



HIT Policy Committee Final Transcript April 7, 2015

Presentation

Operator

All lines are now bridged.

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

Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee. This is a public meeting and there will be time for comment at the end of today's the meeting. As a reminder to those commenting comment if limited to three minutes.

Also, to those in the room and those on the phone if you could please state your name before speaking as this meeting is being transcribed and recorded.

Also if you are Tweeting today the hashtag for today's meeting is #HITPC. And with that we'll go around the room to take roll and we'll start with Lucia.

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

Lucia Savage, ONC.

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

Anjum Khurshid.

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

Chris Lehmann, Vanderbilt.

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

Charles Kennedy, Aetna.

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

Paul Tang, Palo Alto Medical Foundation.

Lisa A. Lewis – Chief Operating Officer – Office of the National Coordinator for Health Information Technology

Lisa Lewis, ONC.

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

Jodi Daniel, ONC.

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

Troy Seagondollar, Kaiser Permanente.

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

Kim Schofield, Lupus Foundation.

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

Marc Probst, Intermountain Healthcare.

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

Neal Patterson, Cerner.

Paul Egerman – Businessman/Software Entrepreneur

Paul Egerman, citizen.

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

And Deven McGraw just walked in. And on the phone we have David Kotz?

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

I'm here.

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

Hi, David. David Lansky?

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

I'm here.

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

Hi, David. Gayle Harrell?

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

I'm here.

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

Hi, Gayle and Chesley Richards?

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

Here. And Terry Cullen?

Theresa Cullen, MD, MS – Director, Health Informatics – Veterans Health Administration

Here.

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

Hi, Terry. Thomas Greig?

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

Here.

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

Hi. Anyone else on the line?

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Hi, this is Mike Lipinski, ONC.

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

Hi, Mike.

Mike Lipinski, JD – Senior Policy Analyst – 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

Okay, with that I'm going to turn it to you Lisa.

Lisa A. Lewis – Chief Operating Officer – Office of the National Coordinator for Health Information Technology

Well, good morning everyone, I want to thank you for being here, Jodi and I are going to tag team today. Karen is on a plane and sends her regrets she wasn't able to get here in time and we may see her later but she may just not be able to make it.

We know that you are all very interested in the proposed rules both our 2015 CEHRT rule and the CMS MU3 rule. We will be discussing those with you today and so we look forward to your comments and questions during that part of the agenda.

I also wanted to call your attention to the fact that last week the comment period ended on the interoperability roadmap and we really appreciate every one of you that provided us comments. We are looking forward to going through all of those and following up if we have any questions. Erica Galvez will continue to be the lead in that effort and will provide any feedback and answer any questions that we might have there.

And we are also in the process of analyzing all of the comments we received on our Federal Health IT Strategic Plan. We hope to finalize both of those in the summer and so between now and then we will be coming back to you with any questions or comments that we might have.

We really do appreciate everything that you're doing to help us continue to advance in the area of interoperability it is key to the nation and to us being able to improve healthcare for all Americans and so with that I won't belabor it, I think, Jodi you might have a few comments?

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

Sure, thank you, Lisa. As Lisa mentioned we just published the ONC 2015 edition certification NPRM and CMS just published their corresponding Meaningful Use proposed regulation as well and we forward to starting to help folks understand what are in those rules and some of the main goals that we're trying to achieve both on CMS's side as well as on ONC's side in putting forth those proposed rules.

We very much look forward to comment both from the committee as well as from the public on these rules, it really helps us to understand how our proposals will be implemented in practice and helps us to understand how we can make them better, more effective, more efficient and also better at meeting our goals.

A couple of things I want to note and I will be doing the updates so I'm not going to belabor this, but you'll notice a shift in ONC proposed rule, something that we've been discussing for some time that while we are absolutely committed to supporting the CMS Meaningful Use Program we're also looking at how we can leverage our certification program more broadly to support delivery system reform, as well as to support providers across the care continuum, as well as other providers in the community that help individuals improve their health.

HITECH authority did give ONC a very broad authority to certify a broad range of Health IT products including EHRs but also broader than electronic health records and it also, while there is very close connection with the Meaningful Use rule and leveraging certified products for the Meaningful Use Program there are also other provisions that talk about leveraging our federal partners and contracts with federal agencies to support the use of standards and certified products.

So, the last key point I want to mention, and I will talk more about this when we go through the rules, is that you'll notice also in our regulation, our proposed regulation that while we have provisions that are required for the EHR incentive program, for the Meaningful Use Program, we also provide some proposal for available or optional certification that vendors or providers may choose for certification that supports additional needs. So, I will leave it at that. I'll talk a lot more about it when I do the overview of the regulation. Thank you, very much.

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

Good, thank you Lisa and Jodi. So, what we're going to do for today is we're going to have data updates from Dawn Heisey-Grove and then we'll have a high-level overview, as Jodi mentioned, from both Kate and Beth...Kate Goodrich and Beth Myers on the CMS Meaningful Use Stage 3 NPRM as well as from Jodi and Mike on the certification NPRM.

Following that we're going to have our final comments for the committee's approval on the feedback to the interoperability roadmap and that's from all of the different Workgroups. So, that's what we have for today it's a little bit shorter than usual.

Let's see and the other thing I want to do is cover approval of the summaries from last meeting. You all got that in advance and I'll entertain a motion to approve those.

W

So move.

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

Thank you and second?

M

Second.

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

Thank you, any further additions? All in favor?

Multiple

Aye.

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

Any opposed or abstain? Thank you. Okay, so I think we'll kick off the meeting with Dawn's update on some of the data I think related to Medicaid.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

Good morning everyone. On our agenda today is the Medicaid eligible professional's progress to Meaningful Use. Before I get started with this I know this isn't the data that you really want to see but because of the extension for the attestation deadline through March 20th we're still working on cleaning the data, scrubbing it and making it look nice so that we can present it to you next month.

So, for now, because most of that progress that we're going to be talking about in May is going to be Medicare progress towards Stage 2 2014 certified technology use and Stage 2 progress we're going to touch on Medicaid progress today.

So, first before we get into Meaningful Use progress I just wanted to highlight a little bit about registration. This is the cumulative trend from the beginning of the program through January of 2015 of the number of providers who have registered across both Medicaid and Medicare and you see that there hasn't really been a plateauing effect, pretty much everybody is going on in a straight cliff and it keeps increasing over time. So, we haven't yet reached a leveling off yet.

When you look at the estimated number of providers, which is the stacked bar on the left-hand side, you see that...and these estimated numbers are based on the Stage 2 Meaningful Use rule that came out a couple of years ago, you see that the proportion of Medicaid providers is about 145,000 that's what they estimated, but in actuality we have 176,000 Medicaid eligible professionals who have registered so far. So, we're actually above the total number of estimated, 538 was the estimate, 546 is the number who have registered so far with the program and most of that increase is by Medicaid professionals.

So, to summarize, if you look at registration as a marker of intent to participate in the program we see an ongoing increasing trend in that participation rate, however, we also note that Medicaid professionals are participating at a higher level than what was originally anticipated and that will have impact as we look through the program going forward because Medicaid providers are on a different timelines than Medicare. Most notably, they can begin the program all the way through 2016 and still get their incentive payments and also they can skip years in their program and we'll get into that little bit more.

So, now I'm going to talk a little bit about attestation patterns. The top bar is the proportion of Medicare providers who have achieved Meaningful Use, that means they've attested and/or been paid for Meaningful Use out of all the providers who have registered with the Medicare Program.

The bottom bar is the same trends for Medicaid providers but remember Medicaid can do...their first year is adopt, implement and upgrade so that tan bar in the middle there are of the 176,000 providers those are the providers who have been paid for adopting, implementing and upgrading but have not yet achieved Meaningful Use, only about 32% of all Medicaid registered eligible professionals have achieved Meaningful Use compared to 86% of the Medicare providers.

So, this chart shows you a little bit of a timeline. The Medicare or the Medicaid Program, it shows you when the providers first attested to AIU, adopt, implement and upgrade, so that first line there are the providers who got their AIU payment in 2011, it's around 47,000 providers.

Then it shows you when they decided to attest for Meaningful Use and they can attest for Meaningful Use any time after they do their first AIU payment. So, what we see here is 40% of that 47,000 providers who did AIU in 2011 achieved Meaningful Use in 2012, another 20% attested to Meaningful Use in 2013 and we are still working on our 2014 numbers and the trend is similar for 2012 and 2013 we're still working on that. So not, you know, between 40 and 60% of our first AIU payment providers have achieved Meaningful Use in 2011 and 2012.

Now, you know, you've seen this slide a while, but I just want to emphasize that for all providers not just Medicare, but Medicaid as well, they have to get two years of Stage 1 before they progress to Stage 2. Medicare providers, they're on a pretty strict timeline, you started in 2011 that means you were scheduled for Stage 2 in 2014. Medicaid providers they have to do those two years of Stage 1 but they can skip around a little bit.

So, what we see here is of all of the Medicaid registered providers, that's that 176 that we saw a couple of slides ago, only 8% of them are actually scheduled to attest to Stage 2 in 2014. Of the group that I showed you two slides ago here in this slide right here where it is the 11, 12, 13 and 14, only that first group, up at the top, that 47,000 providers are actually able to possibly attest to Stage 2 in 2014 but what we see is only 28% of them have actually completed 2 years of Stage 1 so that they were even able to attest or scheduled to attest to Stage 2 in 2014.

So, taking it back up a level, out of all the providers we already have seen this in previous slides, but just emphasize...or previous presentations, only about 4 in 10 providers were scheduled to attest to Stage 2 in 2014, of those providers 7% are Medicaid eligible professionals the rest, the vast majority of them, are Medicare.

So, to sum up, Medicaid eligible professionals have a lower rate of Meaningful Use payment than Medicare providers some of that may be due to program differences that the different programs have on timelines.

Although 4 in 10 registered EPs are scheduled for Stage 2 in 2014 the vast majority of those are going to be Medicare providers not Medicaid providers and that's all I have for today.

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

All right, thank you, Dawn. Questions or comments from the committee? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

So, thank you very much Dawn and this is a helpful presentation and if I understand your presentation right you're saying that the scheduling differences is one of the reasons why the rates are so much lower for Medicaid attestation than for Medicare. And my question is, what are the other reasons?

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

So, Medicaid...one of the reasons why Medicaid providers, and this is a guess, but one of the reasons why Medicaid providers are given that extra flexibility is because they serve a more...they have an underserved population, they have a larger population, they tend to be in more rural areas possibly, so a lot of that may be contributing to those factors on why they're not going to the next stage of Meaningful Use rather than just adopting, implementing and upgrading.

It may be that the financial motivations are not strong enough to move them forward, you know, it's something...some of the things that we're looking at right now but I think mostly it's they're dealing with a larger population of underserved and so it may be harder for them to make that next leap.

Paul Egerman – Businessman/Software Entrepreneur

Could it also just be that a lot of the Medicaid providers are practicing...in practices or practice environments that have much less of an infrastructure...

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

Yes.

Paul Egerman – Businessman/Software Entrepreneur

Than their counterparts and so they do not have as strong an IT department to implement things or to project manage and give them assistance in the entire process. It just strikes me...I mean, I know comparing Boston Medical Center to what goes on at Partners in Boston, the Partner's people have a lot of infrastructure to help every physician attest whereas Boston Medical Center doesn't have the staff to do that with its physicians.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

And that's a very good point. Some of the work that we've done looking at providers who are receiving assistance from the regional extension centers, for example, which targets the Medicaid eligible professionals population, shows that those providers who are receiving that technical assistance are much more likely to achieve Meaningful Use within this population than the physicians, the Medicaid eligible physicians who aren't receiving that assistance.

Paul Egerman – Businessman/Software Entrepreneur

So, there is some total...this program in part is sort of like helping the rich get richer, people who have the IT structures are able to get more of the incentive money than the institutions that serve a poorer population because they do not have that same capability.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

I think that the way I'd look at it is that this population may need extra assistance and we need to look at ways to get them that extra assistance.

Paul Egerman – Businessman/Software Entrepreneur

And ONC is doing that?

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

The regional extension centers have been helping those populations, yes.

Paul Egerman – Businessman/Software Entrepreneur

Okay.

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

And the other point that Dawn mentioned is in the Medicaid Program they have an AIU stage so they can get money to help them actually bootstrap. So, there are a number of things baked into the program to help with the folks that have less of the infrastructure that you point out. Other...oh, Chris?

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

Thank you, Paul, I hadn't anticipated this opportunity to comment on this, but this is something that's near and dear to our heart, 24% of patients in this country are children and pediatricians for the most part qualify under Medicaid.

We published a paper in January in Pediatrics outlying the challenges that are associated with being associated with the Medicaid component as compared to the Medicare component. To say it frankly, the pediatricians have gotten the short end of Meaningful Use.

First of all there is the Medicaid eligibility hurdle of 20% especially in states where Medicaid payments are poor where there are large obstacles to have a large Medicaid panel. There are fewer pediatricians enrolled in Medicaid. The inclusion of CHIP as part of the Medicaid panel has not been completely done in all states it has only been done in about 2/3 of the states. The reporting requirements actually vary across the 56 different states and territories, so things that one state asks of Medicaid panel people reporting might not be asked in a different panel.

And, you know, to add insult to injury, the State of Florida, for example, last year decided unilaterally not to pass on the federal dollars to pediatricians and pediatric hospitals, and pediatricians and pediatric hospitals were not getting paid and we had to lobby the state legislature through the American Academy of Pediatrics and had to do all kinds of pressure to apply all kinds of pressure on Florida for a federal program not to be blocked at the state level.

So, long story short, pediatrics and children, and that's really the point, children an underserved population, a vulnerable population are not being treated as effectively with Meaningful Use as adult patients are and I think it's time that we as a policy group address this and I really appreciate the opportunity to jump in on this one this morning. Thank you.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

I think that Jodi mentioned that earlier that, you know, ONC is working to get all providers on certified technology and adopting and using, and meaningfully using those technologies. So, I think that there are other ways we can do it outside of this incentive program.

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

Any other comments or questions? Good, thank you very much Dawn. I look forward to a more complete report next time when you have a chance to look at the data. Thank you.

All right, well now we're going to move onto an update on the two NPRMs that came out recently one from CMS on the Meaningful Use Stage 3 objectives and the second on the Certification Program. So, first Kate Goodrich and Beth Myers are going to be talking about it from the CMS perspective on the Meaningful Use Stage 3 Program.

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group - Centers for Medicare & Medicaid Services

Hi, everybody it's nice to be here. For those of you who don't know me I'm Kate Goodrich, I am the Director of the Quality Measurement and Health Assessment Group within the Centers for Clinical Standards and Quality at CMS and my colleague, Elizabeth Myers, is on the phone to help with any questions you all might have.

So, before I get started I'd like to sort of set the context for how we were thinking about Stage 3 and the approach to Stage 3 and I apologize that I don't have a slide on this, but I want to put this in context of the delivery system reform goals that were announced by the Secretary earlier this year, because I think that's very important to help understand our approach to Stage 3.

So, Secretary Burwell announced earlier this year goals for moving further on the track from paying for volume to paying for value with specific targets for CMS but also for private payers, we really invited private payers to participate in these reforms and I would say we have a very enthusiastic response.

So, the goals that were set forward were that by 2016 that 30% of all payments out of CMS were tied to alternative payment models like ACOs and shared savings program, bundled payments, patient centered medical homes, etcetera. We're at about 22% right now or at least in 2014 at 22% of payments.

And that by 2016 that 85% of payments are tied to performance on quality metrics in some fashion. And in 2014 we're really close to that 85% number already so that 30% falls within that 85%. And then by 2018 that 50% of all payments are tied to alternative payment models and that 90% of all payments are tied to quality metrics in some fashion.

So, fairly aggressive goals and targets I would say and there are really three things that we've identified that need to happen in order to be able to reach these goals. So, number one is how we pay providers, what I just talked about, right, so really value-based purchasing alternative payment models.

Number two is an accelerated emphasis I would say on care delivery, so that really means for us care coordination, so accelerating on how we can allow providers to better coordinate care across systems, across settings with patients as a part of the team, so patient engagement and shared decision making being a major component of that as well.

And then number three is Meaningful Use of Health IT and transparency of health information. So, we think that what we...or we hope that what we have proposed for Stage 3 of Meaningful Use can help to realize those goals to increase adoption and Meaningful Use of Health IT but also to really accelerate on the care coordination, care delivery piece of that as well.

So, the first slide just, again, tells you sort of our overarching principles for how we approached Stage 3 of Meaningful Use. We really were focusing on providing more flexibility for providers, simplifying the program, reducing burden for providers in direct response to feedback that I think we've all heard over the past couple of years, a major focus on driving interoperability among electronic health records and finally, increasing the focus on patient outcomes in order to improve care.

So, some key points related to the proposed rule that I want to highlight for you. The Stage 3 proposed rule establishes a single aligned reporting period for all providers over the entire calendar year. There is of course the Medicaid exception for that.

