



## HIT Policy Committee Final Transcript November 10, 2015

### Presentation

#### Operator

All lines are now bridged.

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

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is the meaning of the Health IT Policy Committee. This is a public meeting and there will be time for public comment at the end of today's meeting. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. Also as a reminder, we will have time for public comments before lunch and after lunch and it will be limited to three minutes. With that we'll go around the room to take role. Kathleen Blake is here but she is not seated at the moment so then we'll go over to David.

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

Here.

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

That's David Kotz.

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

Brent Snyder.

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

Troy Seagondollar.

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

Chris Lehmann.

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

Anjum Khurshid.

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

Jon White.

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

Paul Tang.

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

Gayle Harrell.

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

Kim Schofield.

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

John Scott.

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

And on the phone do we have Alicia Staley?

**Alicia C. Staley, MBA, MSIS – Patient Advocate, Co-Chair of Tufts Medical Center Patient & Family Advisory Council**

Yes.

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

And Scott Gottlieb?

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

Yes.

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

Anyone else on the phone?

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

Chesley Richards, CDC.

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

Hi, Chesley. Okay, with that I'll turn it over to...

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

Mike Lipinski, ONC.

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

...I'm sorry, who was that?

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

Mike Lipinski, ONC.

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

Hi, Mike.

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

Hello.

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

With that I'll turn it over to Jon and Paul to make some opening remarks.

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

This will be the shortest opening remarks ever. I am not Karen DeSalvo; Karen is unavoidably detained at HHS. So out of respect for the significant efforts that you all made to travel here, wanted somebody at ONC here and, in addition to the fine folks in the room; so here I am. I look forward to the meeting.

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

Thank you Jon. So this actually is an important informational and approval meeting. One, in the morning we're going to hear fr...as you recall last meeting when we were here, we got a bit of a surprise or a gift in the sense of a final rule on both Meaningful Use Stage 3 and the modification and the Certification Rule. So we're going to get report on both of those final rules this morning.

And then in the afternoon we're going to hear from the Advanced Health Models Workgroup, there was a task force that looked at certification requirements in support of advanced health models and so we've got some information from work that's been done by...led or at least charged by ONC to look at this and Joe Kimura's going to be reporting on that.

And then finally we had a taste of the interoperability report we have for Congress a couple of meetings ago and we have our final draft to present to you and get your feedback before turning that over to Congress in December. So that's how our agenda looks for today. I'll entertain a motion for approving the minutes from last time.

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

So moved.

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

Thank you and second?

**M**

Second.

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

Any further additions? All in favor?

**Multiple speakers**

Aye.

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

And any opposed or abstained? Thank you. Okay, why don't we turn it over to Rob Anthony, who's our friend from a while ago and he's back to talk to us about the Meaningful Use Stage 3 and modification final rule.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group - Centers for Medicare & Medicaid**

I've always been your friend not just from a while ago. So I'm going to do a brief overview of where we ended up on final rule, talk about a little bit of some things that I think have come up from folks and I want to make sure that people clarify or understand the clarification on this and we'll talk a little bit about numbers overall for the program as well.

Obviously this goes to the October 6 publication; we did include this link here for folks who want a direct link to where the final regulation is. This is published as a final rule with comment period. We do this on a somewhat regular basis with regulations at CMS, although we did not...have not done it previously with Meaningful Use, but where we see the potential for change and modifying because of what are the perceived issues or changing landscape in certain area, we do a final with comment period. And we are specifically soliciting comments on Stage 3.

And a lot of this, of course is related to not only where we ended up with on Stage 3, but also the impending MIPS regulation and how this will interact with that. So we wanted to keep things open with feedback so that we can consider as the sort of perfect storm of Stage 3 and MIPS come together at the exact same time.

So overall I think you'll see that we aligned with a single set of overall goals for the program. We had a real focus here on reducing burden for providers overall and that meant getting to a smaller set of overall objectives for people to focus on. And that meant really focusing, for us, on what were the high priority policy drivers for health IT.

We did synchronize to a single reporting period, that is also something that we had heard very much from different providers and we got to eventually, umm a, what we think of as a flat stage of Meaningful Use. In other words, we had previously talked about Meaningful Use as a step or a ladder, everybody starts at Stage 1 regardless of a year and you moved to Stage 2 and you moved to Stage 3. With what we've done with Stage 3 and with the Stage 1 and 2, the modifications rule as I'll call that, is get everybody to an aligned set of objectives so that everybody starts at the same place.

And we had had a lot of feedback I think that you've heard as well, especially for larger practices, multispecialty practices, practices that have a little bit more of all revolving door of people that come and go, it can be particularly challenging when you have providers at multiple stages and that was one of the things that we tried to synchronize on. But I do want to emphasize as we go through this that we really looked at what we thought were the high priority areas of health IT usage. So we really tried to focus on patient safety objectives, patient engagement objectives and that was engagement using health IT or the ability to engage with their electronic data and of course, interoperability.

So overall, the timeline sort of maps out like this, and I'll go through this very quickly but right now in 2015, one of the things that we have done is we've provided a 90 day reporting period for anybody; it is within the calendar year. We have moved hospitals, aligned them also to the calendar year. That does mean that hospitals actually can choose a 90 day reporting period within a 15 month period rather than a calendar year, because it does go back to October 1 of the previous year.

In 2016, everybody will be on a full calendar year reporting except, for new participants which will be on a 90 day reporting period. Everybody would meet the modifications requirements in 2016. In 2017, returning participants would be on the full calendar year, except if you are a new participant you will have a 90 day option. If you have chosen to move ahead to Stage 3, you can also do a 90 day returning period.

So the way that it essentially breaks down is you have a flexible year in 2017 which our experience with Stage 2 showed us how important it was to make sure that people had that as they have different timelines to actually get their certified EHR, to incorporate different workflows or different practices into their workflow. And so you have a choice in 2017 of doing a full year at the modifications requirement or 90 days within that calendar year at Stage 3.

By 2018, we will have everybody on Medicare will be on a full calendar year reporting; everybody will be on the same set of requirements, which are Stage 3. There are on the Medicaid side first time participants that can use a 90 day reporting period in that year, but everybody will be aligned to the same set of requirements in 2018.

This is where we are overall right now with numbers, and I know we do this on a regular basis; this is somewhat abbreviated you'll see here. But I particularly wanted to call attention, I think there are a number of different things that are floating around as far as people who have actually achieved Stage 2 and the numbers that I want to call attention to are the Stage 2 breakdown that you see here.

You have a little over 60,000 or slightly more than...I obviously need to get my eyes checked, but I think that's 49% of Medicare EPs that have actually achieved Stage 2. That's 49% of those that were eligible; I think there's a figure floating around, I've heard it float anywhere between 9% to 12% of people who have actually achieved Stage 2 and while that is probably strictly true compared to the number of people who could participate in that EHR Incentive Program, very few of those people are actually eligible to participate in Stage 2. This is for 2014 of course.

So only about 100...almost 122,000 EPs were eligible to participate in Stage 2. And you see we have about a 50-50 split. Now this is when we gave full flexibility for people to stay at the Stage 1 requirements in 2014. I think the fact that...I will tell you that my experience with Medicare programs is, when we give people the flexibility to stay at a lower bar, they almost always exercise that. So the fact that we had 50-50 here, we consider a big move forward.

And then of course on the eligible hospital side, almost 2400 hospitals, and you could see over three-quarters of those moved on to the Stage 2 requirements when they could have stayed at Stage 1. So I think an important thing to keep in mind what we are talking about readiness and what's there, apparently a large number of people did feel that they were ready to move on to Stage 2 requirements.

We'll also be breaking down; I think in the future the payment adjustments. And overall I think you're going to see a shift as we move forward from the number of providers that are paid each year to the number of providers that attested and achieved a certain stage; that makes sense as we are coming to the tail end of paid for a lot of providers, incentives are starting to fall off for a number of Medicare providers. So we'll be focusing on the number of providers that actually achieved a particular stage. Do keep in mind that since we are moving to full year reporting overall, we will really see bumps in numbers not on a monthly basis but on an annual basis because it will be annual reporting for a lot of folks.

I also want to say just before I move on really quickly, that you can see here we've got about 257,000 Medicare EPs that are subject to the payment adjustment. A fairly significant number of those EPs have fewer than \$2000 in Medicare claims. So when you factor that in, it's actually not a huge number of people who are seeing significant numbers of Medicaid patients that are actually receiving a payment adjustment at this point.

And we know, I think you've all heard, we have certainly heard that for some people that has been a financial decision for them. They're just not seeing that many patients, they're going to take a longer time period or timeline to onboard with health IT because the Medicare payment adjustment isn't that significant for them.

I talked a little bit about this participation timeline, so I'm just going to jump into the Stage 3 requirements. And I want to jump into the Stage 3 requirements first because you'll see when we go through Stage 2, what we did was we very much aligned to what the decisions were in Stage 3. The same type of objectives that are in Stage 3 are very much in Stage 2; I think where you see a difference in Stage 3 is that you see higher thresholds and then you see a couple of added objectives that really utilize the new certified EHR edition. There isn't 1:1 match between Stage 2 objectives and Stage 3 objectives because we did combine some of the objectives...some of the measures in Stage 3. But as near as there can be, there actually is.

So we talked a little bit about getting something that was more simple, more achievable that reduced the overall provider burden. You know, we did synchronize on this single stage and single reporting period idea. We did, and we talked a little bit about this when we talked to you about what we had proposed. We removed objectives that...we went through and we looked at objectives in a number of ways and removed those that were redundant because they were reliant on paper-based functions. Things that were duplicative of either more advanced measures or that use a similar EHR technology function or they mirror, for example, a quality measures that we always had.

The example I think I always use about this is smoking status, right? When you look at smoking status, we constantly received in regulatory public comment, the feedback of why are you requiring this as a separate recording objective when you have a quality measure that actually is more robust than just recording.

And then of course we looked at objectives that were what we call topped out. We do this pretty regularly on the quality measurement side, too. There's a certain point where you look at the overall achievement and you say, you know we had a 95% average or mean here; do we really expect that much more improvement in that achievement? Is it reasonable to raise that threshold because then you don't account for some of the off-case scenarios that are necessary to being able to get through.

So we did end up focusing on eight advanced use objectives, many of those objectives have mult...two or three measures. Some of the ones that have three measures actually provide for some choice and flexibility for a provider so that you can select those measures that are most relevant to your workflow.

As I said there is a 60 day comment period on this, comments are through December 15. I would encourage people to submit them electronically; that is the easiest way for us to be able to sort through all of those and make sure that we're addressing all of them. But of course you can submit them through writing as well.

So I'm going to go through briefly, and I think I'm going to mostly focus here on eligible professionals overall; there is some slight difference as you know, but with Stage 3 it's fairly overlapped with Stage 2. There are some slight differences but I'm going to focus mostly on EPs here.

So here are the eight that we ended up with. Protecting patient health information, I think we all know this from the inception of the program, that's really doing a security risk analysis. And of course as time has gone on, we've expanded to think about ideas of encryption and other type of security risks. Electronic prescribing of course was required as part of HITECH; clinical decision support, computerized provider order entry which has been expanded to beyond just medications and labs and now includes radiology orders. When you look at those first four, those really broadly fall into a patient safety bucket.

Then we move on to looking at patient electronic access to their health information and coordination of care through patient engagement. All of those are, I think about having people involved in their own care. When we look at coordination of care, some of those measures are things like using secure messaging, obviously providing people with access to their electronic records either through a portal or through the new API functionality that we introduced.

And then finally I think seven, health information exchange is our, we talked about this when we finalized Stage 2, that's sort of the beating heart of interoperability for health IT and where we focused a lot of that. And then we expanded the options and the flexibility around public health reporting, but continue to make that a central part of EHR Incentive Programs.

So I'm going to go very quickly through some of these objectives and I think most of them are going to be familiar to you. Where there hasn't been a whole lot of change, obviously I won't talk a whole lot but I'll just briefly highlight where I think we do have some change.

As I said this is the security risk analysis; there's not a whole lot that is introduced new here, but we've repeatedly heard from providers, from a consumer organizations especially that as we move more and more of the world into the electronic sphere, we need to be cognizant of the risks to patient information that are there.

Electronic prescribing, we did increase the rate on this for EPs, moved for hospitals into a required measure. This also, by the way, we combined here, you'll see that we not only do the electronic prescribing, but also checking a drug formulary as part of the measure. This is all kind of combined in one area because thematically I think that's a related workflow.

Clinical decision support, not anything that is very different here from what you see in Stage 2. We did combine the drug-drug and drug allergy here as that is also a clinical decision support tool as part of that measure.

CPOE we talked about very briefly. What you see here is medication orders, lab orders and diagnostic imaging orders.

Patient electronic access to information; now this is, I think, where we in concert with our colleagues at ONC really tried to expand the usage and access to information in a way that we think focuses on patients being able to get their information how they want to get it and that was including this API functionality.

Now one of the things that we have included here is that it is a measurement of both things; it is measurement both the provision of the original view download transmit measure that you know from Stage 2, but also the API functionality that is part of the 2015 certified EHR or certified technology edition. And there was a lot of robust debate about this, I think both publicly and we received a lot of comments on it. But I think the end goal here is to make sure that we can begin the development or encourage the development of a robust market that utilizes those APIs and allow patients to access the information in the ways that they want to do that.

Care coordination through patient engagement, I think a lot of this is very similar. We did provide a ramp to usage of the actual information, the access of the electronic information. We did get a lot of feedback about that as we went into Stage 3 consideration about the measure of patients using the EHR and that the 5% was a difficult threshold right now because of the number...because we're sort of the early adoption curve really where patients either don't know that they have access to that electronic record, they don't quite know how to use that electronic record yet.

I think we've talked before about this and the parallels to banking industry is what always sort of comes to mind. I think about the fact that on a daily basis I now visit my bank's website to take a look at my account information and balance my checkbook and make sure that I have not overspent, not that I would ever do that. And that's now a daily routine for me.

But once upon a time when this first debuted, I was hooked on the telephone line that I could go through and call and I could get my last 10 transactions quickly over the phone and I really hadn't adjusted to moving to this new technology. And I think way back in the mists of time that some of us are old enough to remember, you actually had to walk into your bank or wait for monthly statement to go through and do all of those things. And all of them proved to be useful steps forward, it's just that when they first took the step forward, not everybody immediately jumps on to that.

So what we did provide and you have to with this I think, think of the modifications rule in Stage 3 in tandem, we looked at an overall increase where we start with, in 2015 a single case usage to encourage providers to ramp up to what will ultimately in Stage 3 be that bar of 10% of patients actually using that technology. We of course moved secure messaging into this as well; now that is a slight change. We did move from measuring patient usage of secure messaging to using provider usage of secure messaging for some of the same reasons, but I think we had also heard that if the measurement is encouraged on the provider side and they are sending important information, getting that started and using that technology will be more of a kick start than the initial patient usage of this.

And then of course measure three was something that we had heard very much from both patients and patient advocacy organizations and some providers, including patient-generated health data into the certified EHR. Now right now there is not really a standard that is associated with that; I think that's something that we can look at to develop over time as we start thinking about more of the patient-generated data. But it was important to include that information in EHR moving forward.

Health information exchange; I think the new thing here is really the closing the loop. In Stage 2, we had the emphasis on sending that transition of care, that summary of care record to the next provider electronically. What we've really tried to focus on here is thinking of this as a whole healthcare system; not only sending that, but having somebody receive that on the end, incorporate that information into the patient's electronic health record, and then actually doing some reconciliation for that, you'll see that in the next...doing some reconciliation of some of that information, the problem list, the medication list, the medication allergy list with information that is already existing.

So we're no longer just focusing on sending information, you know, it's not good enough to just have it go off into the ether. Not only does it have to go off into the ether, but it has to actually be received and then somehow acted upon as well.

And then public health reporting; I think this has been a little bit of a throw all the balls up in the air and catch them. It rearranges things a lot but I think really in the end what it does is it gives people more flexibility about what registry they want to choose and how they want to report. And that has been an ongoing thing from Stage 1 where we have focused really very much from immunization and syndromic surveillance and we've been increasing the options as time goes on, especially as we've heard from more and more providers working in specialty areas about what they would like to see.

So the reason that I go through Stage 3 first is because I can very, very quickly now go through Stage 2 because the Stage 2 objectives and measures were selected, actually, I shouldn't call them Stage 2, they are the modifications; it is both Stage 2 and Stage 1 that have been selected for that 2015 through 2017 period to match up as best as we can with what we do in Stage 3.

Now obviously there are things that we introduced new in Stage 3, like new options for public health reporting, closing the loop on health information exchange, the putting in patient-entered or patient-generated health data. Those are things that we don't include in the modifications rule, partially because we did not impose new requirements on people who are already participating but also partially because for things like API and patient-generated health data, those things are really incorporated in the next edition of certified EHR.

So the important thing that I want to take away before we leap into this very quickly is that there are no new requirements that are placed on providers as part of these modifications and you do not need to upgrade to a next edition of certified EHR. In fact, with the flex here what we have very much put in place is the flexibility to upgrade in portions so you could have new editions of the 2015 certified technology in place with old edition of certified technology and potentially reach either stages modification or Stage 3. And that was very purposefully done to give that flexibility as people on board because we've often heard that it is difficult to just flip that switch.

So we did the same thing where we restructured those objectives and measures to align with what we proposed. We ended up with 10 objectives for EPs including a consolidated public health reporting objective, nine objectives for hospitals, and that is you'll see, fairly similar to the numbers that you see in Stage 3. Obviously this begins in 2015; 2015 does have a 90 day reporting period to accommodate that.

We did modify that Stage 2 patient engagement objectives that require patient action, and I'll cover that very quickly. We took the same approach in Stage 3 as we did...or with modifications as we did with Stage 3. And just finally to let everybody know, CQM reporting for everybody does remain the same; what we changed here were the Meaningful Use reporting.

There are alternate exclusions and alternate measure specifications for providers here, and that was specifically so that there are no new requirements for providers. So if you were at Stage 1 and you were going to stay at Stage 1, you don't have to meet that higher threshold of what would be Stage 2 objectives. There are exclusions for areas where you would not normally be reporting for Stage 1; so those alternate exclusions are based on where your scheduled stage was meant to be. But it was very important for us not to impose new requirements on providers.

So here you see the overall objectives and measures for 2015 and 2017; obviously a lot of these look very similar; one, two, three, four is health information, clinical decision support, CPOE and electronic prescribing. So that is our patient safety. Health information exchange, patient specific education, medication reconciliation, patient electronic access, secure messaging; these are all in the patient engagement and health information exchange areas; it's interoperability and of course, public health reporting.

I won't go through all of these; I do want to highlight in a couple areas where we did build that ladder in. Obviously we talked a little bit about that patient electronic access; we have moved from the use case scenar...from the percentage scenario that was originally part of Stage 2 that percentage of patients that actually access their electronic record to a single use case and then we tier up as you can see. We go from simple use case to 5% to end up at the 10% that we do. There is an exclusion for that second measure for Stage 1 providers in 2015. Similarly on the hospital side, so you can see this is how that threshold changes over time. The missing arrow is 2018 moving to that 10%.

