeting but I know you all have laptops so you can all go to Google, come on click, click, click and Google Rand Physician Satisfaction okay.

The AMA was looking to do something that would support one of our core objectives which is to support payment and delivery reform by increasing physician satisfaction and one of the things that they found in the report as they were studying this and it was not aimed at all at EHRs was that there is a significant level of dissatisfaction with the EHRs, the usability and Meaningful Use.

And this is not a finger-pointing exercise at the vendors it is a problem that we have to work through together and so when we talk about the seal of approval, physicians are looking for help with use of these programs, because if they don't get systems that work for them better they're going to continue to miss Meaningful Use.

And then my last point would be, I guess it's more aimed at CMS, is on the data and we're trying to parse through this Rob is the dropouts. Okay, we know from speaking to the internist and the primary care doctors that they are dropping out and these are the early adopters.

I know we won't have data, hard data for 2013 until next summer, early next summer, but it would be helpful to aggregate data that CMS provides as people, physicians, EPs who have received a payment at some point in time it doesn't tell you if you met it in 2011, dropped out in 2012, met it again in 2013.

So, we need to see the dropout rate and that's what I'm referring to is recidivism. So, it would be helpful if we start seeing that then we can do some course corrections here, but again we –

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
I'm sorry your 3 minutes are up.

**Mari Savickis – Assistant Director, Medical Affairs - American Medical Association**
I have a lot to say. We want to work continuously with you. So, thanks Rob, thanks Jacob, Judy, I'm missing everyone, but thank you.

**Richard D. Brennan, Jr., MA – Vice President of Technology & Policy – National Association for Home Care & Hospice**
Good afternoon my name is Richard Brennan I'm the Vice President of Technology Policy for the National Association for Home Care and Hospice and also Executive Director of our affiliated Home Care Technology Association of America and also a committed member of the Standards and Interoperability S&I Framework or Standards in Longitudinal Care Coordination.

I just wanted to make sure that you are hearing from committed members of this effort here just to give you a quick background on home health pre-Meaningful Use, our members were adopted at 43 percent rate of electronic health records that far exceeded any other industry as far as the physicians and also the hospitals. Of course then as everybody knows we were overlooked by the incentive program.

However, that doesn't stop us from trying to make sure that there is interoperability and companionship with Meaningful Use, in fact we worked with the certification for commission for health information technology to come up with a companion program that is a completely private program, it is a voluntary certification program, however, we've had a limited amount of vendors that have been able to – that have obtained that certification so that is one problem that we are actually looking for ONC to help with.

We feel that an ONC certification would provide some value to the providers and help the selection of these tools and also still enable the diversity that exists within home care to allow our vendors to be able to operate and deliver tools for specialties such as hospice and others that are within our space.

But, again, I just want you to know that long-term post-acute care even though we're all lumped together is not the same and home health is a standout as far as I'm concerned. What I'm concerned about is that there are new models of care from the Affordable Care Act that are requiring certified EHRs of providers to participate in those programs.

There are also States such as Minnesota that was brought up, that is requiring an ONC certified EHR or an equivalent functional EHR that has both functionality such as a CPOE and also transmission standards with the ability to send and receive summary of care records built into those requirements that take effect in January 2015.

So, we are running out of time for the federal government to initiate a program but appreciate, again the time that you are taking to look at this topic and think of it as a very important topic to look at and we are willing to help in any way possible to advance this cause. Thank you.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thank you and we have two additional commenters on the phone. Do, we want to start with Carol Bickford?

**Carol Bickford, PhD, RN-BC – American Nurses Association**
This is Carol Bickford from the American Nurses Association. I wanted to remind you as the group goes forward on a certification with panels and testimony to be sure that healthcare consumers and their families are incorporated in that public testimony, that nurse administrators who are the key drivers in the long-term care space, the home health nurses, advanced practice registered nurses and nurse case managers, as well as social workers are included in the cohort who provide the full spectrum of the stakeholder conversation.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thank you Carol. Is Chantal on the line as well?

**Chantal Worrall – American Hospital Association**
Good afternoon, can you hear me?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
We can hear you.

**Chantal Worrall – American Hospital Association**
Great, thank you so much for the opportunity to comment and I apologize that I can't be there in person. I just wanted to reflect a bit on the data that was presented by CMS this morning and compare it to a recent report from the Government Accountability Office or GAO.

As you all know the EHR Incentive Program has very specific requirements on hospitals and that includes a testing each and every year. We're now in the fourth year of the program and the hospitals have had the opportunity to attest for each of 2011, 2012 and 2013. However, the data presented to you is always cumulative and is not separated by year and it's really not clear how those data count hospitals that have attested more than one year.

In contrast on October 24th GAO released a report were it looked at hospitals successfully attesting and being paid for each of 2011 and 2012 separately. In contrast to the numbers you heard this morning GAO found that only 48 percent of hospitals attested to Meaningful Use and received a Medicare incentive payment for fiscal 2012. Among critical access hospitals the share was only 29 percent or 386 of 1300 CAHs.

GAO could not look at 2013 because, as Rob noted, the fiscal year ended September 30th and attestation closed last week.

I would recommend that the committee request that all future data presentation mirror the requirements on providers and look at each year separately. I would also invite the committee to look at GAO report, the number is GAO-14-21R.

With my remaining minute I would also like to reflect on the ONC data regarding certifications. Again, the metric presented to this group is not the same as the requirement on providers. Specifically, ONC presented data about vendors with a base EHR certified. The base EHR is necessary but not sufficient for a provider to meet Meaningful Use. In fact, it covers less than half of the objective needed to meet Meaningful Use.

The definition of a base EHR does not include any of the menu items nor does it include a number of core measures. For example, a base EHR has not been certified for a patient portal that supports view, download or transmit nor has it been certified for any of the public health reporting objectives.

In addition, base EHR certification only requires a vendor to support a single quality measure and not the full set providers must report on, again, a single quality measure.

I would recommend that the committee ask ONC to also present data on complete certified EHRs which do include all of the objectives, however, even those complete certified EHRs are only held responsible for supporting a single quality measure. As of this morning the CHAPL reported –

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thank you, Chantal, your time is up.

**Chantal Worrall – American Hospital Association**
Fifteen complete certified EHRs from nine vendors for the hospital space. We're very supportive of the goals of the program –

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
I'm sorry, I've got to cut you off, I apologize.

**Chantal Worzala – American Hospital Association**
We're proud of the hospital's hard work.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
So, we are well over our planned time for lunch. So, maybe we can make it up on the other end. I know Christine is very efficient and maybe we can help ask her to hurry us along. Paul, what time would like us to come back from lunch?

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Yeah, it's impossible to come back in a half hour so what about 1:40 for lunch? Thank you.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
If everyone could take their seats we're going to get started.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Welcome back and we certainly understand – are people on the phone?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Do you want to open? Operator can we please open the lines?

**Operator**
All lines are open with the public.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay, welcome back and apologize for the delay, it's pretty hard to eat in 40 minutes. Go ahead?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Jacob has something to say.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Jacob has something to say, all right and we'll start off with something – a pronouncement from Jacob.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
Pronouncement maybe it's an announcement. I just wanted to let folks know that one of the ONC team who has been an extraordinary value to this group in particular and ONC as a whole has decided to move on and retire from her current role and so I just wanted to publicly express ONC and the HIT Policy Committee's gratitude to Mary Jo Deering for her years of service, congratulate her on all that she has done and all that she will do to improve the quality and efficiency of care in the United States. So thank you Mary Jo for your service and this is your last Policy Committee meeting?

**Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology**
It is.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
It is indeed.

**Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology**
So, I'll be in the audience.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
So, she'll be in the audience.

**W**
–

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**
So, thank you Mary Jo Deering for your service.

*Applause.*
**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Good, thank you. So we're going to – we have two report outs this afternoon. The first is going to be from a combination of Consumer Empowerment Workgroup and the Consumer Technology Workgroup under the Policy and the Standards Committee respectively and Christine I believe is going to lead us through this discussion on Patient Generated Health Data.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes, great, thank you and do we have Leslie on the phone?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Yes, I am.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great, thank you. Well, I know Leslie will join me in saying this Mary Jo you have staffed this Workgroup, you and a number of other folks, but you've been one of the primary and we're very grateful for that. But I will say personally that I have worked with you for a number of years now and there is just no better consumer advocate in ONC and probably in the federal government frankly then you. I mean, you really get it, it's in your heart and I am very grateful for all of your years of service. So, thank you.

All right so I'm going to dive in. So, we haven't talked to you guys in a while but you may recall that there is a Workgroup called the Consumer Empowerment Workgroup and it is a Workgroup of the Policy Committee. There is a sister Workgroup, if you will, called the Consumer Technology Workgroup which is a Workgroup of the Standards Committee. So, let me see if I can work this slide, bingo.

So, we were asked by the Meaningful Use Workgroup to take a look at the recommendations and the functional criteria around patient generated health data and to identify any particular policy issues that might need addressing and in Leslie's case the standard issues in order to facilitate more widespread use of patient generated data.

So to refresh your memory, we had two recommendations that relate to PGHD one was, as you see on the slide, that patients have the ability to electronically submit health information usually focused on or completely focused on structured or semi-structured questionnaires.

The second piece was around providing an obvious or an easy way for consumers to request an amendment to their record online and so that also is of course a form of patient generated health data. So, we held a listening session actually over the summer and have done a lot of work since.

And we started in that session by hearing a definition of patient generated health data. It's a term that can mean many things to many people but the one that we've adopted comes from a paper commissioned by ONC done by RTI and it says the following, patient generated health data are in fact health data, so history, symptoms, biometric data etcetera, that are created, recorded, gathered or inferred by or from patients or their designees to help address a health concern.

They are distinct from data generated in a clinical setting in two big ways. One, patients are primarily responsible for capturing or recording the data as opposed to clinicians. And number two, that patients are the ones that would direct the sharing or distribution of the data to the health care providers or the health system.

So, they are a compliment to clinical data but a little bit different in their source and who distributes them. So, what we heard from the hearing was, number one, patient generated health data is not a new thing it's already part of the record today. We get it in treatment histories, we get it through patient reported outcomes, etcetera. And there are a lot of mechanisms for collecting it.

We had some testimony from an organization that had looked at the environment and who today is collecting patient generated health data electronically and they identified secure messaging, surveys, and device data as some of the predominant ways that patient generated health data are collected today.

We also learned that there are four things that providers need to be able to do with patient generated health data. They need to be able to receive it obviously, look at it, review it, respond to it and record it and by respond I mean acknowledge back to the patient that the data was received that's actually important because otherwise you'll get a lot of e-mails or phone calls, you know, did you get it, did you get it?

And then of course record the data which are pertinent to the situation at hand or that they would like to keep in the record, which doesn't necessarily mean always everything. We also heard that implementation of really well done patient generated health data requires that providers have workflows and clear policies and procedures that sets mutual expectations around how patient generated health data will be handled and that those policies and procedures are really communicated to patients and families and ideally developed in collaboration with them.

So, one of the quotes we had was that when patient generated health data is implemented appropriately then concerns are really addressed and PGHD use becomes very routine.

We also heard about liability. As you know there is a concern, particularly about sort of unrequested patient generated health data and how, you know, you might just sort of, you know, turn the faucet on and get this volume of data and the provider might be liable for looking at all of it and what do they do with it and how do they react to it?

But what we heard was in fact when there is a mutually agreed-upon specified set of information to be shared then there are likely to be workflow and policies and procedures designed around handling that and that's really how the Meaningful Use Stage 3 functional criterion is set up.

It is designed to be something where the provider ideally in collaboration with patients and families would say, the data that I would find most valuable, the patient generated data, would be, you know, this, blood pressure reading from home monitoring devices or whatever and so therefore I want that and I'm going to choose to ask patients for it and we're going to develop some work flow and policies and procedures around it.

We also had a speaker from OCR who talked about HIPAA because obviously the amendments component of this discussion is relevant here and we I think originally thought that HIPAA sort of required more than it did in terms of corrections and amendments. So, what we came to understand though was that HIPAA does provide a very good floor but it should not be considered a ceiling.

And then finally, patients and providers – it was very clear from the testimony that both – all of us really want the same thing which is high quality, accurate health information but we need to do, you know, some work to make it easier and make sure that we're ready.

So at that point the Workgroup turned to our sister Workgroup the Technology Workgroup of the Standards Committee and asked them a series of questions like are we ready for consumer device data or biometric data etcetera? Do we have what we need in order – in Meaningful Use, in the certification criteria in order for providers to be able to receive the data, review it, respond and record, right, those four things that I mentioned.

So I'm going to turn it over to Leslie and Leslie I can help you with slides, who is going to talk a little bit about her work with the Standards Group and then I'll come back at the end with a set of recommendations. So, Leslie?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Great, thanks, Christine, thank you. So, when we took a look at this information we wanted to make sure that we were reviewing standards that already existed that was our bias, can we repurpose and reuse standards that are existing, that are in use and that can be adapted to use for patients and their designees.

So we used the NwHIN guide and we looked to existing standards. We sought advice that helped us to determine that if something has a high adoption and a high maturity level for provider use and even those who got very low maturity level and low adoption for patient use, should we consider that somewhere as middle-of-the-road and the answer was "yes" in fact we should.

So with that lens we looked at standards that existed and had been rated as either highly adopted or maturity level or had already been named in Meaningful Use. So, that's the lens that we looked for. Next slide. I don't see the next slide, so –

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
It's up on our screen Leslie, on slide seven?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Yeah, I'm still, there we go, there we go, got it. So, if look at the top level, from left to right is a continuum of patient generated health data, the first being messaging, the second is structured questionnaire. Third we move now into unstructured questionnaire which might have some very structured fields with a narrative open to an individual, device data and then we move towards care plans which might be an individual care plan and its response, all the way to a collaborative care record which could be an umbrella care plan or care plans together used over a long period of time with the patient or an episode of care.

So, from left to right then we looked at what kind of standards are available today that we should consider? We assumed that the common Meaningful Use data sets standards and vocabulary would be part of the consideration. We felt that Direct with its adoption in Meaningful Use 2 had the prime opportunity to be considered in this next round and for patient generated health data.

We know that there is work is still to be done but there is a huge promise already with the work being done in Direct and the work being done to develop a trusted framework that can apply to patients. We then looked at the work being done in the HL7 Consolidated CDA and this work was started about a year and a half ago to look at how patients and their designees could be integrated into this structure.

And in fact the Consolidated CDA was modified at the header level to now include patients and their designees. Why that is important is it means that this is not a separate but equal data stream, this is really a data stream where there are many members of the care team including the patients and their designees as well as the professionals that can contribute to the health record. So we felt that that information the Consolidated CDA with these modifications would be able to be used for patient generated health data.

