

HIT Policy Committee Transcript May 6, 2014

Attendance

Members present:

- Madhulika Agarwal
- David Bates
- Christine Bechtel
- Arthur Davidson
- Karen DeSalvo
- Paul Egerman
- Thomas Greig
- Gayle Harrell
- David Kotz
- David Lansky
- Devin Mann
- Deven McGraw
- Chesley Richards
- Marc Probst
- Troy Seagondollar
- Joshua Sharfstein
- Alicia Staley
- Paul Tang

Members absent:

- Patrick Conway
- Neil Calman
- Scott Gottlieb
- Charles Kennedy
- Aury Nagy
- Robert Tagalicod

Presentation

Operator

All lines bridged with the public.

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

Thank you. Good morning everyone, this is the 59th meeting of the Health IT Policy Committee. This is a public meeting and there will be time for public comment both before lunch and after lunch. Public comment will be limited to THREE minutes. If you are tweeting today, the hashtag is #HITPC. We're going to take roll by going around the room and then I have a couple of other small announcements, starting with Jacob.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Jacob Reider, ONC.

Judy Murphy RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology

Judy Murphy, ONC.

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

Deven McGraw, Manatt, Phelps & Phillips.

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

David Lansky, Pacific Business Group on Health.

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

Gayle Harrell, Florida State Representative.

Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health

Art Davidson, Denver Public Health, Denver Health.

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

Jodi Daniel, ONC.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Karen DeSalvo, ONC.

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

Paul Tang, Palo Alto Medical Foundation.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Judy Faulkner, EPIC.

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

David Bates, Brigham & Women’s.

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

Christine Bechtel, National Partnership for Women & Families.

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

Devin Mann, Boston University.

Madhulika Agarwal, MD, MPH – U.S. Department of Veterans Affairs

Madhu Agarwal, Department of Veterans Affairs.

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

Troy Seagondollar, Kaiser Permanente and labor representative.

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

Alicia Staley, patient advocate.

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

Chesley Richards, CDC.

Paul Egerman – Businessman/Software Entrepreneur

Paul Egerman, new status Medicare beneficiary.

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

So you all may have noticed we have Chesley Richards from CDC, who is now a member of the Policy Committee, so we're excited to have him. I also – today is a very tight meeting so we highly suggest that you order lunch through the hotel, so if you could take some time to do that now, I will come around and collect your lunch orders, right before the data updates, so that we are all ready to go. So if you could all help us stay true to time, we would really appreciate it. And with that, I'm going to turn it over to Karen.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Well, good morning everybody and welcome back. It's nice to see your faces in person and some of the folks here are able to join us for the first time since I've been the National Coordinator. I'm going to make a few remarks at the end, but in case I lose folks, I'll just say a couple of things now as a prelude, which is, thank you all for your feedback on the working groups, the evolution that we're going to undertake. We have a draft document that is the charges of the various working groups that we'll be sending around to you all between the next two meetings. And have a new SOP, standard operating procedure, for the committee members that because we're losing some folks, which we'll get to in a minute and gaining some new folks.

So it seems like good transition times to put all this in writing and make sure everybody sort of knows why we're here and what we're supposed to be doing and how we're going to work together. So there will be a couple of documents coming around to you all between the two meetings, in advance of June, so you can take a look and make sure that that comports with your thinking. That also is the chance for Michelle and the team to begin assembling the new workgroups. So we'll be looking for folks to step forward and ask to take on tasks, we appreciate the work that goes on now, and we don't want to lose that also, so we're also being sensitive to making certain we complete what the groups have started. But with that, we have some sad goodbyes and I'm going to turn it to Paul Tang, who's been chairing this group essentially for years, and let him do the honors and then we'll hand out some thank yous.

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

Thank you, Karen. Well, as Karen alluded to, we have some folks; three folks who have been with us since the very beginning and I don't remember whether Michelle announced this is our 59th meeting. And I would say that these three folks have been to all of them with the exception of perhaps one or two. They're part of our inaugural committee members and they've been so, so wonderful in terms – to work with and their thoughtful comments during the discussion and the incredible amount of work they put into the workgroups in preparation for committee meetings.

One of the members, Neil Calman, can't be here today, he had some other business that he just got called to yesterday, so I only got a chance to roast him over e-mail, but he – he's on the line? Sort of. Hey Neil, if that's you. Neil nominally represents the vulnerable populations, which we know he serves in New York City, but represents them across the country, always worried about the consumers and patients and disparities in healthcare. In addition, though, he was able to keep his feet on the ground as a practicing physician and understands how do we balance the needs, what we're asking everyone to do with the everyday workflow and work life of the practicing clinician. So that was especially helpful, this balance that we always try to achieve.

Art Davidson nominally represents consumers and he does that extremely well. He also represents consumers in the aggregate, in terms of public health and I have to say that much of what we've done in public health has been attributable to Art. He's been a very able and conscientious member of the Meaningful Use Workgroup. A lot of the work that we did there is because he not only represented public health and consumers, but also reached out to his colleagues and brought their input in as well. So that's – with a very steady hand, you've sha – steered our ship and made sure we covered that area, so thank you, Art.

Judy Faulkner, we can always count on her to represent the vendors. But also, I know in her heart she really represents also her customers, which are primarily providers, and thinking how can they best serve their customers, which are consumers and patients. So, she also gave us that additional perspective and helped us balance the things – our aspirations with realities, both in the developer world as well as the provider world.

So, all three of them were there from the start and through thick and thin, dedicating their time and energies to both the committees and the workgroups they've been on. And we've definitely benefited from their efforts. So want to really thank you for sticking with us and being so generous with your time and your effort and your thoughts. So, thank you.

(Applause)

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

So if you guys would just come – you are actually both forward, but just come over here, I want to give you something from – a letter from the Secretary saying thank you. And also a certificate that you all can have as a cherished memory of your wonderful work here. So Art, thank you very much – and a letter from the boss.

Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health

Thank you so much.

(Applause)

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

And Judy – the esteemed Judy Faulkner, a letter from our boss.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Thank you.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

And a certificate for you.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Thank you appreciate it.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

And Neil, yours will be on the way. We don't know if he is on the phone.

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

– clean up things up in New York City. Do you have any other comments?

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

I just want a note for the record that Mark Probst, David Kotz and Thomas Greig are all on the phone. I forgot to ask about phone members.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you.

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

Although we are passing some of the gavel from the older members, at least a couple if not all three, are going to continue and serve on some of the workgroups of the committee. And replacing them, we have Kim Schofield for consumer representative, Chris Lehman representing vulnerable populations and Neal Patterson, representing vendors. So we welcome the new folks who we will see next month, at least in our virtual meeting.

Let's see, let me go over the agenda. It is a pretty full agenda with a lot of meaty topics. We'll start off with the updates from ONC and CMS, and you'll find some interesting data there in terms of how – in terms of our progress year-to-date. We'll then go into the NPRM comments for the 2015 edition. As you know, those comments are due to ONC by the end of this meeting, so we'll need to approve those. Jodi Daniel will lead us through the FDASIA update that is open for public comment and we're going to form a Task Group to provide the committee's feedback on that. We'll have a brief break for lunch and then Dr. Koh, Assistant Secretary for Health is going to address us particularly about the needs for – the needs of behavioral health and EHR and HIT support of that. Leading us into the afternoon session, which covers behavioral health data segmentation updates from the Privacy & Security Tiger Team followed by the LTPAC and behavioral update in terms of voluntary certification program. So that's a full agenda in time and a full agenda in discussion topics, so, ready your thinking caps. And you should have received all the materials electronically before this meeting, including the minutes from last meeting. So, I'd entertain a motion to approve the minutes from last month.

M

So moved.

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

And second?

M

Second.

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

Any further discussion or corrections? If not, all in favor.

Multiple speakers

Aye.