You see the same thing with secure messaging which originally had a percentage requirement for patients to actually achieve it. As we are moving into Stage 3 to drive provider usage of this, we moved to a reporting period in 2015-17 having this capability working and using that. So fully enabled but not necessarily measuring individual usage; and that's really to give people that transition period as we move into Stage 3 and we have a higher bar for EPs then we did for patient usage in Stage 2. So this is an indication of where that bar is, so fully enabled in 2015, a single case usage in 2016, at 5% and the moving forward to ultimately what we end up at 25%.

And then public health reporting; again, this is fairly similar to what we see. Should I stop here and do questions or...

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

I think that would be good. That was a very quick overview of Meaningful Use Stage 3. Questions or comments from the group? Troy?

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

Thank you, Paul. I just wanted to take a moment and go back and look at the program numbers. What I had heard is a lot of the concerns are over the achievement of Stage 2 objectives and when I look at the numbers here over the years, when you look at 2011, 2012, 2013, 2014, I mean you see a significant number. I mean even in 2014 there were 298,000 that achieved, but when you look at 2015, we're in November, huge drop-off.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Well the system hasn't been opened for most of the year...

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

Okay.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

...so that's part of the reason. And you will now see this moving forward in all years. We will be in December and you will probably have a handful of people that are actually in that category. The attestation system for 2015, and we did this very specifically, knowing that we were proposing modifications to 2015 and we did not want people to attest to the previous. So really all you have there are new people who decided to attest to the original requirements; so that's what that 3000 is. You will have everybody come in, I think the new system opens January 4 of next year and goes through the end of February and that's where everybody for 2015 will come in and attest.

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

Okay.

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

Good, thanks. Chris?

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

Thank you for the presentation; it was interesting and clearly a lot of significant improvements being made. I have a comment; you know, I'm a little per...and a question. I'm a little perplexed by the continued inclusion of drug-drug into the decision support, I mean there's no ample evidence, lots of papers that say that mostly introduces noise and has little to no value, so I'm still questioning this as we go forward.

The question I have is, I'm starting to receive from pediatric EHR vendors' lots of concerns that some states are pushing for reporting in 2015 to be done by next week or there are no payments for 2015 for people un-eligible under Medicaid. Do you have any information about this; is this something that is known to CMS?

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

I'm sorry, there's a push for what?

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

So I have...I've been...several people reached out and said there are certain states, I think Ohio and Arizona were mentioned, were Medicaid eligible providers were told that they have to report by next week or there would be...then after that, the reporting period would be closed for those states.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

For 2015?

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

Yup, if you're eligible for Medicaid. It is my...like I said, I get...I receive multiple e-mails and, you know, for pediatricians it has not been unheard of that Medicaid programs have different requirements state by state and different rules. And, you know, pediatricians have been having had to deal with this hardship in the past. So I'm not...

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Well certainly...sorry.

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

...surprised to hear that.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

There's certainly some variation that is allowed by regulation for what objectives could be added to, especially under public health reporting for Medicaid but there isn't a difference between reporting periods and there may be an extension of some reporting periods under Medicaid. But there isn't an early reporting and the reporting year hasn't finished. I've not heard that, I have no doubt that there are people who have that concern. If you want to reach out to me, I'll be more than happy to put you in touch with my contacts.

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

That's what I was going to ask; once I have some more data on that, if I may come back to you on that matter that would be great.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Absolutely, absolutely. As far as the drug-drug, drug allergy interactions, I think that there are continued concerns about medications that are prescribed and the number of contraindications and issues that happen. At one point in time I was able to quote it off the top of my head the number of people who are hospitalized each year for a drug-drug interaction and I think that's one of the driving areas. I have heard the same thing; we hear the same thing about clinical decision support all the time that, you know let's just turn off all of the pop-ups, this isn't terribly helpful. I do note that there is some evidence that says that it doesn't help. I think we've also seen some evidence that says it does.

One of the things I think we provide for is customization of how that works; that is important so that I think there are number of folks...I personally had the experience of talking with physicians who expressed some annoyance at the drug-drug and drug allergy pop-ups that come on. And when they find out that I'm with CMS, a thing that I seldom tell people when I'm actually in an exam room anymore, they're always railing at me about these requirements that I have to do this. And you know, you walk them through and actually that's not the requirement, the requirement is that there is that check available. How you actually implement that is very flexible by the practice and what is necessary for your patient base. I encourage people to customize their EHR to find a way that works best for them.

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

Very good.

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

Just to add to that...this is Elise Anthony. In the rule, and Rob correct me if I'm wrong, there are provisions in there in terms of the, does not have to be interruptive alerts. So I think that's the flexibility that Rob is talking about. We also worked with CMS prior to the release of the Stage 3 rule to put together some kind of guidance that lays out that alerts for purposes of CDS don't have to be pop-ups, but they can be non-interruptive and that allows for the customization, but also in terms of the alert actually helping in the delivery of care for that particular practice.

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

Thank you. Gayle, please.

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

Thank you very much, Paul. And I just wanted to make a few comments. I was having a little conversation earlier with Paul about the progress we've made on, you know as we move toward Stage 3. And first of all, I think the modifications are definitely in order; I had a great deal of concern about many of the things in Stage 3 but the modifications are moving us in the right direction, I do believe.

However, one of the concerns I have and I hear it from providers across the spectrum, has to do really with the patient engagement section. And as we all know, patient engagement is an extremely important part and one of the goals that we, from Stage 1, have been very much concerned about and moving towards getting more and more patient engagement. But when you have an 80% of unique patients have to be provided with timely access, we have difficulty, especially in inner cities, in rural areas, I think this is going to be very problematic to providers.

Also, you have...there's a culture out there that I think CMS and perhaps HHS needs to have very much a part of an education role for patients and for our population so that we have...we may have laws and rules in place, but it really takes public awareness and public engagement that has to come along over a period of time. I use the example of seatbelts; you can put all the laws in place, and we have laws about tickets for not using seatbelts; but it was really a general public education media campaign that really pushed the use of seatbelts and the same thing with clean highways. Without that and CMS, I believe and HHS has a real role to play in this to be able to make sure that providers have the ability to comply with this. I think it's going to be...the patient engagement section of Stage 3 is going to be very problematic without that and as we move forward, I would like to hear from CMS and from HHS exactly how they're going to do that.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

So I'm a little bit hands tied about what I can say about Stage 3 because we are technically in a comment period. I think that is a great comment to submit; I would encourage that. I do think we are aware that there is sort of an on-boarding process and that's why we did try to design that in the way that we did where we backed off and gave people a little bit of a longer tail. But I think there's no doubt, and we have heard that there are challenges for providers in getting patients to use that.

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

Okay. Anjum please.

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

Thank you and thank you for this very informative presentation. I had two clarifications that I've been asked at different professional meetings. One regarding public health reporting, because in Meaningful Use 3 you have split, you know the public health registries and clinical data registries in two different measures. And so just the thinking behind that in terms of does that...because the public health registry reporting kind of requires them to interact with a public health agency, while the clinical data reporting does not, at least in the...in how it is written. So if you could clarify a little more the reason for that and how that will affect interaction with public health agencies that we want to promote?

And the second question that I got was also from as we see more behavioral health integration in primary care, how does Meaningful Use 3 affect behavioral health providers? And are there certain parts of Meaningful Use 3 that would act differently or create different requirements for them versus other providers?

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

So let me take public reporting. I think the goal actually was to provide more options for people. I think you're right, it could certainly affect some of the public health reporting, but by and large what we had heard from and what we had seen from data were that most people didn't have those options. Either they didn't have a public health registry locally, state, whatever it might be to report to or they didn't do those particular types of things; they didn't give immunizations so there was no immunization data to report.

So over time we have tried to add to what that is and especially as we have heard from more and more specialists that they want to be able to meet things that are specific to their workflow, that's how we began to expand to cancer case specialty registries and beyond that. I...it certainly might have an impact, I think that for a lot of the immunization registries, I think most people once they begin reporting into that, it becomes fairly routine, so I don't think you'll see a huge drop-off from that. The big challenge for a lot of people is really that they just don't have access to one of those. We even saw that in MU...the number of people who took the exclusions for immunizations and even syndromic surveillance was huge and that exclusion was because they simply didn't have anything to report to.

I'm not sure the second question, you're asking will Stage 3 impose additional obligations on what type of...

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

Behavioral health providers.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

So I don't think so; I think that one of the things that we have heard and this is not just about behavioral health, but I think behavioral health was probably one of the more public discussions, about including behavioral health providers within the program, including behavioral health information as part of the electronic health record. I can tell you that there was a lot of robust discussion internally and with external stakeholders about what that might be and how it might look.

Obviously on the participation side, we don't have statutory authority to expand who the program applies to under EHR Incentive Programs. And I think, and Elise may want to talk more about this, as we started looking at some of the health information, I think one of the things that emerged is trying to come to what that dataset would actually be and what the standards for that dataset would actually be was something of the challenge. I think we're all, I'm going to speak out of turn here and Elise is going to give me the evil eye, I think we're all sort of behind that idea as a complete part of the patient record; I think it's just a question of what the timeline looks like.

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

Right, well and just to add to that, I think it's not in Stage 3 right now in terms of kind of data that would benefit behavioral health providers that goes outside of that clinical sphere, but it's something we've thought about in our role and I'll talk about this a little bit during our presentation. But the goal is for the health information technology certification criteria side of the equation to provide those resources for behavioral health providers.

So if you are a primary care provider operating under MU, I think there's an opportunity for you to work with your developer and say, we understand that there are these criteria that ONC offers that might be helpful to the patient population I serve. So that might be things like the social, psychological, and behavioral health data; it might be DS4P, the data segmentation for privacy standard; it could be a number of different pieces that we've included, and I won't steal the show from Rob so I'll talk about it during our presentation. But, in some ways you can think of it as an add-on to whatever may be required for MU, even though it's not in the MU criteria specifically.

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

Okay, thank you.

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

Kathleen.

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

So thank you; I have several comments. On slide 17, there is discussion about the patient electronic access to health information and one of the concerns that I've heard frequently expressed is that many clinicians already have extensive information that they provide to their patients for educational purposes and wanting to be certain that they can continue to provide that and that they don't have to provide new materials that have been developed elsewhere are developed, for example or made available on the electronic platform when they've already found that existing materials work well.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

So I think the question is whether any of those existing materials are already electronic, many of them already are and so that definitely falls into it, but that's also part of the reason why we have measure thresholds. Because we do know that every case is not going to fit into a particular objective; this measure threshold allows a lot of opportunity for patients to not receive that electronic specifically for that.

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

So if something is just converted from that stack of papers that I've got in my patient education area and put into a PDF, and it's in my EHR as a PDF, does that qualify?

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

I am absolutely...once upon a time, I was the person that if you wanted to answer an FAQ, you would call me up, but they moved me to a much less dangerous position. I don't really know the ins and outs, but I would be happy to take the question back to my policy people.

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

Good, because there are many people planning to PDF like crazy. And then my next question had to do with material on slides, it's 38 and it has to do with public health reporting. And really to continue the discussion here, again I've also heard a great deal of concern about the fact that for an eligible provider they have to meet two out of the three measures. And so while they may have access to, let's say an immunization registry that's maintained by their state, there's just no relevance to their individual practice.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Um hmm.

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

I'm not sure that I want neurosurgeons spending their time reporting on flu shots and similarly. So...and on syndromic surveillance and so that leaves them with just one, which is measure three that might be clinically relevant.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Um hmm.

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

And although there are many, many registries now available, I think we'd all agree that not all specialties or sub-specialties have registries available for use.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Um hmm.

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

So can someone truly get exceptions for all three?

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Is it possible for somebody to look at all of these measures and not have anything on which they can report and be excluded and the answer to that is yes. You know, we were very careful, this is a rather lengthy section in the preamble to go through and describe all of the different situations and requirements, but there are a number of exclusions that are built into this specifically to make sure that's...if you were a provider who is genuinely in a situation where you do not have a registry that you can report to, you are not caught in a Catch-22 where you cannot meet Meaningful Use.

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

Thank you.

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

Thank you. Troy, please.

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

Thank you, Paul. One final question; I'm mesmerized by the program numbers. What I have heard is the common theme around not so much around primary providers or the eligible hospitals that have a very robust infrastructure, it sounds more like we have behavioral health, we have maybe rural health providers, inner city providers, neurosurgeons, specialists, so the numbers on the bottom, when I look at this, the Medicare payment adjustment overview.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Um hmm.

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

Now do we have any data or any information on whether that was...these are folks who just opted out or did they not make the cut and in what stage? I suppose it's more of a question about where can I get more information about this or can you just enlighten me here a little bit.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Yeah, so I think part of the challenge that we have is that if you don't participate and you don't come in to report to us, then we really only know what we know from claims data, you know, paperwork reduction makes it difficult to go out and ask more than nine people questions about anything; so it's not as if we can go to 257,000 people and even give them a simple five question survey monkey and say hey, you know what category do you fall into? So some of this is a combination of supposition and claims data; the supposition isn't wild, it's not completely out of the air, it's the criticisms and concerns that we've heard I think since the inception of the program and we know that people fall into a number of categories.

We know that there are people for whom this is just, you know they have a small practice that's already financially challenged; they're not going to implement this because the cost is significant. We know that there are other folks that are close to retirement and so the several years' process of implementing and building this as part of their workflow is not something that they're going to engage in. We know that there are some folks for whom the bar just seemed too high and they made a choice not to participate. We also know that some of those folks over time started that way in 2011 and ended up starting Stage 1 in 2014 or 2015, as we reached more of a critical mass of people participating in EHR Incentive Program.

So while we don't know the exact breakdown, I think one of the things that we can do is we can take a look at the overall figures and see what the breakdown looks like as far as claims and draw some conclusions from that. And a significant number, I wish I had the exact number off the top of my head but, it's over half of the providers who receive a payment adjustment have Medicare claims that total less than \$2000. So that really ends up being, for those people, what is that, that's a \$40 hit. Well, when you think about the \$40 hit, you're probably willing to take that versus the amount of money that it takes to implement an EHR overall. So I think a large number of the people we know fit into the category of making an ROI decision and deciding that that doesn't make sense for them.

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

And just a comment; you know, when I look at the number, we're talking 250,000 providers, and I think of the panels that that 250,000 providers have, I mean typically it's anywhere from 2000 to 2500 patients. That's a significant population base that is not benefiting from this entire program. So I'm concerned that we don't have some way to pull them forward. I mean we had the carrot obviously, now we're in the stick phase. It seems that, I mean, we really need some way to re-incentivize them to come back in because it's not so much the providers, you talk about yeah, it's \$40 a hit, okay. But the one that really is being impacted is the patient, because that's what the whole program was set up to do was to advance our healthcare system and continue to really service those people in specialty practices and services that typically get left behind. So is there, and maybe it's just a discussion we need to have, so another task force or another workgroup that we can look into this and see how we can pull them forward.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

So I would say...okay, so I will say that part of the issue on our end is it's not as if we, as HHS can make a decision to go back and provide more incentives.

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

Right.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

The incentives are partic...are specifically provided for in statute, as is the current payment adjustment. I do think that when we look at MIPS and including Meaningful Use as a portion of this overall delivery system reform, we certainly think in those terms like what are the things that we can do to encourage people to come along? Some of that is in the MIPS RFI that is out and some of the questions that we're asking people. We're certainly thinking in those terms, because I think we have the same concerns, how can we ensure that the most number of people are using this toward better patient care.

I think that, you know there's also though, if you look at MIPS legislation and you look over at the MACRA legislation and you look actually at a number of other CMS programs, there is generally a provision, a recognition that there are providers who are very low volume claims who are not going to be affected by these programs and it doesn't matter what level of penalty you provide, or what level of positive payment adjustment you provide, that just doesn't account for a significant number of what they do.

I mean, if you look at upcoming MIPS, you can potentially earn a 4% positive payment adjustment. But if you do \$1000 of Medicare claims a year, that's not a big impact on your practice, so it's probably not going to be a driving decision about whether you choose to engage in these activities.

Now one of the things that I think we hope is that as we look at what we're doing as far as quality measurement and clinical practice improvement and resource usage and Meaningful Use, that that sets something of a trend in agenda for other people who do quality measurement through other programs, other or other insurance providers and that helps with some of that direction. But as far as what we, HHS can do, I think we have that impact of basically the authority that statute gets us.

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

Good. Thanks. John?

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

...it certainly does seem to me that the focus is on things that really do matter. I was curious if you could provide detail on what you describe as the medication reconciliation and health information exchange. You know, having tried to do that in medications for quite a while, that's difficult enough. When we're looking at allergies and diagnoses that were entered by a different system, what specific actions are you talking about that constitute reconciliation? And if I got the diagnosis from another center, does that create a message back to that center if I am saying so? Thank you.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

So there's a lot of flexibility and always has been in the reconciliation measures for precisely the reason that you raised; the goal is not to say that once you receive a summary of care record, you have to replace that problem list with the problem list you received. The goal is to reconcile that information you received with what you already have and what you as a provider may already know. We don't really provide any further requirements beyond that this has to happen for "X" percentage of patients and that's very purposeful because, you know you may well be in that situation.

Reconciling may be adding that to a past problem list, it might be, you know taking a notation of that. It may not involve...if you have a question about a lab result or you have a question about a diagnosis or you have, you know that may not mean incorporating that as an active problem in the record. That is very much left to the judgment of the physician or the hospital provider. We're not trying to regulate how that should actually happen, we're just trying to push people toward, again it's this closing of the loop; the information gets sent, now we are measuring the information gets received and used.

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

I understand and the goal is laudable, but exactly what we're go...since we're requiring an action on the part of a provider, I think you're being specific about that. Just what is that action, you know how much of a burden are we having to give to the provider in order to meet what would qualify?

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

So we have had some experience, I think, doing medication reconciliation previously. We have not had a huge amount of pushback when we looked at where burden really was for providers, that's not the area that primarily came up. I think that the...I know what you're trying to get at; I absolutely see, you know what kind of guidance can we give people about what they should be doing?

I think there's a justified hesitance on our part to start telling people, this is how you some should incorporate things into your workflow. Our experience with Meaningful Use, and I think with some other programs, has been that the more requirements you place around it, the tighter you try to pull that noose, the more people kind of slip out of it and we want to be careful not to over-regulate essentially. So there's a lot of flexibility built into I think not just this, but all of the Meaningful Use objectives.

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

Thank you.

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

Brent?

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

This is Brent. I have two questions; one, and both relate to continuity of care document. First is, well in your receiving the document in will Meaningful Use re-require that the entire document be brought in or only those components that that clinician views of value because, I mean, if you bring in every time the entire document, you start getting a lot of...a lot more information that's compounding your data storage than you may need?

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

So what we rely on is the common clinical data set that is defined through certified EHR; I think that is similar, it's slightly expanded from what we had previously in Stage 2. I think that in some cases there may be a surfeit of information; I think the overall approach from our end was better an excess than not enough information on that. But we rely very much on that defined clinical data set and Elise, I don't know if you want to talk about it?

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

Yes, so we'll talk about this in our presentation; there's definitely some bleed-over between the two presentations, obviously. In our rule we have a common clinical data set formerly known to many as the common MU data set and that's the key set of information that we think should travel during transitions of care. And that is set up to...for the Stage 3 rule to point to our rule in terms of what that is; that gives us a little bit of flexibility to think about it and to iterate as necessary, but really just focus on the core set. We've expanded it a little bit and we'll talk about that as well in our presentation. It's a big piece of our discussion.