We also looked at the HL7 care team roster which has been harmonized in the Consolidated CDA as well as the longitudinal care team and felt that that was a great building block for future care planning, collaborative care records and so forth without knowing who people are and the roles they play we really can't build to more of a collaborative environment. We felt this was a good first step but advanced care planning in this context was probably not ready for prime time standards as yet. But the HL7 care team roster would be a good place to start.

There was considerable discussion around standards for device data and we had received information and testimony from continua standards. We also received feedback from the Standards Committee and there is a resistance to name a particular standard until, I think there is further discussion, because this has a very fast moving target in the consumer world.

The group acknowledged that data coming out of an EHR is very, very likely to be informed by consumer product standards or more sort of industry agnostic standards as we are seeing the Blue Button establish and the work that's being done in FHIR.

However, data going into an EHR is most likely going to be provider centric and so we need to look at how we reconcile these two worlds acknowledging that by using standards upfront there is an opportunity for us to get more consumer data, more device data into a record then without those standards. So there is some continued work to be done there. Next slide.

So, we made some recommendations and one is that ONC should consider the Direct transport standard for secure messaging and can be used within device data. We should consider the HL7 care team roster standard and the HL7 Consolidated CDA for structured and unstructured questionnaires. This distinction was important there was absolutely no argument about the need to have information provided by a patient at the request of a provider.

So, a patient response, a questionnaire meets that quite well and there was no argument as to the importance of that information in a record things like medication reconciliation to help with care, things that are helping with information about demographic changes and so forth are all easily addressed through structured and unstructured questionnaires.

And we should continue to consider and deliberate around device data. I think there is still discussion that needs to be made there and we also want to encourage standards that support mobile access to patient's data for patient generated health data, however, we don't recommend a standard at this point because we think it might stifle innovation and there is – most organizations are moving towards responsive design that's more agnostic to a particular device type. Next slide please.

So, we also feel there is a really great opportunity to look at a collaborative care document or collaborative care structure that can consider versioning, expanded provenance, reconciliation, data governance and the idea of data curation or curating and this would apply whether or not the patient was involved in that team or not.

But adding the patient and their designee to the care team means that we really need to carefully consider how collaborative care records might take place. This will be very important in informing our ACO initiatives and also informing population health in the future.

We also believe there is an opportunity to align consumer products and provider standards in a more meaningful way and an opportunity to meet and convene about that should be considered. And then also taking a look at some of the work being done on API approach with the Blue Button that could help to accommodate patient generated health data and acknowledge the need for a continued trust framework to be expanded for the consumer and the patient adoption.

For instance as we are using in the Blue Button Plus as the patient becomes more involved than making sure that there is an opportunity to be trusted in the digital ecosystem and we should consider at a future date consumer vocabularies that will support wider consumer and patient and family engagement and the integration of that data more easily back into the record. Christine, I think it is your slide next.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes, indeed, thank you. So, fortunately for you guys you are the Policy Committee not the Standards Committee so you don't have to weigh in on that set, that set of recommendations will go back to the Standards Committee, but what Leslie just told us is that essentially they were able to identify a set of standards that facilitate readiness for patient generated health data in Meaningful Use Stage 3 which is exciting and perhaps we're more ready than we thought when the Meaningful Use Workgroup originally created the menu item.

So, we have a number of recommendations. So, first is that we are ready for the patient generated health data in Meaningful Use but that we actually think you can expand the objective to give providers credit for additional options for incorporating patient generated data so they should be able to not just have to do it – or not just do a secure – I'm sorry a structured survey or semi-structured survey but also do secure messaging or provider approved devices that those should really be different channels that they can choose from among in order to complete the menu item.

So second, being indeed we are really ready as well for the certification criteria around giving patients a way to submit amendments or corrections, or requests for amendments online. And we also wanted to be very clear about the fact that these recommendations apply to both criteria.

So third, EHR technology should enable providers to receive, review, respond and record including amendments and corrections and what we heard from Leslie is that there are standards for those functions and that for provider organizations who choose the PGHD menu item in Stage 3 we do recommend that they establish policies and procedures for handling that data during implementation including, but not limited to, what is the content of the patient generated data that they want, that they will receive, how are they going to receive it? Whether it's the, you know, sort of three above, right, secure message, device or a survey of some kind. How they're going to go about reviewing, acknowledging and recording it.

Also one of the things that we want to encourage is that providers need to actually collaborate with patients to implement the way that they are going to manage patient generated health data because if it doesn't fit into the patient's workflow it's likely going to cause problems in the provider's workflow.

And then also one of the things that we heard that is happening in the field was just sort of a cautionary note that when patient generated data comes into the record and it is flagged as being patient generated that if those data are later shared with other entities such as for treatment, payment or operations that tag needs to go with the data.

And then in terms of implementation our recommendation is that ONC needs to work through all of its channels as well as collaborating with federal partners to really give providers clear guidance on how best to implement patient generated health data and the Meaningful Use requirement in particular and there has been a lot of work that has been done on this.

ONC did convene a – has convened a technical expert panel that has done some terrific work and given some guidance around work flow and implementation issues and so our recommendation is really to get that information out into the field, building on that technical expert panel and to use the mechanisms that ONC has like ONC and CMS websites and tip sheets and the Regional Extension Centers, the Learning Consortium, etcetera.

At the end of the day, we think that new policies are not in fact needed for patient generated health data in Meaningful Use Stage 3 as it's constructed there. HIPAA will govern the data that is in the record and that will include patient generated data. But for the future there is some work that needs to be done, number one, you heard Leslie talk about consumer device versus sort of a provider approved device. We're not ready for consumer device data. So we've got some work to do there.

We also have some work to do with the liability and policy and work flow issues around unsolicited patient generated health data so what happens when a patient wants to share lots of their Fitbit data or some other device data for example and it is literally turning on the fire hose, there is just a lot of work to do there, but that's not needed now because again in Meaningful Use the provider, hopefully in collaboration with the patient, is in fact selecting the data type.

And then almost finally, second to last, there is a lot of work going on to provide patients with interoperable direct e-mail addresses. That was one of the things that was identified as a real enabler for patient generated health data is that patients have a direct e-mail address and so we want to encourage that work to continue.

And then finally, there is a lot, a huge need to do some more work around shared care plans in particular, from a policy perspective not just a standards perspective. How do you handle version control? How do you reconcile across versions? How do you harmonize? How do you know you have the latest, etcetera? And then also, as I mentioned, more work around the inclusion of consumer device data. So, I will open up for questions.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Good, thanks, Christine and Leslie. I have one – in your first recommendation you had provider approved device and you had an asterisk and I don't think you explained that.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Oh, there was an asterisk there. Did we forget the text box? We sure did. So, I think it was intended to explain these are, you know, the devices that a provider might use in practice, you know, whether it's a home monitoring device or another thing.

The words "provider approved" are something that we kind of made up and I think that's been a challenge. But that's not necessarily Fibits, etcetera it's something that's really initiated by the providers because that's where most of the continua standards govern.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So, I think the other discussion we had in the Workgroup is that was also to flag contingency on what the Standards Committee came back with the terms of whether –

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes, right, right, right.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
The standards were not only exist were they implementable and were they adopted.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes that's correct.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Other questions from the group, David?