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

All opposed? Thanks Neil. And any abstention? Great. Thank you very much. And then we'll open up with Jennifer King and Beth Myers from ONC and CMS.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Thank you. Good morning, everyone. So, for the ONC side of the data update today, we have two main topics that we want to cover. The first is some new data on hospital health IT adoption, which allows us to look at the latest trends in EHR adoption and adoption of Stage 2 Meaningful Use functionalities. And the second is our most recent installment in our occasional series on progress to 2014 edition certification, looking at vendors and professionals in that respect. So, just wanted to remind everyone of the slide we showed last month, which lays out the range of quantitative data sources that we're going to be analyzing and reporting on to you all over the next several months. That will help us understand what the experience with Meaningful Use has been so far in terms of implementation of the program and impacts to help inform comments on the NPRM of future stages of Meaningful Use.

So today, we are focused on that first row there, which is new data on hospital health IT adoption, which is from the American Hospital Association 2013 Health IT Supplement Survey. So this is a survey that was in the field from November 2013 until February 2014 and collects information on a wide range of health IT functionalities that hospitals have adopted. It has about a 60% response rate. So first using the survey data, we track every year progress in EHR adoption overall among hospitals. And this is a familiar trend now that you've seen here on many different occasions, but we continue to see strong, steady growth in hospital EHR adoption. So in the last 2 years, EHR adoption among hospitals has more than – about doubled, and it's increased more than fivefold since before HITECH in 2008. As of the 2013 survey, over 9 in 10 hospitals possessed certified EHR technology.

We can also take a look at adoption of all of the – or many of the Stage 2 Meaningful Use functionalities using the survey data. So this slide here shows that many of the Stage 2 functionalities had very high adoption rates at the time of the 2013 survey, so many of them in the range of 80 to 90% or higher. However, you'll notice that there are some objectives that had lower adoption rates, most notably, the view, download and transmit objective, which only 10% of hospitals at the time of the survey reported having all three of those capabilities.

Digging a little deeper into that, this slide shows adoption rates for a range of patient engagement functionalities, including the view, download and transmit functionalities broken out separately. So those are the three blue bars there in the middle, and you can see that all of those three capabilities had adoption rates below 50%, but transmit is really the one with the lowest adoption rate, which supports a lot of the information that you've been hearing from the listening sessions and other reports from the field. There are another couple of data items that might be of interest, in terms of patient engagement functionalities that are not currently part of Stage 1 or Stage 2 Meaningful Use. For example, there at the bottom, about 13% hospitals have the ability for patients to submit patient-generated data at the time of the 2013 survey.

But focusing on the Meaningful Use Stage 2 objectives, in the slide before we saw that a lot of the Stage 2 objectives had really high adoption rates. And this slide looks at the number of Stage 2 objectives that each hospital has adopted at the time of the survey. So the ho – the survey asked about 16 of the Stage 2 core objectives, you can see on the far right there that just 6% hospitals at the time of the survey had adopted all 16 of those Stage 2 objectives, but most hospitals had adopted most of the objectives. So for example, about 6 in 10 hospitals had 13 or more of the Stage 2 objectives, implying that most hospitals are the point where they just need one or two more objectives to be meeting most of Stage 2 core.

And lastly, on this part of the data update, we looked at how this looks across different types of hospitals. So, whether certain types of hospitals have adopted more Stage 2 functionalities during the 2013 survey than other hospitals. And we see that critical access and small rural hospitals had adopted fewer functionalities at the time of the survey. So for example, about 20% of critical access and small rural hospitals had adopted 15 of the Stage 2 core objectives, compared to about 40% of larger hospitals.

So just to briefly recap there, we see a lot of quantitative data to support much of the information that you're hearing from the field in terms of qualitative information, strong steady growth in the EHR adoption among hospitals and really high rates of adoption for most of the Stage 2 functionalities. But some of the problem areas that you've been hearing about are borne out in the data with lower rates of adoption for view, download, transmit and some data that suggests that critical access and small rural hospitals are starting from a little bit of a lower starting point in terms of making progress to Stage 2.

And we expect over the course of the year, as providers upgrade to 2014 edition EHRs, that we will see strong growth in a lot of these capabilities that were lagging, which leads into the second part of the data update here on progress to 2014 edition certification. So these data are with the usual caveat that this reflects progress to certification only and does not give us any information on vendor rollout or implementation timelines, which we know are also really important to provide a readiness to attest.

But first looking at hospitals and their status with regards to 2014 edition certified products. As of April 2014 95% of hospitals were using products or vendors that had products certified to 2014 edition base EHR. So a strong majority of hospitals likely would be able to upgrade their current products or use products from their current vendors to meet base EHR as of April. In previous months when we've looked at this, we've seen disparities across hospital type with regards to 2014 edition readiness and we've seen those disparities narrow. So, there are still some small differences, but across hospital types most of them are using vendors or products that would meet 2014 edition base – or have certified products available that would meet 2014 edition base EHR. On the professional side, a similar story, the majority of professionals using products that have 2014 edition base EHR products available, either it's – their products or their current vendors. And we continue to see some differences by professional's specialty and type; in particular the non-physician professionals are lagging a bit behind in this regard.

So lastly, wanted to take a look at progress to 2014 edition certification from the vendor perspective. So we've seen that the majority of professionals and hospitals are using products from vendors that have 2014 products available, but these next two slides look at the number of inpatient and ambulatory vendors that have ever had a product certified and where they stand with regards to the product certified to 2011 or 2014 edition.

So you can see here the blue sections of this graph show that there are 178 inpatient vendors who have 2011 edition product certified and do not have the 2014 edition product certified. However, the vast majority of this group, 142 of them, never had their products used for attestation in 2011 to 2013. So it's that dark blue segment of 36 inpatient vendors who had products used in 2011 to 2013 and have not yet had those products certified to the 2014 edition. But as we saw in the previous slide, those vendors account for a quite small share of overall hospitals.

On the right-hand side of the graph, you can see that there are 147 inpatient vendors that have products certified to the 2014 edition as of April 2014. And this includes that purple segment there which is 54 vendors who are new to the certified health IT product list in 2014. So these vendors did not have a 2011 edition product certified, but do have the 2014 edition certified.

On the ambulatory side, we see a similar story with about 700 vendors having only 2011 products certified and slightly over half of them had been used – had products that were used to attest in 2011 to 2013. But again, this segment of vendors accounted for a relatively small share of professionals that have attested. And we see that 245 ambulatory vendors have a 2014 edition product certified, including 82 vendors who are new to certification with the 2014 edition.

So that wraps up the new data that we have for you today, just wanted to briefly preview plans for the next data update in June, which are to take the opportunity to look back across the three current years of the EHR Incentive Program, 2011 to 2013. And really dig in little bit deeper and present information on year-over-year progress in the incentive program by a key provider characteristics and geographic characteristics. And with that, I can take any questions that you have on the data from today.

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

Great, thank you, Jennifer. Any questions on the ONC update? David?

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

Do you have any information on how many installs the vendors have, because my impression is that in the inpatient side, a small number of vendors account for a large proportion of the market, whereas it's fairly different from the ambulatory.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Yeah, we do have that information, I don't have the stats at the top of my mind, but it is a fairly small number of vendors that accounts for the vast majority of providers. So, we can do a little bit of the backtrack here. You see that the 25 vendors in the dark green there account for roughly over 90% of hospitals that have attested so far. So, it is a fairly concentrated segment of vendors that are accounting for the majority of hospital attestations similar on the ambulatory side, but less so.

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

Gayle?