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

Okay, because I just think some consideration would be of value, not of what's being sent but what's being received that is elected to be retained by the clinician.

The second question is, is you're sending using Direct and the Direct has a lot of capabilities beyond just sending the continuity of care documents; is there any consideration of requiring the...at some point that it's available to do more than just continuity of care? Because we're finding vendors that have only programmed it to do that function so the other functions of clinicians sharing clinical information between physicians or whatever, other attachments or so forth, is not a capability that is currently supported because they program...many vendors have programmed solely to meet the single requirement of continuity of care...sharing the continuity of care document rather than being able to share other documents that physicians may want securely e-mail between themselves.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

And I don't know if you want to talk a little bit. I you're probably cover the standard used and what's not. I think we've always regarded on the Meaningful Use side and we don't rely on just the Direct standard, I mean that's now we've expanded just Direct. But I think we've always seen Meaningful Use and certainly as we've thought about Stage 3 and modifications, as a floor and not a ceiling.

This is a foundation upon which people can build and they certainly can, and I think we think should innovate beyond what those minimum requirements are. I do know that there are some vendors that have built to this set of requirements; we also know there are number of vendors that have built above and beyond. So I think it's just to keep in mind that in the same way that we don't want to over-regulate and make everybody go down one single path of practice, we do want to over-regulate and say these are the only functions that an EHR can or should have. I think there's definitely room for moving beyond just that set of instructions.

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

Thank you. Any other comments or questions? Gayle reminded me of a point, maybe it's good to step back when we've had this detailed discussion that one, HITECH isn't the only...participating in HIT...having an EHR doesn't mean you have to participate in HITECH. And so HITECH as a government program, private sector can certainly do other things and maybe the more important point is we all as providers need to have the tools we think are necessary to make...to deliver optimal care to our patients; that doesn't necessarily mean you participate in every voluntary program. So Meaningful Use and HITECH is a supplementary program to the primary goal and mission which is deliver high-quality care.

We all think that these tools provide useful tools not only for the care si...care delivery, but also for reporting on what we do and to help us to continuously improve. So we just don't want to lose fac...lose sight of the primary mission that we have. So Rob, thank you very much for this excellent summary and excellent fielding of the questions, so thanks a lot.

**Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid**

Thank you.

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

Now we're going to switch over from the Meaningful Use final rule with comments, to the certification role from ONC and Elise Sweeney Anthony and Mike Lipinski are going to present that.

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

Good morning, everyone. So first I should stop and say, thank you for kind of all of your help as the Policy Committee and also the Standards Committee in thinking through these pieces. I know a lot of work went into the thoughts of the two committees on Stage 3 and also on these rules and all of that was helpful as we went forward, so we really do appreciate that.

I should probably stop and say hello to folks as well, since this is my first meeting as...with the Policy Committee as the Acting Policy Director. So I'm taking over for Jodi and it's been a pleasure. I was Jodi's Deputy for over a year, I've been at ONC for almost 3 years working a lot on many of the things that the Policy Committee touches, so I know many of you through those interactions, but it's a pleasure to kind of increase the amount of work that I'll be doing with you. So, thank you very much. And with that, we will jump into our presentation.

I'm going to do a high level discussion of what are the goals, what are the things that we were really thinking about in terms of accomplishing from the health information technology perspective. And then Mike Lipinski, who is our Division Director focusing on regulatory affairs and federal policy and also known to many of you as our lead reg writer will jump in on some of the specifics of the criteria. So I think Mike is on the line as well and we'll go ahead and start.

All right so first, our goal, as I said is to talk about our...the larger parts of the rule, the goals. We'll talk about some of the updates to the certification program itself and then we'll dive a little bit deeper into the specific criteria and ultimately to the use cases that would apply.

So the overview of the role; so this is part of a larger objective at HHS; as many of you know, the department itself is really about improvement of care across the care continuum thinking about delivery system reform, thinking about precision medicine and a number of other pieces to the overall care improvement paradigm. Health information technology is a key piece of the puzzle as we all know, and as this committee of all would understand. So we think of that as we were developing the rule. There are a couple of pieces in here to note.

When we did the proposed rule there were a number of criteria, much...many more than what we actually finalized. We heard feedback from the two committees as well as stakeholder feedback that came in through the public comment process that there was some concern about the burden, the number of actual criteria that were being...that could be finalized and the impact that that could have on overall development.

What we did is we took a real close look at what were the key pieces that would move operability forward, for example, that would move patient engagement forward and we focused on those and we didn't finalize some of the criteria. We'll talk about what those are a little bit later. With that, because it's a smaller set that was actually finalized, we're...our hope is that that reduces the burden on development and also allows for increased opportunities for innovation.

I said already that we're...we focused on interoperability that was a key piece. I'll probably continue to say that because it's an important piece of what we're doing obviously now and a lot of our work is centered around that.

So this is a quick look at what the rule does in our mind; what are the focus areas? What are we trying to accomplish? What do we think that the criteria and the updates to the program itself will lead to in the stakeholder community?

So a couple; we talked about interoperability already, but privacy and security. So we looked...we took a look at the privacy and security framework and we tried to update it to make it a little bit easier for providers to see what they had before them in terms of a module and easier for them to make sure that the key pieces of privacy and security that we think are important and that we have heard from stakeholders are important are part of the modules that they have.

We also took a look at disparities; how do we address and help providers to address disparities that they might see in their patient population? So we focused on some criteria that we think does that and that includes things like deepening the race and ethnicity standard, CQM filtering is also in there. We talked earlier about the social, behavioral and psychological data elements; those things that we think might be part of the solution, part of the parcel for a provider to think about as they're trying to address disparities.

Jumping to the top, data access and exchange; so pieces obviously related to how information is exchanged what's the core component of that? What is the common clinical data set and what it should look like, but also data portability? How should information move to the benefit of the provider and ultimately the patient.

Patient safety as well, we've included provisions on user centered design, improved pieces for patient matching and then transparency and reliability; and that really goes to the improvement of the program itself. How do we take the program to the next level to give providers more information when they're be...when they're in the position of being a purchaser of a product? And then also ensuring that that product is working once its implemented and in the field.

And then the last two at the bottom are in tandem and we truly think about it that way. So one is continuing to support that EHR Incentive Programs and making sure that the criteria that we are thinking about are beneficial to the behavioral requirements that CMS is putting forward for Stage 3 and for modified Stage 2 as well. And then the la...the other piece of that is other setting support. So this goes to the larger continuum question of, we've focused a lot on Meaningful Use, but there are other pieces of the puzzle. How do we think about how a behavioral health provider, for example, is able to communicate with an inpatient hospital or how they're able to communicate with a primary care provider? What does that look like? And what opportunities do we have in our rule for that to happen?

So let's talk a little bit about the Health IT Certification Program. I'll give the primer that there are kind of two big pieces to the program; one is the certification criteria themselves and the other part is the operation of the Health IT Certification Program. And we don't have Steve here today, but I'll speak on his behalf that I think these changes or these updates are key pieces to improving the functionality of the program and taking that program to another level.

So the first thing to think about is the way that we support the broader care continuum. So what we wanted to do was really be able to allow more access, make it more open and more accessible to different settings who are not meaningful users, for example. So if you think of long-term post-acute care provider who is interested in having certified health IT that would enable them to communicate more effectively, in an interoperable way, with the primary care provider, what would that look like?

So we started by changing some of the nomenclature. So previously we called it EHR module; now it's health IT module and that also goes to a larger goal that, you know, from our perspective EHRs one piece of the puzzle, but they're not the whole landscape of health information technology. So by calling it health information technology module or health IT module, we're capturing that EHRs are one type of health IT, but not all that there is in this landscape.

The second thing is the idea of a complete EHR is pretty much no more in the 2015 edition. In the past you could be certified as a complete EHR, as it were; now the program is going to be entirely module-based for the 2015 edition. What that means is that a provider can work more closely with their developer to say, these are the pieces that ONC offers in terms of certified health IT that I think would be helpful to my practice. And collectively those modules create the puzzle, create the picture for how that provider can provide the care that they need for their patient population.

There is flexibility in that as well. We're not saying that for example, what Mike will talk about in just a little bit, but the base EHR, for example doesn't have to be all in one module it can be across a number of different modules as long as it's all there. So we've included some flexibility in how we think about that, but the goal is for the program to be more module-based. That will also come in handy for other use cases and other settings who are outside of MU, so that they can really be deliberative and in what they're choosing from the program for their benefit for their patient population.

So here, this slide I like to say that the key point on this slide is the fact that the program is agnostic and by that we mean that the program is not designed to only support any particular setting. I'm not going to pick on MU here because it's a key piece to the puzzle and it's a key piece to moving, and has been as we saw from Rob's slide deck, it's a key piece to moving the conversation on health IT and improving adoption and use.

That said, there are other settings out there and what we want to be is a resource across the health IT landscape and across the provider landscape. So you can think of this almost as a buffet in terms of we provide a variety of different certification criteria and we encourage providers to work with their developers to determine what best suits their particular practice.

And in addition, we also support other programs so, and this is a good segue for this slide, there are other programs across the federal government, so the Chronic Care Management Program for example points to ONCs program in terms of criteria that are helpful. And there are also outside entities that are doing the same and we encourage that. You also can think about DOD and the Joint Commission as other examples of where others are pointing to the certification program and are pointing to what we offer as a base in terms of criteria and the need for health IT.

Let me just go back one moment to this slide. The other thing I wanted to point out, and many of you will appreciate this, in the past the certified EHR technology definition was located in ONCs rule. What we've done in conjunction with CMS, as many of you know we worked very closely with them on the development of these two rules, is that that CEHRT definition has been moved to the ON...to the CMS rule.

And what that means is that when you are a meaningful user, when you are thinking about attesting and purchasing a product, all of what you would need in terms of behavioral requirements, what you would need to have, what you need to think about, is in the CMS rule. It does point to our rules, so for example the common clinical data set it points to our rule for the common clinical data set, but the definition itself is now in the Stage 3 rule.

Okay, so we talked about this one. So now I want to talk about transparency a little bit. And this is a key piece of one of the updates to the program itself. And it's an update, it's not completely new. What we're doing is trying to think more about what type of information would be helpful to a provider who is in the position of being a purchaser? What would they need to know? How can we improve the communication between a developer and a provider? And it goes both ways, right; the communication in terms of what the product offers and whether it would work for the provider's needs.

So what we've said, and I do like to read this because the language here is very important, that ACBs must ensure health IT developers can conspicuously disclose in plain language on their website, in all marketing materials, communication statements, assertions related to certified health IT, and that's important. So we want to make sure that the information is ultimately accessible to the person who's going to be looking at it, which is the provider or whatever other stakeholder.

And what type of information, what type of disclosures would it be? It would be the types of costs related to a particular product and that can be cost related to implementing or using the product as well. And that's not just for purposes of the program. So if I am a provider who is thinking about purchasing a product that supports me as a meaningful user and my goal is to attest, the disclosures are not only related to what is required for the Meaningful Use Program, it's related to what that product is certified for.

Other pieces; disclosures would include limitations. So those could be contractual, technical or other limitations associated with the product. And again the goal here is to make more information about the technology available to the provider.

So one other piece that we heard from is, well how do we get that information? I'm a provider, how do I actually access this information; where will it be? And we've tried to think about that as well. So what we've included in the rule is that a hyperlink to these disclosures would have to be made available by the developer. Then that hyperlink would be posted on our website, on our CHPL, the Certified Health IT Products List. And we're hoping that that makes the information more accessible in terms of...and allows more information to be available to the provider in terms of the technology what it does and what costs might be associated or limitations might be associated with the particular product.

In addition there is a transparency attestation in the rule and that would require a developer to indicate whether or not the vendor or the developer would provide the required information upon request. So we want to make that information available, has the developer said that they're going to make this information available?

And as part of transparency, we also think we have a role to play in this as well. So our goal is to make more information about the products available on our website and via the CHPL. The first piece of that is the open data file structure of the CHPL. The CHPL will now be converted to an open data file and the goal there is to make more information readily available and ultimately parsable by different groups who might be able to look at that information and figure out different ways to construct it to the benefit of the provider.

In addition, we are requiring that ACBs Authorized Certification Bodies report on an expanded set of information about health IT products in general. Again, there's transparency that we're asking of developers, but there's also pieces that we are doing ourselves to lead to that.

So next, let's talk about the privacy and security certification framework. So privacy and security continues to be an important piece for us at ONC in terms of thinking about health IT and what should accompany health IT. What we've done is we've updated the framework so that now, and I'm going to jump to this slide and come back. So this slide gives you a really good example of how this would work.

So what we've said is that when a product is coming to us to be certified to a certain criteria, it has to have the privacy and security pieces already attached as it were or paired with that particular module. The reason for that is that we have heard that providers have, in the past have had to try to figure out, here's the certification criteria, does my product also meet these privacy of security pieces. Our goal is to pair them in advance so the provider doesn't have to ask that question. We're saying, these are the pieces that are going to accompany any module that comes to us to be certified for let's say CPOE, for example.

So this chart, and it's a good segue to kind of the resource discussion, we are making a number of different resources available that explain the rule. We understand it's a lengthy rule and it's a technical rule. So we tried to put together charts like these that we think make it very clear what are the requirements, and that's hopefully that is to the benefit of all of the stakeholders so that they can easily see how these work together. So that's how the privacy and security framework would be set up. And the goal again is to remove some of the responsibility from the provider, in terms of underst...know...needing to know what the privacy and security pieces are for that particular criteria; that will be done for them by the time the module is actually certified.

And surveillance; so in surveillance is another key update to the program and the goal is that we've added new requirements for in the field surveillance. So what does that look like? So what our...what we're trying to think about and what we've thought about as we developed the final rule is what...how do we ensure that the product is operating as it should once it leaves the test lab? Once it goes out and it's been implemented, it's in use; how do we provide some opportunities to make sure that that product is doing what it should? How do we help providers in that way and also provide more of an understanding of the effectiveness of the product in terms of certification criteria.

So there are two types of surveillance in the rule now; one is reactive surveillance and that's focused on complaints. So we've...let's say for example we're hearing from a number of different folks through their complaints that this is a problem, the technology is not operating as it should. In that case, we're able to go in and take look at the product or the ACBs would. ACBs would also be able to do randomized surveillance and that would be 2% of annually certified health IT at one or more locations would have...randomized surveillance would happen at those locations; and that's per year.

So these enhan...these surveillance requirements are mandatory. And the other thing to note is that nonconformity or corrective action that's reported would the made available on the CHPL starting in the calendar year 2016.

So with that we're going to now talk some about the criteria themselves, and I'm going to turn it over to Mike, who will start talking about the standards adoption and some of the things that we've finalized versus what was proposed and comparisons between 2014 and 2015. So Mike, with that...

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

Good morning. So I'm going to talk, as Elise mentioned, about the 2015 edition. I'm not going to spend as much time on the comparison between each of the criteria that's part of the more technical discussion of the criteria, but I will give, you know an overview of essentially how it compares to what we proposed and then how it compares to the 2014 edition.

But let's start with the standards. Obviously to improve interoperability you need to keep up with the times and adopt new and updated standards and we also looked to adopt standards in places where we didn't have standards previously. So with this rule, I'll talk about a few of those standards where we did that, but I also want to focus on two important aspects of certification which are the base EHR definition and we've adopted a new base EHR definition specific to the 2015 edition.

And then I also want to talk about what you've heard referenced throughout both presentations already this morning is the common clinical data set which as Elise mentioned, a key set of data that we think should move dur...you know, move with the transition of care but also be accessible, for example through view download and transmit or through an API.

And then obviously, as I was just saying, we've tried to adopt some standards with some of the new functionality and use cases, so for behavioral health I'll talk briefly about that one and then obviously for public health there are a few new options like case reporting and antimicrobial and resistance use reporting where we've actually adopted implementation guides to facilitate the electronic transfer of that information. So let's move on to the next slide.

So the base EHR definition, this slide here just sets the foundation related to the base EHR definition which is, it's emanating out of the HITECH Act, which is called the qualified EHR. We're looking at a minimum set of functionality that we think all providers should have through the adoption of this health IT. And I do want to emphasize that part about establishing a minimum.

So throughout all certification, and this goes again to what you've heard through both presentations is, we're setting a baseline of functionality and capabilities that we expect providers to have and to do. And it's not trying to capture everything through certification, and there are many other use cases beyond certification including the use of standards to support them that we're not certifying and that's the flexibility that's provided to the...to both providers and vendors.

And also, again a reminder because we hear this through stakeholder feedback is that it's a definition, the base EHR that is, and it's not something in particular to get certified. Going forward the only thing that gets certified, as Elise mentioned, is a health IT modules. And so you can have one health IT module that meets the entire base EHR definition or could meet the base EHR definition plus everything else a provider needs to meet the certified EHR technology definition under the EHR Incentive Program. On the flip side, you can have multiple modules that are certified that help a provider meet the base EHR definition as well as the certified EHR technology definition.

Let's move on to the next slide and take a look at what's actually in the base EHR definition. So in the left-hand column you're seeing what are the capabilities that are specified in the HITECH Act that every provider should have and on the right, you're seeing the criteria that include those capabilities within the certification program, particularly for the 2015 edition certification criteria. And the red here highlights new criteria and functionality that we've added to the base EHR definition compared to the 2014 edition.

Further, which...what I would point out is that you see the application access criteria, that's the API criteria and what we've done there is we've split them out into three criteria, and that was based on stakeholder feedback in terms of how developers develop their health IT and would like to proceed with certification. So what we've done here is provide more flexibility and that's I think another point that I would like to emphasize is that while you may see a lot of criteria related to the 2015 edition that support different use cases and different functionalities, we've also tried to split them out to provide flexibility which increases the number.

So using API as an example, we proposed that as one criterion but in this final rule, we adopted it as five criteria. And you've seen the same thing in the past with CPOE; we had all the functionalities wrapped up into one criterion, but again based on feedback both in terms of provider flexibility and vendor flexibility for certification, we split those out into three criteria.

The other thing worth mentioning here, and Elise already talked about it, which is a privacy and security piece. So what we've done now is we made sure everything that gets certified has the appropriate privacy and security capabilities and it's no longer on the provider to ensure that they have those privacy and security capabilities to meet the base EHR definition. The provider will now know that anything that they purchase through the...that's certified has the appropriate capabilities in terms of privacy and security. So let's move on to the next slide. Hello?

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

Mike, did your slide change over?

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

Yes, there it is. Okay, now we're making...yeah, I didn't have any feedback, I was worried I lost you guys. So now we're going to switch from like those...the inherent capabilities that a provider should have to the data that we're hoping will be made accessible about a patient, that is data of a patient that will be made both accessible and also will move with the patient as a patient transitions from one setting to another in terms of care.

So as you see here, this is the core set of data that we think that should be in the common...what we call the common clinical data. And I'm just going to explain this slide a little bit in terms of the colors. So what you see in blue here is data that we've now either assigned a standard to it to improve obviously interoperability. So for example sex; we've now assigned the HL7 standard for coding sex, birth sex that is. We also have, as Elise mentioned, added additional standards so not only do you have the OMB standard for race and ethnicity, you now have the PHIN VADS standards for...CDC PHIN VADS standards for race and ethnicity to provide more granular coding of race and ethnicity.

For preferred language, we've changed the standard there to...which we think is a more appropriate standard for interoperability. Vital signs is a new one where we've actually added a standard so the coding of vital signs. And then immunizations is a new data element that we've added and we've also added standards there better which are CVX and NDC code.