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**
I have the same thing and wonder how this provider approved language relates to the new FDA guidelines on medical Apps or medical devices that are coming from the consumer space. So, they've issued recently guidelines on safety in these kinds of extra clinical devices if you will. I don't know if you've considered those?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
We did not. I think we viewed those as more in the lane of consumer devices than, you know, kind of what we would traditionally think of around, you know, home monitoring for blood pressure or weight, etcetera but where the provider is going to be in the loop of, you know, issuing the device, etcetera and would therefore have the systems connectivity in his or her office. So we did not go down that path because we felt like we weren't ready for consumer applications.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**
Yeah, I guess the reason the FDA issued those guidelines as I understood it was that they were intended for devices or Apps that were being used for diagnosis or treatment at a minimum and so some of those are what you might think of as consumer and some are not and so, anyway, you might want to monitor that situation.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
I think that's an excellent point.

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

**Paul Egerman – Businessman/Software Entrepreneur**
Yes, thanks, great work Christine and Leslie on an important topic. I got an e-mail, a few of us got an e-mail from Judy Faulkner who had to leave and in the e-mail she raised a few comments that I thought were interesting so I thought I would mention it.

One of them is earlier in the presentation you talked about devices and Direct and then in your, I think, first recommendation you say, secure messaging, but her comment is, you know, Direct and secure messaging that seems to imply e-mail services which is really how Direct works, but that's probably not the right interface or the right transport technology for something like a blood pressure cuff, you know, a lot of these devices don't have the ability to do that kind of messaging and so, you might –

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
That's probably a wording issue but the standards – the opportunity can exist where devices can use Direct as a transport mechanism as an e-mail message structure. So, we weren't trying to be as prescriptive as more of an example and we used secure messaging, at least from the standards point-of-view to say what kind of standards are available for secure messaging and that's why Direct was mentioned.

**Paul Egerman – Businessman/Software Entrepreneur**
Okay and then there is –

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So, I would add though Paul that the definition of patient generated health data is broad. So you can imagine that secure messaging might be the preferred mechanism for a provider to collect information about, you know, lifestyle choices or symptoms or something like that. They might prefer to do it on a survey. But the three kinds of options, if you will, were driven by the fact that that's how it's happening in the field today. So it might not be the best for certain types of patient generated health data but by allowing the provider to choose the mechanism and the data type then they can match those up most appropriately.

**Paul Egerman – Businessman/Software Entrepreneur**
Yeah and that's fine, just the observation that for some devices that may not work.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes.

**Paul Egerman – Businessman/Software Entrepreneur**
And the other observation that's and interesting one is if these devices are FDA regulated there's a part, as I understand it, the FDA regulations that say if you connect to a regulated device then you become the regulated device and so that might be a barrier that would cause some EHR vendors to not want to do this.

And it's something that has not been like rigorously enforced by the FDA, but it is something you think about, because, you know as a vendor you know about it and so it might be an area where ONC could be helpful by getting some clarification about how that issue might be viewed for these devices, if there was some clarification on that issue.

And then there was one other issue that she raised which is in your recommendation six on patient generated health data, basically you say sourcing of that data should apply if those data are later shared for treatment, payment or operations which makes sense, but don't you also need the source to be clearly identified when any of that data is viewed internally for treatment not just for sharing, you need to know that you're looking at patient generated health data.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yeah, so I did say that but I think it's not written here so we can make that clarification.

**Paul Egerman – Businessman/Software Entrepreneur**
Okay, thanks.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yeah.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator**
I would like to clarify on the point that Paul, made that same issue came up in the context of the FDASIA Workgroup concerns about the FDA provision that if something is connected to an FDA approved device it becomes an FDA approved device and there was a request from that, you know, from the results of that Workgroup's activities and officially from the Policy Committee to provide guidance on that as well. So, that's something that's now come up in two different contexts so we'll make sure to work with the FDA on that.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Keeping in mind that the FDASIA – the recommendations that came out of David Bates work were completed just before the actual release of the guidance on mobile medical Apps for example.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Correct.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
So, the fact that you're looking into sort of how this all fits together is going, I think, to be really important, yeah.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Another question on the provider approved devices. If it is – well so the certification program wouldn't know what is a provider approved device because I think you meant that – this provider is approving this device for this patient. I think that's what you meant right?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes or even selecting would be another word.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Correct, yeah. So, the certification criteria wouldn't that automatically invoke an EHR vendor would have to attach to all devices since they have no idea what's going to be "approved or selected" for a given patient.

And again, the standards I think is going – well the – all the information we got before this time where the standards were not at all adopted, the continua standards were not at all adopted for a variety of reasons. So, nervous about invoking something that is either not adopted or immature and the fact that it would apply to all devices and I don't know how you would limit that.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Right and I recall you raising that as well at the Workgroup level and Leslie you may want to weigh in, but I think the best plan of action is to provide the policy recommendations to the Standards Committee as we always do and make sure that that indeed is possible.

We might though consider changing provider approved to provider selected or, you know, something like that because it's a little more clear, but I understand that. So, Leslie, I don't know if you want to add anything?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Yeah, I do think we need to work on this there is a varying degree of opinion. There is also opportunity to look at some pilots but there is some future work to be done to get through this. There is a high degree of desire to have this type of patient generated data included it's just are the standards helping to provide innovation or limiting it, are the standards ready for primetime and we need to deliberate more on that.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So, I think what I would say is the recommendation really needs to focus on it is still accurate to say we're ready for patient generated health data through surveys, we're ready for PGHD through secure messaging, we're getting conflicting advice and we think we're ready for provider selected devices, I know that the Policy Committee, a number of members of congress, and others have received a letter recently from device manufacturers saying "yeah, we are ready, we have standards." So, we need to kind of cut through the noise on that. And then if that is the case go ahead and add that to the Meaningful Use criterion around patient generated health data.

**Paul Egerman – Businessman/Software Entrepreneur**
So, is it premature to include devices in the recommendation now though?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
No, I think that that's what the asterisks was sort of meant to be which is the Standards Committee Workgroup has said we are ready for provider selected devices and they've done some preliminary work with the Standards Committee but they need to go back and have the final full discussion there, but given the timeline that Meaningful Use is moving forward on in terms of bringing back recommendations to the Policy Committee we wanted to have that included and then have the Standards Committee tell us if that's absolutely not realistic at this time.

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

**Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health**
Yes, thank you Christine and Leslie. I'm trying to understand the first point and the third point. The first point to me from the Workgroup discussion seemed to be more that there were some options that you didn't have to do all of them.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Correct.

**Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health**
All right, but in the third point you say how to – let's see the third is you record all patient generated health data. So, is the option there or is it – I don't know how to reconcile those two.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Oh, okay, I see what you're saying Art. No that's not what we intended. What we were trying to say is EHR technology needs to have the functionality for receive, review, respond and record period not necessarily every piece of patient generated data under the sun but it's really under – it is whatever would be chosen under the menu objectives.

**Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health**
So, maybe you could just refer to that?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So, we can just clarify.

**Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health**
Yeah.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yeah we can clarify that.

**Paul Egerman – Businessman/Software Entrepreneur**
So, when you say the standards are there for these functions are you referring to the amendments and corrections or are you referring to receive, review and respond?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Receive, review, respond and record and that's what you heard in Leslie's presentation was the going through all the standards that enable that, that those are definitely there.

**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, I'm a little confused also so maybe you can help clarify this for me Christine or maybe Leslie is the one. These would be certification requirements for an EHR that they have the ability to consume patient generated data that is structured questionnaire, it is device information coming from a selected device and that they would be able to use all of that within all EHRs, it's a certification requirement. Would that – on the device section of it would that mean – would the vendor then have to have the ability to consume all devices or would there be selected devices that they would be certified to consume the information from?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So, good question and that's essentially what Paul was asking earlier and that's what we need for the Standards Committee to weigh in on. Does that make sense?