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

Thank you very much, Paul. And I was interested in, as far as specialties go for physicians, for providers, have you gotten – do you have any breakdown as to those, the vendors that are available or have gone out of business by specialty as well?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

So you can see a little bit of that at the high level here, where we look at the certification status of physician's current – the products and vendors that they use to certify in 2011 and 2014. And you can see that in terms of surgical specialists, primary care and medical specialists, they're roughly similar. Radiology, pathology, and anesthesiology are a little bit behind in their certification status. And then there are bigger differences when we look at the non-physician professionals who do account for a relatively small share of the overall eligible professional population.

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

Follow up, is there any correlation as to vendors? Are there more vendors in specific specialties that are not going to have a product for 2014? Do have any breakdown of that kind of thing as to what vendors are more successful by specialty? And what are not going to be participating and who's going to be kind of left holding the bag?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

So we can provide greater breakout of information like this here, but this suggests that at these broad specialty categories, there is not much of a disparity right now in which vendors have moved forward with 2014 edition certification at this point in time.

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

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and 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 glad you brought up – slide. My concern is this far right category. When you look at those, and I will call them professional entities, I think you referred to them differently. But anyways, those are a lot of holistic care categories, I mean, you talk about podiatry and chiropractic's, optometry, different things like that, I mean, what are we doing? Has this data been shared with the RECs? Really what I'm looking at is how are we fixing that, are there any plans? I know you're doing the data part, but have you shared this with any of the RECs or anybody else that would really have a game plan to say how can we bring these up?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Yes, so we do from the ONC perspective provide these data regularly to the RECs and another sort of community of practice outreach efforts at ONC. Others around the table may be able to speak to other outreach efforts that ONC or CMS are undertaking in terms of these provider group specifically.

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

Yeah and it's not just these groups, but it's also our critical access hospitals, that program. Obviously, I mean its critical access for those disparate populations, so I'd really – that's got me concerned.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Yeah and in terms of the progress the to 2014 edition certification, we see critical access hospitals have made great progress over the past couple of months. And we do see, for example, with the Stage 2 adoption data that they are starting from a little bit of a lower point, but that is certainly a key priority for ONC and the RECs working with them to get them there.

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

Thanks. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Thank you. It was a, as usual, good presentation, Jennifer. I have a question about your slide number six where you show adoption rates. And my question is, is adoption rates the same as usage rates? So when it shows like whatever it is, maybe 10% have the transmit function, does that just mean that people have installed it or does that mean that the patients are actually using it?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

So that's a great clarifying point. These data by and large refer to adoption of the capability and don't necessarily reflect the level at which they're being used. So this does not tell us that patients are using the transmit functionality.

Paul Egerman – Businessman/Software Entrepreneur

So that would say that maybe 10% of hospitals have implemented it but of those, some percentage of the patients might be using it.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Correct. Yeah, and unfortunately the survey doesn't have data on the level of use at this point.

Paul Egerman – Businessman/Software Entrepreneur

Okay.

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

Well thank you very much, Jennifer that was very, very helpful. And we'll turn next to the CMS data update from Beth Myers.

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

So we'll be going through this rather quickly today, I understand it's a pretty packed schedule and I think there are probably only two slides in here that everyone wants to be seen. So, our current registration information, we did have 12,000 new registrants in March, which is encouraging and we are up over

310,000 Medicare eligible professionals registered for the program to date. That slide is very hard to see, but what I wanted to point out in this one is the Medicaid totals. We are now up to the 38,000 who have participated in Meaningful Use through the Medicaid program that is 24% of eligible professionals who are participating in the Medicaid program are now meaningful users.

Overall numbers, we're at 371,673 professionals who have been paid in the program to date, and that's our total number, it's over 22 billion. And this is an exciting percentage to see as well, we're up just under 95% of hospitals have registered for the program, so that's a good measure of full awareness and scope and beginning to be readiness, which I think plays into a lot of what Jennifer was just talking about. And we are almost at 91% of hospitals who have been paid, this is for Meaningful Use or AIU.

We have registered eligible professionals, but I want to move onto this one because we are up to 68% of eligible professionals have been paid for the program. That's just revisiting what I've just said. We did have 64,000 new participants attest for the 2013 reporting period. And here's what I think everyone wants to see. These are our 2014 attestations through May first. We have 225 eligible professionals who have attested for the 2014 reporting year that means that they participated during the first quarter that was available to them, 61 of them are new participants and we have 50 providers who have attested to Stage 2. We have 30 eligible hospitals who have attested for the 2014 reporting year, 8 of them are new participants and 4 have attested to Stage 2.

We have also received a number of hardship exception applications, I know that that's been a big question of how those are going. We had 72 eligible hospitals who applied before the April 1 deadline, this is for the 2013 reporting year, which links to the 2015 payment adjustment period. And 66 of the hardship exceptions were granted based on the documentation provided by those hospitals and 6 applications have been dismissed. I want to make it clear, that is not denied, that is dismissed, those 6 hospitals applied for it this year, when they didn't need to. We also have 600 eligible professionals who have applies to date. Just a reminder to everyone, the deadline for eligible professionals to apply for the 2013 reporting year, 2015 payment adjustment, is July 1, 2014. And with that, we'll go to questions.

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

Great, thanks, Beth. Any questions? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Great. Again, thank you very much, Beth, a good presentation. If I – I want to make sure I understand your slide number 12 correctly, that there are only 4 hospitals that made it to Stage 2?

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

That have attested to Stage 2 at this point, yes.

Paul Egerman – Businessman/Software Entrepreneur

And only 50 physicians.

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

Yes.

Paul Egerman – Businessman/Software Entrepreneur

And I'm looking at that in conjunction with Jennifer's presentation, it says like all the hospitals have this software, if I understood it correctly. So, with only 4 through the first seven months of the reporting year, my question is, is Stage 2 successful?

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

That is an excellent question. I don't think that we have enough data, again, to answer that question yet.

Paul Egerman – Businessman/Software Entrepreneur

So we don't have enough data to know whether or not it's successful?

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

I would say that we have a very slim amount of data right now. We have – we are encouraged by having people who have attested to Stage 2, given the anecdotal evidence that has said that no one will be ready. But as we have mentioned, there is, as Jennifer's presentation pretty clearly outlines, there are some functionalities that are required for Stage 2 that are not fully implemented across all facilities yet. So that's what we're keeping an eye on both on the ONC side and on our side.

Paul Egerman – Businessman/Software Entrepreneur

So it's really too early to tell if it's successful. There's a lot of anecdotal information. Is it also too early to make changes to Stage 2?

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

We would require any regulatory authority to do that, so that's not something that we can discuss in this forum.

Paul Egerman – Businessman/Software Entrepreneur

Okay. Thank you.

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

It's a little bit like how many people turn their homework in early.

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

Right.

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

I had one question, you said 66 hardship exemptions were granted. Do you know about what kinds of exemptions were those?

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

So it was a pretty wide range, I've asked for a review of them so that we can get some more data. I do want to point out this was using that first version of the form that we got out very, very quickly. And so we've made changes to the form and we're progressing to continue to do that. There was quite a bit of confusion, so we know that we need to provide more guidance. And we're actually getting feedback from those who've gone through all of the documentation as well. So, we have a project where they're basically going to help us figure out what were people confused about? What did people apply for? When did they apply for one version when they should have applied for another? Because that did actually happen a few times, that people applied for the wrong category. But when we scanned through all of the documentation, were able to grant that those 66 were all valid.

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

Great, thank you. Judy?

M

Paul?

Judy Murphy RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology

I'm understanding that there's interest and concern about the health information exchange. I know that Jen's shop just together a data brief related to health information exchange as it was reported in the American Hospital Association survey. So I might suggest, if the group thinks it would be a good idea, that next month she could report on that data as well, because I think it's quite informative in terms of the infrastructure that's being laid and the exchange that's actually occurring, which again might give some intelligence as to what's going on with Stage 2.