Unique device identifier is a new piece of data related to implantable devices for patients, and we believe this will improve patient safety so not only as you saw in the base EHR definition will providers now have the ability to capture this information, they'll have the ability to also send this information with a transition of care. And then we've provided more specificity to the information that we think will support the longitudinal care of a patient, and that's related to the assessment and plan of treatment, the goals and health concerns, which this information can be captured in a Consolidated CDA. Can we move to the next slide?

So this is just a quick numbers overview, and this goes back to my point about the number of criteria. So as you can see here, we had initially proposed 68 criteria. We added six additional criteria, criteria that as I mentioned split out the API functionality but also provide new criteria...excuse me...for alternative settings where you wouldn't have to get certified for instance, to Direct, but you would still have the ability to capture information in the common clinical data set with the appropriate vocabulary and then be able to both create and receive a Consolidated CDA with that information. And then it doesn't focus so much on how you get the information from point A to point B.

So I'll...I'm going to talk again, like I said, briefly about this but what this shows here is a comparison also to what we proposed. So there are 14 proposed criteria/functionalities we didn't adopt; I'll briefly touch on those on the next slide. What I won't spend so much time on is going through each individual change that we made with each of the criteria compared to what we proposed or as it compares to the 2014 edition. What you need to know in a general sense compared to 2014 edition and overall compared to the proposed rule is that what we did is we tried to focus on those functionalities that improve interoperability and then reducing burden in terms of certification and development for vendors.

And we think by doing so, this should help them focus on those interoperability pieces, as well as the usability of their products for providers. Those are the two of the areas in which obviously we...stakeholders have given us feedback, you know focus on interoperability and focus on the usability of the product so we've tried to do that in terms of what we finalized in terms of the 2015 edition. So let's just move to the next slide.

So this is just a table; this is if you wanted...we have this entire presentation available on our website and if you wanted to go through it on your own time without a presenter, this kind of gives you a key so you can understand the following slides. So let's move to the next slide.

So right here is a quick summary of all the criteria or requests for comments that we had in the proposed rule of which we did not adopt. We explain all our reasons within the rule and a lot of it focused on the maturity, the widespread...the adoption, how widespread the adoption was of a standard, so in all these cases and then also whether the functionality had a particular use case that is supported; so based on the stakeholder feedback, fact-finding and further analysis and consideration of all that, we determined in the final rule not to adopt these criteria at this time. So we can move to the next slide.

And then this is just a listing of the unchanged criteria; I'm going to just quickly go through it. It essentially, like I said, tells you...in some cases there were some changes compared to what we proposed, but that didn't affect whether or not the criteria was unchanged for using test results for efficient certification to the 2015 edition. Again as you can see, what we did is a lot of dropping of some of our proposals in the interest of focus on interoperability, which led to some of these criteria that were initially proposed with a lot of changes to become unchanged compared to the 2014 edition. Move on to the next slide.

So I want to just...maybe we can just quickly jump through all these slides. I think if we go down to I think maybe slide 31, can you get through that? All right 30...so one more slide. I guess I was wrong on that, one more slide. All right, okay. So this...one of our goals with the rulemaking was to again continue to focus on patient safety, which we've done through all our rulemakings as well as through many efforts outside of rulemaking, including the work that I think many of you guys are familiar with through FDASIA, the safety...Health IT Safety Center Roadmap, also the action plan...Patient Safety and Surveillance Action Plan that we put out a few years ago.

We've also tried to include some of the focus on patient safety through certification. So what this slide does is summarize a lot of what we've done in this rulemaking that focuses on patient safety. So you have the patient matching for transitions of care. We have a few patient matching provis...excuse me, data that we focused on and in some cases using standards again, such in FAX we used the HL7 standard for phone number, we used the Telecommunication Union Standards and then actually for address, since you're using the Consolidated CDA, the focus is on the HL7 postal format standard. And then obviously I talked about the UDIs so you have both the ability to record and exchange that. And then you have two provisions that we first adopted in the 2014 edition based on information and research done by IOM and including their recommendations that came out of that research. So that was a focus on safety enhanced design. So we have a criterion that focuses on...on a health IT module that's certified to certain capabilities. I'll use CPOE again as an example, that also...the developer indicate what the...some of the testing they've done related to those capabilities. We've expanded the capabilities that this requirement applies to and then we've also set a minimum threshold of test participants for summative testing.

So those are...and then we, based on what we've seen with certification in the 2014 edition, we've also got...we've also added some specificity right in the regulation text as to what information needs to be submitted related to the user-centered design process that developers use. And then all this information, as Elise mentioned earlier, becomes available to the general public through the Certified Health IT Products List and then it can be download, analyzed, represented in a different format for the purposes of that stakeholder group.

And this is...this holds true again for QMS. So with QMS we also started out with the 2014 edition, but this time, as compared to the 2014 edition, a product cannot be certified unless it uses either a QMS...identified QMS such as by the federal government or an SDO or it shows how it's QMS maps to one of those standards. As you can see here on the side, there's no longer ability to get through certification by attesting that you don't use a QMS. And that's again an incremental approach, so from where we started with the 2014 edition. Can we move on to the next slide?

So another key goal of our rulemaking is addressing health disparities. And what this slide does here is kind of bring together all the different finalized proposals and criteria that focus on addressing health disparities. So as you can see here, we've added through, and this is part of the base EHR definition through the demographics criterion, that's the ability to record sexual orientation and gender identity and that's using SNOMED codes, so we're doing it in a...through a standard to improve interoperability.

I've already talked about the patient race and ethnicity. And then another key component to improving care of a patient is capturing some of this information such as social, psychological and behavioral health data. And we have a criterion now in which a health IT can be certified to that can show it has the capability to capture this certain information and capture it in a structured way using for the most part, SNOMED and LOINC codes.

And then filtering of QMS, so there's...excuse me, of CQMs, Clinical Quality Measures. So we've done this also in a standardized way, where appropriate, with the particular data elements and also focusing on the QRDA. So again, this will help improve, we think, give the tools to providers to improve care of their patients, particularly disparate populations.

Elise mentioned the Data Segmentation for Privacy, also a functionality that we've included in this final rule. We have a patient health information capture criterion; we provide flexibility for certification there. And then lastly the accessibility of health IT; so this applies to all health IT certified under our program and this is taking the first step like we did with QMS.

So here a provider's going to have to...excuse me, a developer is going to have to identify what accessibility standards or federal laws for accessibility that their health IT complies with. But they can get certified, as this is a first step, they can get certified by indicating that they don't comply with any of those federal laws or standards related to accessibility. However, as I mentioned earlier, that information is then available on our Certified Health IT Products List and we know there are, based on the comments received on the rule, a significant amount of stakeholders that are interested in this area and I would suspect they'll be able to get that information, identify which vendors are or are not complying with federal standards and make that information repackaged and available to the general public. So let's move to the next slide.

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

So here I'm going ahead and walk through some of the different use cases that can apply and that...we'll talk a little about MU, but we also want to talk about some of the other settings...and I know that's an area that the Policy Committee worked on what, about a year ago already; time flies. So we want to highlight some of those as well.

So in this slide, this is really a resource. I know the...at least here in the room, the print is pretty small but it's a resource slide and the goal here is a really quick overview of the criteria in the rule, where they're required, where they would fall under helping a provider to attest to Meaningful Use and where they are optional, which we've heard would be helpful for different providers.

So just to look at this really quickly, but again, this is a resource slide. In the first column you see the things that are mandatory for any product that's coming to us for certification, and that's the QMS, the Quality Management System, as well as the accessibility-centered design.

From that there's conditional, and that's the second column, conditional certification criteria. And those are things that are required, depending upon the module that you're bringing for certification. So we talked about the updates to the privacy and security framework; depending upon what module you're bringing, there are certain privacy and security pieces that would attach. The same concept for safety-enhanced design elements as well.

And in the middle, this huge column in the middle, those are the pieces for Stage 3 that would be required based upon the objectives and the measures included in Stage 3. One note here is, depending upon what a provider inten...what measures a provider intends to use for attestation, that could affect this a little bit in terms of what that...their product as a whole, all the puzzle pieces look like once its put together.

And then the last column here, all the way at the far right, these are items that are not required for a particular program, but can be beneficial to providers, depending upon their particular patient population and what they want to achieve, what they'd like to see there. So things here would DS4P, for example, some of the social, behavioral and psychological data elements as well as things like the care plan.

On this slide, this lays out the objectives, kind of the main objectives in Stage 3, as included in the CMS rule. Again, this just gives you a snapshot of what is included in the Stage 3 rule and then let's talk a little bit about what that looks like.

So this is affectionately called our cake slide, and we start at the bottom and we build our way up. And the goal of this is to show you what could a product look like as the meaningful use provider for Stage 3. So you would start at the bottom in what on our deck is the red, the red sections on the bottom. As I said, the mandatory requirements would be the quality management system and the accessibility centered design. You go one step above that and you bring your conditional things, depending upon what's coming for certification; you build in your privacy and security, your safety-enhanced design and the C-CDA creation performance.

You go one step up above that and you fall into the base EHR that's required by us, and also there's a cer...corollary to that CEHRT, being certified EHR technology definition. And then you fall into the purple area which in the middle there and that purple area captures the certified EHR technology definition from CMS and what is required there.

You'll notice that the patient health information capture, that is required as part of the CEHRT definition but is also a piece of one of the objectives as well; so that's why we note objective 6 under that. And then you have CQMs, which obviously are required for a meaningful user; family health history and then the measure calculation.

Above that you fall into your objectives; so this is where you get some of the optionality in terms of what criteria you might actually need depending upon the type of provider you are and how you intend to attest to Meaningful Use.

A couple of things to note that folks I'm sure have heard about; there are some updates to transitions of care; corollary there is the common clinical data set. APIs are also included if you look at objectives five and six on view, download and transmit. And then option...the objectives overall just note that there's flexibility; so objective eight for example, public health. There is flexibility within that objective, as well as a number of others. So you could see a situation where what you are coming to...what you would need for certification might be different depending upon how you intend to attest.

This slide is again another resource slide; this is some of the comparison between the 2014 edition and the 2015 edition. Again, just to highlight here the flexibility that we've included in terms of pulling out or separating some of the certification criteria so instead of having multiple functionality within it, it might...it's more focused. And for that reason, the API...CPOE and API, for example, are now six criteria, which is one of the things that Mike had mentioned earlier.

On this slide, this is what I mentioned a little bit during Rob's presentation in terms of thinking about what you might need as a provider who is outside of the Meaningful Use Program; so you're not a Meaningful Use provider, but there is value to using certified health IT.

So the example that I often give is that a patient is being discharged from a hospital, they're going directly to a long-term, post-acute care facility on a Friday night. What information can travel with them at that point? Can the skilled nursing facility or the nursing home see their medications? Can they see their medication allergies? That type of information that would be important and use of certified health IT by that long-term acute care facility can help that communication; that interoperability that needs to happen, we recognize it's not just limited to Meaningful Use providers but is across the care continuum, and that's what we're thinking about.

As opposed to let's say that same patient is transferred on that Friday night, but the information is only available in the inbox of somebody who doesn't come in until Monday. Shortening that window from when that information is actually available is important, and that's part of what we're thinking about in terms of interoperability and making the program more open and accessible to these other settings.

So here you have long-term, post-acute care certification. I want to note on this slide, example only, this is just an example and this goes to another point, back to transparency, right? Making the information more available about the technology to the provider and our goal is that the provider developer communication continues to improve and this will be part of that puzzle. So if I am a provider working at a nursing home and I want to think about the technology I need, that there's a conversation that's happening with the developer about what that could look like.

So here's an example. One, if you're coming to us for certification certain things you have to have, and that's the quality management system, again an accessibility-centered design; same thing for the conditional. Above that we get into some of what the Policy Committee looked at, what about a year ago now, Paul? And that's transitions of care, so making sure that that transition can happen smoothly and effectively; so that criterion is included here.

The other is the reconciliation and incorporation of that information. So this is something that Stage 3 talks about generally in their health information exchange objective. So sending, receiving and then being able to reconcile. So reconciliation also could be key here for that provider population. And then the care plan and that could be an important piece of the puzzle for such a provider.

And then here, just to highlight, I'll just focus on the blue section at the top here for behavioral health providers. So similar situation, what does a behavioral health provider need? So here's an example only of what that could be, transitions of care here again, reconciliation and then social, psychological and behavioral data. This is not to say that we think that such data is only beneficial to a behavioral provider; that could be very beneficial to a primary care provider. It depends on the population that you're looking at, right, or that you're serving. So with that said, we've included it here, but it's not the only place it could be useful, and then the data segmentation for privacy standard as well.

So that brings us to the resources and in some ways, we hope that this is really the most important slide. We know that this is a lot to take in in terms of what that 2015 edition would do and we want to merely make sure that we are providing a number of different resources in a number of different ways that can help for the consumption of that information across all stakeholders.

So the final rule itself obviously; but the presentation, we have a full presentation that includes a complete breakdown of what was changed versus the proposed versus what's in the final. And that's a quick resource if you want to see what the rule does in about, I don't know was it 50-60 slides, that's the place to go.

The other thing is that test procedures; so the test procedures are being rolled out. We've also included, and working with Steve's team on certification companion guide and the goal there is for that to be in some ways, I don't want to say a one-stop resource, but a very complete resource of things that are related to a particular criteria; that could be FAQs, for example and the specific pieces of the rule as well.

The other thing that I would note is we have included on our site, and we continue to include more not one-pagers but we aim for about two; two pages that highlight specific areas of the rule that we think might be helpful. So there's one on DS4P; so what does it mean to be able to segment for reasons of privacy? And what are the pieces in the rule that do that? So we've included something that includes somewhat of a plainer language background on that. There's one on patient engagement. There's one on disparities, on the pieces on the...disparity. So we hope that those are also going to be a resource for stakeholders.

So with that, I'll open up for questions. Mike, is there anything else you want to jump in on before we open for questions?

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

Nope.

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

All right, questions?

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

Well thanks Elise and Mike for a very helpful summary. You know as the HIT Policy Committee, we aren't as close to certification rule as the Standards Committee, but this was really very helpful and shows clear responsiveness to the feedback you've been getting; thinking about the transparency down to the cost. Thinking that the surveillance, something we've heard a lot about.

And thinking about the approach of being agnostic to, you're separating yourselves from how can we give information about HIT modules that can benefit anybody, all providers across the whole continuum versus just being tied to Meaningful Use. So really very helpful, in fact policy kinds of philosophies in the certification rule; really very, very helpful. Gayle, comments and questions.

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

Thank you very much, Paul. I just have a couple of comments and a couple of questions. Certainly the transparency aspect of this and putting that out there is extremely important for providers as they are purchasing things and that is a key component; thank you for doing that.

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

Um hmm.

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

Another question I have is, I didn't see much in the way of usability and could you perhaps give us a little more detail on what you're doing within the rule of certification to make sure that the products that are going to be out and they're certified have some...that there is a consideration for usability.

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

So Mike, maybe you could talk a little bit more about the safety-enhanced design and how we've incorporated that into the conversation or into the final rule.

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

So sure, most of our user-centered design/usability is focused on safety and that's the safety-enhanced design criterion. And so what we've done with that is, as I mentioned earlier, we've applied it to more capabilities and, for example, we've applied it to demographics because actually data has shown that so many of the safety related areas begin with the data entry on a patient; so we've applied it there.

We've also, like I said, provided...set the bar in terms of summative testing that they're doing and some of the information they need to provide. And we've relied heavily on the guidance and instructions provided by NIST, and we reference those within the final rule and as part of the requirements of the information that are...has to be made available through the test results.

And then we said...we took comments related to setting a minimum threshold for test participant and while we give guidance to the types of users that should be part of the test participants, for example, we indicate that if it's not a clinical capability, it's okay not to have a physician being the one as a test participant; but where it is a clinical capability such as CDS, that we would expect that the type of folks that are...that would be using this capabilities would be part of the test participants. So we've done that.

And then we set the number of participants at 10. So that...and what we found, there's data that shows, and remember, this is balancing of both burden and goal of increasing patient safety here; we set it at 10, based on the public comments we go. And data shows that by at least having 10 participants, you reduce medical errors by over 80%. So that's some of the things we've done on usability. We haven't gone into usability for all functionalities; we've tried to focus on patient safety primarily with our usability testing.

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

Also I'd like to follow up a little bit on your discussion on APIs. And there's one segment where...one section where you're speaking and you do have some requirements on the vendor side for APIs.

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

Right.

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

Are you...where are you going with that actually for those who are going to construct the APIs and are going to be building those and interfacing? What ability do you have to have any certification potential for perhaps the APIs that will be built?

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

So obviously we're focusing on the vendor provider side here. So we're talking about the API and we're focusing on the data again, that common clinical data set, so that's the data that they need to be able to make available and it's a read only requirement here. And so they have to make that data available, they have to be able to get there right patient.

We're not foc...and then the other point of it is, is that we haven't set the standard so we've looked at where things are from the functional perspective as to where the industry is moving and we haven't set a standard as to what would...for this criteria now, focusing primarily on functionality. But we expect in the future that we would move to a standard as hopefully the industry will coalesce around a standard and we indicate that for example FHIR has some promise there.

The other point is privacy and security; so we apply our, you know our privacy and security framework to the certification of these criteria so that gets into obviously access and authorization. And also they have to establish...they have to show the ability to establish a trusted connection using you know either the encryption or the hashing consistent with SHA-2. So that's some of the functionality we're talking about in terms of certification to an API. And then, that's part of the base EHR definition so we expect that functionality to be available to a provider as well as to meet the requirements under the EHR Incentive Program, in terms of making that API available to patients and use of their third party apps.

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

Thank you.

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

I'm going to add here that this is one of the areas where we received a lot of feedback that this is important and it's important to have in the rule that there is some innovation in there. And as Mike said, allowing the industry to coalesce around what would be a standard or to allow some of that innovation to happen. So what we've included in the rule is the functionality pieces, but we do look forward to the opportunity to fine tune that further in possibly a future rulemaking. And we look forward to what the industry brings to bear on that as well.

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

I think this is an open field and can potentially become the Wild West, so we want to make sure, especially on the privacy and security aspect as APIs are developed...

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

Yes.

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

...that we make sure that we have those constraints in place.

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

And one of the things that we're...that the pol...the FACA will be doing is looking at this API task force and that, I think some of those questions would be part of that conversation. I don't think this is the end of the conversation, I think it's...this is...we're continuing the conversation and what we've included in our rule moves the conversation forward, gets developers to think about the functionality that's needed. It's supportive of some of the requests we've heard from CMS and others, but at the same time the API Task Force will be able to look at some of those questions in terms of, what are the risks or what are the pieces we need to consider in terms of privacy and security, for example, in APIs?

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

And Jon White had a comment on the usability question.

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

Yeah and then I'll chime in too on the APIs, just quickly. So as your token visitor from the Standards Committee I felt a little obliged to speak up. So in terms of the usability, everything that Mike and Elise said absolutely correct, you know, fundamentally focused on improving the safety of the products and trying to enhance that. You know, regulation's always a balance, right, and you don't want to get in the way of folks that are coming up with really great user interfaces or great approaches to, you know, or applications.