It allows providers the option to start Stage 3 of Meaningful Use in either 2017 or 2018 but all providers are going to be required to reach Stage 3 by 2018. So, this gives providers an extra year to start then what we've done before and we think this is responsive to...we hope this is responsive to feedback that we've received particularly around Stage 2 and the ability to reach those goals under the timeline that we had finalized.

And again, simplifies the reporting requirements by allowing flexible measures under three of the objectives so these include the health information exchange measures, consumer engagement measures and public health reporting that would allow providers some flexibility that would really fit best within their own patient population and their own practice.

So, reducing burden, again, was a major overarching principle for us. So, what we've done, as you all are very aware there is currently the core and menu approach to Stages 1 and 2 of Meaningful Use. So, we have reduced the number of objectives to eight which really includes a single set of measures across all providers, they are of course slightly tailored for differences between eligible professionals and hospitals.

In order to do that what we did was we looked at performance on all of the existing measures and we removed measures that we thought were redundant or that had received widespread adoption or were, as we say, topped out. We removed measures that allowed for...that were paper-based for example.

We also realigned the reporting period into a single reporting period for all providers. So, hospitals are able to participate on the calendar year instead of the fiscal year. And then I think...of course I'm biased, I'm the quality person at CMS, but we aligned on quality data reporting and really are focusing on electronic submission.

And so two things to point out here, as you no doubt have noticed, if you've read the rule, we did not propose specific electronic clinical quality measures. What we plan to do is propose those measures within the existing payment rules. So, we will be proposing measures, electronic quality measures for eligible professionals in the physician fee schedule rule and for hospitals in the inpatient prospective payment system rule.

And many of you know this, but for those of you who don't, you know, this was a very explicit focus on tying the program to the existing quality programs and really with a significant focus on improving outcomes and quality. And within CMS we actually undertook a reorganization to pull the Meaningful Use Program into the quality programs organizationally so that we really could focus on that alignment which is why you see me here today.

The other thing to point out on the next slide is that we really have been focusing, we wanted to focus on advanced use of electronic health records. So, we proposed to streamline the structure of the program to focus on the objectives that support really advanced use of EHRs and quality improvement including health information exchange.

We also think that the proposed flexibility for health information exchange objectives will ensure providers that are caring for the same patient can better share information with one another so that they can better and more effectively coordinate the care that they provide.

And to this end we have proposed the use of APIs in order to enable the development of new functionalities to facilitate information exchange between providers but also with patients. We think APIs can be enabled by a provider or a health system or provider organization in order to provide patients with access to their health information through a third-party application that may have more flexibility than existing or current patient portals.

The next couple of slides I'm not going to read through these for you, but you've got them in front of you I think. So, this just ties...this slide here just ties each of the program goals and objectives to fundamental delivery system reform goals.

So, one of the things you see here is that many if not almost all of these objectives tie directly to the National Quality Strategy, we've tried to make some explicit links between these objectives and the goals and priorities of the National Quality Strategy and the CMS Quality Strategy. That was done very, very deliberately.

We think that many of these program goals are responsive to what we've heard from you through the HIT Policy Committee, but obviously we want your feedback on that. I'm also not going to walk through this slide in any detail but this just shows the reporting options for Stage 3 and the certification addition required by CEHRT that's required for providers depending upon their first year of use, but again, I'm not going to walk through this in great detail.

And then finally, we want your comments no later than May 29, 2015, this is the website for you to go to in order to submit electronic comments, we of course will still take comments by snail mail or by hand, or courier even.

And then I know that this is the rule you've all been waiting for is the upcoming rule around modifications for the Meaningful Use Program for 2015 so we announced on January 29th that we intended to engage in rulemaking this spring looking at some changes for 2015.

So, number one is shortening the reporting period to 90 days, realigning hospital reporting to the calendar year, and then modifying some other aspects of the program in order to match some of the goals that we've talked about, again, related to reducing burden, reducing complexity and achieving our delivery system reform goals.

You see Dr. Conway's blog there, you probably have all read it but if not there is the link for it. And we do anticipate that this rule will be out very, very soon. And that's all I have.

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

Great, thank you, Kate and I'll just remind people about our schedule, so she mentioned that the comments are due May 29th we have a little dis-synchrony between our committee meetings and that date so what our plans are, this is April, is to present our near final draft recommendations from all the various Workgroups at our next meeting which is May 12th I think and then we're probably going to take the comments we get back from this group and then have another call meeting before the 29th so that we can have a final committee approved feedback.

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

It's May 22nd.

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

May 22nd would be

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

For the call.

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

Our call for the committee or everybody could just agree with what we present on May 12th and that would work as well. Okay, thank you Kate and we're going to move on now to the certification NPRM.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Do you want to ask questions?

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

Actually why don't we go ahead and do this first, yeah, while Kate's up there.

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group - Centers for Medicare & Medicaid Services

Oh, sure.

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

Any questions to Kate? Christine?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Thank you and I guess I'm not completely positive if it is you or Jodi that I should ask this question to, but I just want to understand a little bit more about the options for portal versus the open API component and I think the intent is right which is what we actually I think intended all along in our thinking on the Policy Committee, which is how we can, you know, kind of make sure that patients don't have five different portals and five different logons and how can I kind of pull that data into one place and so that was the idea behind view, download, transmit.

I don't know to what extent today Apps are the marketplace that enable that, but we also were pretty clear at the time of thinking, you know, we didn't want everybody to have to implement a portal if you were using, you know, Microsoft HealthVault or something else then we wanted that to count. So, I think in some ways this might be catching up with that, you know, thinking, but in other ways, just in reading the rule I'm not completely sure that I understand it.

So, if there is a provider that says, well, I don't offer a portal but you can use anyone of these three Apps and, you know, pull your health information out of my system are we going to end up with a situation where I now have three or four Apps, which is the same to me as three or four portals, right, I don't care if it's a portal or an App, I have three or four different places that are silo'd from each other that I need to go to or I have to be able to pull all into one and so now I'm pulling some from portals, some from some App and putting it into this other place that I want.

I think the thing that concerned me about the rule was it left it up to the providers to decide, well, do we go onto to do a portal or an API, or whatever, when I think it really should be the place of the consumers choosing since it is my data that's kind of spread out. So, I just wanted to understand a little bit more about how you guys envision that?

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group - Centers for Medicare & Medicaid Services

Sure, so I think this is at least partially ours to answer and Jodi if you have something else you want to say, so I don't want to tell you something wrong about the details of what we wrote in the rule, so I think our goal was to provide some flexibility but that's helpful comments you're saying and I can certainly see the concern there, but I'm going to ask Beth if she wants to add anything here since she understands the details better than and I do of what we actually wrote in the rule.

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services

Sure, thanks Kate. So, this is an excellent question and this is actually exactly why you'll note that in the patient electronic access objective we proposed a series of alternatives. So, we've proposed our basic, this is the proposed structure, so the objective and measure, and specifically for that measure we identified that a provider could use a VDT functionality which is the current standard, so the current certification standard or an API.

But then we also proposed three different alternative options that represent different use cases and mixes. So, in one case it would have to be that the provider uses a VDT and an API. There is a VDT or API and API, so in other words, we did this mix of what the use cases should be and we're seeking comment on those.

So, at this point because it's an NPRM obviously I can't identify if any one of those is sort of preference, I don't think that we actually look at it that way. I think what we need to know is if we can get some comments back and your recommendations on if these different use cases represent pros and cons in different ways and what are the pros and cons for the provider, what are the pros and cons for the patient, what are the pros and cons on how this could be leveraged in the future for greater and lighter functionality.

So, we have a series of those sections in there, we do very much urge you to take a look at those alternative options and consider how those use cases would be impacted and I do think that actually from the ONC certification side there might be...when Jodi comes up this might be a good thing to address as well, because there is some related on their end looking at how the functionality and certification would actually happen for APIs.

So, I think we recognize that there may be a challenge in the use case that we're trying to identify through the proposed rulemaking process as much feedback as we can on how that would work.

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

This is Jodi Daniel, I'll just add, I agree with what Beth is saying and this is an area where we've requested...we've particularly asked for public comment I think we really welcome the feedback on how to make this work.

Our goal is to create an open ecosystem for patients to be able to use different applications or different products to be able to access their health information through various sources and so we do ask for feedback for comment on how best we can do that on our side, you know, are there requirements, are there...do we need additional terms of use, are there additional, you know, technical requirements that we should be putting forward in our certification rule as well to help foster that ecosystem. So, again, I think both sides were...this is a new territory for us and we welcome comment on how best to achieve that goal.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

I'll make a request, I think that because you guys decided not to do detailed briefings for the Policy Committee's Workgroups before the HIMSS meeting we're in a really big time crunch and there are very technical components particularly of this piece of the rule that I don't think we understand, at least I can tell you I do not, and so I think...I totally hear your intent but I think we need some help from, at least the Consumer Workgroup, in figuring out and maybe hearing from some application developers, you know, what...is it going to cost them extra to be certified by ONC in terms of using this API, is that cost going to be passed onto consumers, which is going to be a real problem for low income individuals, does this mean...you know all the kind of questions that I'm asking around does this mean I could potentially have three or four, or five different Apps going on?

So, I just don't know because it's a technical question. If we could get some help...we only...I mean, I think our Workgroup only has one meeting scheduled before the Policy Committee so we have to maybe address that number one and then number two get some technical folks to help us in those calls to really understand this otherwise I don't think we can comment meaningfully for you guys.

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

Okay.

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

What I'll do is because this obviously is an integration between the CMS rule and the certification why don't we have Jodi go ahead and present and then we'll collectively...because it's going to be all addressed I think in tandem if that's all right.

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

Okay, great, thank you very much Paul and the committee. We are going to provide basically a broad overview of some of the goals and some of the key provisions that we put forward in our proposed rule for comment. Obviously we can provide more detailed assistance with the Workgroups as needed to help folks understand the rules.

I wanted to start by thanking the ONC team that worked nights, weekends, crazy schedules to try to get this rule out, we have a really small but dedicated team. Mike Lipinski is leading our rulemaking team and I want to give a personal thanks to him, he is on the phone to help answer some of the more detailed questions that folks may have.

It looks like there is bar that's missing there, we're having some technical difficulties here. Okay, so I want to start with our Health IT goals and apparently access has been dropped but that is not intentional access is one of our key Health IT goals and you should have it in the slide deck in front of you. Sorry about that.

So, I wanted to highlight what our key goals are and then some of the provisions and some of the policies we proposed in our rule to support these goals. So, the first is interoperability and you have heard ONC and Karen DeSalvo talk extensively about our focus on interoperability, on having health information not just captured and being used by the clinician who is seeing the patient immediately but also to have information follow the patient across the care continuum and be shared with the patient. So, there is a huge focus on interoperability in our rules.

The second is access to data both by patients as well as providers.

The third, I'm calling this user or market reliability, it's also thinking about making sure that providers can rely on the products that they are purchasing and that there is some consumer protections in place like privacy and safety and I'll talk more about that.

And then the fourth is supporting the care continuum. So, we've talked a lot about how do we leverage our certification program, how can ONC really support the interoperability and Health IT use to improve care across the care continuum, to improve health across the care continuum not just limited to the providers that are covered by the Meaningful Use Program, as Chris pointed out, but really to cover all of the providers that are seeing patients as well as some of the community supports that are necessary to help improve health.

Okay, so, I'm going to take each of these in turn, talk a little bit about each one and then open it up for questions.

So, the two key points I want to focus on in interoperability is both our focus on standards and vocabulary and the transitions of care. So, first we have new and updated vocabulary content standards to improve interoperability. I'll say a little bit more about this when I talk about the common clinical dataset, but just for example, we have added more...we've added standards on patient sex and on vital signs to our common clinical dataset.

With respect to transitions of care a couple of things I want to highlight, first, we have proposed using the Consolidated CDA release 2 which is more constrained to promote interoperability than release 1.1 which is what's in the 2014 edition.

We are...we also talk about testing a Health IT module to both releases of the Consolidated CDA so to 1.1 and 2.0 for creation and receiving in order to facilitate backward compatibility with Health IT certified to the 2014 edition.

So, you heard Kate talk about that transition year, we want to make sure that information can continue to flow while some people may be on 2014 edition and some people may be progressed to 2015 edition certified EHR technology or certified Health IT.

With respect...as we had done in our release 2 of the 2014 edition we proposed testing and certification for sending and receiving consistent with the EDGE protocol so we talk about dividing the creation and the sending for transitions of care purposes, again, this is...the goal here is to support providers being able to have more options for exchange of health information.

And then finally, we have proposed rigorous testing to ensure that a Health IT module can identify a valid C-CDA template to use correct vocabulary standards, to detect errors in document sections and entry templates, and to perform XDM processing, all of this is with the goal of reducing errors and improving interoperability.

So, again, still sticking with interoperability I wanted to focus a little bit on the 2015 base EHR definition which focused on the functionalities that all users of certified Health IT should minimally possess consistent with HITECH Act requirements.

So this is really foundational. The foundational set of capabilities that focuses on those that are in the HITECH Act as well as those that we believe are critical for any EHR system.

It's a little hard to see but there are three here that are in red, these are new to the 2015 edition base EHR definition versus the 2014 base EHR definition. We've also removed from the base EHR definition the privacy and security certification criteria, I'll talk a little bit more about this and how we've actually...I see this as an enhancement of privacy and security, it's not in the base but we do have it...I'll talk about it a little bit more in a few slides.

And I also want to note that just as with the 2014 edition the base EHR definition can be met with one Health IT module or multiple Health IT modules. So, it doesn't mean...you can be certified, a product can be certified to one or all of these different criteria and the provider to have the base EHR just has to have all of the criteria from one or multiple certified modules.

So, I mentioned the common clinical dataset, this is the key health data that should be exchanged using specific vocabulary standards and code sets where applicable. We mention in the interoperability roadmap the goal, and I have it up on the slide, for between 2015 and 2017 to send, receive, find and use a common clinical dataset to improve health and healthcare quality. So, this is aligned with our interoperability roadmap goal.

In the 2014 edition we call this the common MU dataset, we've just changed the name to common clinical dataset. Again, we're trying to demonstrate the leveraging of our certification program beyond Meaningful Use, just a change of terms there isn't any other implication than that.

This is the dataset that should follow the patient for a transition of care and should be accessible to a patient. So, these are the key things that we think need to move and they're aligned with our interoperability roadmap.

Okay, moving onto access, so to the area Christine has been asking about, so first before I get to VDT and APIs one of the other key pieces of access is data portability and making sure that providers have access to their data even as they're switching products or have access to a set of data for a particular timeframe.

So, the data portability provisions are focused on the common clinical dataset and what's different from our 2014 edition requirements is that for data portability criteria to be met it must be user enabled and permit timeframe configuration.

So, we've heard some complaints that for somebody...for a provider to be able to access the data under the data portability requirements they needed the vendor to get involved or they needed specific training, or there were a lot of hurdles to jump over. So, we focused on it being user enabled as well as permitting timeframe configuration so that a provider can determine they only need a month, a year, two years, etcetera.

So, moving onto the consumer side of access, so we have VDT, view, download and transmit, which is similar to the 2014 edition and focuses on patient enabled functionalities as well including the API. So, we talk about...we have certification requirements for both VDT as well as for API.

For API this is now in the base definition for providers, base EHR definition. The data...the scope is limited to the CCDS, so the common clinical dataset, it is for the get/read oriented request, so there are lots of different things an API can enable we are certifying that a Health IT module can handle a get/read oriented request and that's the minimum for certification. So, it doesn't get to the update or delete capabilities just the create and read.

There are security requirements a developer must demonstrate a trusted connection can be established between the sources of API and other software, we don't specify...we don't provide a lot of detail on that but they do have to be able to attest to that.

And then we also require documentation. So, there must be accompanying documentation on the technical implementation requirements as well as terms of use for the API and both of these must be made publically available on the CHPL.

Again, this an area where we've requested public comment whether we have the right requirements in there, we're trying to build a trusted ecosystem for patients and consumers to be able to access their data using their application of choice and we look forward to some comments on how best to do this.

Okay, now user and market reliability, there are four categories here that I put under this bucket, privacy and security, patient safety, surveillance and certification maintenance, and transparency.

So, I mentioned about privacy and security being taken out of the base. What we have proposed is that Health IT developers would need to meet applicable privacy and security certification criteria depending on the other capabilities included in the Health IT module. So, we still have our certification criteria for privacy and security and we're tying it to particular functionalities.

So, for example, if a Health IT developer presented for certification of a Health IT module with transmission to immunization registries, that capability, it would also need to be certified to certain certification criteria on privacy and security including authentication, access control and authorization as well as auditable events and tamper resistance audit reports and end user device encryption.

What we were trying to do is remove the responsibility from the provider which is the way it currently is in the 2014 base EHR definition approach to ensure that the technology that's certified provides the necessary privacy and security criteria when they purchase that functionality.

With respect to patient safety, we've done a couple of things, first safety enhanced design, we're trying to ensure usability and safety enhanced design for expanded set of capabilities as compared to the 2014 edition certification criteria.