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

Great. Thank you, and with that – oh, go ahead.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

I would say, be happy to do that but also wanted to point folks, in the meantime, to several information products that are available on our dashboard website, so dashboard.healthit.gov. We have a lot of the data in more detail that I presented here today along with, as Judy mentioned, some more information on the health information exchange side of things as well.

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

Dashboard.healthit.gov?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Exactly.

Judy Murphy RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology

– send that out because I think the link to the data brief as well, because that was just published yesterday.

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

Right, thanks. Was that Neil?

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

No, it's Marc Probst. I just wondered, I don't have the data in front of me, of the 66 exemptions, were those hospitals or providers?

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

The 66 applications that have been accepted for a hardship exception are all eligible hospitals their deadline was April 1. The eligible professional ones are under review right now and their deadline is July 1.

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

Okay, thank you.

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

Michelle, did we capture the folks on the phone, I may not have –

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

Yes.

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

Okay. Great, thanks. Any other questions? Thank you Jennifer and Elizabeth for informative updates. We look forward to next month. Okay, next we're going to hear from the Certification/Adoption Workgroup. They had been asked to comment on the 2015 edition NPRM and will seek your approval for their comments, subject to any comments made here by the committee.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So good morning, everyone, we've got a pretty full set of comments to give you. We've got about an hour and a quarter so hopefully there'll be some time for some substantive discussion as we go through this. Before I forget, I want to thank Kate Black on the ONC staff, who's really been extremely helpful in pulling all this together and helping me and the committee stay on track for getting you material to review. So, it's been delightful working with her. Thanks to the members of the workgroup, we had some lively discussions and some of which are being remembered, I'm sure. And so we responded to 8 specific areas in the NPRM, and we've got some overall comments to bring with. So, we'll be going through these sequentially.

And I want to give one of those big questions that doesn't really have a clear answer, before we dive into the details. Because I think a lot of the time that the workgroup spent was actually in the tension between some great goals about wanting to have a learning health system, about achieving the Triple Aim and looking at the policy levers that are available to us. And wanting to use those to actually make a difference and use technology that has proven value. So, sort of, this is where we want to be, this is our vision, this is the goal that we're pretty much aligned to.

And then within that specifically, what is the role of the certification program? And as you'll see, there's a lot of sort of push-pull about if you do certification right, it looks like it can be helpful. If you do it wrong, you get things that add to everybody's workload and may not actually achieve anything of value other than we met certification requirement. So I'll pause for a moment so you guys can reflect on, so what are we trying to accomplish here, not for discussion, just a moment of reflection. We do – we're usually very charged to the agenda, so just a moment, where we want to wind up?

Okay, so the workgroup's supportive of ONC's intention to ease the burden of the regulations by having these more frequent NPRMs and to achieve governmental progress. Where we were concerned about is, for this to be successful it's all in the details and in some cases, we really didn't have either the time or expertise to completely dive into the details or we had some real concerns that some of the changes were less than incremental. And so you'll see that as we go through the specific responses. And one of the big concerns was around where there are new things that we would like to explore.

So we wanted to encourage, for example, to jump way ahead to the end, so this Blue Button Plus that looks to modify how view, download and transmit is done. And so there were some questions about whether we are trying to use certification as a way to explore something new or whether, in fact, the things we were looking to explore were already in use, and therefore would make sense to bring forward certification to say we've got a proven thing that we could work with. So, trying to get that balance right about encouraging innovations that are already happening, but not locking in things that are not really ready yet for prime time.

Yeah, so certification in and of itself has sometimes been described in ways that suggest that because it's certified, it will bring developers into the marketplace, and we didn't really see any indication of that. We have seen people using voluntary certification when their customers might not need it to create some kind of market differentiation for themselves, but that that in and of itself, really wasn't necessarily signaling that this was a proactive thing on the part of the vendors broadly.

We did feel that the interim NPRMs, if you will, these more frequent NPRM could work as a way to signal where ONC is going, where the other federal organizations are going, but we were concerned about false signals. So where there's real clarity within ONC and its federal partners about where we're going, then having an interim step could be really good. But if it turned out that too many of those interim steps became dead ends, then they'd be spinning up a lot of work that in the end didn't go beyond the initial NPRM, or the initial regulatory cycle.

We felt that the cost estimates – so we heard from one software development organization that the cost estimates that ONC was using were probably an order of magnitude low for what they had actually spent to get their product certified. So a suggestion that ONC reassess how it comes up with the numbers, but also our sense that there are two other large areas of cost that are not accounted for in the current costing effort. And those are provider costs to actually take the software on, make the changes to workflow, do the training, get it rolled out, and do the tweaking that has to happen to actually make it be useful. And that there's then ongoing maintenance, support and various kinds of subscription type costs that providers might have that don't get seen in the initial round of what we have to do, but over time, can add up. So these might be costs to acquire educational materials. They might be costs to have standardized vocabulary. They might be costs to implement interfaces or manage and maintain interface. So looking more broadly at what the actual costs were.

I also wanted to bring back our five-factor framework, because elements of this kept resurfacing in our discussions. And I would say that really in many ways the second one about aligning with existing federal and state programs, really seemed to be the one we felt that ONC and the other federal agencies, particularly other aspects of HHS, we would really like to see better coordination. So to way oversimplify it, because it just happens to be recent, there was the ERF Prospective Payment System NPRM was just issued and it had some reporting requirements. But those reporting requirements are not particularly aligned with the systems that ONC is certifying and it technologies that ONC is using for reporting. So it would be great to get their alignment around that.

I think that is an example, we could pick any of the – almost any of the mandated data reporting that the federal government has and is using alternate methods than have come through the certification process. Oh, I'm sorry, or inpatient rehab facility – it's my other – it's the afternoon presentation. My apologies and thank you for asking, Paul.

Okay, let's see if I can stay focused and on time. Incremental rulemaking, so increments are great if they're really incremental and if they're heading towards – if they're aligned with the future direction. So this really was the place where the workgroup struggled a lot of how do we balance these things off. And one person's sense of incremental might not be the same as another's. So, under the second bullet are some general guidelines that we came up with about what would be good certification, if you will. When have things matured enough that we know that the standards are beyond folks around the table in a ballot process, that this is a good idea to a couple of very tiny pilots to demonstrate its technically feasible to some real use examples.

So this is actually part of EHR that's providing care and it does well the thing that the standard was intended to help it do. So we'd like to build on a lot more existence proofs and ideally those have enough of a base that it's not just a onesie exception, but it's beginning to actually get a feel of, what is this thing. And where standards get prematurely locked in to certification, it then slows down the update cycle because now people have to meet certification requirements. And if they discover there are glitches in the standard, it's harder to do the balancing act of maintain the standard when you know you have to actually fix it to get where you want to be.

So we identified some areas that we felt were where we could get agreement and we thought were, in fact, incremental, so if there are changes to the certification process itself that worked out with the certification bodies and in fact is a small step in changing the process that would be fine. Where there are technical updates, fixes, including updates to standards, with the notion of like a point release. So we're used to major releases of software that bring big functional changes and then small adjustments, bugs get fixed, minor additions to workflow, functionality get brought in, but truly minor and error corrections.

And so we know that there have been some error corrections in the past, whether they're through an FAQ process or an issuing of, oh, this piece is wrong. And so an interim update cycle that actually pulled all that together might be helpful, so you're not chasing after a bunch of incremental notices, you've got, okay, this checkpoint everything's been pulled together. I have a stable place to check. We also felt that the extent to which the NPRMs are used to ask questions, that those were great things to solicit input, as long as it was clear this was more of a flavor of an RFI or advanced notice of proposed rulemaking and not strictly tied into updates to the regs and the certification requirements. Okay, so I think that hits the highlights on this one.