So on the one hand you don't want to go too far, but to the extent that you want to try to be able to, you know, raise that floor, I think that's what we've tried to do in the rule and will continue to do within the limits of our authority. You know, I would call out wonderful private sector efforts like, Kathleen, the AMA and colleagues at MedStar who have recently announced a separate initiative focused on improving usability; that's a great...I love seeing people build on the floor of what we've done at ONC and you know, raise the floor up and then there...our colleagues in the provider community are trying to take that a little bit further and I encourage that sort of thing. I think that's a great thing.

On the API issue, I'm going to channel some of your colleagues on the Standards Committee and remind you that there's a lot of activity right now in the private sector around APIs. So, we're not necessarily in a position where we want to be like, okay, here it is, here's your API; love the fact that the private sector is kind of jumping into this with both feet and we will work along with them and trust to verify that it's doing what we say it is.

Lucia promised she wouldn't say anything during the meeting, but I will just, you know, double down on the privacy and security aspect of the API, you know and API is not just the standards right, it's kind of the business rules that two folks put together to interact; the privacy and security is an important part of that. So, it's multidimensional, it's kind of cool like that, but I think that we're going to look to work very closely with our colleagues in the developer community and other communities as this plays out. So, to be continued; it's going to be an interesting, fast-moving conversation.

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

Thank you. Devin?

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

Great, thanks. I actually want to pick up where Gayle left off with usability because that was definitely the thing that stuck in my mind as well. And first it's good to see that it's part of it and I'm glad to see that it remains so, but the focus on safety is a bit disappointing. You know, last time when we had the joint meeting someone was sitting over there, talked about the 500 clicks it took to do the nursing admission. And I totally understand about stifling innovation, but the reality is there's been very little innovation in this space, so I do wonder if this was an opportunity to set a benchmark so maybe innovation would come and meet it.

Safety, usability has been pretty well established, lots of research; I'm sure Chris knows, you know for two decades now, but it has not yet translated to the type of usability that the constituents we represent really are demanding. So agree with everything in there, but you know, ask the Standards Committee, you know, what's the roadmap, you know because are we looking five, 10 years down the road; that's just a really long time away and unfortunately it just doesn't seem like the private industry without some prodding is really coming up with major change in usability in the products I've seen anytime recently.

And it ties directly into other parts that you talked about. So for instance, you talk about social, behavioral elements; so that's great, you know these discrete elements. But the reality is those discrete elements are generally unusable and so most of the clinicians who are getting us transfers of care, cannot really use that information because it's often tucked away in little spots all over the EMRs that they receive them in.

And you talked about the transferring of the assessment and plan sections, but those are not uniformly put anywhere, so they don't actually come over in a usable fashion either. Some places may tuck them into their encounter records, others may tuck them into notes, some may put it into a discharge summary, a transfer of document summary; I build those for...so I know that they're tucked all over the place and I just am not aware of, and maybe I'm missing out, how C-CDA harmonizes that so that it really is using.

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

So, I can answer the question on the data elements related to assessment plan...of plan of treatment or plan of care and help...that. You're correct in that terms of behavioral health information that it's not currently part of the consolidated CDA, so we're not testing...or excuse me, not part of...yeah, part of the common clinical data set or being tested as how it's captured in the co...so therefore not being tested how it's captured in the Consolidated CDA. However the other data elements, we are focused on making sure that's in a section, a particular section of the consolidated CDA.

So the sections that we currently point to actually involve the care plan template, but what we're looking at now, based on you know talking with the curators of the consolidated CDA is whether there are other...within the CCD template sections that could be specifically created to capture that information.

So overall your point is well taken in that we don't want this information to just be crammed somewhere in the consolidated CDA, not easily accessible and we tried to deal with that too with the UDI. If you look at the requirements where we say it has to be in the, you know, if you're presenting it in the consolidated CDA, we're hoping...it's...say it's captured in the procedure section template. So we are trying to provide the structure to capture that information so that when it is transferred through a transition of care that it would be easily found, so to speak. So, we are addressing that issue is the point about your point is what I want to get across.

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

Any other comments or questions? Otherwise, thanks for a comprehensive and digestible update on the certification rule. Thanks Elise and Mike.

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

Our pleasure.

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

So I think this morning has been very helpful from a high level, very quick summary of both the Meaningful Use Stage 3 rule and the certification and I've really learned a lot; so I think it's thanks to the panelists. Okay, we'll open to public comment and then probably we'll break earlier for lunch and then...and maybe shift up the schedule, if that's okay with everybody.

## **Public Comment**

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

Operator, can you please open the lines? While we wait to open the lines, if there's anybody in the room who would like to make a public comment, please come up to the table. And a reminder, public comment is limited to three minutes.

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

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

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

While we wait to see if there's anybody on the phone, we did receive a number of comments through the public chat. They're very detailed comments and there are quite a few of them so I think what I'm going to do is just share them with the committee, because it would get lost if I tried to read them here. And it looks like we have nobody on the phone so we'll break for lunch early.

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

Okay. So we have an hour allotted for lunch, so if people don't mind, we'll just resume back at 12:45 instead of 1. All right, thank you.

### **Operator**

All lines are bridged.

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

And we're going to start out this afternoon with a report that ONC had prepared about how do we make sure that the HIT certification program supports our new models of care and this feeds up into the Advanced Health Models Workgroup and I think I'll turn it over to Kelly Cronin to introduce the topic and the panelists.

### **Kelly Cronin, MS, MPH – Director, Office of Care Transformation – Office of the National Coordinator for Health Information Technology**

Thanks, Paul. So just to give you a little bit more context about why we funded this work, you know, there's been a lot in the literature and a lot of convening done in recent years around what...the health IT requirements for accountable care or more broadly, sort of delivery system reform. But given the Medicare Access and CHIP Reauthorization Act and some of the specific provisions specifically section 101E that has some requirements for eligible APMs, or alternative payment entities and that calling out certification of health IT, we felt that it was a good time to really sort of take the opportunity to get a good synthesis of what is known and what are the needs among the provider community that are really on point to implement these new models of care and payment?

So we commissioned this work with the idea that we would build from the existing literature, do some qualitative research among health IT vendors and provider experts who are sort of leading the implementation of these models. And then supplement that with a technical expert panel so that we get sort of an up-to-date perspective on what's really needed to perform well in these new models. What are the tools and what are the types of health IT products and services that are needed for success?

And in doing that, we hope it'll inform the way ONC and CMS consider these new provisions in MACRA and more broadly, sort of where do we evolve our portfolio of work to better support these models. So with that, I'll turn it over to Lamot du Pont with Manatt Health, who partnered very closely with Scott Afzal and the team at Audacious Inquiry. Together they led and performed this work.

**Lamot du Pont – Senior Advisor – Manatt Health Solutions**

All right. Thank you, Kelly. So my charge today is to walk us through the purpose and the process and then I'll turn it over to my colleague Scott to address some of the findings and then when Joe arrives, we will talk about some feedback from the workgroup.

So, as we advance the slides; let me dive right in to the purpose. So our purpose can best be framed by us having to answer two questions. The first question is, what are the health IT capabilities, what are the components of the technology that providers will need to be successful in alternative payment models? That being the first question, the next question is, how do we ensure that those capabilities are in the hands of providers in time to be successful in the emerging models?

So we took those two questions, as Kelly indicated and used that as our charge to do qualitative research, to organize a technical expert panel and prioritize a list of capabilities. I'm going to walk through those now. And just to give some context and some framing, there are five considerations that framed our work.

The first is the alternative payment models that you looked at, there were three; accountable care organizations, bundled payments, and patient-centered medical homes. Each had very different business rules, processes and requirements, but as they are identified in MACRA, those were the focus of the research efforts.

The second is a timeframe. We did a little bit of crystal balling that MACRA as a context establishes January 2019 as a date of demarcation. So we used that to project forward what would the marketplace look like in terms of the capabilities?

The third consideration was scope and we had a narrow focus on the technology capabilities. As an earlier panelist and committee member mentioned the idea...notion of the business processes and the staffing and workforce issues are critical and vital to success within the context of alternative payment models. But our scope was focused on those elements of certification of the technology. And as a result, when we talk about this it will be wrapped and focused on the technology.

So while our scope was narrow, our interpretation of technology was broad; it wasn't limited to electronic health records. We were considering tools and products along the lines of population health management capabilities, analytics, referral management tools; scope in that sense was broader than what has traditionally been the confines of Meaningful Use.

And finally there was this notion that we were not entering this exercise with a preconceived notion that certification would be the way to best advance the adoption of the capabilities in the marketplace. We recognized that there are additional levers in terms of comparative tools, incentives and others and so as we walk through this, it's important to note that we looked at the health IT capabilities that could be certified, but we in no way make a prescription as to what should be certified.

So our initial process for qualitative evaluation and research included both interviews and a literature review and we used these to refine our understanding of the marketplace and eliminate where the key challenges are today. So, because of time limitations we can't go through the full list of challenges that were identified, but I'd turn your attention to three that persisted and reemerged consistently throughout the research.

And the first was with respect to referral management. The ability to monitor and track appointments to be able to effectively close the loop for referrals was something we heard loud and clear from the marketplace.

The second is effectively engaging patients. We heard from both providers and vendors that this remains a nascent state in terms of understanding what works most effectively. We heard also that patients are suffering a bit from a little bit of portal exhaustion and the capabilities to engage effectively are still emerging.

And finally the third element is the ability to monitor updates and track risk stratification and have that actually embedded in the workflow is something that was identified as a capability that would be helpful for providers that are involved in alternative payment models.

So we needed a construct, knowing that the full constellation of capabilities were enormous, we had to start with a framework. And what we did is we resurrected an accountable care framework that the CCHIT put together in 2013. So this framework may be familiar to some of you; it was a way to organize and walk through and be able to prioritize and identify what was important, where there are gaps in the market and what could certification address.

So the CCHIT framework includes seven processes that you see at the top of the screen. They're flanked by 64 individual functions and then 270 discrete capabilities. So not wanting to torture our panel of technical experts, we went through a process to winnow the 270 capabilities down into a manageable framework that would allow us to prioritize those that are the most important among all those that are important and offer a lens to help us focus efforts for advancing their adoption in the marketplace.

So the filtration process; we used three filters. The first filter was to take the 270 capabilities and remove those that were strictly administrative functions. For example, the ability of a parent to schedule an appointment online or using an application is an important capability, but because our focus was clinical, we decided to leave those off the final list.

The second filter, the functions that were identified as not being as critical as other functions, relative to what we found in the literature and the interviews were also removed. And then finally the third filter was those capabilities that were already being addressed under both the 2014 and 2015 editions for certification.

So moving through those filters we went from 270 capabilities, 250 were filtered out and we arrived at 20 capabilities. So those 20 capabilities we asked eight representatives from provider organizations involved in alternative payment models to help us rate and give a rating, a normative value across four dimensions for each capability.

The first dimension was asking them how critical is this individual capability for success in the marketplace and scores ranged from one to five. The second and third deal with gaps in the marketplace; so the first gap we asked them to identify is the extent to which there is a gap and how big with respect to the availability of the capability in the marketplace.

The third filter addressed the gap around the capabilities integration into the workflow and their sense currently how that fares. And then finally we asked for the fourth dimension to get a rating on the extent to which the market would be able to cure the existing gap, absent certification. So by walking through these four dimensions, we got a sense of the criticality and a gap in the market and whether the market forces, left to their own devices, would help ensure the adoption and widespread availability of this capability in the marketplace.

So that's the process. Now Scott has the pleasure of talking about our findings.

**Scott Afzal - Program Director – Chesapeake Regional Information System for our Patients (CRISP)**

Thanks, Lamot. So these are grouped; as you can see there are 20 total capabilities, we've clustered them into groupings, but I'll walk through here. So 20 capabilities and eight groupings; just because one is last doesn't mean it's unimportant. These were the ones that as Lamot described through that filtering process, were winnowed down but are still all deemed to be critical functions.

As we start at the top care plan, and I know Dr. Kimura may make a point on this when we gets to his comments, but overall the care plan discussion had a lot of attention in the technical expert panel. The important point that was discussed is that the concept of creating a standardized care plan doesn't necessarily suggest that it's a uniform care plan for a particular patient with a particular chronic disease, that there can still be individualized and specific plans for an individual patient while still getting to standardized document constructs to facilitate interoperability and exchange.

There were 11 capabilities that rolled up into this care plan overall cluster. And specifically within it we wanted to call out a few specific points. The really fundamental concept of making a care plan broadly accessible by care team members; the fact that it tracks accountability for that individual patient and it's got the capability to capture and monitor goals and milestones associated with that particular patient's goals.

Moving onward to referral management, we had two specific capabilities; one associated with identifying the individuals who are responsible for a special referral task and then to integrate provider lists into the referral process. So if a patient does have a preferred provider that that's accessible and a referral process can adhere to that patient's preferences with respect to their providers.

Moving on to multiple communication modalities; this was discussed as a very valuable capability, a relatively significant gap in the marketplace thinking about secure texting or instant messaging. There was discussion about the concern of miscommunication over communication modalities such as inadvertently, I think we've all had a missed text here and there, but the clinical impact and the safety impact of that modality.

Moving onward, notification of test and intervention results and the discussion of not only notifying the ordering provider but accountable providers within a given alternative payment model, who should be aware of those results and who, for example may want to update a care plan with those results.

Data extraction in a standardized format; so we know here this speaks to basic interoperability, but this is a pretty broad concept as you talk about certification of different tools that are supporting large-scale data analytics, all-payer claims databases and other infrastructures at potentially a state level that could be leveraged by individual provider organizations trying to understand performance within their organization.

Risk stratification certainly noted as a foundational element for effective care management. Half the panelists believed that the market would cure this particular gap by that 2019 date that Lamot alluded to.

Quality performance measures; this was noted at the workgroup level and I'm sure there will be discussion on this that this was towards the bottom of the list and storing of quality metric data of limited value. This was a relatively nuanced capability in that it wasn't necessarily speaking to the value of quality measures and the ability to capture, communicate and calculate measures, but rather to store QRDA calculated measures locally so that you can do benchmarking back in time should measure definitions change over time, that you've got the already calculated measures within your certified technology.

And then lastly, data visualization within products; many of you are familiar certainly with things like lab flow sheets and the ability to visualize information over time and see trends. This was of lower relative, again relative importance as many applications in the market currently have these feature sets and the market will potentially address these by that 2019 date.

So the next step in this process and we've taken the first step on this, but we're in midst of this process, is grouping those capabilities into certain categories with respect to the ability to certify. And so what you'll see on the next slide here are five categories that define whether or not a particular criteria would be readily certified or not. Now this is again to a point Lamot made, could be certified not should be certified.

So as we look at the first, and I'll provide some examples just to put this in the context for everyone. So the first capability or category A, the capability requires a new certification criterion and the criterion is mature. So there is a viable standard that exists to pursue certification. Example could be that texting and multiple communication modalities using the security criteria is the certification point.

Category B would be capability requires changes to existing certification criteria. So there's a viable standard, but its current use is optional. So take for example the care plan template within the C-CDA release 2.1 which is a currently an optional template but to meet the use of a standardized care plan within an alternative payment model requiring that release would be the certification step.

Category C is capability requires maturation of potential standards and functions. An example here would be integrating preferred provider lists into the referral processes and a necessary update to the HPD or healthcare provider directory standard to enable that particular function.

Category D is the requirement would require development of a potential standard or function. An example here would be updating a care plan with available results and we go back to that concept of incorporating results into the care plan, there needs to be a place to put those results in the care plan.

And then lastly, standards exist but policy levers or demand needed for certification to have an impact. And the example we note here is the ability to have standardized data exports from non-EHR sources, going back to that APCD-like example as the most notable example.

So with that, I think we're going to turn it over to Dr. Kimura.

**Joe Kimura, MD, MPH – Deputy Chief Medical Officer – Atrius Health**

Thank you Scott and I apologize to the committee for my tardy entrance here. So, first off I think the report as it was reviewed by the Advanced Health Models Workgroup, I think first and foremost clearly acknowledged the tremendous amount of work that went into aggregating all the information and bringing it to the workgroup. And I think the workgroup really enjoyed the opportunity of being able to speak about, how does this fit together with the thoughts around where advanced health models and the thinking about where we wanted to go in terms of the care delivery model going to the future.

I'm going to guess it's this one; got it. Right. And I think the three major observations that we put together were that one that the challenges identified in the analysis were generally consistent with what the workgroup's own participants experiences were, and in particular, through the APMs provider, sort of the APM provider perspective.

The importance of effective closed loop referral management and the role of the care plans were two particularly strongly resonated areas. And again it dovetailed with a lot of the discussions that the workgroup engaged in in the spring around care plans and the interoperability roadmap discussions.

In particular, to be successful the workgroup noted that APMs would generally need to one, integrate information from a broad and widening array of sources, not just sort of in the traditional data sets that we think about that we're using today, but expanding the kinds of information that would be needed to support new types of interventions. Navigating a whole set of new relationships and priorities, particularly around care delivery.

And then finally defining and tracking the shared responsibilities among an expanding scope of caregivers. And this is another area where the workgroup was very...wanted to emphasize that in the future state of an advanced health model there would be lots of other new individuals and roles played around how to support patients and communities in terms of optimizing their health.

And because of that sort of a feedback, if we aggregated it to a couple of bullets here, the first was pretty strong through the workgroup discussion was that while this analysis definitely highlighted some areas, I'm going to...I spent the morning talking about attribution models, so I'm going to jump into specificity and sensitivity; where the specificity of the things that were identified were definitely acknowledged.

And then there was a question about, should we explore and incorporate additional perspectives, either from the patient or the person perspective, other caregivers perspective as the workgroup envisions the success of any APM partner, that the success of these other partners and their engagement would be integral to the APM provider's success and that the current analysis strongly reflects the provider perspective from that area.

Taking that provider perspective though, two additional functional domains were highlighted by the workgroup. One was the importance of bringing the output of data analytics or any of the data elements into the operational care processes through decision support or other areas. So that general capability, whether it's risk numbers or anything along those lines, that needed to be...that capability of bringing that information or that output into the workflow is highlighted.

And secondly the importance of performance measurement in an APM going forward in the future and the cycles around thinking about quality, at multiple different levels; but to be able to meet targets and to meet the expectations of accountability, we needed to be sure that the quality measurement and the ability to use those quality measurements to drive performance improvement was a...needed to be something that also was highlighted.

And then to the point that Scott was bringing up around care plans, we again discussed deeper in the area, and the workgroup struggled a little bit thinking that again, the conceptual importance of the care plan was absolutely acknowledged and the importance of promoting policies that advance the use and the usability of care plans I think was something that everyone felt pretty strongly about.

I think there is some tension there around, do we know enough about care plans and are the standards that currently exist geared more towards episodic care planning as opposed to the person-centered longitudinal care planning that we may envision that needs to be supported in the future. And therefore, was...were we ready to move to certification around some of these areas? And I think we sort of ran out of time as that discussion went forward, but again the workgroup definitely acknowledged the importance of this and how central this will be to the success of an APM.

And then finally, the last two sort of directed points was to prioritize the integration of patient-generated and again, patient device-generated health data as well as this concept of bidirectional engagements of a patient with the APM providers. And I think that pulls me to the end of discussion.

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

Good, thank you. Questions, comments from the committee members? Kathleen.