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
Yes, because, you know, that is a huge burden if you're talking about – there are many different types of insulin monitors, there are many types of blood pressure monitors and things of that sort.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Right.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
So, would the standard have to be – does that have an impact on the manufacturer –

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
I – you know, I can't –

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

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yeah, I can't speak to that I don't know if Leslie can only because – well, I'm not a technical person but I think connecting directly to the device versus what I think Judy was raising which is maybe the device sends a message using a Direct transport standard which the EHR can consume, I can't speak to how it would be done that's really what – the policy recommendation is designed to trigger the Standards Committee to make sure that it is doable and we've gotten some early – we asked the Technology Workgroup to take this on because we needed to get some early feedback on whether that was possible.

One of the things that we heard in the hearing was a very clear call to include devices and people saying "we're ready" and other people saying "well, we're not" and, you know, and so that's why Leslie's Workgroup did do that work and that will go before the Standards Committee.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
And the same question goes for questionnaire, structured questionnaire, how who is going to decide what's within the structured questionnaire?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Leslie, do you want to answer that?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Yeah, so the Consolidated CDA in general whether it's used for a patient or provider generated data allows for different structured templates and today under the patient generated health data portion of that standard we have templates for questionnaires, we have templates for a variety of different things that might be amended, corrected and so forth. So the template structure is there.

By modifying the Consolidated CDA in a way we have at that high level it gives us an opportunity to constrain future document types always to include the patient and their designee. So, we inherit all of the benefits of the Consolidated CDA going forward anything that's there for the provider would be there for the patient.

So, the structure is there but of course there is no mandate that says what the content has to be there is just a structure to create a questionnaire and a response to that questionnaire to be included within the record.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
One more question if I may a follow on?

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Yes, go ahead.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
Now you really did not address unstructured information. Do you anticipate having some kind of ability for the record to consume unstructured information?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
We felt that right now where we could get unstructured information were two ways, one is it comes in quite successfully under secure messaging whether that secure message is coming in through a portal functionality or an untethered PHR that's a habit today.

The other opportunity is using a structured framework like a – consider an envelope or a structure that says it's this type of data where the patient can then enter an unstructured narrative within it those are both accommodated. But the idea of a structured for a completely unstructured response we felt was premature and not needed today simply because of the secure messaging capabilities within a portal.

**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**
I wonder if I could ask a question about the statements around standards as well, because I'm not sure we're all talking about the same level of standards. So, when you refer to a structure or section Leslie and not content, a little nervous whether we're accomplishing what we need to in terms of incorporating some of these device data into an EHR in a way they can be used and operated on inside the EHR.

And the other thing and this goes to Art's, some of these maybe not consistent, so in three you say the standards are there for these functions and you refer to the functions receive, review, respond and record?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Well it's anything that the Consolidated CDA has today, it has for the patient in this one. So, today if you get an inbound Consolidated CDA you have to see the EHR structure is there to say "yeah, I acknowledge that, I've got that." I have the ability to respond. I have the ability to do anything with that that I could in any other type of response. So, it's the same.

Now some organizations will choose to do that within their App and some for their particular portal and use the Consolidated CDA to transport back and forth.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So, I'm not sure that's the same thing as I think we mean by standards and being able to use.

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

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Which is to make use of rather than to just transport a container –

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Yeah, because if you have data that comes in at the actual field level it's completely consumable, it's the same structure as you would get from another provider, it's just now you have the additional information on who generated it, if the patient generated it their role, time, date stamp and so forth.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Paul what we were talking about in this case is, you know, obviously it's going to come in, okay, so we've established that, review, right, that's a pretty basic function that's already existing, responding to it so that the patient knows you've got it and what Leslie is saying is that the Consolidated CDA does enable that and then recording or, you know, brining in the pieces that you need from that.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
But here's one of the differences –

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
And changing it –

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Here's one of the differences, let's say it can deliver, it can transport results from a clinical lab for example. If it's coming from the whole PG, the patient generated has a different nuance to it, so there is a function, we've talked about it in the past, of a provider may receive it, but there is a function of sort of incorporated into the EHR that is not true of labs and that was one of the things we wanted to get at. There is sort of a staging that happens with patient generated data that doesn't occur with the clinical lab.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
I don't understand that Paul.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Correct, with a clinical lab you've got an order and an order response you can accept it directly into the record it comes in. With this particular structure it assumes that there is someone who accepts it into the record.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
It assumes you're going to accept it right away?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
It assumes someone is going to, you know, that there is an active mechanism that says I'd accept it or not.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
And that's built into the standard?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
That is capable within the standard, it is not – it's a knowledge within the standard. The function would happen within the EHR. But we assume – it's just as you described Paul with the lab you assume that something is coming in with an order and an order response that will zoom it, it's not necessarily tethered into an inbox for someone to review this would be coming into an inbox or require it to be – it has the ability to be consumed but it does not assume that it is going in automatically. Does that make sense?

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So, you're saying this standard specifically for PGHD has it transported – has it incorporated – it goes to an inbox rather than gets filed automatically is that what you're saying?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
It has the same structure as any other Consolidated CDA coming inbound which is not like your example of the clinical lab where it goes in with an automatic response to an order. So, I think we're covered I'm probably just not describing it in a good way but I feel confident in it.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So, but, you know, again, I don't want to get hung up in the standards debate because we're the Policy Committee so what we needed to do though was to sort of make sure that our policy recommendations were feasible and we believe we've done that with the help of, you know, Leslie's Workgroup and then that will make the rest of its way through the Standards Committee.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So, I think the one missing step is getting the Standards Committee to hear Leslie's Workgroup report and then adopting or –

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Right, that's what I'm talking about that's what I mean about they need to go to the Standards Committee.

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

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
And that needs to complete the rest of that process. They've done some early work already, Leslie has presented, but again, because of the timing we needed to come first with the policy recommendation so that we could not hold them up since Meaningful Use is trying to move forward in the next month or so.

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

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Okay?

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Other questions or comments?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Jodi has one.

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

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator**
Thank you, so this is great work Christine and Leslie. I'm really impressed with the amount of work that you all went through to come up with this and I have been in and out on some of the conversation so I know I was part of some of the debate that was going on.

I just wanted to highlight one thing. I know that this was based on an ask of the Meaningful Use Workgroup to talk about what's right for Stage 3 and to help think that through but based on some of the questions that were coming up about remote devices and the like I just wanted to be clear that the charge of the Consumer Empowerment Workgroup is not necessarily limited to Meaningful Use Stage 3 and the charge for the Health IT Policy Committee is not necessarily limited to Meaningful Use it is broader.

And so to the extent that there is recommendations that may be coming out that, while this may not be right for Stage 3 but this is something ONC should do or this is something we'd want to pursue that those recommendations would be perfectly within scope and that this committee and the Workgroup is in fact charged with a much broader portfolio than just recommendations on Meaningful Use.

So, if there are some issues where based on conversation, you know, this is not just – maybe it's not Meaningful Use Stage 3 but important stuff that should be done even if it is not tied to the incentives program or things that we may want to put in as functionality for EHR technology that those are appropriate conversations to be having.