We've also...we also have provisions on quality management systems and in the past there were vendors or developers had to identify what kind of QMS they used, what kind of quality management system they used to develop, test and implement and maintain their capabilities of certified technology, but they could say they used none, that is in the 2014 edition, that would not be permitted under the 2015 edition.

Surveillance and certification maintenance is another area where we have added some important provisions, we've proposed new requirements and parameters for in the field surveillance under the Health IT certification program.

So, this is really about the ONC ACBs ensuring that certified Health IT modules can perform the capabilities in the production environment not just in the lab looking at how they are implemented and used. This is via randomized surveillance and reactive surveillance if they are complaints and really what we're hoping is that this can help improve and identify any performance issues as well as can help enhance safety by identifying any potential medical errors that may be caused in the implementation in the field.

And finally, transparency, we have broader and more detailed information that must be made available than is in the current 2014 edition. There are additional types of costs that we would require to be disclosed by a developer that a user may incur to implement or use Health IT for any purpose within the scope of its certification.

We also added a new transparency provision regarding potential limitations including contract restrictions that would limit a user's ability to implement or use Health IT for any purpose within the scope of its certification. All of this information would have to go into the Health IT developer marketing and communication materials in plain language as well as be posted on the CHPL.

And the last of the four goals, supporting the care continuum. So, prior editions of our certified products, of our certification rules really focused on the EHR incentive program, really focused on the Meaningful Use Program and making sure that there were products that were certified to the capabilities that were necessary to comply with Meaningful Use. We are still focused on doing that and we have worked very closely with CMS to make sure that our certification program and our certification criteria aligns with the Meaningful Use Program.

But we also are proposing to make it more accessible for and support other programs as we move into delivery system reform. So, this is...so one thing we're doing is we're changing...we changed EHR module to Health IT module. So, in the past we called it an EHR module, we're now calling it a Health IT module. There are some criteria that we currently have in our 2014 rule that really go beyond what we would call an EHR like lab information systems or health information service providers who may get certified to certain criteria.

So, this is actually aligned with what we really have done in the past, but also to make it clear that the certification program may go beyond EHRs as well as be leveraged across the care continuum including by long-term post-acute care providers and behavioral health providers who we've heard a lot from as well as pediatricians of course.

So, we tried to make the certification more efficient. The Meaningful Use measurement requirements are now part of the EHR incentive program versus a certification program requirement. So, where there is a particular requirement for Meaningful Use measurement they're in the Meaningful Use rules as opposed to the certification rules. This means that if a developer is serving a provider that is not participating in the EHR program then they don't have to build the capability into their module and get certified to it if the provider wouldn't necessarily be using it or needing that.

Finally, we do have some available or optional certification criteria that we have put in including those that support health disparities, these are not part of the base, they're not required for the EHR incentive program, but they are areas that we thought were important policy priorities that we should put forward and that we've heard from various different entities that would be important for them in adopting EHR technology or Health IT technology.

I wanted to highlight as we are saying we're trying to leverage our certification program for more programs that we actually have already done so. So, the physician self-referral law and Anti-kickback Statute, the fraud abuse laws already leverage the certification program for EHR donations, the CMS chronic care management program requires use of certain certified Health IT as part of that program, the DoD procurement for EHR system also references our certification program for that effort.

And finally, please comment, we really, really, really review every comment we get and it helps us to think about the policies we've proposed, it helps us to think about how we can come to good final rules. The comment period closes on May 29th as was mentioned. I've given links and I'll leave this up for the comments if people want to jot them down, if you don't have it in front of you about where you can review the rule and comment.

We also do have a public comment template for people to use to provide comments in a way that helps us to process them most efficiently. So, I will stop there and I will gladly take any questions. Mike is there anything you want to add before we open it up for questions?

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

No not at this time, thanks.

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

Thank you and Kate do you want to join the panel and then we'll have questions. Now these are more on the area of clarifying questions about the rule, as you know we're going to go through an intensive exercise of trying to provide formal feedback about the rule over the next month.

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

And if I could just make one other comment, while we are in this comment period we are really helping to clarify and to restate what's in the rule to help point people's attention to key provisions in the rule that you all might want to pay attention to, but we're not, you know, we're going to stick to sort of what's in the rule as far as responding to the questions that are asked.

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

Okay, fair game. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Thank you, Jodi, as usual very informative and concise presentation, very much appreciated. I have a couple of observations and questions, one is when we were talking about the Medicaid numbers earlier I made the comment that gee it seems like our system is favorable towards large organizations than to poor organizations. And my question is, isn't that the same thing true of our certification program? I mean, we have this slide up here for comments, it's interesting that Christine said she read something she didn't understand, I read through not all of the NPRM and I found it to be almost incomprehensible, I mean it references other regulations, it references implementation guides, you know, the document itself is over 300 pages, but if you look at everything you have to read to read the whole thing, it's like well over 1000 pages and I don't understand how is an entrepreneur or an individual physician, or a Medicaid provider supposed to read through this and be able to make comments?

And just to give you an example as to how I think it is set up for large organizations you talk about your quality program. The quality program now requires testing by 15 people, well you might have a customer, a small vendor who doesn't have 15 customers and so I guess they can't get certified if they only have 14 customers or if they have 15 customers but not all of them want to participate in testing.

And so my question is, is first if you're a small organization what are you supposed to do?

Second clarification is, you point some things in certification that aren't required for the Meaningful Use Program but maybe required for future programs. So, what does that mean if you're a vendor, if you're a vendor of say, you know, nursing home software you're not covered by this. Do you have to read through all of that material because you think someday you might be covered by it?

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

So, I'll take the last question first. So, just by way of example, and I'll...if there were a different program that was going to leverage our certification program that would likely go through its own process, so for instance the two top ones here, the Stark and Anti-kickback Rules and the CMS chronic care management rules, those go through notice and comment rulemaking.

So, if in fact another program was going to reference new criteria that we had put forward in our rules, in our certification rules that would go through another notice and comment period and folks would have an opportunity to weigh in, you know, before that would be something that would be connected with another program. So, there would be adequate opportunity for folks to be made aware of the leveraging of certification criteria in another program.

Paul Egerman – Businessman/Software Entrepreneur

Well, I'm not sure that's quite right. I mean, the SGR has passed the House of Representatives has some mandatory requirements about this whole issue of access and there is no comment period there so the legislature can...federal state legislatures can mandate certification criteria without public comment and so they're working on the assumption that what's in the criteria is right, but my concern is people might ignore this under the idea "well, I'll look at it later" and that later might not be possible.

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

Most likely, if whenever there is legislation there would likely be follow-up regulatory action to implement that legislation. I'm not going to comment on current legislative activities, but typically the administration will put forward regulations to implement any changes in legislation.

Lisa A. Lewis – Chief Operating Officer – Office of the National Coordinator for Health Information Technology

I would like to add, this is Lisa Lewis, I'll just add I think it's important that we do position ourselves well. As you saw in the SGR legislation, and in other pending legislation if you're tracking it, there is a huge emphasis on our certification program and the possibility of potentially decertifying and also positioning ourselves to be prepared, as Jodi said, for other programs that will leverage the certification program to move us toward interoperability. We are all pushing in that direction and I understand your point very much and look forward to that being part of the comments that you provide.

I think we all need to look at this and figure out collectively how we move forward because there is potentially pending legislation as well as the rulemaking process that we have to continue to progress against.

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

This is Mike Lipinski, I just was going to add a few comments. Paul on the one point about the...I think you were referencing the safety enhanced design, the 15 representative test participants is just recommended it's not...we're not proposing it as a requirement. We are asking comments on that and whether there should be a specified number of cohorts and who it should be made up of, but right now it's just a recommendation based on, you know, NIST guidance.

And then as to reaching out to like I guess, you know, smaller either developers and/or providers, you know, ONC is very cognizant of that and actually we were taking steps already to do that so, like, we are in touch with like the accessibility communities, the rural and veteran populations we have already had particular people that are going out and presenting to them. The same on behavioral health we're working closely with SAMHSA as well as HRSA to get specific targeted presentations of our rule to these folks.

We also intend...I know there is a lot to read in the rule but as we noted at the end, you know, we're willing and we intend to work with, you know, these other, you know, outside of the EHR incentive program groups about what is important in terms of certification and we recall, you know, the past recommendations and comments from, you know, the Policy Committee on how to approach that and I think we've taken that to heart and said, you know, we'll look to see, you know, what are the most important capabilities those providers should have such as, you know, transitions of care and privacy and security and work to issue guidance and disseminate guidance along those lines once, you know, we have a final rule out. So, just wanted to mention that we are cognizant and we are trying to take steps.

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

Okay, we have a number of comments, we're going to extend this session a little bit so try to keep it to the clarifying...we are being invited to have a vigorous response in terms of our comments back on the NPRM that we'll go over in the next meeting and then the follow-up phone call, but Neal, please.

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

Thank you. Jodi thanks for the presentation. I'm going to ask kind of a global question. This seems to me to be a moment of the major shift from using incentives to digitizing the United States Healthcare System, to using basically a certification program including down to moving away from EHRs to HIT so that more applications come under the program. And the incentive side is going to shift over to CMS on the payment side and the quality. So, isn't this the shift? Meaningful Use money is gone?

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group – Centers for Medicare & Medicaid Services

I mean, the Meaningful Use money is gone I think by law.

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

Yes.

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group – Centers for Medicare & Medicaid Services

Under Medicare, sorry, I am sorry that is what I'm responding to. And I think in pulling in the elements of the Meaningful Use Program into the quality reporting programs we sort of see those elements becoming the foundation for the quality reporting programs and there are various incentives and payment adjustments that are tied to those programs as well, but in terms of what's required for Medicare for Meaningful Use I mean that is sort of outlined by statute how that...when the incentive money ends and the payment adjustments begin.

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

I personally I think that's brilliant on your all part. I'm not going to speak from the rest of the world, but from an ONC point-of-view that leaves certifications as the lever.

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

Yeah so...

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

And certification is expanding pretty broadly here. Paul and I are both entrepreneurs, I did not read the 300 page document that linked to thousands of other pages, but, so, you know, it seems like this is going to get to be a fairly significant compliance to be able to access marketplaces.

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

So, I'll just say a couple of points and then Mike if you have any other comments as well. So our certification program, the ONC certification program is voluntary, so we don't require folks to comply with our certification rules. It is other programs like the CMS Meaningful Use Program or the Chronic Care Management Program, or others that tie to our program so that folks are all following the same set of standards and we can build toward interoperability.

So, for instance, you know, when we have, and I'm going to go back here, some of these optional certification criteria, you know, this is...so exchange of sensitive health information, data segmentation for privacy, we heard about that from the behavioral health community, SAMHSA was very interested in that, you know, it may be that, you know, this is not something that is required by us or by CMS as part of the Meaningful Use Program but it's something that we've heard enough about and that folks are looking for a standard on and looking for a consistent way to implement something that is really necessary in the behavioral health space and so we put forward a proposed certification criteria to address that need.

In all of these cases we are responding to needs and stakeholders feedback that we have received for areas where there are holes or needs for them to provide care to their patients. So, you know, just as a context we did not...ONC did not make up these criteria, these are based on what we've heard either from our other federal partners, from outside stakeholders that have particular unique needs such as the behavioral health community or the like.

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

And this is Mike Lipinski, I was going to add that, you know, we obviously put out our interoperability standards advisory and so there is where we're identifying use cases where we think particular standards should be used to improve interoperability which is also a voluntary approach.

I think to look at certification I would say that, you know, this is where if a program thinks that, you know, believes that certification to that standard and that particular functionality is necessary for the insurances that certification provides, you know, we will, you know, provide that criteria, that ability for certification but I think as, you know, from our policy position it's as Jodi stated, you know, it's whether other programs believe that, you know, certification is the necessary lever in this particular instance to ensure that, you know, the functionality is there and they're using the appropriate standard, but there is also other means such as like I said the interoperability standards advisory where you can, you know, voluntarily adopt standards that we're identifying for particular use cases.

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

...but I've always been amazed that you ignore one of the largest requirements out there and that the national identification for interoperability.

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

Well, as we've said in the past there is prohibition in our HHS appropriations that prohibits us from creating...from using federal dollars, federal HHS dollars to create a unique patient identifier. We stand ready to, you know, if congress changes their position on that and gives us authority to do that we will move forward on that. In the meantime we are acting within our authority.

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

Which doesn't mean there can't be opinions expressed.

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Can I please follow-up on that one?

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

Go ahead Mike.

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Can I follow-up...

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

It might be...

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Yeah, our transition of care criteria proposes some elements for patient matching. So, I mean, that is a step that we've, you know, sort of taken to address that to make sure you have the right patient. So, you may want to look closely at that, that we proposed as part of the transition of care criterion.

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

Jodi, I do have a question, this is Gayle on the phone.

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

Gayle you're in line, you can't see but you're in line, in a long line unfortunately.

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

Okay.

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

But your card is up. Can I ask everyone to please be concise and it's clarifying only mainly because we're out of time. So, Troy?

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

Thank you, thank you very much. Listening to Paul and Neal, I mean, everything that they have talked about, I mean, I could echo again, but, you know, I don't want to editorialize it and belabor that. One thing that I'm seeking clarification on, now keeping in theme with the collect, use and share grand scheme we're at the point of sharing which you're right Neal, I mean, it really does point to the technology aspect of it and the certification aspect of how do we get this data from one vendor to another vendor.

The standard, and this is written in the NPRM and I read all 300 pages and I agree with you Paul, to reference all of the different points to go to where the certification declarations are made and come back, and try to piece it all together is an arduous task. I'm trying to make an executive summary and I can't get it down to less than 40 pages, it's not quite an executive summary.

Anyway, the C-CDA is our standard now for sharing information. Within the NPRM I notice that there is kind of an opening into the relevance, sharing relevant information from provider to provider, I'm curious how that is going to play out and what that exactly means and, you know, I get down to the discreteness of sharing medical implant device UDI, you know, there is a lot of different devices, there are pacemakers, which are Class III implantable devices, absolutely definitely, you know, the next provider of care needs to understand that there is a pacemaker in place and how to access the tracking information on that.

But there is also Class III implantable device screws during an orthopedic procedures, plates that really don't have that much relevance or pertinence at that point in time, what's the proposal? I mean, what...when we talk about relevant data how are we actually going to play that out from your point-of-view?

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

So, on the common clinical dataset, and I brought this back up, it is...for UDIs specifically it is for implantable devices. Mike do you want to...could you give additional context on this, on the appropriate and the UDI requirements?

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Well, I mean, other than, you know, it is, as you said, the implantable device list so it's, you know, what's been implanted in the patient there are particular data elements of the UDI that we expect to be captured and parsed such as like the device identifier, expiration date, batch lot things about information so that would be what would be tested to ensure that they can, you know, the serial number, that they can capture that and record that, change it, update it as needed.

And then for a transition of care we would expect any particular patient that had, you know, UDIs should go with that patient's health information. I'm not sure...I mean if you're saying should it be limited to, you know, particular devices only, you know, we haven't really broached that issue in the rule and, you know, again, welcome comments on that.

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

Well, I appreciate the opportunity to do so. And it's really...you know I gave that as an example of the level of relevant data that could be shared and as you all know, I mean, if I brought in an example of the C-CDA, aka the summary of care, and I dropped it on the desk, we have not been able to get one of those printed versions and I'm glad that the printed version is going away because we're running out of trees.

We have not been able to share a printable C-CDA that's less than 80 pages and even in an electronic format there is no way that a clinician is going to read through, you know, 80 pages or 50 pages of electronic format data and try to integrate that into their own EHR that they have on the receiving side, so I...yeah, yeah.

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services

This is Beth Myers, if I may chime in on that particular point that you've made here.

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

All right.

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services

The C-CDA and the question of the length of the C-CDA and how to limit is something we're also seeking comments on in the Meaningful Use rule. We did include a proposal in the Stage 3 NPRM that what we're looking at from the Meaningful Use stand-point is that a provider has to have the capability to send all data, specifically we looked at problem list and labs because those are the ones that are sort of the biggest items that we hear from providers that, you know, they create 100 page long documents and they're really a challenge.

So, what we're trying to kind of balance between and what we proposed in Meaningful Use is the ability to send all should all be necessary, which there are use cases where it might be and the assumption of clinical relevance.

What we found as a challenge, and you'll note that in the rule, is how to define clinical relevance because it may vary by provider, it may vary by patient. So, we actually do think that it may be best that providers actually determine for themselves what clinical relevance is, but what we've done in the proposal rule right now is stated that we want you to have the capability, through your CEHRT, to be able to send all of these records but then there could be limitations placed on it by the provider in conjunction with their vendor.

So, that is a change from our current policy and it's explicitly designed to address this particular issue from a Meaningful Use stand-point. We do expect to receive comment on that and hope that you will consider commenting on that as well so that we can further refine that policy for the finalization.

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

So, we have a couple of choices, either we...so we're out of time but I would like to entertain these questions so if we could please keep them to clarifying questions and we don't need to debate the topic itself here because we'll have plenty of time to do that in our calls leading up to the next meeting. Christine?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Thanks, so two hopefully quick ones, one is you guys have said in the rule that it's the final stage of Meaningful Use, is that true for the CEHRT Program too? I just want to double check.