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

I am delighted to see the emphasis and the high rating that was accorded to the closing the referral loop process because I think that is certainly an exa...a fine example of the need for interoperability. A comment just in terms of what we've experienced in terms of a pilot project that's been done through the PCPI is the importance also of incorporating the question that is being asked by the referring...by the referring physician of the consultant. It's remarkable how often that question is not known and huge amounts of time and energy are spent trying to tease out what the question might be.

And then the second area in which we've had some experience is with regards to the urgency of the referral. And we have found that there is a great range of variation in terms of in our pilot again, some physicians thought that an urgent referral meant a patient should be seen in 30 days. I'm a cardiologist; generally if it's urgent, I have to see them that day or the next morning or else they'll be in the emergency room. So we actually had clinicians make that distinction and come to what we might call terms that they could agree upon.

And then the third part that I think just merits mention is that we've envisioned this as a triangle, so I'm pleased to see that you plan to have patients and caregivers involved because what we've realized is the triangle just breaks wide-open if you don't have all three participants; patient, referring physician and the consulting physician all have a shared understanding. So we've seen this as a very fruitful area for future performance measure development is, quite simply, being able to ask a patient, do you know why you're going? Did your question get answered? And then was it acted upon subsequent to that? So kudos for the work done so far and we'll be happy to provide more comments going forward.

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

Great. Thanks. Anjum?

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

Thank you for the presentation. So as we think of advanced payment models and advanced, you know living models and think of a more person-centered approach, the value of a person-generated data and that data that is not routinely collected within clinical processes, keeps on increasing. And so my question was, was there discussion around how do we capture like more diverse data like images and videos and other kinds of things that are generating and capturing a lot of the patient activities that may impact outcomes? Or for that matter, just unstructured data, like capturing that even from medical records.

**Scott Afzal – Program Director – Chesapeake Regional Information System for our Patients (CRISP)**

So I don't believe in the 20 capabilities that we arrived at that there was any specific detail pertaining to the structure of the content other than talking about the structure of care plan documents and the use of C-CDA templates for exchange. So using that construct of the CCHIT capabilities that we started from, I don't believe that there are any included. Lamot, I don't know if...

**Lamot du Pont – Senior Advisor – Manatt Health Solutions**

There was with respect to getting the results of the order from labs, radiology and interventions into, but as Scott mentioned, we were constrained by the CCHIT's framework. And so the elements that you illuminated fell through the screen process, not because they weren't important, but because they were either addressed in other capabilities or didn't rise to the ones that we wanted to showcase for next steps relative to that.

Another important point in this process is that we encouraged the technical expert panel to give us feedback. If we had inadvertently orphaned or missed something, in fact we started the 19 and they insisted that we add a 20th around referral management. So, the process was open and we are open to other types of capabilities that we may have inadvertently missed.

**Joe Kimura, MD, MPH – Deputy Chief Medical Officer – Atrius Health**

Paul, can I just add a little bit because I think we touched upon that a little bit in the workgroup, too because I think the capabilities and that was a lot of the vision of what I think the workgroup members were thinking as part of, that's how care delivery will evolve going forward. But given this aspect of thinking about sort of moving towards what are policy levers and certification opportunities the, did we know enough around that to be able to push along those areas? I think we didn't quite resolve that discussion, but it wasn't again because it wasn't thought that those areas and those types of data were going to be important in the future.

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

So I'm going to piggyback on what Anjum just said. So I...if I look at the overall presentation I would say the most important, so remember, this is for electronic technology support of advanced health models, so the models where we're going to go towards. I would say that the list that Joe reflected that...the list that Joe talked about that reflected the workgroup decision were as, if not more important than the final list that came out of this process.

So I'm wondering as I listened to the process, there was this massive filtering pro...this filtering process that went ahead before you gave it to the TEP and I think a lot of the important stuff fell out at that point. So to Anjum's point, the focus...we're now really focused really on people instead of patients only and the incorporation of their social support, etcetera is certainly one of those. The patient-generated health data is another example and that came up on Joe's list.

And the other is the learning health system which really is a focus, I think, of HHS and learning for what reason? Right now quality measures, which is our...when we talk about pay for value, you're paying for something and that something is the, in theory the placeholder called quality measures. The only function that comes here is storing the output of the quality measure and that I think misses a big part of this whole equation in terms of learning health system. And who has to learn? It's the people at the front end of care, directly interfacing with the person in front of them with the benefit of all that learning that's happened, even on their panel or the panel of the entire United States.

It seems like we would like to have and more than it seems, we would like to have functionality at the point of care that takes advantage of all that learning and that's sort of not found here at all. And so I'm nervous, if you look at the feedback you got from the workgroup, how is that going to be incorporated into the report is, I guess, the big question that I have?

**Lammot du Pont – Senior Advisor – Manatt Health Solutions**

So I think we're also looking at a couple of things when the dimension is, we'll identify areas where both the workgroup and other feedback outside of where we had collected information will be used to guide the analysis. And I forgot to mention at the outset that this is not the conclusion of the conversation, this is the platform to continue the dialogue. So we by no means want to have a tight prescription as to the pathway forward. So and taking the analysis for what it's worth is going to be one of many inputs.

I think the other thing that's important to look at is the time frame and the learning health system being a construct that has a horizon for full development, maybe in a...setting that out beyond 2019 and where we looked at what the discrete capabilities that it's put into a certification process, really need to turn quickly in a timeframe by the end of 2016. So I think that the work that is organized here will be a step forward and will be a continued pathway and it's important to keep in mind the outstretch goals that you've identified and make sure that we're building towards those. So we'll incorporate that into our analysis.

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

So just one clarification on the 2019 versus 2016, why are you saying it's only 2016 that we have our change in order to meet the needs of 2019?

**Lammot du Pont – Senior Advisor – Manatt Health Solutions**

Well, as part of the interview process in talking with health IT vendors, there was the indication that in order to be able to develop specifications, they needed sufficient lead time to get those capabilities in place. So if you're thinking of in 2019 to have a capability in place, health IT vendors and others need to be starting work relatively soon and then the certification tools and criteria need to be defined and specified. So when we look at this, 2019 may seem a long way off, but there's a lot of work that needs to be done and timeframes start to move back.

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

Well we've been through this in the Policy Committee and our normal lead time was 18 months, so it just seems like you have twice that right now. Just don't want...want to take advantage of the lessons we learned from Meaningful Use and being able to push far enough so that we have what we need by 2019 and I'm feeling a little bit nervous about what you've spec'd out compared to what I think we're going to need. According to the Secretary's timeline, by the end of 2018, for example, I just think we need a whole lot more and the focus is really different from what you came up with the 20 for them to concentrate on. I'd focus it more on what Joe's feedback was, I guess, personally. Gayle.

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

Thank you very much and kind of tagging on to your question about the learning health system and incorporating, again putting the patient...making this patient-centric and individualized. I don't know where you are picking up things such as behavioral health and what...and also long-term care, things that we have under HITECH no ability to...we don't have the levers that we have with Meaningful Use. So how are you incorporating that within your 20 principles? And can you give us a little better definition as to what you would anticipate in order to pull those aspects of healthcare into this whole model?

**Scott Afzal – Program Director – Chesapeake Regional Information System for our Patients (CRISP)**

I might start just by suggesting that the absence of a particular capability from this list doesn't suggest that it won't exist in the marketplace and that there are exchange functions that are occurring today amongst providers that are already performing within APMs. And so this list is not all-inclusive of all things that will occur in the marketplace. And so to the extent that providers are already beginning to exchange continuity of care documents that are inclusive of some of that content, those functions are evolving in the marketplace.

**Lamot du Pont – Senior Advisor – Manatt Health Solutions**

And we also heard loud and clear from the interviews and from the literature review that that is one of the challenges is being able to get those types of data that have heretofore been locked into those entities that have been outside of the traditional clinical continuum. And as Scott mentioned, that there are efforts afoot to try to incorporate and build them in and remain at an emerging state. And so relative to the list that was presented here, it may have fallen on 10...in the top 15. It was identified as a critical component, but in terms of a pathway for the near-term, by 2019, it was identified as a lower priority relative to the care plan, referral management and some of the other capabilities.

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

Troy, please.

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

In regards to the slide ranking the capabilities, you know I know you've teased it down to what 20 or so, 22 is that right?

**Scott Afzal – Program Director – Chesapeake Regional Information System for our Patients (CRISP)**

Twenty.

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

Twenty, wonderful; okay. What I'm really curious about is, I mean where can I actually see that 20 listed out? I see the generalities and appreciate that.

**Scott Afzal – Program Director – Chesapeake Regional Information System for our Patients (CRISP)**

Right, right. We can make that available to the full committee. It was presented to the workgroup last week, but we'll make those details available.

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

Okay, great. Appreciate it.

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

Great, thanks. Chris ?

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

Thank you. That was a great presentation and interesting work; I had a question. We were sitting during lunch and we were discussing alternative payment models and we're talking about the unintended consequences. I know this is not what you were charged with, but I was wondering if you had discussions about what requirements, what functionalities are necessary to discover potential unintended consequences that might arise from payment models? You know, if you measure some other things that you're not measuring will fall by the wayside, potential trying to move patients out of populations, etcetera. So I was wondering if you had some thoughts that you'd care to share and...or if you actually wrote something up that somebody...that I could take a look after?

**Scott Afzal – Program Director – Chesapeake Regional Information System for our Patients (CRISP)**

So you're right that that wasn't within the scope of our focus area. Kelly, I don't know if you have any particular comments you're interested in adding to that?

**Kelly Cronin, MS, MPH – Director, Office of Care Transformation – Office of the National Coordinator for Health Information Technology**

Yeah, I'm not sure to what extent this came out in the interviews, but...working? But I think that one of the things...observations we've heard about, and I tried to sort of monitor informally is the degree to which ACO silos are forming in the market, particularly in large urban markets. And a lot of the data aggregation that's really sort of the heart of what they need to do for population health management and data analytics are creating a lot of sort of warehouses that are walled off, if you will. And the exchange capabilities that they need go beyond their provider network in an ACO.

So, I think there is a real interest in, you know, as a part of all the work we're doing for interoperability roadmap, to really try to think, how can we start to, you know, have a greater set of policy levers around these alternative payment models that help with more ubiquitous exchange regardless of what provider network you might be in or not. We'd like to exchange.

I guess there's also this reality that, I mean there's data to support this, a large proportion of clinical encounters are happening outside the provider network for an assigned population. So it's in the ACO's best interest really to be able to get notification in a real-time basis when someone shows up at a hospital that's out-of-network. So some of those capabilities are advancing in the market, but there are many, particularly large urban markets where the levels of exchange are not where they need to be to really support these models?

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

Okay, Devin?

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

Thanks, this is really helpful and I think I generally have experienced similar priorities. Because I don't know all the details of the capabilities, maybe could just get a quick answer to one. So like the first one, the care plan, 11 capabilities. In my experience I've seen many different upper versions of a care plan and I'm just wondering how advanced this capability that you're talking about, how...I've seen a lot of low kind of bar care plans that actually I don't think really drive...would not be that critical to me delivering an alternative payment model system and is that what this is achieving, just that minimum bar or is that kind of best case scenario? These 11 capabilities you're doing the kind of Cadillac version that really can make a game changing difference in your ability to deliver population health?

**Scott Afzal – Program Director – Chesapeake Regional Information System for our Patients (CRISP)**

All right, I'll start. Yeah, so I'll say that the concept was that there is uniformity in a lower bar standard to what should be included in a care plan, but not to the level of saying that all again CHF patients' care plans should look just like this, that there's still individuality to a care plan. But given the relatively extreme variation in care plan document creation today, how do you get to some common standard where you can expect as a consumer of a care plan that I will see, you know patient goals for example and care team members incorporated into that document.

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

I'll take that pause to kind of give one additional comment about that which is, I mean I totally understand that the contents varying from institution to institution but since you guys are focused on the technology, in particular are there features that, you know, are more advanced, the seamlessness of the integration and all those kinds of things that you're expecting to be in there? Or, you know, and I'll let you answer.

**Joe Kimura, MD, MPH – Deputy Chief Medical Officer – Atrius Health**

Yeah and I think that was the sort of the crux of the back-and-forth and I think even within our AHM workgroup in the spring talking about the interoperability roadmap, the conversations of do we know enough around what actually constitutes, you know the relationships, the effective correlation between what's in a care plan and effective outcomes in terms of value? And do we know enough about that to stamp something that says, this should be certified as a function within the care plan, fully acknowledging that we're expanding the definitions of who's involved in the care plan, where that information needs to go and what time and how do you confirm that?

So a lot of that depth I think was discussed and I think that was where the workgroup did express a little bit of the hesitancy, but acknowledging that is there some minimum level that we should be advancing to sort of make sure that we don't lose it in the exercise of trying to delineate all those things that we still need to figure out. But, I think...it was one of the things that we discussed in the spring, too in the workgroup to say, is there a way that our workgroup could accelerate the thinking around that to be able to get us to a place where it could lend itself to some easier spots and foundations for certification?

**Scott Afzal – Program Director – Chesapeake Regional Information System for our Patients (CRISP)**

Yeah and if I could just build on that thought for you a tangible example on some work I'm involved in where there are a number of facilities producing care plans internally that they're using. And they've gone through a process with a multidisciplinary care team to create care plans on a specified cohort of patients that have a certain level of high use or complexity. And they'll share numbers of different types of utilization, number of ER visits, number of orders that are drastic reduction and correlate that to reduction in overall in cost. But to the unintended consequence question, is the balloon just getting squeezed and those folks are figuring out that that hospital isn't going to do the thing they've been doing over time so they go to the other facility. And that starts to speak to the value, or one of the values of care plan exchange, the ability to ensure that another provider engaging that patient has an opportunity to understand what that first place that engages them knows about.

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

Great. Kathy.

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

So and I almost hesitate to ask, but you've mentioned that there were 270 filters or items that...to which many just were filtered out. So my hesitation is, but I'm going to do it anyway is to say, we'd like to see what those items were, just to get a broad sense of what are the issues that are considered to already be fully addressed, taken care of and we're past that point, so it's more than just the 11 in the care plan.

The second has to do with the struggle that I am having with saying that we have this huge opportunity for...in alternative payment models for people to be innovative, creative; they're assuming risk in ways that they've not in the past and yet at the same time given the long timelines for developing some of these capabilities within health IT systems. Will we use today's version of the C-CDA as the standard and then find that that just doesn't meet a) the needs of those participating in alternative payment models, but b) that we don't get the kind of return on investment or the expected returns of moving towards alternative payment models. Because I'm not sure that the current C-CDA is accomplishing that and so I would just caution from using that as the only route for alternative payment models because I think we'll just be missing a very big chance.

**Kelly Cronin, MS, MPH – Director, Office of Care Transformation – Office of the National Coordinator for Health Information Technology**

I can respond to that in part if you'd like. I mean, I think that there...and there are others in ONC really who are responsible for our standards portfolio, but beyond the C-CDA, there are many other standards that will be supporting this work. And even within some of the refinements of the C-CDA, there is the referral note now that will capture, for example the reason for the referral. So if products are certified and tested to that, there'll be more consistent capturing and exchange of that when you receive a patient from a referring physician. So it's one example that you mentioned before.

So I think that this is one of many standards that we'll be supporting, transitions of care or perhaps the exporting of data that we'll, you know, include through the key data elements that you'd want to know about someone, but it's certainly not the only one that we would need or expect to, you know, be advancing as part of ONCs work in partnership with standards development organizations and whatever we do through lawmaking and testing.

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

Thank you. So Lammot mentioned that this is the start of the analysis, is it...what's the...will we have an opportunity to hear follow-up or how does that work?

**Lammot du Pont – Senior Advisor – Manatt Health Solutions**

So we're still in the process of digesting some information, so the technical expert panel is providing additional detail on the gaps with respect to individual capabilities being integrated into the workflow. In addition to that, we're also doing an exercise in making sure that we've thoroughly defined the details of what could be a pathway for certification for each capability. So that is a process where we're looking to the experts on certification standards to help inform the process. And so at the end of that analysis, we'll turn it over to the Office of the National Coordinator for Health IT and then it is our understanding that there are other opportunities and venues to influence and communicate and discuss pathways for alternative payment models. I don't know, Kelly do you want to speak on...

**Kelly Cronin, MS, MPH – Director, Office of Care Transformation – Office of the National Coordinator for Health Information Technology**

Yeah, I mean we have not teed up another date to discuss this with this committee, but I think you know we'll be getting some input on some related questions in the MACRA RFI that's out there that CMS put out and clearly to the extent that there's going to be any consideration of how to implement section 101E, they'll be a rulemaking process around that. And yeah, I mean it'll be a continued dialogue, we're in the process now of trying to figure out what's next.

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

Good. All right, well thank you very much, thanks for the work, and thanks for reporting out on it for discussion. I guess...

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

Nope, I tried...there you go. I'm sorry. All right, in my sole official act of this meeting, I would like to introduce you to our next presenter, Dr. Paul Tang, who's going to review the report of the Interoperability Task Force. Dr. Tang, the floor is yours.

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

Thank you, Jon. So this is a repor...a request actually from Congress and I'll show you the exact language in just a minute, asking us...asking the HIT Policy Committee to report on the barriers to interoperability. I'd like to first thank the task force members, which represent a diverse group and I want to give a special shout out to Julia Adler Milstein and Mickey Tripathi who did a yeoman's job in providing some of the initial draft that we worked on.

So for this presentation, I would like to review the charge and the process, summarize...we've done a number of head of workgroups, Micky headed up a workgroup on interoperability. We've had hearings related to interoperability, so we want to summarize what we've done in the past, but we also want to come up with new recommendations that would accelerate the pace of process towards widespread interoperability, that's the charge to us.

Speaking of charge, here is the statement from Congress, both the House and the Senate Committees on Appropriations asked us to look at them. I mean, they were understandably frustrated that from...they've been hearing about the pace of interoperability being slower than people would like or expected so they asked us to look at the technical, operational and financial barriers and what's the role of certification? It could be a positive one or potentially even hindering interoperability; so we looked at these issues.

So the objectives of the report, as I said, one is to summarize the barriers that cause, we think contribute to the slow process. Two, what recommendations have we had in the past related to interoperability. Then to spend a focused time on financial and business barriers, because that probably holds a big key in terms of how to move the ball forward more quickly, and we make near-term recommendations to accelerate the pace.

So, the past recommendations; we charac...we categorized them in these five buckets. One is the lack of universal adoption of standards-based EHRs. Secondly, the impact of the operations workflow which is so critical to making things happen. Third, the complex challenges of privacy and security when you have widespread availability of health information. Four is the fact that this is a collect...collective action is required and not only that, it actually has to be synchronous. And finally, we focused a lot on the incentives, either weak or in some cases actually misaligned.

So first, under the lack of universal adoption; in order to have exchange and interoperability, you need two to tango. So at first you have to have the critical mass of providers that even have these systems and have the data in these systems before we can effectively exchange them. So that was point one. Meaningful Use Program has been very successful in increasing the number of folks who have...of organizations who have electronic health record systems and are populating these systems with patient data. And the certification program has played a big role in laying down some of the ground rules on what a system that is going to be called certified has to have in order to promote interoperability. But that is necessary, but not sufficient.

We've had some examples of rather focused efforts in interoperability that have been successful, such as e-Prescribing or lab test result exchange. A lot of the success is due to it being...having a small...relatively small number of provider stakeholders that are involved in that and then relatively small number of effectors, in terms of getting that information to flow interoperability.