We look to this committee to provide us advice broadly on Health IT policy and health information technology infrastructure and health information exchange and we get input from our other federal partners on things that they want us to get insights from and, you know, we hope to bring more and more of that to this group as time goes on.

So I just wanted to put that in there so that as we're having this conversation if there are things that you have been discussing that go beyond Meaningful Use or may not, you know, kind of be tied to the Meaningful Use Incentive Program that those would be appropriate as well.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yeah, thank you very much and actually much of this last slide is exactly that, right, so I mean, I think there is some very acute need around care planning and how we advance that ball, etcetera.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
I think Paul –

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Judy?

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
**So along that same line, I got a little worried when I got to slide nine and I don't know if it would be easy to go back. Slide 8 had very specific recommendations that I believe were the standards that were actually being thought of related to Stage 3, but when we get to this one, I'm thinking that this "recommendations for development" actually means beyond Stage 3.**
**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
Because almost none of those could get done in time for Stage 3.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Correct.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**
Is that right Leslie?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Absolutely, Judy. Absolutely we just recognize that this keeps coming up over and over again that when you include the patient in the ecosystem then things – there are new things that happen, people want to talk about stuff, they want more collaboration that takes place. And the need for collaborative care structure for documents is going to be needed for the ACOs, it's going to be needed for population health, it's going to be needed just when you expand beyond the four walls of your organization.

Now add the patient and their family member we really need to get a handle on how we manage sort of that virtual document structure or a collaborative care platform that could help form a very broad interoperability use rather than the sort of asynchronous move a document here get it back mode. Is there a way to elevate that and think about collaborative care in a new way and that is a longer-term project but I'm very encouraged by the level of interest that's already been shown by Doug and others to advance those ideas.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
The recommendation that impact's Meaningful Use number one under your policy?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
I'm sorry, can you say the first part, I didn't hear what you said.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay, if you go to the slide with the first policy, yeah, is that your – is number one your main recommendation that impacts Meaningful Use recommendations –

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes, I think that is the essential one, yes.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay and then the strong –

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
And I think I would just say also to note that amendments and corrections piece which was covered in number two is important to say yes, you know, that's a good idea we're ready for that and then there are some other things that we need to do in terms of implementation.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Could you advance two more slides to the one with 10 on it, oh, no, there we go 11, that last statement you said that the standards group was recommending Continua, I think probably that you didn't intend that to be in our policy recommendations right?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
You're correct.

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

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes, thanks.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Yes, good catch, thank you.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay. So, you would like approval of number one or all of these?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Well, I think all of them with the modifications that we have talked about. So, I think we have the clarification that Art raised, we had a clarification that Paul raised, we had – I need to fill in the, you know, asterisk thing, so with those three. I think –

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
And then this one about the standards? Yes. How does the group feel? Is there a motion to approve the policy side?

**M**
Motion.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Any further discussion? All approve?

**W/M**
Aye.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Oppose? And abstain? Thank you Christine and Leslie.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Thank you.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Okay our final discussion is an update report from the Quality Measure Workgroup represented by Helen Burstin and Terry Cullen. I don't know whether Terry is –

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
No, Terry is not available.

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

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
So, it's just me. Hi everybody. We're really glad to be back again. Last time we talked to you about the deeming issue and we've really tried to roll with some of that into sort of a broader conversation as was suggested to think about the right concepts for Meaningful Use Stage 3. I do want to thank Kevin and Lauren in particular for a lot of great staff support here. So, oh, I have the slides, here we go.

So, again, at the November discussion there was general support for the deeming proposal but it was pretty clear that there was not a lot of clarity of how that would the operationalized so there was recommendation that we go back and really think about after the Meaningful Use Workgroup discussion that we really focus more on concepts and gaps specifically for Meaningful Use Stage 3 as deeming will not be further pursued at this time.

So, nonetheless though I thought it was important to include two of the slides we shared with you at the last discussion about deeming because I think this is still to a certain extent sort of the Holy Grail of where we want to go in terms of the ultimate measurement. I didn't want to lose sight of it. I think this is still the recommended framework it was just very difficult, at least point in time, to think about how you

operationalize that to eligible providers and eligible hospitals.

But still I think the big core areas here of moving to outcomes particularly patient centered outcomes understanding issues around utilization and costs are all things that are themes that you'll see come forward but again this broader framework I still think personally still fits quite well to at least the vision of where we want to go.

Secondly, these were the deeming criteria we had put in front of you. And again I'd make the argument again these were actually quite good as we think about the criteria we might want to use to think about which measures we should push forward with in terms of development and use for Meaningful Use Stage 3, particularly that first section on the left here which is specifically that we want to make sure that these quality measures with leveraged data from HIT systems, for example CDS, we want to increasingly make sure we get to those patient focused longitudinal care measures which will require interoperability and sharing of data across sites as well as across different types of data as you'll see both EHR and claims as an example. And we want to ultimately be able to support more of the work around health risk status assessments and outcomes.

The second column there was more the ones that had emerged out of the ACO Subgroup which you'll hear from next month in their hearing tomorrow, but more at the population health level, but I still think some of these might be applicable as we move forward as well that as much as possible we'd like to have a preference for measures that can be used across multiple programs, can be applicable to populations and certainly where benefit outweighs burden and promotes the sense of shared accountability, being able to see data across sites and providers for example.

So, onto the brief presentation so we took a slightly different tack and there is so much data here about measures currently under development, a lot of work that's gone on that we actually decided to send a survey to each of the Quality Measure Workgroup members to get their input on the measure concepts and potential objectives for Meaningful Use Stage 3.

What I'll share with you is an early compilation of about 10 or 11 folk's recommendations and we'll continue these discussions but wanted to sort of get a sense today of what would be directionally appropriate and get your input.

So, this is a somewhat busy slide but Lauren did a great job of actually being able to put so much information on a single slide. So, this shows the major domains listed here on the slide. They're a little difficult to read in the black there I apologize, but for example, care coordination, patient safety.

The ones that are marked in red, the sub-domains in red are specifically the ones where there are no current measures under development even though those have been identified as priority areas in the past.

The yellow area has been a bit of development one to three concept somewhere in the development process and the green ones are where there are at least three and even within those when you actually start to dive deeper even the ones that are green sometimes don't go quite as far as I think many of us would hope they would go, perhaps in iterations going for.

But this was sort of the backdrop for where we are and I think you'll see there is still unfortunately a great deal of red, particularly in patient safety, particularly in person and family centered care and around some of the issues of appropriateness.

So, a few high-level thoughts and Paul asked me to keep this brief so I will. Here are a few of the subdomains. We specifically asked the committee to identify, the Workgroup if there are any other subdomains that weren't on that prior slide that we should really put forward and here are a couple of highlights.

Several people emphasized how under population and public health we should think about community health measures that would be meaningful at the point of care for the providers. No additional subdomains for a few of them and a lot of focus around care coordination as being pretty complex obviously and wanting to add some important subdomains here which was not just that you had a care plan or that it was a shared care plan but are you actually managing to that shared care plan as sort of going further perhaps.

And even perhaps going further than that, that given the realities of care coordination it should be a multi-provider care planning and execution rather than it being single person, single provider. There was also interest obviously in – you heard some of this just from the previous presentation around patient and family engagement and particularly wanting more domains, subdomains and work around shared decision-making and patient understanding, experience of care and patient and family governance of decisions. So, lots of good work there.