Okay, complete EHR, Steve Posnack and I had a side conversation about maybe we got some of our details wrong on some of this. So I guess a footnote to the workgroup process of we definitely spent a lot of time going through this. And there may have been examples of where having the right expert or the right specific piece of experience would have really clarified something. So in retrospect, one of the things that we were missing was, we didn't have the certification bodies represented on the workgroup. And they could have probably clarified some things about what the actual certification process is from their side of things.

And I think around complete, it was sort of the struggle between what we want to have and what we think we can deliver. So providers would like to know, I have everything I need at a technical level to achieve Meaningful Use. But that's a pretty complicated thing because it's got to be the right kind of provider, it's got to be which if any optional certifica – any optional Meaningful Use objectives you've chosen, right, and it's got to work in your environment. So there may be a lot of things that you need to add to make the thing work that makes complete a little bit of a misnomer. Even though in other ways, it's sort of technically correct, it met all of the checkboxes that ONC put together for the modules. So I think that there was some struggle about what this thing was. So the issues were, how do you continue to have this concept of complete without setting people up to be surprised, like it said it was complete, but now I need extra things.

Single versus multiple certifications, this was one of those sort of technical questions of, if I'm getting my product certified as modular and I've got 20 modules, does that mean I have 20 cycles through the certification body? Or no it's the same as if you had complete, there's one cycle through the certification body, but there are only fewer boxes that they're going to check that you achieved. So an area of maybe we're not creating the overload we thought we were creating. Clearly having separate process for CQMs, this seemed to really hold up finalizing a lot of the 2014 edition systems.

And I suspect these are going to grow more complicated before they get simpler, as we get better at creating truly e-specified quality measures that are actually integrated into the care process. It's a pretty complex, sophisticated thing to do that and do it well and have reproducible data that reflects the actual care that's given. But when you do it well, it's terrific, you don't have to have someone who periodically does chart abstracting to find out how you are doing, you can see moment-to-moment how you're doing and the process of submit – generating and submitting the quality measures should become really, really easy. But we're not there yet and so it seems to be slowing down a lot of the certification process because they're bundled now.

Continued sense of value in modular because people may just be buying pieces, especially people outside of the Meaningful Use Program, and even within the Meaningful Use Program, so jumping I guess to six, a provider might want to mix and match modules from different vendors. But right now it's not clear which vendors are selling modules and which aren't selling modules and if they only certified as a complete product, then my understanding is that today you have to buy the complete product, even if you're only going to use a piece of it. So, there may be some technical details to sort out in that description, but that's our understanding.

Number five is one of those tricky things of, we'd really like to have components that work well together, whether from one vendor or multiple vendors. And when the Certification Workgroup was first working on this four or five years ago, we decided that you can't really do that. The goal of testing for interoperability is really tough within a product that all the pieces are truly integrated and work well together, and testing across products, you get combinatorial explosion. There are thousands of pairwise things to check, maybe tens or hundreds of thousands of pairwise things to check. So it's a value, but we don't know how to execute on it.

And then if complete is discontinued, and this was one of those, actually was meant to be an update to the slides, we had some comments in our discussion that I couldn't figure out for my notes what they said, so I apologize that number 7 got left in here. But I think we had some thoughts about what to do on complete – trying to recognize the sense of complete is valuable, but how do you communicate accurately what it is. And so, for each of the seven, we've got further breakout, I think I've really hit most of the highlights here. Let's see, yeah, so we want to keep the idea, but we're not sure how to do it well. I know, you have the same problem, right? We talked about –

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

– question marks –

Larry Wolf – Health IT Strategist – Kindred Healthcare

Sorry, sorry, let's go back to question marks. Single versus multiple certifications, I think I've already hit the highlights on this. We want to keep it simple and not introduce added bureaucracy and cost, and it sounds like we may already have that option. Talked about separates for the CQMs, modular is valuable – should work together. They may certify components but may excel them in groupings of some kind. No, I guess the question mark was, even though they're modules, you could have – there could be enough modules to be complete. So that's I guess the flipside of when do you have a sufficient number to be complete.

And I guess I'm wondering, this didn't come up in our discussion but in the attestation process you get to identify all the pieces that you've chosen. I wonder if, in fact, it wouldn't be a useful function of the CHPL that you could pick and choose pieces and get some kind of macro assessment of the pieces you chose give you all the modules among them.

Certification packages, so this was an interesting swing in our thinking. At the very beginning, this sounded like, hey, this could be a good idea. By the time we got done we thought, it's just adding confusion. Partly the confusion was naming, that we had packages that were given names that were very close to the names of modules and so what was in addition to the module? And the line of thought that looked like it actually might be a value of packages, would be sort of like in the same way that complete has value. If you know what set of criteria you're trying to meet, what objectives you're trying to meet, and making sure you have the modules to meet those objectives would be a good thing.

So, on the assumption that one of the reasons ONC is looking at packages is that other federal agencies are saying, we would like to have software certified, and that this might be a way to group together the things that they're looking at as certified that there would be value in that. Of, there's an XYZ Program that CMS is running and if you're in that program, you need these 7 modules, so having a way to lump those 7 modules together would be a good thing.

ONC certification mark, this one was fun for us because it sounded like this was an issue between ONC and the certification bodies and so we were like, go for it, that that looked like something very straightforward to address. And our understanding is that this is about having a single certification mark that ONC would design and issue, and that the certification bodies would use as a way to say, this software has met the ONC certification criteria, because today the individual certifiers are creating their own marks.

We had some vendor comments about how they use third-party logos and that while some vendors prominently display the certification mark that they got on their website, others take the approach of, we only use our own logos in any literature about our own products, and so there wouldn't be any certification mark. And so as long as this is an optional thing for vendors, we had no vendor objections. And it seems like a nice clarification that everybody would have – be issuing the same certification mark for the same thing. And clearly some of the certification bodies have extended the kind of services they offer and that could be something completely different.

Okay, non-MU certification, here we're in an interesting naming thing. So, this is really saying, in order to meet a Meaningful Use objective, the software needs to count things for you, needs to generate numerators and denominators. And that if you're not in a program that needs those counts, you might not need that capability in a software and it might be simpler if the software didn't do it. So that's my understanding of what the intention is here.

Our first question trying to sort this out was, we didn't know what effect it would actually have on the market and in particular, the effect it would have on the cost of developed software. If you were starting from scratch and you were planning to do one or the other, then you can build these things in from the beginning or exclude it from the beginning, and that might reduce your cost. If you had to support both because you had some users that were in a federal program that needed you to count things and other customers that weren't in a federal program and you were producing two flavors of a product that were only different by this one feature. Then you potentially might be adding complexity, because now you have a feature that can be turned on or off and that adds complexity and cost.

And finally, that for some things, it's worth counting even if you're not getting paid to count them. So you might not be in a Meaningful Use Program but would still like to know how often an alert occurs and what a provider does about it. You might want to know how often CPOE is used. So those counts ,might actually be useful, even if you weren't in a Meaningful Use Program. So in general people felt that the goal should be to minimize the extra overhead that's created when instrumentation is added to the applications to maintain usability to get away from some of the problems in the MU1 software of check boxes being arbitrarily – seemingly arbitrarily added, so that things could be counted. But as those practices have matured, hopefully those arbitrary check boxes are going away and things are actually being more embedded in workflow and work process.

So, in the end I think our sense was, this was adding complexity and where it was intended to simplify things, we didn't think it would simplify things. It also added to our confusion, because as you'll see, we have a very similarly named, but very different topic about to come up. I think I've covered all of these points. Oh finally, the distinction might create confusion on the CHPL. So, it's one more thing to communicate on a pretty full website of, is or isn't doing the numerator counting that I would need if I'm in a particular program.

So, this one has a health IT stuck in the middle, but otherwise is the same heading. And it took us a while to sort out what was actually being asked for. And this was a good example of where some specific expertise probably would have helped the workgroup. So we spent a fair amount of time churning around what a children's EHR format is, so even though there were links in the NPRM that got us to useful documentation, getting there, reading it, understanding it, really didn't happen as fully as it probably should have. But it might, in fact, be exactly the kind of background work we'd like to see done before things come up for certification.