But the EHR-to-EHR, just to use that...not to say that's the only area where we need interoperability, but that is one foci, has progressed more slowly. And you can think of it compared to banking, but banking has a relatively refined number of data types like currency; EHRs have thousands of data types and we exist in a very fragmented health system with diversity of providers, diversity of locations for those providers and diversity of the EHR system.

APIs, as you heard earlier in the certification discussion, application programming interfaces, is a promising development and is part of Meaningful Use Stage 3 and is part of how the rest of the Internet...economy works. And so that is something we're looking forward to and the vendors are responding to this call for public APIs and the request by others applications developer to open up their systems and have information to flow between their system and others.

Next topic or bucket really is related to operations workflow. So every time you stick in a technology, it changes the workflow down the, you know to all of...things that touch our lives like smartphones changes our workflows, many times for the better but it does take getting used to. In a fragmented system like healthcare, it's particularly a challenge because there are so many parties involved and the workflow really isn't very...isn't very similar from one area to another or with one healthcare worker to another. So that just presents a challenge, it's not something we can't overcome, but it does slow up progress.

As I mentioned Meaningful Use Stage 2 started this process by asking to have interoperability be demonstrated for certified electronic health record system technologies and summary of care, that is sending a CCD from one setting of care to another, was a big start. But once you start sending this information around, it uncovers the next hurdle or the next barrier which is, how do you make sense of the information that just arrived on your doorstep and how do you process that and how do you prioritize it and how do you incorporate it? So that is, as you heard in the discussion this morning about Stage 3, that's now going to become a requirement that you be able to receive this data and be able to act on it and incorporate it into your records.

Privacy and security has always been not only important, but challenging. So it's ground zero, everybody absolutely feels it's essential and this is very sensitive data, so we've got to make sure that it's built into all of our systems. The interesting part about that, like with the workflow discussion is, when you start asking, well what has to be coded in...or codified into the systems, what are the processes, what are the rules, what criteria do you have to meet? It gets pre...it uncovers how informal processes we...how informal the practices were in the past in the paper-based world.

So a person would handle a piece of information a way, sort of like the policy states but you can't cover all of the possible types of data that you're handling in the policies. Well that gets exposed big-time when you try to program of these electronic systems. So when you do this, when you convert from paper and informal processes to a prescribed process in the electronic systems, lots of questions get raised.

A third area we've talked a lot about in this committee is HIPAA. It's a comprehensive legislation from now to 20 years ago and we all recognize that not everybody can even possibly understand all of the provision in HIPAA, just because it's so complex. And it's common that the default answer is no; no we're not going to exchange this because of "HIPAA."

Well we know that many a times people think that HIPAA may prevent such an exchange when in fact, it allows many of these exchanges. So just understanding what is and isn't allowed would go a long way to actually freeing up information to be exchanged in a responsible way.

Many providers don't understand that even though HIPAA required providers to make information accessible to patients, it was permissive in the electronic world. HITECH changed that; if you have an electronic form, then it must be shared with patients in an electronic way.

And then of course the state laws cause variations in practices and regulations. That means it's difficult for every well intended entity to share information when it may be to a patient in a different state which has different laws. So it just makes everything complex. And chances are, there's no one single nationwide solution that would cover the entire country.

Moving on to this notion of collective action; so for every successful exchange, the whole takes two to tango principle, multiple parties must act collectively but also at the same time. So we heard providers trying to attest to Meaningful Use Stage 2 and some providers had to go to great lengths to make sure their recipients were also able to receive that information. And of course that really complicates matters when everybody has to not only work on the same thing, they have to achieve their readiness at the same time; it just makes it complicated.

So the thought is that, and there are so many of these rules of the road that have to be in place for you to safely and effectively exchange information. It would be nice because almost every entity, every entity exchanging with another entity goes through a process of making sure that it is safe to exchange information. If you have that each one point-to-point or peer-to-peer, it just gets complicated and it takes a lot of time. It's almost as if we'd like to have model ways, model rules of the road so that information can be exchanged safely in all places and not just one organization to another.

So networks are emerging. They could be regional, they could be statewide, they sort of go that last mile so you get data from one place to another and then make sure it gets into the EHR or the HIT system at the recip...at the receiving side.

It would be nice if there were vision or portfolio of HIE functions that support interoperability on a nationwide basis. I've already described the many things that would have to be in place, from the standards to the policies, but you'd almost like to bridge sort of a network of networks and have a way of bridging that in a consistent way across the country.

We think that the federal government plays a unique and very powerful role; it's a healthcare provider and it's a healthcare payer, the biggest one. So it definitely is not only a beneficiary of this work going forward, it's a huge influencer to this market.

Moving on to incentives, where we're going to spend a lot of time. It's obviously a key either inhibitor or promoter of change to happen. At best in the current fee-for-service world, it's at best not encouraged and potentially we've even seen that it discourages people from sharing information. We heard some of that in our interoperability hearing as well as our advanced health models. So the traditional model doesn't actually create an incentive for providers to exchange information. They're not necessarily demanding it then of the market or the vendors and the EHR vendors in turn are not necessarily focusing their development efforts in this area yet this is key, interoperability is key to achieving value-based care sort of period.

So the motivation is there, in the sense that the Secretary in a very positive action has said, we're going to have 30% in these alternative payment models by the end of 2016, that's one year away; 50% by the end of 2018; definitely a help in terms of creating some certainty around what's the pace of change. So we heard a lot in our hearings that organizations are moving in a directionally right place, but the question is, are they moving fast enough? And so for the folks who really want to go to that new place where we're accountable for a population, not just transactions, they are frustrated with the pace of progress in the systems they use being able to exchange information effectively.

So let's continue on that, and that's where the task force spent most of its time looking at those financial and business barriers and trying to come up with ways that would accelerate the pace of change. We were answering the following questions, you know, what are the...what are these business barriers? Who are the stakeholders involved? What's the impact of the barriers? What has to be addressed by initiative? What are being addressed now and what are the gaps and what still needs to be done in order to quicken the pace? We did conduct a couple of virtual hearings, reported on that to you two times ago, two meetings ago; so I'm going to skip right to the recommendations which will have findings and then recommendations.

So our first one, our first recommendation is around having meaningful measures that help consumers and payers to make a decision. The finding is that the current performance measures are generally process measures; we've heard that over and over again. They're not specific or meaningful enough to help payers or consumers make decisions about providers. They would like to have, they consumers and payers, would like to have measures that matter, measures that help them choose amongst providers or health plans.

In order to do that, in order to have providers act in ways that would give them that data, providers need clear and actionable and specific measures that would assess how they're doing now and allow them to improve under a payment reform. So having that need defined, it's been defined by many groups including Institute of Medicine, but yet despite the need for these measures the traditional measure developers are not adequately producing the measures that matter that effectively leverage this new HIT infrastructure using interoperability.

So to make a point, so the National Quality Forum is an endorser of measures, but it does not create measures; so it has to wait for somebody to create and submit the measures to be endorsed. So the quest...the problem we have is the pipeline is not full of measures that matter that are needed. So that means we need not only development, but this development function takes funding.

So that leads to the first recommendation that we do fund, and this is a report to Congress because they're...it may need federal funding for the development and the use of meaningful measures of HIE-sensitive healthcare outcomes and resource use. So these would focus on coordinated care, on affordable care.

So one example measure, now we haven't thought this in detail, but it gives you the idea of the ki...an example of the kinds of ways we're thinking; that is, what if payers said, there's no reimbursement for medically unnecessary duplicate orders? Well, all of a sudden you'd have to know whether your order is a duplicate or not; all of a sudden you'd have to communicate or be in communication with all of the people participating in the care of that individual. Then you would know one, whether it's duplicate and two, whether it's medically necessary or unnecessary. So again, we haven't thought through the details but that's the kind of idea behind a "HIE-sensitive" health outcome and resource use measure.

The second area has to do with measures of developer performance. I was quite interested to hear from the certification presentation about how we're thinking much more about transparency in that realm. Well here's another area of transparency we'd like to propose.

So as was stated, we've heard the complaints many times and ONC heard it as well, is this one time in lab certification doesn't produce predictable, affordable, practical implementation or effective value in the field. So you either need...so some kind of surveillance, and that's what was proposed or is now finalized in the certification role. Some kind of way to make sure that something that follows the certification criteria actually lives in the field and causes information to flow.

So we felt that a lack of transparent performance measures, because mostly certification in the past has sort of been a black box and they show up at this label of certified, but it doesn't necessarily say does it really perform that way in the field. So we were as...we were saying that there's a lack of transparent performance measures that could be used by providers in assessing whether a provider...a vendor's product or developer's product would perform as certified in the field.

And these transparent measures, as was proposed earlier, would be useful in surveillance; to just know...to track how are the vendors or developers doing in real life in the field. Once again, there's no entity that's currently either charged or feel it's their mission to develop these measures, yet we need these measures to be developed so that we can report on them.

So federal resources may...would help speed the progress towards a single set of measures that could be reported across vendors, and made public on this new website that we heard about earlier. So our recommendation two then is to fund development and use of HIE-sensitive vendor performance measures for certification and for public reporting so that providers can make informed decisions.

So an example set, again we didn't look at this in detail, but just to give you an idea of what we're thinking; it's nice to know the numbers of exchanges which is common in certification rules but that's just the denominator. We would really like to know what of these data elements were actually viewed? Turns out some anecdotal data we have from some of the providers who have exchanged data show that a very small number are actually even viewed, let alone the next step which is incorporated or reconcile this data into your record and have it be a part of decision-making on those patients. So you heard about how some of Meaningful Use Stage 3 is approaching that.

The third area is...may be one of our strongest which is, what we heard is that the provider organizations are going in the directionally correct direction, I mean are directionally pointed in the right direction...and I still have too many directions there. But at any rate, but the notion that...and that's because people know that pay-for-value is coming, but right now it's a broad program, pay for value instead of for volume, but it doesn't have a specific things that vendors or providers can target their efforts towards.

And in some sense, that's what we heard from our hearing is that people want specific measures even though, and of course it would be targeted so let's say two or three years down the road, so that they can design and perfect their processes to achieve that level of performance that's being measured. Because without specific measures for example, then when faced with internal priorities, and you're saying well, we've got to go for pay for value, you don't have a specific thing that you're going to do and so other internal priorities take...trump the efforts of interoperability. So that's why we think that specific criteria down to the specific performance measures that would be keyed in to...at some future date would, we believe, catalyze specific actions that would speed the pace of achieving interoperability by both providers and vendors.

So that goes into our third recommendation that, this being to Congress, so the federal government through programs that CMS administers set specific HIE-sensitive payment incentives, which include specific performance measure criteria and the timeline for their implementation so that we can have clear objectives of what must be accomplished at the beginning. I mean, it goes, you know, it'll change over time, under alternative payment models.

So for example, these would cover, you know how would you prove to the payer that you are conducting coordinated, high-quality, safe care? How can you prove that you're coordinating across not only the health continuum, but the social service continuum? It goes back to the person-centered rather than just patient-centered. And then while you're designing these payment rules, need to incorporate mechanisms that respond to some of the complaints about information blocking. It does occur; make sure that these payment mechanisms can identify and discourage information blocking activities.

In our final recommendation, the background is, what's chang...why are we making this now? What's changed? What's learned? Why in 2015 are we making the following recommendations? Well the Secretary's already set a timeline for delivery system reform; the 2016-2018 are ambitious but achievable stakes in the ground.

The information landscape has changed dramatically even in two years, certainly in the five years; now that EHRs...the majority of American residents have their health information in electronic systems now; that's dramatically changed. We now have the ONC Interoperability Roadmap that's been published, but we need follow up, public and private action. It's one thing to have the book on the bookshelf, we now need to turn it into action.

So there are a number of activities that are going and we're appreciative of those, but still they're siloed. They usually have one or two stakeholder groups involved. But it seems like we need a coordinated blueprint for the...all of the stakeholders, and there are many that are involved in this process, to get together and even understand what it is that has to be done and by whom and when.

The notion that we need this collective action that I just described is complicated by the synchrony provision, that we all have to do it and we have to be responsible for our part at the right time in order for us to test the end-to-end at all.

So we think that without a specific charge and specific timelines for all of the stakeholders and their collective action that...the collective action that's called for in the roadmap, it's just not going to happen fast enough. It may happen organically, but that's probably not fast enough for the delivery system reform timetable that's been called out. So we think that using the convening power of the federal government and the enduring private sector business interests are required to pick up the roadmap and to act on it in a sustained way.

So our recommendation is that we convene a major stakeholder working summit, it's not a talking summit it's a working summit that's co-led by these two major sectors, the federal government, let's say ONC, CMS and the private sector to act on the ONC roadmap that's put in place so that we can take the timeline, get it defined and accelerate the pace. So the outcome of this working summit would be to enumerate and define the action plan with the milestones and the accountabilities. I think there are people who should be and need to be accountable that don't even know they're part of this picture of "interoperability." And that this FACA committee, HIT Policy Committee, could provide a venue for a quarterly process.

So not only do we want the timeline spelled out and the milestones and accountabilities, but we need to follow up and HITPC could be a venue for let's say quarterly progress reports that helps the information exchange and helps the coordination and helps with the accountability of the public private efforts towards this widespread interoperability.

So in short, achieving interoperability in healthcare is substantially more complex than other homogeneous domains like an ATM yet despite its complexity, it's still required. It's still required in order to execute health system...health...delivery system reform and in a timeline that's been laid out by the Secretary. And the intersection of the pace that we're going now to the pace that's needed just isn't matching up.

So the task force believes that we need to have this multi-stakeholder group define the "national work plan," commit to the synchronous collective actions that we've enumerated and to accelerate our pace of achieving interoperability. We think a clear driver to that would be specific financial incentives with specific measures, HIE-sensitive measures that would matter to consumers, providers and payers. And that this action should take place in the near-term if we're going to pick up the pace.

So with that I'll turn it over to you, Mr. Chair, to lead us through discussion.

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

A master of presentation as always, Dr. Tang; thank you very much. It's a tremendous amount of thoughtful work, thank you for leading your colleagues and bringing this to us for discussion. So, with that, let's go to Gayle first, to my left. The floor is yours.

**M**  
Surprise.

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

Surprise. Thank you very much, Paul, very, very informative and thank you for your hard work on that. You know, interoperability has been on the forefront of this whole discussion; I've been on the Policy Committee since 2009 and we've talked and talked about interoperability. And I keep asking, when are we going to get there? And you do lay out somewhat of a roadmap here, very specific recommendations and I think they're well targeted.

However, does ONC have the statutory authority and the finances to carry out your recommendations? A convening group such as the workgroup you are proposing requires resources, it requires authority to do so and I don't know, and I need ONCs opinion as to what the next step would be to empower that kind of event ongoing with resources.

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

Good question. I'll remind you that this actually is a report to Congress so...who has the power to grant authority and funding. But let me back up from that though and say, so recommendation four was to convene a single working summit that hopefully would catalyze, based on the compelling output of the summit, catalyze ongoing activities that are hopefully partially sponsored by the federal as well as the private sector.

So can...does ONC have the ability to convene that summit, I think so and Jon can correct me; it's because they are the national coordinator of activities and this is one of those coordination activities. Do they have the funding to continue with ongoing actions? That's why we limited the initial recommendations to a working summit to sort of set the game plan for the whole country according to and using the ONC interoperability roadmap as the base point. So we're thinking that it doesn't have that much financial implication or doesn't necessarily have to have that much financial implication and the authority to convene a summit as the Office of the National Coordinator seems within its scope.

Now there are a couple of recommendations the call for funding, use the term funding, and those are to develop measures. Now CMS certainly does, as part of its routine business, fund measures to be developed; maybe it already has them, maybe it needs some special appropriations from Congress for these particular kinds. But I'm sure they're thinking about at least in the one category for the provider side working on the measures. But we're just saying it has to be...there's a long lead time, like a three year lead time in the whole measure development space and we can't wait if we're going to achieve the timeline that's laid out by the Secretary.

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

Follow up if I may.

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

Absolutely...I think Elise may have a response...

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

A follow up if I may and you know, certainly Congress has the ability to fund these kinds of things; I see this as ongoing, I don't know that one convening of a workgroup or a summit is going to continue...is going to develop the kinds of things that this Policy Committee has talked about for five years, six years and still we are not there. It gets very frustrating and to me, I don't know and I question whether a simple workgroup, that even an ongoing summit with the workgroup coming out of it, has the power to do the kinds of things that are really essential to make interoperability a total reality.

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

Well it's a fair concern and it's one that the task force certainly discussed. I put back up the slide where we say well, it's your question, would now be any different from six years ago? Well a lot of things have changed; one is, now we have information in...electronically stored in EHRs, didn't have that five years ago almost at all. We didn't have a timetable and the delivery system reform even five years ago. And this whole...the move towards pay for value and alternative payment models is a motivator. We're trying to, once again be sort of handing off from the push to the pull from the payment side and we think we're at this sort of nexus where there are just enough, and again, back to the hearing, people are saying we're directionally correct but we don't have the palpable specific tools that we need in order to go directly in a focused direction.

So we're trying to push it over the edge, in a sense. We think we're at a tipping point from the setup of the capabilities and the incentives in a general way, but we need to push it over past the tipping point so essentially the market can take it over. So that's the hope and the rationale behind this recommendation for a single meeting.

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

Thank you.

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

Elise, did you have a response that you wanted to...

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

Well first I just want to echo the thanks for the committee responding to the congressional request and we really do appreciate the work that you're doing on this. On the resource question, I think it's something...I don't have much more to add than what Paul said; I think Paul summarized it very well that this would be a report directly to Congress. Resources is always something that we have to consider in anything we do and is something that we would consider as this would go forward to Congress, but it would have to be an ongoing conversation of course.

And then the question I had is Paul, could you talk a little bit more about the timing? You just mentioned three years in terms of the development of the measures and in the report it says kind of some things that could be implemented in six months. Could you kind of talk a little bit about how those work together?

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

Good question. Each one of these, so let's look at the HIE-sensitive outcome measure which would take three years to get it all the way through endorsement and of c...but, you've got to start somewhere. So we're proposing that each one of these four recommendations be started in the near-term, in the immediate term. So you could, very quickly and would want to, start the development, identify the measure developer, start the development of these measures and then convene the summit and also really be clear and specific about the performance measures that are being used in future CMS programs. So we think all those can be started within the next six months.

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

Dr. Lehmann?

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

Thank you; Paul, thank you for this presentation and this report. First I want to start off and applaud you for the focus on the incentives. What you did by doing this, you really told us it's not the technology, it's not the lack of data, it's not the lack of EHRs, it's not legal barriers; what it is, it's all about incentives and I think you hit the nail on the head. But I think you might...the recommendations might not have gone far enough. And you pointed out, and the reason why I'm saying this, you pointed out, you used the word information blocking, you pointed out that there are incentives to not play.

If you have, as you suggested, HIE-sensitive outcome measures for example. As a competitor to you, it might be in my best interest not sharing that information so you get penalized and I can capture a larger share of the market. And I know you would never think this, after all the years I've known you, you're such a wonderful person, but somebody has to pay attention to the fact that there are some bad actors out there and that's always a possibility.