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group – Centers for Medicare & Medicaid Services

No.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay and then the second question I have, in a bottle of brevity, is...I did my best, oh, wait I'm not done yet, Jodi the slide you had about the optional components of certification including things that help address disparities, exchange of sensitive health information all that bottom bullet there, can you just talk to why that's optional? I just am confused because it seems so totally linked to the delivery system goals and it seems really clearly linked to the MU objectives. Where they not ready for primetime or why were these things optional?

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

These are new areas for us some of...for each one there is sort of a different reason of why we've made it optional and I'm not going to get into all the detail, but, you know, in some cases, you know, particularly some of the social psychological and behavioral data that is fairly new and is something that's still sort of emerging and that, you know, it's sort of new territory for us and we thought it was best to do it that way.

You know, again, this was in negotiation with CMS and Meaningful Use, and trying to...they were trying to simplify and cut their objectives to a limited number of core objectives. These were things that we had heard a lot about that we felt were important to put forward as criteria. Mike do you want to add anything to that?

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

I mean, not much more than that. I mean, all the criteria I just want to say like from a developer perspective, you know, all the criteria besides the requirements of the certification program such as like, you know, QMS and then the conditional requirements like patient, excuse me, privacy and security or safety enhanced design they all are then kind of optional after that and what we're saying with these ones, these ones are I guess another way to look at them instead of calling them just...they're not associated with the EHR incentive program.

And actually, I can't say that we point to any particular program that is currently, you know, referencing these particular ones yet but these...I think what Jodi said, you know, we found from, you know, certain stakeholder feedback that these were important that we should offer them that some providers and developers would utilize these criteria, these functionality certification...

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

A lot of it is a balance of how much we think, I mean to get to Paul and Neal's point we're trying to balance what is required and absolutely mandatory for any EHR system and then some optional criteria that we are hearing from certain settings or certain providers, or certain segments of the healthcare delivery system that they need, but it's not clear that it's a widespread need, so it's a balance.

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

Thanks. Charles?

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

Okay, so as the insurance guy on the HIT Policy Committee, I think Kate's comment about linking the payment system to Meaningful Use is probably one of the most brilliant things we've done, so, but of course I'm biased.

But my question is when you think about linking the two, and I see CMS more and more making explicit linkages between the two, the question that prompts in my mind is, depending on how you approach the payment reform has dramatic implications on the technology necessary to make you successful and just two quick examples, if we have bundled payments, interoperability might be a lot less relevant or important to me in successfully executing a bundle payment strategy versus MSSP risk share/gain share where interoperability might be very important but I might even think something like a federal management tool would be even more important for me being successful in that structure to manage leakage and keep it so to speak.

So, my question is, as you think about linking the payment system with the enabling technology infrastructure is the money driving the solution, is the solution aligning the money or is it coordinated in any way and if so where would that coordination occur?

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group – Centers for Medicare & Medicaid Services

That's an interesting question. I'm interested that you think that bundled payments wouldn't as much require the interoperability, it seemed to me that they would in the same way that shared savings programs would, but we can talk about that off line certainly. You know if...

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

Just real quick the point I was trying to make is a bundled payment constrained episode of care...I'm not saying interoperability has no value but if you have a whole population of people interoperability arguably would have more value.

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group – Centers for Medicare & Medicaid Services

Absolutely, yes, I mean, I think we see the need for interoperability with all of these new payment systems. I wouldn't say that we are explicitly thinking, at least from what I've seen, but there are others at CMS who may feel differently or are having different conversations, you know, specific aspects of Meaningful Use of EHRs or Health IT, or specific aspects of how providers are able to coordinate through things like referral management tools and that sort of thing with specific payment models, maybe that's something we should be doing more of and it's an interesting thought, but I think we feel like the interoperability piece, the tie to quality piece is fundamental for any of these new payment models.

It probably would behoove us to think in a little bit more detail about specific options like you're talking about, but I think we're sort of thinking about it a little bit higher level than that, but I'd love to think about that some more with you.

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

Okay.

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

Good, thanks, Charles. Chris?

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

Thank you, Paul. Jodi, thank you for an excellent polished presentation. I just want to throw out there that we're really glad that the Notice of Proposed Rulemaking didn't come out before the winter holidays. The Office of No Christmas is known to do that so this was much better timing that's my only comment.

The question that I have, the clarification that I have is Paul said something that I thought was spot on that this whole Notice of Proposed Rulemaking is incredibly large and it's difficult and burdensome. The AP had three interns pouring through that thing for a month to come up with a 70 page summary. So, my question is, are there other resources or are there interests in providing a high-level summary that would provide people actually the ability to provide comments?

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

For this...for either of us?

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group – Centers for Medicare & Medicaid Services

For both of us?

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

Either one who wants to answer it but Jodi is really the person, the Notice of Proposed Rulemaking is what I'm targeting.

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

Okay. Mike do you want to talk about some of the documents?

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Sure.

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

Okay, thanks.

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

So, you know, this is our first actual public presentation on the rule today. We're having a more in depth one planned obviously for HIMSS. We also are working on, you know, slides and presentations for the Workgroups of both the Policy Committee and Standards Committee. I understand and I appreciate the concern related to, you know, the links and the difficulty of reading the rule.

It's a legal document so it has to be drafted in certain ways, consistent both with our guidance from our Office of General Counsel as well as procedural requirements of the Office of the Federal Register like for instance there is like 30 pages at the end of the rule about incorporation by reference and then the Reg text itself is almost 100 pages. And then you have proposals both for the 2015 edition as well as proposals for the certification program which is over 100 pages.

So, it was putting, you know, both the 2015 edition and the certification program into one, you know, rulemaking because, as you guys know, rulemaking takes a lot of time and there wasn't really the time to split those two things out and then you also deal with like I said, you know, the other requirements that I mentioned.

I don't want to make excuses for it and we know that is a concern from stakeholders and as I mentioned earlier we're trying to do outreach, specified outreach. We also plan to do more documents to try to make this more easily understandable.

If you've seen already there is a one page like table out there trying to show you how the criteria splits out, you know, after a final rule we intend or hope to put together one document that would have something like all the criteria, all the standards that go with it, all the frequently asked questions, all the interpretative guidance for each particular thing together at one place, you know, we've tried to do that in the past if you're familiar with like our MU tables which align everything as much as we can together between the stage, the criteria that supports, you know, that particular objective and so forth.

So, I mean, we appreciate your concern and we're trying to address that through, you know, both presentations and then supplemental guidance material more of which we have the ability to issue after a final rule than we do with a proposed rule. So, just want to recognize that concern. We understand it.

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

And I just want to also add that we are planning to do, besides presenting at HIMSS, we know not everybody goes to HIMSS although we do have a large stakeholder group there, but we will be doing a webinar as well that will be available to the public to help explain some of the...to walk through the criteria and the rule in more detail than I've done today so that folks can have an opportunity to hear from us, you know, the really detailed walkthrough and that would be available publically to folks.

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

That's a good point...

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

Thank you, I think that would be very helpful.

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Yeah I just want to mention there will be joint webinars conducted with CMS. CMS has regular both provider and vendor calls in which we'll conduct webinars and then ONC will try to do like deep dive webinars as well, as well as we're accepting, you know, requests for webinars and presentations for like consumer groups that we have already on the schedule. And then the Standards Committee meeting will also be a more in depth deep dive presentation on the particular standards and criteria as well.

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

You know we also...I'd just like to say that in the rules themselves we really tried to provide like detailed explanation of what we've tried to do. So, you know, sometimes the certification rule, and I'll say this as a lawyer not a technologist, sometimes the rules can be complicated and what we try to do is actually in the preamble, so not just here are the rules and we give you the regulations but spend enough time in the preamble to walk through it, explain what the rules mean, why we're doing it, how it's a change from the 2014 edition and, you know, that takes time, you know, we can make it a lot shorter by cutting that all out and then people would complain that we didn't do a good job explaining it. So, it's always a balance, you know, we try to spend time in the preamble explaining, you know, more in plain English what the detailed specifications are that are in those long documents that Paul said we reference in the incorporation by reference section.

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

Okay, thank you. Anjum?

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

Thanks, Paul, I had two questions, but one of them was asked by Christine and I hope that we have time to discuss this further in another occasion because I still see some contradiction in the goals that were stated by Kate in terms of, you know, accelerating care coordination and improving like the value being created in the health systems by HIT and putting some of these as optional criteria which kind of are...to some extent I think they are not necessarily in line.

But my other question involves something that Kate had mentioned in her presentation around advanced use including some flexibility on health information exchange and the clarification I wanted was is this the general health information exchange as a verb or are you thinking of really some policy that promotes HIEs as shared infrastructure for interoperability and for other kinds of data sharing?

Kate Goodrich, MD, MHS – Director, Quality Measurement & Health Assessment Group – Centers for Medicare & Medicaid Services

So, I'll start and if Beth is still on the phone she may want to add in. So, what I was referencing there was with three of the...the measures that tie to three of the objectives have some flexibility in there in terms of what providers need to meet.

So, in the health information exchange objective there are three measures providers must attest to all three of those measures, but they only need to meet the thresholds or whatever for two out of the three understanding that for some providers one of those measures maybe more difficult for them to meet than another, but Beth if you're still on the phone anything you'd like to add to that?

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services

Sure, so you'll note that in the HIE objective, and I apologize if there background noise I've had to get in the car here, the HIE objective as Kate mentioned has this flexibility to choose two of three. And the three themselves are an expanded version of the send, so the one that we already have right now in Stage 2 with a higher threshold.

And then the second one is a sort of closing the loop on the concept of information exchange, right, so we're looking at the receiving end. So, how are you receiving or requesting or querying for an electronic health record for your patient when you have your fist patient encounter or receive a referral.

And the third one is information reconciliation which we've had before which is in a medication reconciliation format but this is expanded and also includes other clinical information. So, it's really this concept of a closing the referral loop from the Meaningful Use point-of-view and sort of continuing the information flow so we're not just talking about send we're also talking about receive and consumption of data and then again you pick two of these three items on which you would have to successfully meet the threshold to demonstrate Meaningful Use.

From an IT stand-point I think what you really want to look at are the ONC side of things and things like the interoperability roadmap. Obviously I shouldn't speak to that I should allow the ONC folks to do so, but what we're talking about from a Meaningful Use stand-point is meaningfully using your technology to make these connections.

The technology itself and how that works are really governed by this larger concept that ONC has been expansively looking at and we've been supporting that is pretty exciting information and pretty exciting direction.

So, I think looking at these things in partnership, looking at the Meaningful Use rule, the interoperability roadmap and the ONC CEHRT rule kind of gives you a picture of that broader perspective of how we're looking at health information exchange and the flexibility both of the Meaningful Use side and the technology itself.

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

Thank you. And Gayle, last but certainly not least, we'd never forget you. What you couldn't see was there were a lot of cards as you now know and we were just going in order.

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

Yes.

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

But, thank you Gayle, you're up.

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

Thank you so much and I have a very basic question and it goes back to really the authority to promulgate this rule that is going to deal with optional certification criteria. And for the last 5.5 years, 6 years as we've existed as a committee and ONC has tackled Meaningful Use and the implementation of HITECH it's been very, very clear that, you know, laboratory exchange particularly when you talk about psychological and behavioral health kinds of information was never part of HITECH and certainly continuing care afterwards, you know, whether it's nursing home care, hospice care or whatever that they did not fall under HITECH and, you know, it's always been a problem that we felt they should have been but they were not there.

So, with the optional certification does ONC have legislative authority to do this? And also do you have budget authority to spend the money to do that and not that I'm saying it's not a good goal because I think it's a very good goal, but I think it's a very basic question that needs to be answered where is the authority to move in this direction?

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

So, I'll start that and then Mike might actually have the statute in front of him and can be more specific than I am since I'm talking from memory, but our certification authority is to create standards, implementation specifications and certification criteria for health information technology, it is not limited to EHR technology and it is not limited to certified EHR technology as connected to the Meaningful Use Program. The Meaningful Use dollars and the Meaningful Use incentive program was limited in who it could apply to, but our certification authority broadly references health information technology.

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Yeah, I mean, just to reiterate and the same with the certification program not just the adoption of standards, implementation, specs and criteria but we have broad authority to administer, recognize a certification program for the certification of Health IT it's not limited to like any particular type of Health IT or to any particular setting.

And to get to other point, so in leveraging it...so just to give you an example, there is the potential of this other criteria to be leveraged again as people have alluded to or drawn, you know, their conclusions, by other HHS programs or even private entities and for example, if I was just going to give an example, you know, maybe SAMHSA does leverage some of this criteria through their grants program and says that if we're going to give you grants we want to ensure that you have these capabilities and so that would just be, you know, one particular example, it wouldn't necessarily be us telling anyone what you have to have, it would be another program that would be possibly offering money either through grants or otherwise for that adoption.

So, and then obviously there is cost in building a testing infrastructure and there are different ways to do that and I won't get into that now, anywhere from conformance testing to just attestation and demonstration of capabilities.

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

I'd be happy to talk with you off line if you have particular concerns or questions, or wanted me to walk through it with you.

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

Yes, yes, well, I certainly feel that this is needed, however, I just want to make sure that we are not overstepping and we don't have bureaucratic creep that is, you know, very common, but I do appreciate, you know, that HITECH is not the entire outlook that's only part of what we were trying to achieve here. Perhaps we should have gone down this road a little earlier in making some recommendations.

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

Well I will assure you that we worked very closely with our general counsel on making sure that we are acting consistent with our authority to Neal's point earlier, we are very clear on where we don't have particular authority to take action and where we do and we work with them very closely to make sure that we're not overstepping our bounds and that we are acting consistent with our authority, but it's a good question, thank you for asking it.

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

Thank you.

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

Thank you, everyone, so, thank you Kate and Jodi, and thanks to the committee members and please engage robustly in our next month of commenting back because I'm sure they...so we're going to be providing all this information back to them, they will definitely review it as they go towards the final rule and hopefully we've contributed to giving you a head's up on what you might find at HIMSS. So, look for a big room and lots of time.

All right we're going to move onto the interoperability roadmap comments. As you know we've had some draft thoughts presented last month and so now we're finalizing these. These are going to be things that we vote on so that we can give a letter back to ONC.

We're going to start off with hearing from the Interoperability and HIE Workgroup which Micky Tripathi and Chris Lehmann Co-Chair.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Okay, great, good morning everyone, thanks for the opportunity to present the findings from our Workgroup. Let me...oh, here I've got the clicker. So, just want to make sure that we give credit both to my Co-Chair, Chris, as well as to entire Workgroup, we've had very active engagement and real multi-stakeholder engagement as well, so, you know, always want to give thanks to the volunteers who spend an extraordinary amount of time, more time than anyone I think would reasonably expect people to spend on, you know, these volunteer activities. So, we very much appreciate the Workgroup's contributions here.

So, we also want to, you know, appreciate Kory Mertz who is our ONC staff support who provides great support to us. What we're looking at is two areas of the interoperability roadmap and I'll try to be careful as I think in all these conversations we had the discussions of the interoperability roadmap happening and then the NPRM came in, we'll try to separate and not stray into NPRM conversations because we'll have the opportunity obviously to go into those details and restrict our comments to the roadmap.

We have two areas that we're focusing on, accurate identity matching and reliable resource location as the two areas and presented some preliminary recommendations and now we'll present the final recommendations here. So, we've gone through a number of meetings just like every other Workgroup has so I won't bore you with the details of those.

And I'll give some general themes first off that really cover, you know, both areas at a high-level and again we've presented these before so I'll go over them quickly and then we'll dive into the patient matching and then the resource location and I think I'll ask Chris to do the resource location and I'll do the patient matching if that's okay.

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

Yes.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

So, you know, first off the Workgroup recognizes the importance of identity matching in a reliable resource location as roadmap categories. So, first and foremost we agree these are things that belong in the roadmap as things that directionally as an industry we ought to be pointing to and pointing to all the various pieces and how we want to get there.

We do have concerns about the aggregate number and complexity of the critical actions, as we described before, that hasn't changed. As we dove down into those we still remain concerned that 36 critical actions in these two categories alone, 20 of which are supposed to be in the 2015-2017 timeframe with multi-stakeholder kinds of governance and input required for these things to all happen, that was just a genuine concern that, you know, the Workgroup had I think about just sort of looking at it at a high-level.

The third point is that we think that the roadmap ought to make clear that it is articulating an interoperability floor rather than a ceiling which is to say that you could look at any one of the things identified in the roadmap and point to examples in the industry where the industry is racing out ahead, you know, of this and so we just want to make clear that what the roadmap is articulating directionally is sort of a floor and is not intended to, you know, stifle innovation or prevent people from moving forward in different areas.

And then the fourth high-level comment relates to this...to the idea of coordinated governance, which I think we raised before. We appreciate certainly that there is, you know, sort of a challenge here as we think about governance and governance as it relates to interoperability so we're not sort of discounting the complexity of that question.

On the other hand there are a number of the critical actions that have coordinated governance as being a critical path, you know, sort of forum in terms of how the details of a particular critical action or a particular area are laid out and there is no detail on what constitutes coordinated governance.