So there were experts around tables who defined child's EHR. There were some CMS – HHS-funded pilots, I guess HHS not CMS, funded pilots to try it out and there were some evaluations of that work. So that's exactly the kind of legwork we'd like to see happen as things move into certification, but we didn't really have time to assess any of the details of that. So it looked like a good process, but until we realized that, we were concerned that someone was inventing yet another immature set of standards that would be rolled out without understanding it.

Practice transformation though seemed like it was still – we're in a very early time period of figuring out what we need to meet the new payment reform directions and is a place where a lot of innovation is happening. It would be a great place to be learning from what's happening in the market.

Let's see if there are any other general things to address here. Yeah, so again a concern about increasing complexity, the more pieces and parts there are, the harder it is to keep track of everything and so as additional federal programs leverage what ONC is doing, clearly there will be more demand being put on the certification process. And so whatever is done through certification and how it's presented back through the CHPL, I think needs to give people clear handles on how do they manage the complexity for the programs that they care about. So having views that might allow you to see, oh, I'm in this program, this is the stuff I need to see, that you can set early as a filter, might actually be a helpful thing.

Additional patient data collection, so this was a good example of lumping things together. So we had 4 things that felt to us to be in many ways to be different, disability information, sexual orientation and gender identity, occupation and occupational history, and military status, military history. And we felt it was actually important that these be addressed separately and not lumped together. And that while traditionally these are seen as things that might flow into demographics because demographics have been the way that we look at populations. We slice and dice the information and can look at disparities, that we probably needed to expand the set of data that our tools let us slice and dice by and get more at what's in the chart itself. Sort of in the same way that the e-Clinical measures are beginning to say, we want to actually have data in the chart that drives the measure rather than having abstracters as people go through and tag things that a lot of these were very similar.

In addition to being useful around disparity issues, a lot of these are also selectively very helpful for care. So it may not be the case that every time everyone gets care, that any of these come into play. But it could be for certain individuals that they're hugely important, whether it's occupational exposure to things, whether it's involvement in military and exposure to the military the all kinds of things that create health problems. Disability, sexual orientation, gender identity in specific context all of these things are very important to the care process. But also in another context these are things that maybe are irrelevant to the process and shouldn't be on a demographic sheet because that information on a face sheet is generally very available throughout the care process and it is easily distributed and published if you will. And so, even though all patient data should be equally respected for privacy, we know that some is more or less effectively private.

So, here are the details on each of those. We also had questions about the data sets and the coding being used here, particularly on disability status, sexual orientation and gender identity. It looked like a lot of the suggestions were coming out of surveys and that surveys in many ways have a very different focus than that care process. And so, you may want to know different things and be asking different questions. And so this was another area where we felt there was a balance needed to be made between things that were being prescriptive because ONC was choosing something that maybe isn't a good something to choose and the need to move forward in these areas.

And so for disability status, we specifically said maybe this is an area where S&I Framework could be an area where things could be used to further develop what would actually be a good set of questions. Sexual orientation and gender identity, I think there even have been a note in the NPRM about IOM is working on this, so things are in process. And then something that came up in some of our discussions, which I think is really a good point, which is as much as we're saying we want to see standards that are in use before they get sort of locked down in certification criteria that they didn't need to be used widely by everybody. If they were used in a specialty area and demonstrated their value, so people had worked out the kinks of how is this useful as a coding system. That that might very well be enough of an experience base to expand them beyond that initial use, that they didn't need have to have a similar broad-based pilot before they moved on.

I'm also reminded of the wide variety of providers we've got in this country and we could very well have pockets of things being used very heavily that are not in our general awareness. And so I think in some of the early days of ONC, there was a lot of discussion about finding bright spots and I think that's probably still really good advice is, go find places where people are making these things work today. And those are the things to try and generalize.

Military service, as much as DoD and VA have had very public lack of interoperability and a continued push for interoperability, we felt like this was a good example of, there's already information out there. Maybe the best way to get this is not to ask the patient, but with their permission, to ask DoD and VA for information and be able to import that information. And finally occupational data, I think this was a great example of given the right clinical situation, you would really want to know it. But in many cases you don't care or some passing information is plenty like, do you mostly have a desk job or are you hauling heavy objects around all day? What chemicals are you exposed to? All those kind of things and that over time, having history here becomes really important. But again, capturing history might be complicated and there was some discussion about even having the right technical structure to capture good history wasn't as obvious as people might think on the surface. So this was one of those, get the details right before you roll out a methodology really broadly.

Blue Button Plus, so we know there have been some great examples of Blue Button being used really well, and people getting a lot of value out of it. Most of the discussion here focused on trying to move forward the view, download and transmit capabilities and the NPRM talks about the complexity of the current transmit process and that maybe Blue Button Plus is a way to simplify that process. And we felt this was a good example of let's get some serious pilots going to know the technology really works and addresses the problem. We have what looks like an underused feature or an unusable feature, depending on your perspective at the current moment with transmit. Earlier data presented showed very low adoption, but we don't know why there's low adoption. Is there low adoption because consumers don't care? Or is low adoption because it's too complicated? Or there's low adoption because – we don't know, so, a good area to do more exploration and to allow the marketplace to innovate and find those examples and bring the spotlight to them.

And the extent to which there is evidence of, this is a good way to do it, then certification becomes a great way to help communicate to consumers that the thing you're going to do has been through a formal process. And at least it doesn't have obvious problems, technical problems or privacy and security problems. And I think that's the end. Okay, let's get to the list.

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

Okay, thank you Larry. I think I'll open up with a comment that it struck me, I'll go back to the complete HER question, question, question mark.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Um hmm.

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

And I wonder, as you are talking about the workgroup discussion, it sounded like people were ascribing a different purpose to the MU certification than to another kind of certification. It sounded like potential purchasers wanted the reassurance that they had something that could function for patient care, and in addition, comply with satisfy the Meaningful Use. That almost, and I'm going to use one organization's name, but want to talk about more generically, the CCHIT, which actually was created specifically for that purpose, to try to give reassurance to a purchaser of an expensive system that is expensive to implement, to say that this would be comprehensive and satisfy your needs – your clinical needs.

I think people are looking, particularly with the complete EHR designation, for that same purpose. And yet Meaningful Use, and I think most of the regulatory certifications are more of a floor and were never intended to be a comprehensive certification. And I wonder if that is a distinguishing point we should talk about. So if you think about ONC certification for Meaningful Use, versus let me describe the other one as a market enabling certification, the "CCHIT model." Then we might have two buckets and be able to think of them a little bit more clearly. So if regulations are really to look at floor certification that meets some programmatic need, what's an example of a programmatic need? We – in order to understand how healthcare is delivered in this country and what disparities arise, you need to capture certain disparity variables that may not happen on its own by market forces. So that's an example of a regulatory certification requirement. It's analogous somewhat, I think, to like conditions of participation, that is, in order to be a Medicare – to pay – to get payment from Medicare, you have to meet certain conditions of participation. That doesn't describe all the things that you do, it's just a floor that has some programmatic benefit to the public.

If we think of that – if we think of the certification in that bucket, regulatory floor versus the comprehensive market reassurance, then we might be able to answer these questions more clearly. So if I were to answer that question about complete EHR, I probably would say no, if I used that bucket, because we were never set up to either prescribe, specify a complete EHR. And so the confusion that it generates in the market might be because we've labeled something that satisfies – people want it to satisfy a different purpose that the program was not designed to meet.