That said, one of the questions that I have and that I want to throw out there is, you know the reason why banking works and the reason why I can go to a bank in...to an ATM in Croatia and withdraw money from my account at Bank of America is that there is a significant financial incentive for the bank to make that information available.

And my question to you is, I didn't hear you thinking about or mentioning the possibility actually to pay for sending information. And I want to know why that isn't considered and why that not might be a viable approach to that until you actually have HIE built and up to speed and capacity? If you were to pay institutions for sharing the information they have, they would be standing in line to push out information to others. So, I would love to hear your thoughts on that.

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

Okay, so I'll start with your first question on the incentive, I mean, you like the fact that we focused on incentive. And our focus on incentive wasn't because that's the only reason people act, but as we pointed out, when you have a bunch of internal, I mean a changing world causes all kinds of demands on your resources. And when one area poses more of a compliance or financial impact implications than another, then the other just sort of falls down. And so we think that specific incentives would help interoperability achieve parity with other internal priorities.

The second of pay for...pay for data in a sense. We didn't discuss that specifically, I'm not sure it would be favorably ruled on by...it would get a favorable CBO ruling because they just have to pay for it and we didn't want to get into that realm. So we were looking at ways, how in the existing payment systems do you reward behavior that we want to reward, which is the coordinated care, the safe care and the less use of duplicative resources.

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

Great. David?

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

A very, very helpful report. I have two points, I guess one is a suggestion and the other is a question. I'll start with the suggestion. As it happens I'm working with a group of NIDA-funded centers, National Institute on Drug Abuse funded centers and while I was sitting here an e-mail message came in. They've been discussing the challenges around 42 CFR Part 2, as you can imagine. And in the security and privacy section you mentioned HIPPA and HITECH and state laws, but I would suggest that maybe adding, although it's a specialized case, 42 CFR Part 2 as a major barrier to interoperability in between drug abuse treatment centers and the likes and primary care. And some of them go so far as to say that that law increases risks to both providers and to patients because of the lack of information sharing so maybe there's a way to work that in. I know ONC can't change laws, but Congress can, so this might be our opportunity.

My question is, again about security and privacy and whether your group found any...whether the problems are related to technical limitations, technology that actually still needs to be developed, or whether it's a lack of standards that need to be developed or whether the technology is there and it's more about organizational or workflow protocols that's the issue?

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

First of all, the Part 2 statute, it's somewhere in our materials, it's just not on the summary.

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

Okay.

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

Not that we're lobbying for a change in laws, we're trying to do as little of that as possible right at this point. With respect to the tech...which barrier of the five categories is the overruling? I think it's what Chris said, in the end, people...it's a very resourceful country and a very resourceful industry and they will get the job done as long as other things don't get in the way; other things can be competing, you know, priorities, etcetera.

And so the thought is, if we made the incentives clear and specific that we could...this topic of interoperability could compete with the other priorities. And that those every...whether it's standards or technology or operations workflow, that can be addressed and could be dealt with as long as the priority was there. And they felt the common denominator was a lack of clear, specific financial incentives.

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

All right, Kathleen?

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

Thank you. And so several comments and points to make. In terms of the whole issue of financial incentives, I think there is something that is missing here because financial incentives vary across the various participants in this arena and an incentive that's not mentioned here is preservation of time. And the reason that I say that is that the government can always print more money, but no one is able to create more minutes in the day or in the year.

And I think that if you look at incentives for participation and for exchange, we've all, if we've had clinical practices, we have dealt with the issue of spending inordinate amounts of time trying to track down data from multiple patients, multiple facilities; sometimes at the very last minute. And so I think a very strong case can be made here for saving time and time wasted is time lost.

And I do have to reference a study that was done by the RAND Corporation in concert with the AMA that said what is the key think that clinicians in practice want when they go home at the end of the day? They want to know that their job is done, that they took care of everybody and that people are kind of settled in and that the work is done, at least until the next day begins. And so that also, I think, is a very high motivator that I think needs to be communicated.

Because if you look at, and I refer to I think it's Lisa Rosenbaum's recent article in the New England Journal about the impact of health IT and the inordinate number of comments to her article, 140 some at last count. And what people talked about is being just inundated with material and not knowing how to use it or being able to use it, which gets to my next point.

I think we really have to reconfigure how we think about health information exchange and interoperability. I mean, how many of you get a gift and the gift is nicely wrapped, you look forward to opening the package, and there's something that is valuable to you inside that actually helps you take better care of patients? And so if we could look at the information being exchanged as a gift, a gift of information and time and my being able to take better care of my patients, I think that would be a way for us to move forward.

In terms of on slide 21, you do talk, and I could not support you more in this, about the need for measure development funding. And yet at the same time I'll also say that there currently is quite a bit of funding that is provided by CMS and by AHRQ and by others to do performance measured development. But so often the lead time to get that funding, to implement the project, and go through all the various hoops, results in the kinds of delays that you've talked about.

Our experience, and so I'm wearing my PCPI hat now, our experience has been that the measures such as the ones you've mentioned, are in the greatest need for funding because they are not disease-specific. If it's a disease or condition specific measure, oftentimes that professional society or a patient advocacy group, somebody owns that condition and they want that measure. But in the crosscutting areas our experience has been, it is very difficult to garner those resources and be able to develop those measures. So I'm very supportive of having it be these crosscutting kinds of measures.

And then lastly, I think that...I find it challenging that there is just at the header, meaningful measures for consumers and payers. I really increasingly think it's meaningful measures for everybody and it is...because otherwise we're at risk of demonizing some to the sort of focus on others. And this is a whole arena in which we've had way too much sort of sending the ball or putting, you know the hot potato on somebody else's sort of worry list. And so I would just ask the group to think about whether there is some more inclusive way of describing this because anybody who's left out will probably not be happy.

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

That's very fair and yeah, that was only a title so I think we obviously can include providers in that and I think that's well deserved.

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

Yeah, it's a...

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

I'll just give one anecdote about the gift and the time. So I do have clinic on Monday mornings and sometimes people show up having been to the ER and it is a true gift when all I do is click and I see the discharge, I mean, it is the difference between making a good decision and good follow-up versus maybe a potentially bad one. So it's def...it's truly a gi...that's exactly how I feel, actually. So it's truly a gift and maybe we can talk about that let's say under the clinical workflow is that that is one of the intrinsic rewards of having good interoperability for sure. Absolutely.

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

Enough said about that. All right, Brian?

**Brian P. Burns, MA – Deputy Director, Office of Information and Technology – Department of Veterans Affairs**

Thank you. This is near and dear to my heart at the ITO and I appreciate the report. A couple of questions I have; first of all, in terms of the incentives, do you see the value in tying the incentives to, for instance levels of interoperability as we've talked about preservation of time and also organization of workflow protocols? If we take just simply HL7 where we have technical and semantic and process, do you think there's value in tying incentives to the level in which you operate?

Second one is similar, what about gradation of standards? What I mean by there is going from say version "X" to version "Y," or even within the version the level in which you do the fidelity of the mapping of the information. Say anatomical pathology, you might map one organization to categories, another one organization to subcategories.

And then the third part, I guess is if we look at the performance measures in terms of operability and our end goal is patient care and clinical operational improvement, do you have any recommendations or lessons learned of how you actually show the correlation effect or the causal relationship of how interoperability actually works with the performance measures versus it being masked or an interaction effect of actually getting to the more end goals?

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

With respect to your question, incentives for achieving various levels of implementation; we did try to make it outcomes oriented. So in sense again, it's looking at Meaningful Use where Stage 1 you have to say hey, you have to have these functions in your EHR and you have to have these transactions. We always imagined Stage 3, which is where we are now, as being outcomes oriented saying, hey look it's great that everybody knows what everybody is doing and you're working on a coordinated shared care plan. And so that's why we gave some of the examples of, if you had all this other stuff, then you would do good jobs at this instead of here's your...so we tried to stay away from anything that was close to process measures; that's not an easy task, but that was...it was the intent of our examples.

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

Very good. Devin?

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

Thanks again Paul, this is really great and I know I've heard a lot about this from you guys. The one point that I just wanted to, and it's kind of tapping into what Kathleen said, it was slide...hold on a sec, 25; the recommendation two for funding sensitive vendor performance measures. Most of that was volume based, how much of this activity is going on? Even with the percentages it's still the denominator is volume and that's exactly the kind of thing that is good and appears good, but doesn't account for the time problem and then exactly can exacerbate it.

So a story from this week in our user group of all the EMR users. A lot of questions about reconciling outside meds, and it happens in three different places and you have to do it repeatedly every visit and depending on the Surescripts versus the external parties interface, you actually have to the same process two or three times. Each one of those would count for the denomin...to the numerator; so it would look great and we actually could drive up our exchange numbers using that process, but we would be wasting time.

So I understand you guys didn't dig into it, so that's fine. But actually I would caution almost kind of pushing back on whoever is going to be...that measure and say to avoid those volume metrics, because that's kind of the least...the low hanging fruit that everyone goes to and then starts a chain where we end up in that same place again. And I really would hope that we could do a next generation that does take into place...take into account time, satisfaction, user friendliness, all those things.

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

So in some...I mean, it's a fair...and as I tried to disclaim, these are just examples without sharing details. But another one that I did remove was, percent of the times when you were about to order something but knowing an external result changed that order.

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

Right.

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

That saves time of the rework, it saves...the patient's safe and it's high quality. But I didn't know how to make that extensible. But at any rate...

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

I feel like put it out there anyway.

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

...that's where we're trying to go. Put it out there anyway, okay. Okay, I can put that back in, but anyway, that is an example where it's a gift, like you wouldn't have had to order, oh whoa, I'm so glad I didn't do that; that's a true gift.

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

All right, one last time; all in? All right, then I will finish it off by saying, in the spirit of the disc...Paul?

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

I think we do need to approve this because this is going to be essentially the report that goes to Congress on behalf of the committee.

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

Ah, okay. In that case, I will ask for a vote on approval. All in favor of accepting...approving this report as written?

**Multiple speakers**

Aye.

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

Any opposed? All right. Oh yes?

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

May I ask a question, because we've certainly given considerable feedback and so, a process question which is, will this feedback that's been provided by the group be incorporated prior to submission of the report to Congress?

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

Chris, was that your question or did you want to ask...

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

I have another procedural question.

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

Okay. All right, in that case; so Paul, as the author, leader of the pack, what do you think?

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

Be happy to. Afterwards we'll just circulate a re...the document, which you didn't have...in fairness here, you didn't have time to absorb. So we'll send...we'll incorporate some of the results...feedback here and then circulate that for, I guess it would have to be an e-mail approval then.

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

Hey Michelle, are you good with that?

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

Yes.

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

Okay, all right. Dr. Lehmann?

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

Okay, in our vote on this report, what does it imply? What's the effect of it? Does it mean this group endorses the report as is? If so, then the point that I would like to make, while I agree with everything that you said Paul, I think it's incomplete as I pointed out in the not discussing payment for data. So I'd like to, you know, make that comment for the record.

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

So I think what I would suggest is that at this point, you're saying to Paul, yes, please move forward with accepting our feedback, there's no reason you should really stop and go back to the drawing board on this. The final report will be circulated again for comments. So, let me turn to Elise for a second, is the request for the report for Congress, is that from the Policy Committee proper?

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

As opposed to...yeah, it's from the Pol...

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

It's from the Policy Committee.

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

...from the Policy Committee, goes directly to Congress.

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

Okay, so in order for...and just a procedural question again; in terms of final e-mail round of acceptance, does it require unanimous vote or does it require just a majority?

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

No, so for Policy Committee it's not unanimous vote, it's majority vote.

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

Okay.

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

And so, there really weren't, I mean, we certainly will integrate all of the changes that were discussed today and we'll do our best to capture them the best way possible. But it didn't sound to me like there was anything that was of major concern. So we'll move forward, integrate the changes, share them with the group; but for the most part we got approval on the major recommendations that were shared.

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

I think the only thing is Chris's comment, I think the Policy...majority of the Policy Committee would have to agree to put that in, I think.

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

Yeah.

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

Because that's something new that we didn't present, it's an idea that came up here.

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

Okay, yeah. So I guess Chris, in that spirit, I suppose if you want to write a dissenting opinion you can. But I think the point is well taken. But yeah, so...okay, so Paul is going to move forward, he'll circulate the final version by folks to e-mail. And in the spirit of the discussion, thank you for your gift, which focuses the federal ethics guidelines, I must say is valued at under \$20, so we can accept it. So, just kidding.

Okay, and with that we're on to the final portion which is public comment, yes?

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

Yes, but I first want to thank Paul, he's done a lot of work over the summer; we always keep him busy. But Paul and I have spent many hours working together on this, mainly Paul, me just doing little things. But anyway, I just want to thank Paul, he is a gift, so thank you.

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

This is not a tit for tat. Michelle of course runs our FACA committees and was...also stepped in to be the liaison for the Interoperability Task Force; so she's done a lot of this work.

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

And one more thing before public comment; so we, as you all have probably noticed, back I think it was in June, Paul announced we're doing a little bit of a transition based upon where things are, based upon wanting to make the best use of everyone's time, staff resources, and also where things are headed within the industry. So we started to, you know over the summer it was fairly quiet as far as the workgroups went. We started to move more towards a task force model similar to what the Standards Committee done.

We are going to continue that evolution; we're going to have more of a hybrid model going forward. So over the summer I'm sure you saw how quiet it was, but...and at the last joint meeting we announced a number of joint Health IT Standards Committee task forces with the Policy Committee. We've noticed that as the conversations move forward, it's much easier to have both sides at the table to make good decisions that involve both policy and standards together. So the three task forces that we announced at our last meeting were all joint Policy Committee and Standards Committee task forces.

So going forward as part of our hybrid model, and also based upon a lot of the discussions that we've had today, a lot of the past discussions that we've had about the strategic plan, the interoperability roadmap, MACRA. A lot of future work will be focused on delivery system reform and so we are going to maintain four of the current workgroups, but they will function much like task forces. And they'll be only asked to meet when there's a specific charge or a specific question based upon needs.

So we are going to maintain the Strategy, I'm sorry, the Health Information Exchange Workgroup, the Consumer Workgroup, Privacy and Security Workgroup and the Advanced Health Models Workgroup. And so, like you saw today, the Advanced Health Models Workgroup was given a short-term charge and an ask and they quickly worked on the project for us; this was much shorter term than normal, but it is a good example of how things will go moving forward.

And we will be sunsetting the Strategy and Innovation Workgroup and the Implementation, Usability and Safety Workgroup. That doesn't mean that those are not priority items, there likely will be task forces based upon those topics going forward. So, just wanted to give everyone a heads up on where things are headed. You'll see this via e-mail as well. We'll be following up with the Chairs of all of the workgroups to make sure they fully understand what's happening. And of course if you have any questions, please feel free to reach out. So, thank you.

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

Any questions or discussions about that that you'd like to ask Michelle or the rest of us? Okay.

**Public Comment**

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

Okay and with that, we'll go to public comment. Before we go to the phone, there were a number of public chat comments again, so we will be sharing a long list of public chat comments with the committee after today's meeting. So if there's anyone in the room that would like to make a public comment, please come up to the table. And I'll turn it over to Alan to open up the lines.

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

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

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

And it looks like we have no public comments. So our next meeting will be in December and it will be virtual and then our January meeting will be in person again and will be a joint meeting with the Standards Committee as well.

**Paul Tang, MD, MS – Vice President, Chi Innovation and Technology Officer – Palo Alto Medical Foundation**

Great and thank you everyone and safe travels back. See you in December and hear from you in...wait, see you in January and hear from you in December. Thank you. Happy holidays, I guess.

**Public Comment Received During the Meeting**

1. Marq Walker: EHR software developers continue to lag behind public health reporting requirements. AR has 3 registries which have declared readiness: immunization, syndromic, and cancer. However, numerous ambulatory EHRs still cannot produce error-free syndromic tests, and we have NO knowledge of ANY ambulatory EHRs which can produce HL7 test files for our oncologists and other specialists who treat cancer. Additionally, NONE of the ambulatory EHRs are proactive in producing HL7 functionality for specialty registries or the CDC national survey registry. In 2015 EPs can claim the alternate exclusion; however, 2016 is looming on the horizon and many Arkansas EPs are considering dropping out of MU because they cannot meet the public health reporting measure due to vendor barriers. What will CMS/ONC do to require EHR vendors to select a clinical data registry or specialty registry so that EPs can meet the public health reporting requirements in 2016?

2. Thompson Boyd: Regarding the CMS Presentation about Clinical Decision Support (CDS) when appropriately designed and well managed CDS is abruptly turned off, providers swiftly request that CDS be turned back on, as soon as possible, because the value of CDS becomes clear as a patient safety measure. With CDS, the provider also feels more confident that their orders are more accurate, meeting the needs of the patient. Thompson Boyd, MD. Hahnemann University Hospital. Philadelphia, PA
3. Thompson Boyd: Advanced Care Models: May wish to add the notion of having a Shared Vocabulary. Then, the terms will be known and understood by the stakeholders. A Shared Vocabulary will also aid with data integrity, and with the reporting of quality metrics. Thompson Boyd, MD. Hahnemann University Hospital. Philadelphia, PA.
4. Marq Walker : It does not appear that CMS/ONC have given enough consideration to the fact that software developers love the profit that they are able to build into "modules" and how those modules can hijack a provider's ability to afford the technology required to be a meaningful user. For example, software developers hold Arkansas EPs hostage by refusing to provide HL7 test files unless the EP purchases the interface to the registry -- even though the Arkansas registries cannot accept data in "production mode" and are only accepting test data in the form of pdf files. Some of the interfaces are several thousand dollars, plus subsequent "support" fees. I am concerned that the cobbling together of modules for 2015 certification will add complexity to the costs that EPs are expected to incur. This is the reality that our team of Outreach Specialists is seeing in the field across the state of Arkansas.
5. Missy Willoughby: It is heartening to hear someone say that 18 months is needed for development of HIT capabilities. But do remember that the discussion related to having the certified functionality for APMs in the marketplace by 1, 1, 2019. The developer/vendor would need the finalized criteria defined and the 18 months to develop and QA the functionality. Then, there is time to have the certification testing done and the deployment to the end-user sites. At the sites, the implementation of training programs, evaluation of new workflows and needed changes, etc. must occur. So, the urgency to have the final criteria/functionality defined is there. It will be much more than 18 months from definition of needs to the implementation and use of the functionality. Thank you.

**Meeting Attendance**

Name	11/10/15	10/06/15	09/09/15	08/11/15	06/30/15	05/22/15	05/12/15
Alicia Staley	X	X			X		
Anjum Khurshid	X		X	X		X	X
Aury Nagy					X		
Brent Snyder	X		X	X		X	X
Brian Burns	X	X					
Chesley Richards	X			X			
Christoph U. Lehmann	X	X	X	X	X		X
David Kotz	X	X	X	X	X		
David Lansky		X	X	X		X	X
Devin Mann	X	X	X		X		
Donna Cryer			X	X		X	X

Gayle B. Harrell	X	X	X	X		X	X
John Scott	X				X		
Karen Desalvo		X	X	X	X	X	X
Kathleen Blake	X		X	X	X	X	X
Kim Schofield			X	X		X	
Neal Patterson		X	X				X
Paul Eggerman		X	X		X	X	X
Paul Tang	X	X	X	X		X	X
Scott Gottlieb	X	X	X		X	X	
Troy Seagondollar	X	X	X	X		X	X