So, that lack of specificity makes it hard with any particular critical action to say, yes we support that, no we don't and at the end of the day, I think we felt as a Workgroup, that in many cases it was unable to endorse or reject a particular critical action that said, coordinated governance is required for this without having a better understanding of what would constitute coordinated governance. So, that's just, you know, an overall point and I think we come back to that in some of the detailed comments as well.

Fifth high-level point and then we'll go into the details, is, you know, we believe the roadmap should include record location as a long-term goal based on identity matching so the two pieces that we're looking at one is identity matching, how do you match patients across different entities and the other is resource location capabilities, so how to identify providers which would be the first example of resource location whether it's individual provider or entity level provider, you know, when I have those two pieces in place, that's what we're commenting on today, it naturally suggests an ability to be able to record location and there are many places that are already starting to do that seeing that as a need to be able to, you know, sort of facilitate in a better way being able to query for records.

So, certainly some private activity is already underway, CommonWell, Massachusetts Hlway, the statewide HIE in Massachusetts and others are already embarking on record location as a function and that seemed like a natural, you know, sort of next step that the interoperability roadmap could include.

We just, you know, point out on the bottom there is, you know, to the extent that CMS has infrastructure or the ability to provide data to the market that could enhance that we come back to that in the resource location where they're doing that with NPPES, there is certainly the ability to have information put together from CMS that might be able to facilitate record location as well.

There is obviously a lot of complexity related to privacy, access all of that and we just point to this as an example of the kinds of things that one might think of creatively in terms of existing infrastructure that CMS could use to help the market overall.

So, let me dive into the accurate individual data matching, I'm not going to read every word on each slide, you've seen some of these before and hopefully had the opportunity to read them. I'll just cover them at a high-level and then hopefully in the questions and answers we can respond to any of your detailed questions.

So, the first point that we would point out is that, you know, technology standards are necessary but definitely not sufficient to establishing accurate and reliable patient matching. So, we just want to make clear that there is a complexity here that needs to be appreciated in the roadmap and so we shouldn't have the sense that all we have to do is work on certification and standards and this is just done, it's not done and it also raises the caveat that setting requirements that say that you must do patient matching in this instance or that instance is fraught with, you know, a lot of, you know, sort of bad possible unintended consequences because we're not just talking about technical standards, we're talking about a lot of business clinical, you know, sort of data sharing, governance conventions and legal issues as well and so it's not so easy to just say that, you know, we're going to have a top down perspective on what constitutes good or bad patient matching.

The second point, we do believe, as a Workgroup, that there is value in communicating a best practice minimum set of standard data elements for patient matching. So, I'll show on the next slide and I'll jump to that in a second, the interoperability roadmap does have a recommendation for a minimum set of data elements that ought to be used in patient matching.

Our sense is that such a set should be sort of promulgated as a best practice and ONC does a terrific job of, you know, sort of convening stakeholders, seeing where pockets of excellence exist around the country and being able to communicate that and share that and we would, you know, certainly encourage them to keep doing that.

But we also agree, I believe, as a Workgroup that such a set should not be required for patient matching nor should it be the basis for defining Meaningful Use or EHR certification requirements. So, to the extent that those data elements are available, and this is something...this is feedback that we actually got from the Policy Committee last time, was a concern expressed that patient data matching requirements should not be an additional certification requirement.

So, in response to that one of the things that we've done, and Kory Mertz did a great job here helping us with this slide, on the left-hand column you see the elements that are listed as recommended as minimum data elements required for patient matching from the interoperability roadmap and we have mapped that to the 2014 edition certification requirements and you can see there that just a few of those things would be required under the 2014 edition certification, not for patient matching mind you, but for other types of requirements.

And then we've also put in the 2015 edition NPRM which identifies...and it was referred to actually in a question that Jodi got related to a set of data that are identified as being something that should be included in transitions of care for quality patient data matching, patient matching. It does not have a requirement that says that these data fields have to be included every time or that patient matching has to use these data elements every time but it is noted there as I said of data elements that ought to be included in every transition of care summary.

So, you can see there that as you take down almost all of the categories or data elements that were recommended in the interoperability roadmap are actually covered in the 2015 edition NPRM as a transition of care summary requirement.

There is one inclusion that was not a part of the original recommendation from the interoperability roadmap, you see that down at the bottom, and that is place of birth. So, that's not something that was recommended there but is included in the NPRM as a requirement for inclusion for patient data quality as a part of a transition of care summary.

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

Can I comment on that one?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Sure, yes.

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

So, one thing we would like to point out on this slide that while the interoperability roadmap uses gender the 2014 and 2015 editions have sex and we discussed this in the committee and as a pediatrician the gender I believe or we believe to be favorable, is better to be using than the sex.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

So, coming back then and responding to the concern that was expressed at the last HIT Policy Committee meeting, you know, we believe that in looking at what the recommendation was coming out of the roadmap and comparing it to what certification is likely to require for other purposes, not specifically for patient data matching, that there is, you know, enough overlap there to feel comfortable that, you know, we can say that certification is going to cover most of the data elements that would constitute the basis for good patient data matching, patient matching, sorry, I keep saying data matching.

But we also agree that it shouldn't be made a part of a separate certification requirement nor do we believe that it makes sense to say that in every case of an interoperability exchange that patient identity matching is required according to these data fields. Rather we would say...and then the reason for that is there is a lot of variation. Some of those data fields may not be available and it depends on, you know, the particular provider organization, the data sharing arrangement they have.

In other data sharing arrangements they have done...those data sharing arrangements have spent a lot of time to try to get out of having to send 10 data fields for, you know, dynamic matching at every encounter. CommonWell for example is building an ability to not have to do that and essentially pushing it upstream so that you have more deterministic matching but it is there and available based on matching of MRNs for example.

So, that's why we think there is so much variation and complexity in the market that it doesn't make sense to require a certain set of data fields be required every single time, the market is headed that way, the data will be made available in an EHR and the EHR and the user will have the ability to use that data for patient data matching according to the use case that they believe makes the greatest sense.

So, that really gets us to the next point which is that locally driven data governance such as the data sharing arrangements that were defined as a part of the JASON Task Force recommendations will really be the prime motivators for use of the minimum dataset and addressing technical and business requirements beyond the minimum set and what we're pointing to here is just that there is a lot of other complexity, as I noted at the beginning, that is really outside of just technical standards that are really more the purview, you know, sort of naturally and practically of the data sharing arrangements that are formed to share data so things like data assurance, which source is the source of truth, data quality, how are emerging issues resolved and maintained because they're always emerging issues in this, you know, voluntary data elements, how are...you know what should be included those are...that's a highly dynamic set and something that really shouldn't be instantiated as, you know, sort of a top down requirement because that is just, you know, going to be always dynamic and it's going to be very setting specific.

And then finally accountability, who is responsible for what those are the kinds of things that data sharing arrangements like CommonWell, like Care Everywhere EPIC, like, you know, Healthway, like the Mass HIway, like the Indiana Health Information Exchange that is part of why those data sharing arrangements form is to resolve these kinds of things and each of them resolves them in a different way but they resolve them according to what the market needs in those particular settings and that seems like the appropriate place for that to happen.

Finally, as I said, ONC can play just an enormously valuable role in convening implementers as they do today with S&I Framework activities, other activities there is no one better place to identify best practices and try to share those and promulgate those as best practices and, you know, allow market visibility into what's working and what seems to not be working.

And then finally, this is, you know, sort of a very specific particular point, there is a particular critical action item that we've, you know, sort of described there that says that in the 2015 to 2017 timeframe stakeholders should develop and pilot tools and technologies for establishing performance metrics. We just want to point to that to say that this really ought to be moved out we think as something that is in the 2018 to 2020 timeframe not because we don't think performance measurement isn't important but because we have to first define what would constitute performance measurement before we start saying, establish the tool and technologies for establishing performance metrics. So, that's a small specific point that came up a number of times in the Workgroup.

And then finally, some of the additional data elements just to make sure, yes, some of the additional data elements that we discussed, we did back away from making a specific recommendation that said, this is what the Interoperability Workgroup recommends as a minimum dataset.

The reason we did that is because as soon as we embarked on that it became a pretty thorny conversation, we started with, oh, how about first name, last name, birthday, then all of a sudden someone says, well what about this and what about that and we realized, well wait a minute we're just providing comments on the interoperability roadmap there are other places perhaps to do that. So, we decided not to do that at the end of the day.

But we certainly discussed that the interoperability roadmap recommendations coupled with what looks like is going to happen from the 2015 edition NPRM requirements for other purposes seems like a completely reasonable place to start and we did discuss that other things like mobile phone numbers, e-mail addresses, place of birth, social media IDs, direct addresses, which is not mentioned there and would be a subset of e-mail addresses would all be the kinds of things that one would expect to see going forward included for patient matching depending on the data sharing arrangement and the availability of that data. I'll turn it over to you now.

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

Thank you. Thank you, Micky, so we also tackled the reliable resource location section as Micky pointed out and the good news that we have to report is that there was very little controversy, that there was pretty much agreement on the high-level issues that were addressed in this section.

So the most important critical issue that the committee brought up is that we believe that most of the reliable resource location critical action items, Micky already alluded to that, cannot be accomplished in the 2015-2017 timeframe and probably should be moved to 2018, 2020 or beyond.

We are looking here at the N1 section this is about the proposed resource architecture and as you can see, for most parts, the committee had very little discussion on this and there was general agreement.

There was some emphasis put on the different items so the Item 1, which we believe is something that should be kept within the 2015-2017 timeframe was to identify the architecture and workflow for the resource location, then subsequent items like prioritization of the participants and services that are to be discoverable, the determination and development of standards and APIs, and the rules of the road for participating in distributive management of resource location, as well as demonstrating those standards and APIs in trial implementations were based on committee feedback things that we have recommended to pushback. And the same thing...so that's the point N1.2-5 should be moved to 2018.

We also discussed the need that we probably should have specific use cases that we can rally around to drive the technical and business requirements and the development of the architecture.

And lastly, the Working Group supports the various ONC initiatives that are concerned...that are contained in the N2 section. Again, we felt that there was not sufficient time to do this in this very short time period and as Micky alluded to, we're discussing being favorable of adding direct addresses and ESI information to the NPPES and making the NPPES information openly available to support resource location.

And the overall discussion was that this should be done in the spirit of open data initiatives rather than as a providers directory service to let the market define the services and the uses. And I think that's our last slide.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yes.

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

And I think we are open for any questions.

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

So, as I said we're going to have a series of four presentations and if we could keep track of whether you approve each one, so I'm going to open it up for questions to the Interoperability Workgroup so that we can establish whether we can approve that section as we go, because at the end we're going to have to approve the whole feedback.

So, questions of Micky and Chris for their section? Troy is your card up or no?

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

Oh, I'm sorry I didn't take it down.

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

Okay. Any one on the phone? Okay, that's a task of approval. Okay.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Thank you.

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

Thank you. Thanks Micky and Chris. Next Deven and Stanley are going to talk about the Privacy and Security Workgroup response to the roadmap.

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

I don't know if we'll have Stan on the phone or not, he was plugged in for an earlier time, so, but we'll move forward without him, but his assistance was great in pulling these comments together.

So, like the previous Workgroup there is a lot of text on these slides and given the shortness of time I'll highlight the key points, most of the text is explanatory text to sort of illustrate or frame some of the bigger points that we make. We kind of take advantage of these comment periods in order to flesh things out with a little bit more detail, we don't always have time to share that detail in these presentations, happy of course to answer any questions.

So, we also had some overarching comments that we thought were worth making in addition to answering some very specific questions on two particular sections of the roadmap, here are our Workgroup members many thanks to all of them for their participation in pulling these comments together.

In terms of our overarching comments we think it's really important that ONC in the final iteration of the roadmap take steps to clarify language in the roadmap regarding the relationship between what is called basic choice, which would be the choice of a patient to either opt in or opt out of having their records shared and existing laws that permit the sharing of health information for purposes like treatment and care coordination without the requirement to obtain patient permission.

There was a lot of discussion and questions about whether the fact that the roadmap talks about patient choice means that ONC is actually urging that basic choice be provided even in circumstances where the law would allow the data to be shared or exchanged without necessarily needing to first ask the permission of the patient under the theory that the patient would presumably want that information to be shared and the law allows that information to be shared.

I just actually took a look at the comments that HIMSS submitted and they address this very question, you know, is ONC saying that basic choice is required or are they instead saying that when there is choice that is being provided that we need a way to be able to honor that.

And in the roadmap essentially the language in some places is clear and in some places it's not clear. So, we are suggesting that ONC make that clear and instead sort of be more consistent with the language for example that appears in the national near-term goals which emphasize that exchange is permitted for certain purposes without an individual's permission and that when you have the sort of basic choice of opt in or opt out when it is offered to individuals it's offered in a way that can be standardized so that it is more easily captured and able to be honored and then of course where you have more granular choice such as what is required under certain state laws and federal law governing substance abuse treatment that having some harmonization in terms of definitions used might smooth a pathway to interoperability in circumstances where those types of choices are provided to patients and are required by law.

So, we really think the roadmap needs to focus first on removing roadblocks to exchange pursuant to existing law rather than engaging in sort of conversations about where may be the law around choice ought to be, it's not to say it's not a valuable exercise to continually think about what sorts...how we're engaging patients in these decisions and what sorts of choices might be made available in the future, but to the extent that existing law allows for the exchange of data for treatment and care coordination, in a secure way the roadmap should focus on enabling that and removing what the obstacles to that might still be notwithstanding the legal authority that is clear to exchange.

So with that sort of background laid we went into addressing some specific questions that were asked of us. The first section, Section H of the roadmap, really deals with consistent representation of authorization to access information. And here the term authorization does not refer just to whether the patient has authorized access to health information, but instead it refers to the bigger concept of authorization which is the legal authority to be able to access information and share it, which in some circumstances could be because the patient has authorized it but in other circumstances is because the law allows for that sharing or even in some circumstances, such as public health reporting, it requires such sharing that's authority to be able to access patient data or share it and that's the bigger conceptualization of it and it is through that frame that we addressed a number of questions.

One of the questions was, you know, who should ONC convene to develop policy recommendations and a framework to enable consistent decisions about authorized access to health information and not surprisingly we said you should convene a lot of people, a broad array of stakeholders and the purpose for the convening is really to determine what are some of the common obstacles with respect to demonstrating the legal authority to access a record particularly for treatment and care coordination purposes and starting with circumstances where consent may not be required but nevertheless there are still uncertainties that occur out there in the marketplace about whether and to what extent information can be shared.

Clarification from both state and federal regulators, there's a lot of confusion, about state law in addition to confusion about federal regulators, about what needs to be demonstrated in terms of legal authority to access information. And the focus really should be on some specific high-impact use cases that achieve the interoperability goals of years 1 to 3 of ONC's 10-year vision and ONC could work with stakeholders to define a set of these high-value use cases or examples that might provide additional regulatory guidance, achievement of Meaningful Use objectives for example, sharing within accountable care organizations are just two examples of again these high-impact use cases where are there still questions arising in the marketplace about whether or not you can share data and how can you demonstrate that the legal authorization to share data for that purpose is there.

So again, some of the suggested priority areas include, how do you demonstrate that you have a treatment relationship with the patient that provides a sort of authorization to share for treatment purposes, how can that occur? We actually came up with some suggestions about this when we met as a Tiger Team that the Policy Committee endorsed and in fact having regulatory blessing of those or other specific examples could really go a long way toward easing that pathway.

There was a question that came up about role-based access, does an individual who is trying to access data do they have a proper role authorization in order to be able to access data and our response to this is that ONC really ought to focus on facilitating the entity-to-entity exchange and allow the entities themselves to come up with the role-based access policies that allow that data to be triaged within an organization.

HIPAA already has role-based access provisions in the security rule and entities are expected to deploy role-based access protocols but within their organizations the interoperability roadmap should not necessarily be worried about how those organizations triage that data that seems unnecessarily detailed, focus on the entity to entity exchange and allow entities to make the role-based access decisions internally within those organizations.

What might also help would be clarifying that the sending organizations themselves are not legally responsible for how a receiving organization routes the communication to the provider in accordance with role-based access controls that might be able to relieve some uncertainty.

It surprises me, as an attorney, how often people say to me "I'm going to be held responsible for what that recipient entity does." Well, you know may be on the front page of some newspaper, but not under the law and the more clarification that can be provided on that point I think the better off we could be from an interoperability stand-point.

There are continued questions about sort of whether there's a role for ONC or regulators to set some sort of standards around defining roles and we continue to think that role-based access is really an internal exercise. But nevertheless we recognize that some of the granular state laws that require the sharing of data may in fact require some role harmonization across a high-level and that when ONC goes through the exercise of working with states to try to harmonize some of these laws it could come up that some role standardization at a high-level could be needed in that particular circumstance.

So while acknowledging that the internal processes should be left as internal policy, we have reserved, for later discussion as part of the harmonization exercise that ONC has already put on the table, that you'll see in the minute, we think is very valuable, that there might be some higher-level role standardization that could be helpful in allowing compliance with some of these more granular consent requirements.