That – so the government certifying things to meet “conditions of participation,” may be the private sector like a CCHIT model, should be set up to meet the market-enabling conditions. I think that question or concept may apply to a number of these questions that you tried to – that your group provided sine feedback on in terms of 2015 NPRM – 2015 edition NPRM, which is an MU-enabling certification or regulatory certification. Does that concept make any sense to others and does it help? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Great, thanks Dr. Tang. First, let me briefly try to respond to what you just said about the complete EHR. When we discussed that in the workgroup, we understood that there was some confusion around the word complete and did not want to have the expectation that it's complete in terms of like taking care of patients. But there was also a concern that consumers or purchasers, really wanted to know, am I buying anything I need to buy in order to achieve – in order to get this Meaningful Use incentive payment? And so that's where we saw the value.

I did want to circle back to your entire presentation Larry, and first I just want to say, thank you for your presentation and also thank you for the job you did in leading the group, this was not easy. The Certification and Adoption Workgroup met in a very intensive schedule and we had spirited discussions on a number of topics. And it's hard to describe why they were so spirited, sometimes when you get into technical issues, people show more passion than you would expect, but things were very spirited and Larry and Marc Probst did a terrific job in guiding us through that and maintaining their patience, I appreciate that.

As I look through your presentation sort of in retrospect, I wish we could have just focused on the certification process, instead of trying to deal with some of these specific items like Blue Button Plus or military coding. That that might have been something some other workgroup could have just as easily or not easily, but just as well provided feedback on, so it seems like it would be thinking forward to separate out the process from the content might be very – certification process itself and the content might be beneficial.

I also had one observation that Larry did not include in your comprehensive presentation, but one of the things about this 2015 edition certification NPRM is, it is really hard to read. It is really hard to read and figure out what it says. If you look at the regulations, it's over 200 pages long. The regulations refer to other regulations and then they refer to these things called implementation guides and you have to read, if you really want to figure out what it's going to cost and what – you make a comment on it, you have to read through all of that material. In at least one case it refers to an implementation guide that hasn't been published yet, or hadn't been published as of like 2 weeks ago. And it's really hard to make an informed comment on something when the specification hasn't been published.

And, in making those comments, I would say that this is a process in which a small vendor doesn't stand a chance. It is total – it's like almost impossible for a small vendor to read through all of that stuff and be able to comment on it, and especially if the vendor wants to like write a single module of the total process. I don't know how a small vendor is supposed to do that and I don't know how anybody is supposed to do it when you refer to implementation guides that haven't been published yet? That means that people have to participate in the balloting process itself, in order to make comments and understand what's going on, which sort of suggests the only people who really know what's in this 2015 NRPM are like the insiders who put it all together. It's very hard for anybody else to know what's going on.

So, I meant that as it relates to – that comment as it relates to small vendors. But I also make that comment as it relates to the more foundational issue that Larry is raising, which is, there's a lot of material here that's just never been done before, it's totally new for EHR systems. And to take things that are totally new and untested in like real, on the ground environments and to do a national rollout through certification is at best, dangerous. And it's especially dangerous when you think that the ONC is now going to put its logo on each one of these things, you have to wonder, what does it mean when there's a government logo on a certification regulation? What is the expectation of the purchaser? Do they understand that this is some technology that has never been used before?

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

Thank you. Troy?

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

Thank you. Paul, thank you very much for the explanation, I appreciate that. I mean, it did clear up some of the things that I was thinking of, but I have to look, I go back to slide 11, on point 5. And you spoke of integration and I read this paragraph and it's a little counterintuitive. I mean originally it says provider's value components that work well together, but then later on it says ah, its complex and we really shouldn't test or certify for it. The problem I have with not testing or certifying for it, I mean testing – certifying maybe, I mean that's pushing the envelope, but at least testing for it.

The ultimate goal, reflecting on your first question, to ponder is that we're really supposed to be sharing information and that data needs to be shared. Well how do we know that it's a viable product, if we don't at least test for that integration? And then we get into level of interoperability, yeah, I understand small vendors will struggle with that, but at some point we have to say, okay, we need to start integrating this data, it needs to be shared. And if we don't insist on that happening, or at least go through the steps to see where the gaps are, we'll never make headway on this whole thing.

So again I mean, the frustration goes right back to what the providers said, they value components that work together, not just internally, but externally. I mean, there's a big push to say, okay, you need to share this not only with the patients but other providers, with other hospitals and not just report it for MU purposes but actually share it so that we have a more healthy population across the United States. And a much more integrated healthcare system, that's what I see as the ultimate goal in this and without doing that, we'll never attain it.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yeah, well this was really responding to the notion of the way in which the modules work together functionally and how they might integrate into the workflow, so clearly important issues within the provider organization, but a lot of those – the usability issues hinge on how a particular provider chooses to implement something. I think the broader area of information exchange across providers was an area where the work group really felt very clearly that those were things we should push forward on and is an area where certification can be very helpful, because it creates clear standards, clear distinctions. And in fact in the past, where certification created optional – optionality in the standards that that was probably a bad thing because it said if you do A or B, then your system has to do A and B in order to handle the information. And a single standard sort of like VHS versus Beta, we didn't actually have players that played both, right, the battle got fought and in the end, one won and now everybody streams. And so –

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

That is true.

Larry Wolf – Health IT Strategist – Kindred Healthcare

But I think that the issues that you're raising about the goal is to improve care and coordinating the care requires sharing information and that requires clear standards and that's a thing certification can help with.

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

Right. And even if you think about within provider practice, just like anything else, I mean, I have a lot of tools in my shed, I don't buy one type of tool, I buy a number of tools from different manufacturers and they all have benefits. One may build it a whole lot better than the other one, but when I bring them together, the ultimate goal is, I build a house. So I think that's really along the lines of – it's kind of a simplistic analogy but, when you look at the whole thing, I mean providers and hospitals, they need different tools and some are built better than others for different purposes. And if they all don't work together, you're never going to achieve the goal.

So even looking at that lower level, those modular testing, from one to the other, those have to share the information. I mean, I think about now we're delving into home health and the information that's captured in ambulatory area, in the hospital area, that's integral to that home health period of care. And if those systems don't communicate, well, then it's all done by paper and everybody has to review it again, print it out, hand it to them. They'll go to the patient's house and do a comparative analysis and then they'll enter in their own system, print it out and give it back to the people when they go back to the ambulatory clinic. So anyways, that's what it's all about. Thank you.

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

Thanks, Troy. Judy Faulkner?

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

I thought this was a very interesting presentation, thank you, Larry. And one of the things I did note, because I went back and looked at everybody in the committee there. You had 60% providers of care – direct providers of patient care, and 12% software developers and I think that brings a list of interesting and challenging aspects of everything that we're doing there, that they see through different eyes. And I wanted to say that I think that's really important and as much as the Policy Committee could keep adding people from those two backgrounds, I think that those who actually personally develop and those who personally provide care, that will, I think, be helpful.

The other thing, Troy is I don't know, when you talk about testing the different products, are you thinking that the healthcare organizations would do that or the vendors would do that?

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

Umm, well I think it should be something that is validated by a third-party entity. I think in-house, you have the availability, as a vendor or as a manufacturer, to assure that it is communicates within your own house, and you have a very large integrated system. But what about those other companies that are building separate modules for specific purposes? Those – we need to have assurance as customers that when I buy that, that that information will transfer across, at least in some shape or form, that way we begin the wheels turning on that interoperability, which we seem to struggle with all the time.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

I think we get into the combinatorial explosion that Larry mentioned earlier, when we try to figure out how do we put it all together that way. And I think your point is a great one in that the standards for interoperability are too loose. We were talking with folks recently about HIE standards, the problem that appears to be there is, you'll have a whole bunch of vendors we'll say and the program to the standards. But there are lots of different standards, so they don't talk to each other because one programmed to this standard, another to that. I was told just the other day that there are about 20 different standards and they're programming to different ones. So, if – we can't test them all as a vendor because there are too many combinations and you can't test them as the provider, because it may be too difficult for you. Then if, in fact, people can concentrate on let's get those 20 standards down to one, then you're going to be much better off in making sure it all works together.