And again, if you look here these were the highlighted gap areas from our previous work and here were some of the concepts that were identified by the group. So, the first couple were around equity and population health. There were some folks who made the comment that perhaps we didn't need new measures around equity but what we need to do is we make sure that we can consistently capture the variables we need to stratify our current measure to be able to look at disparities and reliably and consistently capture that data in our systems.

That we want population metrics meaningful at the point of care. A move from sort of basic management to really optimal management. Are we achieving the highest possible outcomes for patients? A lot of interest in appropriateness of care not surprisingly and a follow-up comment from Kate Goodrich for example linked that specifically to thinking about for example appropriateness measures and overuse measures linked to the choosing wisely campaign and there really being some opportunity there.

Patient safety and particularly patient safety defect rates. There was also a comment about the need for more in the ambulatory patient safety space especially around procedural ambulatory safety, measures again that cut across that brought patient centered episode of care, patient reported outcomes and not just functional status for patient experience but actually patient reports on some of the other critical domains like care coordination.

Cardiovascular risk, beyond just can you assess it but getting towards patient activation and achievement of treatment goals. And then moving beyond having did you assess functional status to begin thinking about post-procedure status or recovery times and delta measures as well as we've talked about before. So this was the broad set of concepts that we heard about from the committee.

And we then asked a series of additional questions to hone in on a couple of topics we had been discussing over some time. So, the first again harkens back to the topic you've talked a lot about today around patient reported outcomes and we specifically queried the members of the Workgroup about whether they would support broad inclusion, broad support for inclusion of PROs as an objective and overwhelming the answer was yes.

And there was a sense that perhaps that could give us the ability to be not quite as prescriptive on specific tools or measures. There were a couple of concerns raised one specifically around not losing sight of how much work there is to do around the data infrastructure and a second comment which David Lansky had shared with me and he could probably elaborate on today which was really thinking about what are those functional and data management issues that would really help enable adoption of PROs and Meaningful Use Stage 3. So, a lot of foundational work not just focusing on the measures themselves but how do we actually get to the point where these can be used and adopted?

A couple of last slides here, risk adjustment and social determinants of health was another thing we queried the Workgroup about, very much strong sentiment that these variables should be collected and try to standardized as best we can and a couple of comments about leveraging existing tools to make sure we have that kind of information.

Hybrid measures was another issue that came up and specifically here the idea was being able to leverage both claims in EHR data to be able to get towards some measures for example of efficiency and other areas. Allow us to get towards attribution for crosscutting measures. For example a couple of people made the comment that it would allow us to hold teams of provider accountable as well.

Some recommendations, again more foundational work to be done is the need to map which elements from claims and which from clinical data are of most importance to the outcomes desired. One isn't always necessarily better depending on what you're looking for. Utilization certainly is often best done with claims for example.

To support QI we want to make sure that claims data is validated and available in a timely fashion, which is certainly not the case currently in most places. There is really a lack of maturity of these melded data sets although it's something we've talked about for a while and we need variables to help us link across those claims and EHR data sets to merge data and we specifically need time and data markers as well to make them meaningful.

Lastly, we had talked in the past about this idea of an innovation pathway and the idea here would be that potentially Meaningful Use participants could waive one or more of the objectives if they were able to have other approaches to get to higher level measures. So, a conservative approach might be a certified development organization for example. An alternative approach might open the process to any eligible provider or hospital but could constrain it in some ways.

So, we posed that to the group and there is general support continuing for the idea of an innovation pathway, a lot more work of, if you would like us to continue to think about how to further define what that innovation pathway looks like.

A couple of suggestions for example that perhaps you should specify that the gaps for the measures for that innovation pathway should specifically be the gaps we need to close anyway. And then a thought about thinking about how this then links up to the broader efforts to consider where are the gaps in meaningful and useful measures for example for specialties and others to make sure we're moving towards an aligned set of gaps and closing those gaps and with that I'll turn it back over to you Paul.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Great. Thank you Helen. Reactions from the group? Gayle?

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
A couple of questions, first of all when you look at, I believe it's slide five, and you're showing the green, the yellow, and the red domains, various measures that are under development. The ones that are green I assume have – these already have e-Measures in place? These are e-Measures we're talking about?

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
Yes.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**
This is Kevin Larsen, yes that's correct.

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

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
Although some of them may not be fully developed yet. They may be in process or they may be more concepts.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**
Correct, well some of these are already in Meaningful Use 1 and 2 and then some are under development by CMS and others in HHS for a timeline of MU3.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
So they will be present for Meaningful Use 3, yes?

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**
They will be ready in time for rulemaking for Meaningful Use 3.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
And they will have been validated? There is a validation process.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**
They will – like the Meaningful Use 2 measures they have the same process that we went through with those measures so there is always a validation step in that process. We can go into detail about those sort of particular challenges of getting things ready for the timelines but they will have the same kind of process as MU2.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
Second, my next question is – in those areas where you have very few measures that are available, are these going to be menu areas where people do not have to select them? And if they don't fit their particular practice area are there going to be options?

Does Meaningful Use Stage 3 anticipate various options for selecting especially when areas – for instance, population health or, you know, patient engagement you have minimal standards in place. You know what's going to be the flexibility in order to meet Meaningful Use Stage 3?

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
I'll defer to Kevin or Jacob.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**
So, I think that's the kind of question up for discussion here at this committee that this group is to give us advice, the government, about what you recommend and so that's why we're bringing this to the committee.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
This is very problematic, very problematic.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
I feel like David should go first he's the quality guy. I'll put mine in the queue but it may be answer by the time you get to me.

**David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health**
No, go ahead Deven.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
Well, my only question – my only thought was that this is sort of part of the bigger picture of Meaningful Use Stage 3, right, that we're going to have to consider in terms of sort of the criteria, how much we're going to be able to accomplish through deeming, to what extent will measures help us get to the sort of outcome based piece that we are looking for?

So, in some respects this sort of feels a bit premature to dive into this but this is helpful information for when we have the bigger conversation about what Stage 3 should look like.

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
And some of that also may be related to the fairly significant lag time for getting some of these developed, so getting something in the queue even if you're not fully ready to say this is the one we'll use is important to start on this path I think is some of it.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
So, this might be a good time to interject another overwrite, it's basically to echo what Jodi and Jacob said before about this committee. One, this is HIT Policy Committee. Policy recommendations to the government about HIT policy broadly, we've certainly spent a lot of our time in Meaningful Use because it has had $30 billion behind it.

But so in the context of this or even the prior discussion it's generally how are we going to deal with quality measures which you know is and becoming more important and more significant in payment reform.

Consumer generated health data important, going to be more important. We've made and I've a comment for Christine's presentation, you know, what's the recommendation for MU 3 only because that's the most time urgent thing not because that's the only thing we're going to deal with respect to patient generated health data.

So, the same thing for this, the Quality Measure Workgroup, yes, we're sort of on the same trajectory, in other words, coming up with some final recommendations, final thoughts in January that isn't the final time we can even be making statements they still have years even, you know, even after we render some kind of sort of opinion and we have the NPRM to respond to.

So, there are multiple opportunities. We just were trying to do our first recommendations by January. Quality measures is something that's going to be with us for a long time and ascending in importance. So, what Helen and Terry are working on is what is the pathway, the trajectory, the roadmap for improving quality measures which we're so unsatisfied with today sets and so what you've heard is – and like this – so the subdomains currently is – I guess what I heard Kevin say is that this is stuff that we either had in the earlier stages or it is in the pipeline.