We got a standards question that we said the question is more appropriate for the Standards Committee to review. And then in Section G we really do get to the set of questions that are specific to permission of the patient to be able to collect, share and use identifiable health information, again, this is a subset of authorization to access a record.

We had a question about whether states are ready to collaborate on the issue of permission and why or why not and of course we don't really know the answer to that, but we hope that they are ready to collaborate but we recognize that these are complex issues and states have a lot on their plates. We think there's a role for the federal government to play in being a convener for efforts around harmonization of laws and certainly ONC could play this role.

Some early focus on creating some standard definitions that could be used by states in order to harmonize those laws could be very helpful. We hope that as payment reform proceeds that imperatives to exchange could grow stronger and could be a forcing hand for states that are not involved in that dialogue today to come to the table.

And we think there's been a lot of really good work done by NCVHS in terms of sort of trying to lay out some granular categories where state laws currently have been enacted that might be a good place to start in coming up with some standard definitions.

What other methodologies to be considered to allow interoperability even in an environment where patients, sometimes by law, have choices or have been provided with choices as a matter of policy, that we highlight work that was done by the Social Security Administration in coming up with an authorization to share a form that has been used in every state for disability determination to release information so that the Social Security Administration can make those judgment calls.

We said how about the feasibility of something like a do not call registry for patients to register choices in circumstances where they are provided and consent repositories is another model.

Again, what we need is something, you know, given the state of current law, given that we're not empowered to change it whether we like it or not, how can we create this sort of seamless interoperability that works within that legal framework and what types of tools can we use to facilitate the collection and honoring of patient permissions and circumstances where it's required or provided as a matter of policy.

We had some questions around the technical ability to persist consent so that it might be collected in one place but then is persisted with the data as it is shared across settings and there is one federal law that absolutely requires this and that's the Part 2 substance abuse treatment rules, but other laws do not necessarily have that sort of data stickiness for the consent law. They sort of apply at moments in time are you sharing it from one provider to another and then when the other provider has that data if they're not governed by the law or they're in another state they may in fact not have a law that requires them to look to whether the patient has provided permission before they can give consent.

So does the consent need to persist and does the persistence of that consent actually potentially add confusion down the road because providers are not working in the legal environment where they have to look for it or they see a consent form but it's not necessarily one that they have to legally honor, maybe they want to honor it, maybe they don't.

So, I think the technical ability to persist consent does not necessarily change the policy framework in which we're operating and we essentially advise that achieving this technical ability to persist is going to be necessary in some circumstances but not in others and may in fact...creating that technical ability may in fact create some confusion down the road for providers who are, again, not obligated to comply with that law so a somewhat short winded way of the long-winded response that we had to that.

We also though think that it's important in circumstances where patients are making a clear choice to exchange data but are getting pushback or resistance from providers in sharing data that there ought to be mechanisms for making sure the patient's desire to exchange data in that circumstance occur.

I think way too often we just assume that the circumstance is that the providers want to share data and the patient is creating the obstacle to exchange by not providing the consent when in fact in most cases when patients are asked they say "yes" and far too often it's the providers who don't want to exchange for a variety of purposes either because they're confused all about whether the law allows them to exchange or they have proprietary interests at stake that make them very concerned about the patient taking their data and going elsewhere for care and this issue needs to be addressed and that's the subject of item number two and may in fact be a reason to persist consent to overcome those circumstances. I'm getting to the end here, we had a lot of questions.

Again, emphasizing that...to focus on sort of the interoperability roadmap should focus on enabling exchange even in circumstances where consent is not required because that frankly is HIPAA and that governs exchange in a lot of circumstances but where basic choice is provided we should have the mechanism to honor that and some standardization and conversations around that and standard definitions can be very, very helpful and similarly working on the harmonization of the more granular laws that are already in place both at the federal and state level in terms of coming up with definitions that's going to take a significant amount of work frankly because it does involve a lot of states coming to the table and coming to agreement on what those definitions should be.

And then I think the last question we had was around success metrics. Obviously linked to interoperability goals, we have some suggestions here about some sort of near term goals for achieving some progress around demonstration of legal authority and achieving communication of patient permission to access in circumstances where it's either required or done as a matter of policy beginning to convene the dialogue with the states, issuing a lot, a lot, a lot of very specific guidance about what is required and where are the limits of legal liability so that people are not constrained from moving forward in circumstances where they clearly can.

And I think that's basically it. I really tried to do a high-level summary because I know we are out of time and yet it still took a long time because a lot of thought went into the text of this so happy to answer any questions.

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

Good, thank you, Deven. Scott?

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

Thanks, I couldn't get a view of what your sense was about the role-based rules in HIPAA and whether they've been helpful here or an impediment. I have to admit I'm not familiar with those rules...

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

Yeah.

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

In HIPAA but I'm obviously very familiar with HIPAA. Are the role-based rules in HIPAA, as I said before, something we can lean on here or are they an impediment to the flexibility we want to afford or something else?

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

No, they're...so HIPAA requires organizations to come up with role-based...approaches to role-based access...

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

Right.

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

But they're not hard and fast rules and so what you'll see is that organizations come to very different decisions about how to deploy that from a small practice that, you know, doesn't have very many categories of role-based access frankly, probably if at all, to a large hospital system that may in fact provide limited access to clerical teams but much greater access for clinical care teams.

So it's hard for me to see how they've become an impediment but yet sometimes with exchange there is a desire to send for treatment purposes to a treating team and to have some assurance that on the recipient end that only that treating team is accessing that data and this has been articulated to ONC as a potential obstacle to interoperability when the law doesn't necessarily create a dynamic for that least at the HIPAA level.

Sometimes with the state laws though...I know of one in California for example that says you have to share it with another treating professional and if you're sharing mental health data it has to go from one institution to another institution but the legal permission is for sharing among treating professionals so there's a role-based piece...

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

Right.

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

That comes into that but it's not one that necessarily is introduced by detailed legal requirements that come into place in HIPAA.

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

So we would basically be proposing to establish a more granular framework for this than what's required under HIPAA and there wouldn't be any tension there?

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

No, we're not proposing that all. Actually what we're saying is ONC should focus the interoperability roadmap on entity-to-entity exchange and let the organizations themselves...

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

Okay.

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

Decide role-based but we do acknowledge that as ONC goes down the pathway of examining and helping states come to the table to try to harmonize what some of these state laws say that there might become a need to sort of standardized at a very high-level some role-based controls.

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

And last question.

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

Yeah?

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

We were supposed to do that on the auspices of what we're trying to do here as opposed to trying to go back and address it through HIPAA which might be more difficult.

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

That's correct.

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

All right.

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

Okay. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

First it's a terrific presentation Deven as usual, but this is really very good and very helpful, and I like the way you laid it out. I'm curious about the sort of consistent representation about basically requirements that people have to share their data and my question is...I have a couple questions about that, one is, well are there any exceptions?

I mean, supposed a provider thinks the other organization is just playing a bad actor and is doing something that is bad for patients or has privacy violations and my other question is, is this only for treatment or are you saying it needs to be mandatory if a patient wants to use an App to get data for themselves?

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

You know that's a really good question Paul. So, HIPAA today, under the HITECH amendments, in particular, if a patient wants to exercise their HIPAA rights to get access to data and have that directly sent to another entity they are permitted to do that under HITECH and the exceptions for that kind of access are extremely narrow, you know, there is one involving whether doing that would be a detriment to the patient, but I don't believe it can be exercised in circumstances where the physician or healthcare provider just says, well that's just a bad idea, right, it has to be an issue where it would be harmful to the health of that individual for some reason but otherwise that right to be able to get data and have it sent elsewhere is an absolute.

But it is also something that is triggered by a patient request for information and usually on an episodic basis and I think what the Workgroup was thinking about are circumstances where patients are asked for authorizations to share for treatment purposes or maybe even more broadly for a set of research uses and the circumstances under which that might trump what a provider might want to have done with that data because of, again, proprietary concerns.

And so while admittedly we didn't sort of spend a lot of time fleshing through all of the pieces of that, and that would probably be an important exercise for ONC to do if they were going to head in that direction, we thought it was a use case in general that was worth some further attention and that's essentially what we're saying in our comments to the roadmap.

Paul Egerman – Businessman/Software Entrepreneur

And that's helpful especially the research example is helpful.

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

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

But I just want to understand, is this only for treatment purposes? I mean, what about if a patient has an App and wants to get their data using the App can a healthcare organization say "no, we don't like that App."

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

I don't...well, first of all, no I don't think they can do that under HIPAA if the patient is making that request under their right under HIPAA to get a copy of access to their data and have it sent to any entity they choose, any entity including, you know, we rate baddoctors.com.

Paul Egerman – Businessman/Software Entrepreneur

So, in that example if you have an App that performs badly, that basically upholds the patient's data every second so it creates a huge load on the provider's database, the provider can't block it.

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

That's interesting. Lucia is putting up her card so I'm going to let her...I'm sort of thinking through how HIPAA would broker that, I think there are some security considerations that a provider can...

Paul Egerman – Businessman/Software Entrepreneur

Well, it's not necessarily a security issue...

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

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

But it's an issue of cost and...

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

Well, it is, so the patient gets the data in the form or format that they want when they're exercising their HIPAA right but the entity has to be able to produce that and in a circumstance where it is...would create an issue for the entity to be able to honor that from a security perspective or unreasonable demand on resources that would not...that the patient wouldn't be paying for I think those are issues that would enable the provider to push back and that's already an existing law. Am I right about that Lucia?

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

Yeah, I just, I think sort of look at it a few levels up, I think that the tension that we've observed that we asked for guidance on was making sure that there was good dovetailed reconciliation between the technical empowerments that were being built into the CEHRT rule 2014, view, download, transmit, 2015 we proposed the view, download, transmit with the API, and the obligations of the physician to honor so that the physician and the patient have the same understanding about how the patient accesses that data or gets that data to another person who is helping them in the system and that could be another provider, it could be a social worker in their community that they choose to disclose information to.

So we want to engage the patients and we needed clarity, that was the question is, do we need clarity about how this all works and I think your question is actually pointing out exactly what Deven said is, yes, it would be helpful to dig in and maybe more than one use case but clarify two use cases and standards how all these rules work together.

Paul Egerman – Businessman/Software Entrepreneur

Right, I mean, the classic way you do...one of the classic ways you do a denial of service attack is you simply request consistently or persistently a whole boatload of data and that prevents anybody else from doing anything and so you have...the provider has to be able to reject certain vendors or certain applications otherwise they can't operate.

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

Yeah, I'm not...

Paul Egerman – Businessman/Software Entrepreneur

And that becomes inconsistent with the concept that you're required to respond.

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

Yeah, so just to clarify what we said in the recommendation, we did actually limit it to treatment purposes and we did frame it as that ONC should consider how to do this but we would be more than willing to add language to sort of think through the sort of full range of possibilities here and...

Paul Egerman – Businessman/Software Entrepreneur

Because there needs to be some kind of a carve out if there is some activity or some actor...

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

Sure.

Paul Egerman – Businessman/Software Entrepreneur

That is somehow damaging the security or providing...requiring an onerous level of processing to respond to the request, you know, and to me that carve out is really important otherwise you're going to create a system that just plain isn't workable. I mean, people haven't really thought through what it's like to take these EHR systems and expose a lot of data on the Internet to, you know, thousands of millions of people.

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

And there's a lot of people out there who sometimes accidentally can create a huge workload, processing workload.

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

Agree and understand and I think that what you're saying points to that we have a very complicated environment here. We have a certification rule which specifies minimums for technical capabilities. We have some federal programs that use that rule for other purposes like the Meaningful Use Program and then we have the actual HIPAA rules themselves which of course are promulgated by OCR.

So what we're sort of looking for is, as a coordinator or convener, what can we bring back to the complexity of HHS agencies involved in this to get better information out to patients, providers, researchers about how to make this all work in an appropriate way.

We're not saying that a particular way is appropriate, we're saying "oh, yes, it seems like people are confused about this" and it sounds to me like the Workgroup doesn't disagree that confusion exists.

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

I think we could also add, I mean, again these are comments that are being forwarded by the committee to the roadmap. I think we could add the point you're making Paul that this is something that would need to be considered.

Paul Egerman – Businessman/Software Entrepreneur

Thank you.

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

It is covered under the HIPAA security because the integrity of the database is part of security so that gives the provider the authority to protect their database.

Paul Egerman – Businessman/Software Entrepreneur

Right but where it gets complicated is, where you're saying, well the patient has a right to get their data and so then how do you balance that right...

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

With what may put your own system at risk.

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

Yeah.

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

But as Deven pointed out the actual way you get it isn't guaranteed and if the way you're proposing interferes with the integrity of the system than I think you have the ability to give that information in an alternative way.

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

Yes, that's true but I don't think it hurts, again, it's a comment period...

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

Correct.

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

To note Paul's concern...

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

Exactly.

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

As well as the way HIPAA handles it, which may not always be really widely known.

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

Right that's correct. Okay, any other comments or questions? Thank you once again, Deven.

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

Thank you all.

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

I'll transition to talk about the next Workgroup. Okay and is Joe on the line?

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

I'm here.

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

Great, thanks, Joe. So Joe and I Co-Chaired the Advanced Health Models and Meaningful Use Workgroup and we're going to be talking about our charge that I'm going to show to you in just a second but first want to acknowledge all the diverse members on our Workgroup we had representatives from patients or consumers to quality measurement, to health systems, to ACO, to vendors so a nice diversity of Workgroup members. I want to acknowledge our staff support, Alex Baker and Samantha Meklir, who were really great at preparing a lot of this information and giving us some of the background.

So our charge to Workgroup...what I'm going to talk about is the charge we had, the prioritization process, the vision statements we came up with based on the Appendix H use case submissions, the assessment matrix we came up with and the lessons learned.

So, the charge to us was to develop a repeatable process that is the main output from this Workgroup of how to prioritize use cases that have a high impact on the Triple Aim. We were to test it against the use cases that were submitted by both the federal agencies and the public and documented in Appendix H of the roadmap, and then recommend who should participate in this ongoing process.

So first a little bit on use cases from and interoperability point-of-view it's a statement that helps us understand the problem to solve, the data needed to address the problem and who are the participants and the workflow implications of working on this interoperability use case.

Now there is a tension in use cases between wanting to have broad coverage for all of the potential stakeholders and yet having to be specific so they can be actually useful. So we tried to balance those. What we're looking for is to find use cases that are either in the upper right quadrant, high-impact, high readiness, i.e., low hanging fruit or high-impact that we're not quite ready for but we'd like to cross that gap by addressing the barriers to having that use case become a reality.

So, we took a two-step process much like reviewing grants, one is to figure out a way of assessing them or scoring them and then based on that score to decide, make strategic decisions on what is, in this case, a high priority for the health of the country and the individuals living there.

So, in our process what we did is we identified the important attributes of high priority use cases. We then...one of the attributes was impact and we chose as criteria the Triple Aim. By just applying that Triple Aim impact we could actually reduce the proposed or the submitted use cases from 56 down to 15. We organized them into thematic visions and then then applied the rest of our criteria for the use cases that I'm going to describe in just a bit and then stepped back and say, hey has this worked, what value has this been.

So, the first must pass prioritization component is impact and as I said we used the Triple Aim as the criteria, healthy people and communities, better care, affordable care. So, we had each of participants rate that from a one, minimal impact on goals to three.

Based on that we ended up with reducing that, as I said, the 56 submitted use cases down to about 17 and then we further clustered those into five visions and these are them, first of all the first one talks about really everyone who participates in the persons health needs to have the right information at the right time to make more informed choices.

The way we wrote it is that all members of the health team, which includes the individual and family caregivers, have appropriate access to real-time information, you know, of a comprehensive longitudinal nature that crosses organizations so that each one of them can be a participant in shared decision making fully informed by the data available.

The second point is that people are going to be increasingly responsible for their health both clinically and financially. So they need to be empowered by the data, the knowledge and tools in order to make their own health decisions.

So we wrote it as individuals can appropriately access, interpret and engage in bidirectional exchange of information which would include the upload of personal originated data, we used to call that patient generated health data, about their health status with members of their health team so that together they can effectively manage, the individual can self-manage, and make shared decisions.

The third point is that we need to have data cross the continuum and without regard to the business boundaries that's an important one in that's a big stickler we have right now, but stated as a vision it is that all health team members, remember that includes the person and their caregivers, their family caregivers, have appropriate access to share information across the continuum, including the home, noting the care transitions like letting people know, the health team, know when a person goes from one site or one care responsibility to another, identifying gaps and supporting the coordination of that individual's care and health.

The fourth has to do with the learning health system. So, they are secondary users of the health data that try to improve, constantly improve, what's going on and to learn from it and create new knowledge.

So, we've written it as really talking about the aggregate data, the de-identified clinical claims and other health data such as data from public health sources or social determinants of health that are linked and matched, you heard this before, from multiple sources so that, I'm using robust identity management, so that we can further knowledge as in research, gain public health information and continuously improve the delivery systems.

And finally, dealing with public health, we feel that there has to be a bidirectional flow of data to and from public health agencies so that can be used in every day decisions such as in every day health management or care management.

So, we wrote it as providers report and received, that is it's bidirectional flow, public health data routinely is a byproduct of using an EHR or HIT to provide care and use public health data to guide patient specific clinical decisions and interventions.

So these five vision statements we think actually capture a lot of the high priority use cases that we looked at in Appendix H. I'm not going to read the details here but for each vision there was one or two use cases that we lumped under that vision and you have a larger print out so you can read.

Those use cases then are more specific such as in the 1.1 it comes under the vision of all the stakeholders in an individual's health need to have the right data. Well use case 1.1 says healthcare professional accesses and imports elements of common clinical datasets on an individual that they're treating from the EHR or other providers who have cared for the same patient in order to improve coordination of care across settings.

So you'll notice it talks about, in this particular use case the health professional team, talks about the common clinical dataset, it talks about access and imports, it talks about using that within the context of an EHR and coordinating across care settings. So there are a lot of elements of that one statement, that one use case that can drive the requirements for how do you realize that use case and we have that for the other vision statements as well. As I said there should be a printout by your spot, your chair.

Once we do that, know what are important or impactful, we have other criteria we look at, one is the programmatic needs. So the three programs we chose were one National Quality Strategy priorities, safety patient engagement, care prevention or preventive care I think it should say, community affordability and coordination.

The second is the delivery system reform goals such as the 50% through alternative payment models by 2018 and third the interoperability roadmap in the three timelines 3, 6 and 10 years.

So we looked at and scored potential candidate use cases according to these programmatic needs that were obviously set by either the Secretary or interoperability set by ONC for the country's benefit and we rated those zero to two in terms of the relevance to these programs.

The third part once you know what's important and you know what fits the programmatic or strategic needs then you've got to know when is the country ready and we looked at a number of determinants of that question that is, when is the country ready.

So we looked at the business and the culture environment is there a clear business case supporting the adoption of "x" use case or are there penalties, disincentives for adopting that, what about the cultural environment?

For technical are the standards there? Are the products there? Are the interfaces there? What's the effort required by the software developer to get this...to meet the needs of this use case?

Stakeholder and cost-benefit considerations, what's the level of effort not only the financial but what's the level of effort required to either create this, to adopt it or to purchase a solution that addresses the use case.

And finally, the policy environment, we just heard about privacy and security sometimes those are barriers in terms of getting the data to flow hence there might be policy considerations or barriers to a particular use case in data sharing. So we rated each one of these elements from a negative two to plus two, it's either very adversely affecting the realization of that use case or it's very supportive.

And then finally, we wanted to understand how does it benefit each of the multiple stakeholders that participate in health and health care? And we rated this from a negative two a positive two.

So if you put it all together and there is a bigger printout by your chair, but let's take a step back and this was supposed to be animated, so if you look at the right-hand red square you can see that's under the stakeholders, we did a pretty decent job and the color is not showing through here as well on your printout, mostly green or light green saying that we're really addressing by the high priority use cases and visions that we've selected pretty much benefit the stakeholders across the board.

Then if you look at the left larger rectangle you'll see that actually for most of the vision, really does cover the National Quality Strategy components pretty well. The one that's not covered by the red rectangle are the bottom two rows that are dealing much more with the aggregate information such as for the learning system, research and public health, as well as the sharing with public health.

The narrow vertical rectangle shows you that we probably don't do...we don't have as good a coverage in the community component of the National Quality Strategy by the existing use cases and visions.

And finally the middle section vertical rectangle shows that the area where there's the most effort or potentially burden occurs to both the providers in trying to implement this or the software developers in trying to develop these systems.

So you can see stepping back and looking at the color code, as I say it's much better in the printout than what you're seeing on the screen, very good comprehensive coverage to benefit most of the stakeholders, quite good in terms of covering these use cases, covering the needs of the various stakeholders and additional attention might be paid to the needs of communities in improving their community's health.

So, what are lessons learned? We took a two-staged approach to first figure out and assess the technical considerations of a particular use case or vision. We then looked at what are the strategic needs that the country has to improve the individual's health and the population's health.

We found that the attributes that we picked seemed to be appropriate. They seemed straightforward to assess in terms of trying our voting example on them and we recommend additional analysis let's say inter-rater variability or using the Delphi method in order to achieve consensus among the various voters, we didn't have a lot of voters in our little Workgroup there may be a lot more when you play it across whether it's the federal agencies or the state government departments.

So, the matrix view allowed us to get a global view on how well, how good is the coverage when you apply these use cases and how well does it address the programmatic needs that are set at the federal, state or stakeholder level.

Here is an example how federal agencies could use it to see how it fits with their programs for example. States could use it in their own priorities for that particular state or go down to the community or county levels and the beneficiary, communities, can look at it and see how these particular use cases cover their needs and what they themselves might...what actions they could take in order to participate.

So in summary, we've come up with a prioritization process that looks at the impact of a use case or vision, how it addresses programmatic needs, how it assesses the market or industry readiness in terms of phasing and how does it benefit the various stakeholders?

We've come up with some...these are not the end-all and be-all in terms of use cases but we used the use cases proposed in Appendix H, used our method against them and came up with these five vision statements and eight use cases as priorities and examples. So, at this point, Joe, do you want to add anything?

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

No I think that was...the one thing that I think was helpful was it seems like we reached a point at the end of our process around balancing the complexity of those numbers but being transparent around the rationale.

I think we have a lot of discussion in the Workgroup around making sure that whenever this information moved to the strategic decision-making point that the distribution and the numbers and how people were viewing them was valuable information so the Workgroup I think decided not to condense that sort of grid any further than what it did. Thanks.

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

Good point. Questions, comments? All right.

Lisa A. Lewis – Chief Operating Officer – Office of the National Coordinator for Health Information Technology

Thank you, Paul.

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

Okay, thank you. Next reporting out is the Consumer Workgroup led by Christine Bechtel.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay, so I have a lot of content here and that's because we were asked to review and comment on two whole sections of the roadmap. So, you guys have a slide that essentially gives you what I think are the kind of most meaty salient points and then you have also been provided with the full text of our letter that we've submitted to the Policy Committee. So let's dive right in.

I'm going to go pretty fast so if you guys...if I'm glossing over something or, you know, I've missed something you want to talk about just raise it in the Q&A.

So first of all a big thank you to the members of the Workgroup because they worked very, very hard on this, there was a lot of content to cover in a pretty short period of time as usual and thank you also to Chitra Mohla for her support as well throughout this process which has been really, really critical.

So as you guys recall the charge of the Consumer Workgroup is really to focus on how we can leverage Health IT to engage consumers and families in their care, to enable those partnerships between patients, families and the care team and to elevate consumer voices so that we're co-creating the system with consumers instead of for them.

So, at an overarching level, we looked at the building blocks, you can see the kind of colored building blocks here. We looked at those building blocks together and really felt like, similar to the federal strategic plan, there were some pieces missing around where are the people, right?

So when we looked at the supportive business, clinical, cultural and regulatory environments section we felt like that would be better reframed as driving that essential partnership between clinicians, patients and family caregivers that this was the building block that was missing and we felt like since the...you know creating the supportive environment is already actually called out here in B, that there was a reframing that could occur to really show that you can't really get to interoperability without these partnerships, as well as rules of engagement and governance and all of the other things you see listed here.

We also suggested a couple of other big picture structural suggestions one is to blend Section C and D. You guys know that there are like a million calls to action in here, it feels overwhelming to people and there is a lot of like we have to do 73 things right now.

And so one of the ways that we felt like we could bring parsimony would be to actually blend Section C and D because when we have Section C which is focused on consumers, Section D which is focused on providers and that while there is definitely things we need to do individually there is a lot more that we could do collectively together that would also end up really making this a streamlined interoperability roadmap and a much more powerful approach to advancing interoperability.

So we did also make a couple of comments just about the language in the interoperability roadmap and so while we...you'll see a lot of the calls to action still reflect the existing language in there, things like let's not call it a care plan let's call it a person centered plan because it actually turns out to be more of a planning process than a care plan and it also touches on other things outside of what we sort traditionally think of as healthcare like community services and supports, and so you can see that more on all of these things in the letter.

Okay, so let's dive into Section C. The first thing...this is again the section that is focused on consumers and it starts with really trying to foster cultural change for individuals including what the roadmap calls demanding and using their health information.

The Workgroup really felt, we talked about this last month, that the notion of asking consumers to demand their health information was just no longer appropriate at this time, first of they have a right to it under HIPAA.

Second of all we don't want to create a tension in the relationship between patients, families and providers so this really isn't about me marching into my doctor's office and demanding my health information, that at this point going forward, the 2015 to 2017 timeframe, we should really be talking about how we can bolster consumers using their health information with support from their providers and so we made lots of comments on that.

A next thing in this section that we talked about was the call to action around contributing patient generated health data and amendments. We agree completely, I think our comments though here was we actually need some obvious easy ways for consumers to suggest corrections and amendments to their health information much sooner than what the roadmap is proposing because we're obviously seeing providers, I mean, sorry patients, families really using and downloading their health information now. So, they have this right under HIPAA, we just need to make it easy and we need to make it easy for providers also to be able to respond to those requests for correction.

And we also talked about the fact that when we're trying to get, you know, consumers to use Health IT and use and contribute patient generated data or make amendments we really have a lot of work to do still around some things like language access and really being able to meet the different needs that different patient populations have and thinking about how do we design a system that meets the needs of the most vulnerable because if it works for them it will work for everyone.

So we did make a number of comments around sort of yes we like this call of action and we need to accelerate it. I'm probably going to skip over some of those today because I feel like we are going to be tight on time and I know that I'm the last thing standing between us and lunch so I'll keep going.

But we did focus a lot on person-centered planning. Person-centered planning we felt like is a really essential use case for interoperability, it really supports and reflects that partnership between patients, families and healthcare providers and that there were probably some data gaps and also some real functionalities missing in that in the way that consumers think about a person-centered plan they think about it more as a bidirectional communication process driven around my health goals but more importantly my life goals. And so how we make that platform really work as something that creates interoperability and the ability to share information across the entire care team is going to be really essential.

So, we made some comments around patient generated health data in a couple of different places in the roadmap and essentially we said, look we actually know a fair amount already, there has been some great work that ONC has done through the FACAs and through technical expert panels and white papers so leverage that.

This isn't really about cataloging best practices as it is, what do we already know today, how do we identify more advanced best practices and in particular when we think of PGHD we really have a need to make some progress around devices and wearables, and the standards that will allow us to begin to flow that information into healthcare.

So we still, and this is me not the Workgroup talking, we still I feel like kind of have this jihad around the standards for devices and we really need to do something here to either recognize and move forward with what we do have or develop new, or whatever it is we need to do but that's still a big gap I think in our view.

We also...and I'm going to get to this later, so I'm going to say it now because it's relevant here too, which is we felt like the roadmap had a lot of calls for patient generated health data which we completely agree with. The big challenge is how we make that information actionable for providers.

So, you know, if I upload my Fitbit data it shouldn't be incumbent about my provider to sift through, you know, volume and volume after volume of data. So we need to really have some tools that make the information easily actionable and detectable for healthcare providers.

We also noticed in the roadmap that particularly in Section C there were probably three or four different areas where the roadmap called for the government or consumer organizations, or other people to help patients understand their ability to send, receive and use health information.

There are also other components around understanding privacy and security and understanding value and so we felt like all of those components needed to be wrapped up into a single more comprehensive digital health literacy strategy so that we can help consumers understand their rights under HIPAA, understand their responsibilities when we're operating in a framework where HIPAA isn't in play, particularly with mobile Apps and things like that, best practices for how they can protect their data, the value of Health IT and electronic health information as well as, you know, privacy and security so those components of both value and trust need to operate in tandem and they were sort of allover in the roadmap and so we're suggesting doing some streamlining and really creating kind of a single focused effort that pulls all of these pieces together.

So the Section C2 is, you know, continuing to focus on providers and technology development. We felt in this area that there were some calls to action again around patient generated health data that we needed to make it easy for both sides to both contribute and use, move some of our timeframes up here and the third piece is, oh, providers should welcome and use information from others to avoid duplication testing. We totally agree with that but it's not just about other providers first of all it's about consumers and family caregivers and you'll see as well one of the things we commented on in the next section on providers was it's not really helpful to say you should just value it, right, providers will value, if it's actually useful to them, so that's where the action needs to focus.

Okay, so I'm going to skip the top one here because it's essentially the same thing I just talked about with rolling kind of privacy and security education in with education on value and that kind of how to use health information.

We also made a comment around segmentation of data that the roadmap calls for behavioral health information to be able to be segmented and we said well it's really any data that I feel is sensitive as a patient.

Okay, so the top call to action here around consumer advocacy groups is again harkening back to let's get a single digital health initiative here that we can focus on altogether and the important role that government plays in laying that kind of a strategy out and the consumer groups would be happy to support, but we really need to have a more comprehensive approach that blends the action of all agencies and there was a lot of good stuff on this in the Federal Health IT Strategic Plan as well.

And then the next component was about helping individuals understand and sustain engagement in managing health. We felt like "yes" but really what we need to make sure is appropriate to the interoperability roadmap is actually enabling the technology to do that.

That, you know, this call to action was perhaps a little bit broad. There's a lot going on in trying to advance patient engagement in their health and in their care so we need to be really focused on making sure that the technology supports it.

Do you want me to take questions Paul now before I go to Section D or continue on?

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

I think you can go ahead.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay. So, Section D, as I mentioned, is focused on care providers and it's titled partnering with individuals to deliver high-value care but I'll tell you that there's not a lot of partnership in this section it's almost exclusively focused on calls to action for providers even though there some really important things and not only that consumers need to do but vendors need to do in collaboration with providers and the federal government as well.

So we wanted to better emphasize that partnership but more importantly this section to us felt pretty overwhelming. This is like, you know, we hear all the time from providers that they've got a lot going on, right, Meaningful Use, PQRS, ICD-10 and there's a significant focus in this particular section on process. So there's a whole kind of bucket that basically says we need to...providers should create workflows around interoperability.

The main comment I think we made in this section in terms of how you can bring parsimony is don't focus on...don't focus on the process focus more on the outcomes you'll create a lot of parsimony that way and you'll really get to what matters in all of this. And then again combining this with Section C could help a lot to create some of that parsimony.

So, the first call to action in this section is around, you know, providers routinely expecting electronic access to outside information. Again, we need to build the tools and interfaces that actually make that information actionable and useful and easy to digest so we're actually suggesting here that this isn't probably the right call to action it's a new one that's really focused more on vendors.

Second, I think I mentioned this before, it's really not about just recognizing that valuable clinical information lives elsewhere because we know that if it is valuable in practice providers will use it. So we have to sort of make the right thing to do the easy thing to do here.

So, providers and their organizations should ensure contracts and agreements that they sign and re-sign with vendors include all the things that advance interoperability and none of those things that don't as I would say.

So and here we felt like we keep hearing...we've heard this bubbling up to the Policy Committee over the last several years that there are information practices or fee structures that vendors will use sometimes that actually pose a barrier specifically to interoperability. So, not only do have to pay to build the interface to your local HIE but some vendors will charge for the data that flows from the HIE into your system, you know, and there are many examples of that.

So we felt like it wasn't just about, you know, kind of what are the necessary requirements but it was also there should be a call to action specifically about making sure we don't have any really unreasonable barriers in contracts as well.

And then we also commented again on the call to action that says that the systems need to be configurable based on use case. So we said look there is really a priority use case here for a bidirectional person-centered planning process that is really rooted in those shared health and care goals. That this was something that in particular should be a priority and so Paul we'll sort of pass that back to you for your use case work.

So we agreed with this call to action which is around clinical decision support but we also made comments throughout the roadmap that we need to begin to integrate or at least compliment clinical decision support with shared decision-making.

So while CDS tends to be focused on the providers there are definitely shared decision-making tools that consumer's need and how we can bring those two elements together is something that we thought was an important element for the roadmap.

So, on call to action 12 that you see on this screen, so we felt like, you know what if we've already called for providers to start doing this earlier, which the roadmap does, and we have quality measures and payments much more aligned, which by this time in the roadmap it does, this timeframe is 2021 to 2024 here, then you don't need a call to action on this because it should happen as an outgrowth of that aligned payment and the previous work.

So this...there's a Section D3 on accurate measurement and we made a lot of comments on there and so what we've done here is kind of aggregate some of the most relevant calls to action and put our comments all in one place for you guys today.

So the first theme to this section is we felt that there was a missing emphasis on the need for the federal government to really invest in the development and more advanced clinical quality measures. You know we've done a lot of work since back in 2010 right at the Policy Committee where we really tried to identify some more advanced eCQMs, we're still not there and that piece was really missing.

There is just no business case for anybody other than the federal government to develop the kind of measures that we need which are longitudinal, outcomes focused, include patient reported outcomes, all of the stuff that's hard that really gets to value, no one else has a real business case to develop. So that, you know, having the government play that leadership role here is really, really essential.