And then you saw two more slides that said, well even the Workgroup has come up with gaps that we need to work on and they're getting feedback on, hmm are they are on the right track, are these the gaps that we're more interested in like shared care planning, you know, the engagement, population measures? If so then their charge is how do we develop a strategy for filling those gaps in a systematic way. And I think that's the question, partly the question that's being called.

So, I think we all want to make sure that we satisfy the initial opportunity which is Meaningful Use 3 and are on a trajectory to getting better and better measures. Is that a fair statement then? So with that in mind, let me continue. I think David Lansky was next and then Devin?

**David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health**
Thanks. Thanks Helen. I think this is really good stuff and it's going in the right direction. I'm wondering, I'm thinking about Christine's presentation and Leslie's which took a different slant toward the acquisition of patient generated data. And the slant that was interesting was doing that standard's analysis what's currently available.

And part, as you know, one of my concerns is that we probably I think should focus less on the measures as an HIT Policy Committee because other people will decide what to measure and what to pay for and all of that and focus more on the capabilities of the IT platform to produce those measures.

And if there was a way to take this slide that we're looking at and kind of slice through it on a sort of CT scan and say what is the underlying capabilities that are needed in the IT environment to produce these data or these types of data and what can we do to stimulate the vendors and the providers to have that capability in a generic way, it will be a little bit, Paul, like our plug-and-play discussion we keep having, that would be a really productive exercise to try to launch the industry in a direction which is more flexible and capable of generating a variety of measures as the environment calls for them which we can't predict today.

We know some things like we're going to need longitudinal measures, we're going to need data from multiple settings to be integrated. We're going to need data from patients as well as data from clinical systems. And we have to be able to produce a variety of measures from that ecosystem. So I would love to hear – to see some work done to focus less on what measures fill each cell and more what capabilities are needed to propagate measures for a variety of purposes.

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
I think that would be a great suggestion David and I think it's something that the Workgroup would really embrace and in some way of having this is as the roadmap and then working backwards to think about the functionality this gives you also a nice reality test of what's even feasible. And what the timeline would likely be for that functionality to be in place. Agree.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Devin? The other Devin.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
This is going to be hard for me to get used to.

**Devin M. Mann, MD, MS – Assistant Professor; Attending Physician – Boston University School of Medicine; Boston Medical Center**
It doesn't happen that often I have to be honest.

**Deven McGraw, JD, MPH, LLM – Director – Center for Democracy & Technology**
And you too I'm sure.

**Devin M. Mann, MD, MS – Assistant Professor; Attending Physician – Boston University School of Medicine; Boston Medical Center**
This is really neat work and actually I'm really thick in these kind of issues with our EMR implementation right now at our hospital. One area that I'm sure is somewhere in here, I'm just not sure which category you guys think of this as, but it's very important to me is kind of the provider side of the satisfaction burden and kind of efficiencies. Where does that subdomain really lie in your mind? And how do we make that a quality measure as we roll out these additional requirements?

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
That's an excellent point and certainly we've thought a lot about that around feasibility and the feasibility of underlying these measures. I think because this is specifically the electronic quality clinical measures, clinical quality measures there hasn't really been as much of a focus on anything that's not a clinical measure per se as part of this Workgroup, certainly not beyond that. But, again if this is something you'd want the group to talk about we'd be happy to be to.

**Devin M. Mann, MD, MS – Assistant Professor; Attending Physician – Boston University School of Medicine; Boston Medical Center**
Right, yeah, because when I see things like efficient use of facilities I think that's as clinical as, you know, efficient use of provider's time or efficient usability that supports, you know, kind of practitioners type of license, all these things we keep talking about and until it becomes a quality measure I have a feeling it just doesn't quite get the same airplay is it maybe should.

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
Excellent point.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Gayle you're about to put your –

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
One more question. Is the Workgroup working with our other federal partners, CMS in particular, when you look at things like PQRS and trying to make these quality measures, the e-Quality measures work into other payment systems or incentive programs and whatever so we avoid some of the duplication of reporting and things of that sort. Are you, as you really start coming down and defining these –

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
Absolutely.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**
And pushing to have the development of them. I would assume that's part of the goal so that you can eliminate some of the duplication of reporting.

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
Yes and we specifically have CMS as part of the Workgroup actually even reached out specifically to Kate yesterday to make sure I got her sense of what is important because we do want to make sure that those streams come together.

It's also just, you know, from a quality measurement perspective it's hard to imagine how you could measure many of these gap areas on this list with anything but an electronic data platform. We haven't been able to do it claims. We haven't been able to do it paper. So in some ways this is the future of quality measurement period not just going back to this point again, its' not just Meaningful Use, it really is sort of the future of performance measurement broadly.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
Any other questions? Thank you Helen. So, it sounds like you are in the right path and just need it done by next month.

**Helen Burstin, MD, MPH, FACP – Senior Vice President for Performance Measures – National Quality Forum**
Okay, we'll work straight through the holidays.

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
You know, I'm going to take the opportunity – this has been a very constructive and productive day I think. It's interesting that the morning has been a lot of sort of the timely things that we have to meet like accounting of disclosures for example. And in the afternoon we've been working on more futures oriented things and just want to piggyback on my comment and then David Lansky's comment which is we're about HIT policy and as we look forward, this is the close of 2013, as we look forward to 2014 want to look at what strategic kinds of advice we can be giving.

We've been under such a timeline as ONC and CMS have been and we want to make sure we don't overlook the strategic or the global picture. So, one of the things we've mentioned in previous meetings is, yes we do get preoccupied with a lot of our urgent time sensitive policy recommendations and we still are as witnessed by today's full agenda but we also want to make sure that we don't overlook the bigger ones.

So, if you wouldn't mind submitting either to Michelle or me some of your items to tee up, particularly on the strategic nature then we'll try to tee up the homework to do in preparation so that we can have a more informed and productive discussion on these strategic areas, just don't want to forget that, but here's the, you know, the year-end request for all of these comments so that we can kick off and be at the gym in January and start working out towards our new resolutions.

But we want to make sure that we don't overlook that. So, if you wouldn't mind just taking some time and sending Michelle and me a copy of some of the topics you think we ought to look at from a strategic point-of-view we'll try to work those into our work plan for 2014.

So, you heard from the Consumer Workgroup about the need to – patient engagement is one of our top priorities. How can we step back and do a good job at that? Quality measures is definitely in our future, how do we do a better job at it? It certainly – someone was talking about burden. It is one of the things that people complain about the most and it may be one of the least appreciated. Let's do a better job at it.

We have an opportunity. We've got to get the systems. We've got to get the pipeline in place. And then the new models of care and the new payment models will all be upon us overnight virtually. So we have got to try to beat that timeline.

So, that's our wish for 2014. We are going to open for any other comments about either that or other suggestions as we wind down 2013 and go towards 2014. Why don't we open for public comment please?

## Public Comment

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Operator can you please open the lines? And while we do that if there is anyone in the room who would like to make a comment please come up to the table. As a reminder public comment is limited to 3 minutes. Thank you.

**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 – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
It looks like we have no public comments. So we ended on time who would have thought?

**Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation**
We pretty much ended on time. Thank you for your forbearance in a very full agenda. Thanks for your work in this entire 2013, wish you all Happy Holidays and see you in the New Year when we have another full agenda, but anyway, thank you very much.

**Paul Egerman – Businessman/Software Entrepreneur**
Great job.

## Public Comment Received During the Meeting

1. Would there be a separate certification for LTPAC and behavioral settings? the system needs (standards, patient data collection and workflows) are very different between these two settings.