We also said that there are a couple calls to action that call for the development of measures of interoperability. We said that we weren't sure if that was the right approach, that we need to really think about the purpose of interoperability, care coordination, communication, improving health outcomes so how do we again focus on the outcome or at least something that's closer to the outcome like robust meaningful care coordination as opposed to measuring technical interoperability.

In the same vein, if we start to pay for outcomes that actually require interoperability, people will develop workflows and systems to achieve those goals real fast. So how do we outline a strategy for revising our current measure sets, getting those new and far more robust, and therefore challenging and value-based measures, into the pipeline, getting them into federal programs for payment and, you know, a lot will happen from that process alone and again you can really streamline this section of the roadmap.

So and then D4 is the section I mentioned earlier which is entirely focused on measuring the process and the workflows of interoperability and creating lots of, you know, kind of very processy you need to have a workflow around, you know, information exchange but we think that will just happen naturally if we're paying for the right things, if we're measuring the right things, if we're supporting that partnership and that planning process between consumers and providers. So we actually suggested that this whole section should be rethought.

We did not comment on the section on training and maintenance of certification we just felt that we weren't the right group to do that. We weren't particularly equipped to know, you know, but I think we will get public comments from the training and maintenance and certification community so that's good.

And then we did comment a bit on the next section which was innovation and basically research, generation of new knowledge, and we said we need to think about how to better include patients and families and consumer advocates through participatory research, you know, the methodologies that PCORI uses are really solid around how consumers are shaping the research priorities and part of the implementation and governance of research, etcetera. And again here was an area where we felt like the federal government has a huge role to play and it's not really articulated particularly well in research and so that was an important piece.

So, I think we're close to the last section here, so D7 is transparency and value engagement of patients, families and caregivers. So this is interesting because it's where we start to see more of a focus on value which I know Charles is going to be really excited about, so we made some comments around making sure that in fact it's not just payers and purchasers, and providers in regional efforts to measure quality it really has to be consumers.

And when you look at call to action four it's hopefully immediately obvious why I say that and why the Workgroup said that, which is that when we start to think about routinely using cost and quality data to make shared decisions in healthcare if you don't have consumers at the table, figuring out how that's done it gets real dicey real fast.

So there's...every bit of research that's ever been done with consumers around cost and healthcare shows you some very immediate pitfalls when you start to bring cost into these discussions it can create, if done wrong, a real fear of are you rationing my healthcare, are we back to the, you know, old bad HMO days, you know, all of those kind of risky elements come into play and so making sure that patients, families and consumer advocates are really clearly part of this process is going to be very, very essential.

And then the same thing here in terms of the 5th call to action working together to develop test and implement credible indicators of value (a) consumers need to be involved (b) there are some similar calls to action earlier in the plan, so we completely agree but another opportunity for creating some streamlining and parsimony.

Okay, so in this section we also found a call to action that is about consumers or I'm sorry providers supporting consumer facing activities like online scheduling but the timeline for this was 2018 to 2020 and so we felt like first of all there is a fair number, not all of these, that are included in Stage 2 of Meaningful Use.

Second of all, a lot of these are really key to continuing to bolster and build consumer support for health IT so they are as worried about, you know, all of the things we know that they can be and so how we do this now as a way to show value and increase transparency and trust is going to be really essential particularly since they are the taxpayers.

And then, you know, again another comment here about when we think about reducing the burden of care coordination I think when we start to pay for care coordination and better outcomes that we'll actually create some real efficiency there and so shifting that focus.

Okay so I know that was a lot and how can I answer questions?

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

Good, questions, comments? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Yes, let me say, thank you Christine for an energetic presentation as you pushed us through a lot of material very rapidly. I have some observations but I first have a question on your very first slide, your slide number two where you list...

Christine Bechtel, MA – President – Bechtel Health Advisory Group

The Workgroup list?

Paul Egerman – Businessman/Software Entrepreneur

The workers list and my question is as I looked at your list I notice you do not have any EHR vendors or it looked to me like any vendors in your group and I'm curious to know why that might be?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

First of all I don't choose the Workgroup, but Conversa is actually a vendor, a technology vendor and I'm trying to look through the rest of our folks, but at the end of the day I think you would want to ask ONC that.

Paul Egerman – Businessman/Software Entrepreneur

Okay, because it seemed to me having some EHR vendors could be very helpful on some of the topics that you discussed.

And the observations I give you is, I liked your comment about segmentation not just relating to behavioral health, there are a lot of areas although you probably want a carve out for any infectious disease you might not want that to be segmented.

And I also very much liked your comment about focusing in terms of interoperability metrics on outcomes as opposed to other metrics because, you know, the outcomes are important and I really wish that this were greater focus. I just think that, you know, we can't decide...interoperability is like inherently good thing but, you know, it's only a good thing if we're accomplishing something with it, you know, that's my comment. Anyway those are my comments.

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

Paul we're certainly open to having former vendors and citizens join the Workgroup. I think next was Charles.

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

Yes, just two quick comments I'll share, I'd like to maybe challenge the ascertain a little bit about much of this is there is a business case for this we need more federal government involvement.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

You mean Charles, just to be...I don't mean there is no business case for this globally but I was talking about the more advanced quality measures.

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

Yeah, no, fair enough and just to share story when Medicare stars came out, you know, I was running clinical informatics for a big health plan and I'll never forget one of the most challenging people for me to get funds from walked into my office and said, how much money can I give you to improve our quality scores.

So I do think there's...even in many of these advanced quality measures I wouldn't...I do think there are reasons to believe that the private industry will embrace quality measures if we appropriately align the incentives even some of those advanced ones.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Charles, I couldn't agree more. What I was...so just to be sure that I'm clear, what I was trying to communicate from the Workgroup which is the business case that lacks is the actual development, testing, validation of the measure itself.

So what happens is today there are many measure developers there's a business case for them but we have a suite of like process and structural measures and all these others, so I'm...I think our discussion really focused on when you think about some of those harder measures like a longitudinal, you know, patient reported measure of improving functional status over time it's very, very difficult to find anyone today who will give you money to develop that measure.

So if the health plans are going to, you know, and the ACO community is going to be totally in on that that's great. But that's why we felt that a federal role was really essential there because it just really hasn't been a strong business case to date.

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

Yeah, no fair enough.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay.

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

Fair enough.

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

Thank you. Troy?

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

Thank you, I'm really pleased that you talked about the patient generated data and the devices out there, you know, we have constant conversations within Kaiser about how can we actually retrieve that data and what's our responsibility once we retrieve it and filters through it.

One of the larger issues we have is something that you actually spoke about and it has to do with the integrity of the devices, are they certified, are they calibrated, I mean these are all things that we have to assure and, you know, you're talking about a Fitbit or you're talking about some health App that we're getting data from. So I appreciate the thoughtfulness of bringing that up and that was the only comment I had for you.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Great, thank you, I think you're right and I think it's not also just about the connection but we also made a comment that, you know, we have to be able to really use the data in a way so we're summarizing, we're aggregating, we're using some kind of logic or algorithm to say here's the problem area or, you know, here's the, you know, awesomeness you just achieved but not pages and pages or screenshots and screenshots of, you know, device data that's too difficult to deal with.

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

And I think the time is prime because the marketplace is really pushing to utilize these devices and how they can be shared with your providers and utilized in your health and dah, dah, dah so we...you know the time is now. We really need to look into this and figure out how will these things be validated and certified and calibrated, and what are our legal responsibilities for all of that, that sea of data that will come in by e-mail or see care message.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Thanks, Troy.

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

Yes, thanks. Deven?

Deven McGraw, JD, MPH, LL.M – Partner – Manatt, Phelps & Phillips, LLP

Thanks for a great presentation Christine. I just of one question and it's in the privacy and security section where the call to action was about providing individuals secure access to their own behavioral health information in a way that is easy to use and enables them to make choices about disclosure of specific information that is sensitive to the individual and/or legally protected. And the response of the group is segmentation of data should include any data that the patient feels is sensitive and not just behavioral health.

Were you talking about the data segmentation approach that's been proposed in certification or were you thinking of segmentation more of broadly?

Okay, because the reason...you might want to just clarify that because the reason why I asked that is because the particular data segmentation standard that we reviewed as a Tiger Team not too long ago and that's been proposed for certification is one that allows for read-only access by the recipient provider, the data can't be used in clinical decision support in order to prevent the possibility of re-disclosure without authorization because the behavioral health data rules have that re-disclosure element in it that really makes things quite complicated.

So, it's a less-than-perfect sort of step toward honoring patient rights with respect to a particular set of rules where the consent requirements do stick to the data and end up having to be persisted across settings. I don't necessarily know that...and maybe...I wasn't privy to your conversations but if that's the approach that you wanted to have applied to a whole range of sensitive data I might submit that I'm not sure we would want that.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Right, no, that was...thank you, very much Deven that's a helpful clarification. That was not at all what we were saying. We were simply trying to help the roadmap be a little bit more well informed in the sense that it's not just behavioral health data that we really need to make it easy for consumers to...I'll reframe without even using the word segmentation, to make choices about disclosure of specific information that's sensitive. So, we were just really trying to...we were talking about that ability broadly speaking so that's a helpful clarification and Chitra will help me make that in the letter.

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

Anjum?

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

Thank you, Christine, I appreciate most of the points that have been made here. I want to focus on D7 which is around transparency, value engagement and knowing that, you know, part of that transparency is also consumer empowerment, you know, knowing that data. Was there a discussion in your Workgroup about any specific timelines around, you know, achieving such transparency sense it is both such an important piece of both D and C I would think?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

So, I'm scanning our letter right now, I think, you know, the timelines are pretty clearly laid out in the roadmap and so for example there is a current, what I would describe as a current, timeline which is 2015 to 2017 call to action where providers should work with purchasers of care to have access to patient out-of-pocket cost and those payers, and purchasers participating in those regional efforts to maximize quality and and value, accessing medical records, etcetera, so there are a bunch that are kind of right now in that respect but they came really out of the roadmap as opposed to our Workgroup comments and Kim is part of the Workgroup so you're, you know...I would welcome you to weigh in as well, but I don't think we had much discussion beyond those timelines on this section.

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

So, your call to action in terms of the suggestions that your Workgroup has made would be in the same timeline that has been described in the roadmap right?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Yeah, yes, I think as the consumer discussions went forward yes, so and we would of course love to see everything done right now but I think we also recognize that some of the calls to action that are in later time periods are there because we really don't really have a great way of getting at those data yet we don't have a great way to build that in workflow and, you know, how do we kind of bridge that partnership with consumers and so I think that will take a little bit of time but there are some that are proposed for the current timeline.

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

Thank you.

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

Thank you, any other questions or comments?

Okay, thank you, Christine. So, I think what we'll do is remember we need to approve these sets of comments so I'll work backwards so it's fresh in our minds. Any...so Deven's point about clarifying the data segmentation modulo that were there any other comments that needed to be edited before being submitted? Okay.

And then on the Advanced Health Models Workgroup on the prioritization of use cases, that matrix and that process any updates to that? Okay.

Privacy and security, we talked about Paul Egerman's concern about the now service attacks and whether that...how does that relate to the individual's right to be able to stack up their data. So there will be some sort of clarification...

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

Yeah, we will add a clarification...

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

Okay.

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

I mean, not...denial of service is one example...

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

Right.

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

But just the security risks that could be inherent in making certain connections...

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

Right.

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

Would need to be considered, yes.

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

Any other modifications to what Deven presented in that section?

And then the first one was the Interoperability Workgroup any modifications there?

Okay, we'll entertain a motion to approve subject to the modification we just discussed.

Paul Egerman – Businessman/Software Entrepreneur

So moved.

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

And second?

W

So, moved.

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

Okay. Further discussion? Okay, all in favor?

Multiple

Aye.

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

Aye.

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

Who was that?

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

David Kotz.

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

Hi, David. And any opposed or abstained? Good, thank you and we're going to be putting together a transmittal letter to forward our comments almost in the deadline for the interoperability roadmap. And Lisa was going to invite Erica to make comments.

Lisa A. Lewis – Chief Operating Officer – Office of the National Coordinator for Health Information Technology

Yes, I wanted to first just thank each and every one of you for the time and effort that I know it takes to work with us and be a part of our FACAs and a part of our working groups. I know this is time out of your already very busy schedules and I know that you do it because of your shared passion for the mission that we all have and so I do want to thank you.

I know we've put out a lot of documents that we are asking for comments in the last few months the strategic plan, the interoperability roadmap, now the NPRM and we cannot do this without you and so we are very thankful that you are our partners and that you're working with us on this.

Erica Galvez I think is still on the phone, if she is, I wanted to just give her the opportunity if she wanted to comment on anything and if not we can move forward.

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

I am here, thanks Lisa. I would just echo your thanks to the group for a very coherent set of recommendations and feedback and I look forward to working on these with the team as soon as we get the transmittal letter.

Lisa A. Lewis – Chief Operating Officer – Office of the National Coordinator for Health Information Technology

Excellent, thank you, Erica.

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

Okay and then we'll open for public comment, please?

Public Comment

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

While we wait for the operator to open lines if there is anyone in the room that would like to make a public comment please come up to the table. And while we wait for that I will turn it over to you Alan.

Public Comment

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

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

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

While we're waiting, one I wanted to extend the thanks to the committee members and the, it really amounts to hundreds of volunteers on all the Workgroups, because these are, as Lisa was saying, volunteer efforts in addition to your day jobs mainly because people are motivated to try to help and it has been over the years since 2009 a real partnership between the FACA committees and ONC, and

CMS so really appreciate that.

Also want to note that...and Michelle you're going to have to help me, there are some members who have also been with us for a very long time to my left Christine Bechtel has been here since the start and has ably led many of the Consumer Workgroups and responses to the various requests that we've had from the federal government and she puts in a ton of time and has been very thoughtful in contributing both her thoughts and in working with leading the of the many groups. So, thank you Christine.

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

Well we are hoping this isn't their last meeting because we haven't had an announcement of their replacements. So we're hoping they'll stay on but the folks that we will be losing, until they name them, the folks that we will be losing are Charles Kennedy, Mark Probst, David Bates who is not here and Christine.

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

So, I want to thank them all for their hard work.

Applause

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

We weren't planning to make a big deal until we officially lost you.

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

...

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

But, yes, so Charles Kennedy who always reminds us of the value proposition we have and it's not just the low cost it's really delivering the value to our end consumer who we all try to represent in these efforts and did you say Marc is departing as well, who reminds us about the efforts it takes for developers to meet this, about the standards and the critical few if I learned that lesson after being pounded on multiple times, but these are all...I mean each...every member who have been with us for so long have been contributing a whole lot to this process and we just really thank you so much for being part of it. Any public comment?

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

No public comment.

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

Okay and so we will see you next month when we are going to be dealing with the responses to the NPRMs, plural, so that's...we look forward, given this little preamble we had today, we look forward to some hearty comments to your engagement in this month that we prepare those comments and to your feedback then that we'll finally approve right before the deadline. So thank you everyone and good travels.

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

Thank you everyone.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Thank you, Paul.

Public Comment Received During the Meeting

1. Mike talks about not having enough time to provide clarity and supplementary documents. Can you imagine what time it takes to take this information and make a design plan for programming. With the volume of changes in the ONC NPRM, developers will have a very hard time getting design, development, QA, documentation, usability testing, certification and deployment to users. Then, all providers in the nation will have to be on certified software for a full year starting Jan. 1, 2018. It will not be possible to do the vendor required steps and then allow all providers to install, test, train and update their workflows. it seems like a long time, but when you really look at the timeline from
2. What is striking about this committee meeting is the utter and complete tone deafness to the struggling EP and the overwhelming and overburdening the front line provider with an avalanche of regulations penalties and meaningless EHR use.
3. Yeah I know, but there is little to no chance of a critical statement to be added to the record. As they cannot stand to hear critical statements from the front line providers.

Meeting Attendance							
Name	04/07/15	03/10/15	02/10/15	02/10/15	01/13/15	12/09/14	11/04/14
Alicia Staley		X				X	
Anjum Khurshid	X	X	X	X	X	X	
Aury Nagy						X	
Charles Kennedy	X		X	X	X		
Chesley Richards	X	X			X		
Christine Bechtel	X	X	X	X	X	X	
Christoph U. Lehmann	X	X			X		
David Kotz	X	X	X	X	X		
David Lansky	X	X	X	X	X	X	
David W Bates		X	X	X			
Deven McGraw	X	X	X	X	X	X	
Devin Mann		X	X	X	X	X	
Gayle B. Harrell	X	X	X	X	X	X	
Karen Desalvo	X	X	X	X	X	X	

Kim Schofield	X		X	X	X	X	
Madhulika Agarwal	X						
Marc Probst	X	X	X	X	X	X	
Neal Patterson	X		X	X		X	
Patrick Conway							
Paul Egerman	X	X	X	X	X		
Paul Tang	X	X	X	X	X	X	
Scott Gottlieb	X		X	X			
Thomas W. Greig	X	X			X		
Troy Seagondollar	X	X	X	X	X	X	
Total Attendees	19	17	17	17	17	14	0