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

Agree.

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

Deven McGraw.

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

Thanks. I hope so since mine was up and Devin's wasn't. So I think I want to clarify what the Certification and Adoption Workgroup is asking from us, as the Policy Committee, because this is part of an open comment period, correct. Because there are definitely sort of streams in this thinking that I would agree with, but some that I'm not so sure about, I'm not sure that I wouldn't – that I agree that there's not a role for incremental voluntary certification. And between you're – so I want to know sort of what we're being asked to do?

And then I want to make an observation, that I – in terms of sort of the comments that are in here, I too think certification should be lean and mean, and focused on the things that have been tested and that we want to make sure are in every system, and particularly with respect to interoperability. Having said all of that, we're also trying to use the Meaningful Use Program to sort of steer providers in a direction where the market hasn't been before, which means a lot of times we're looking for functionalities that in fact haven't been widely used and widely tested. And how do you strike that balance, especially since what you get paid for, or what you get penalized for in the future, it's Meaningful Use of certified technology.

So we have a bit of sort of hands tied problem with respect to where – what – how we want to use Meaningful Use as a policy lever and where, in fact, the technical functionalities are in the standards. And it's just going to be this continuing sort of battle about how we approach this, but I think it is well reflected in these comments. But my question is really about, what are we being asked for here? How can we move forward what this workgroup spent a lot of time doing, but without, I'm not sure in terms of sort of Policy Committee consensus, that we all have our heads in this as much as they have had, to get there.

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

I think you articulated both the problem and the challenge very well, Deven. Instead of battle, let me describe it as a tension and try to come up with a balance. But you're also right that we can't just rely on what's been done in the past, otherwise we'll get what's been done in the past. We renamed the new workgroup sort of a combined workgroup as Advanced Health Models and Meaningful Use of this technology. It's to point exactly in the direction you describe.

So to answer your concrete question on what is expected of this Committee in the remaining time. So they've presented – Larry's done a great job of summarizing the discussion, and you see both sides. Ideally we do have a sentiment that we can reflect back to ONC, otherwise we haven't done our job in terms of providing recommendations. They still digest it all, they've heard it, they've been part of the workgroup deliberations, but in a sense, it would be nice for us to come down one way or another and not leave the four question marks. So it would be nice, just like in Meaningful Use when we respond to the NPRM, we did come back with a response and was reflecting both sides, but then giving a sense of direction. So, it would be nice if we could give a direction in response to the 2015 edition.

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

Oh – Karen –

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

Karen.

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

I mean I would be comfortable saying that the Pol – conveying these sentiments of the workgroup and making sure that they get passed on, but I – but since – getting consensus on all of this, I think would be an enormous challenge.

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

Well, that's why I called it a sentiment.

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

Yeah.

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

So for example, you offered a sentiment that was a little bit in contrast to what the workgroup was saying in terms of let's stick with things that have already been thoroughly tested, etcetera in the market, instead, hey. Let's remember we're also push the edge and pushing towards a direction that has been set by both Congress and HHS, in terms of the new models of care and payment. And we need the infrastructure to deal with that – to address that.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So if I can jump in with a comment that came up many times during the workgroup, it was where there is a policy driver, so if Meaningful Use says we're doing this thing, then it's clear that there should be – in many cases, clear there should be certified technologies to support the thing.

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

Right.

Larry Wolf – Health IT Strategist – Kindred Healthcare

But the concern in the workgroup was, if we're just spinning up interesting technology –

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

Yeah.

Larry Wolf – Health IT Strategist – Kindred Healthcare

– because hey, wouldn't it be cool if, that that probably isn't helpful. So we were sort of nuancing, but maybe sidestepping the question at the same time.

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

Point Karen?

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

If I may, this is Karen DeSalvo for those on the phone. The comment period is closed for the NPRM, but we still have the opportunity to receive the sentiments, the comments, from the workgroup via the Policy Committee. And we would welcome them even if we're unable to come to a sort of single set of consensus, there may be a way that we can move it forward because there was a lot of time and talent involved and I think it's worth having all the input.

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

Okay. Gayle.

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

Yeah, I'd like to just play a little role of legislator here and when I hear this discussion, I'm sorry I missed it, because I was having a disaster at my office, I missed part of the discussion. But I just have got to step it and say, I have sit in the seat – I sit in the seat of legislator and when you authorize rulemaking, you are authorizing it based on the legislation that was passed. So you have to go back and say, within the legislation, what was the intent of certification? And is certification – is the role of certification to drive innovation, or is to make sure that those who are purchasing a product have the ability to meet the standard that is set? And that standard is truly set within Meaningful Use. Because it's a – there's a – you must, in order to receive payment under HITECH, you have, I have purchased a certified product that meets Meaningful Use, and I am meeting – I am meaningfully using a certified product. That's what the basis of everything this committee does.

So truly your innovation, as I read the legislation, takes place through Meaningful Use. You want to use the drivers, the leaders that you have within Meaningful Use to drive innovation, to set that – to give the market the ability to do something. We have a secondary system out there for voluntary certification that is a provider wants to go and know, I need to this kind of aspect. I want to make sure maybe CCHIT has certified that, but I want to know when I purchase it and certification has – mandatory certification to get paid, has to meet what I – what Meaningful Use says I need to perform.

And I think we have got – we don't understand what the role of certification is, and Larry started that whole conversation with his beginning comments, and you are so on target. What is the role of certification? So that's the conversation we need to have and you look within the legislature – within the legislation, you need interoperability, you need the ability to communicate and transfer information from this site to that site to that site, that's what, to me, the basic conversation of certification needs to start around and the workgroup needs to have that focus. When you go back, what is rulemaking? Rulemaking is the implementation of the legislation. So all this conversation really has to come down to, what do I need to get paid, to meaningfully use my certified product, at the end of the day. That's – and NPRMs, advanced NPRMs, need to help facilitate that all helping, so vendors and users are at the same table to make that determination.

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

Thanks, Gayle.

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

My comments, for what they're worth.

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

Thanks, and Jodi, you were going to comment on this?

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

Yes, thank you. This is Jodi Daniel and Steve, feel free to jump in if you would like to kick me under the table from afar. So, there are two separate authorities, one is the Meaningful Use Incentive Program and one is our certification of Health IT. And in order for a provider to – or hospital to receive the incentives under the Meaningful Use Program, they must use certified EHR technology. So, it is a necessary requirement for the Meaningful Use Program. The certification authority that's given to ONC, is broader. It doesn't only apply to the Meaningful Use Program, and can be used – must obviously support the Meaningful Use Program, but also enables us to certify EHR technology for other purposes. And enables us to certify a broader set of Health IT than just the EHR technology we've certified for Meaningful Use.

So our authority is broader, which is why later, when we have the conversation about voluntary certification for providers that are not eligible for the programs, we have that authority to expand our certification and use that lever for broader purposes. We are broadly charged with supporting Health IT adoption, innovation, etcetera, so it is within ONCs mission to certify technology for other purposes beyond the Meaningful Use Program. I'll just ask Steve if he has anything to add to that. Okay.

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

Okay. David Bates?

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

Just to respond to Gayle’s point about what certification’s been good for and what I think it has not been good for. I think it’s been very good for breadth and vendors have added many pieces of functionality that they – that it might have taken them a long time to get around to adding. Specifically many things like population health, they just would not have done that because they’re client base were not asking for that. What it has not done is to ensure that the individual chunks really work well or do exactly what you might want them to. So, you – we make sure that there’s an allergy module, but not that the right allergies are there, that has to – that had to be done separately.

And we’re now at a, I think, a kind of transition point. Now people have adopted and they have records and now what we want to know is, how can we use those records to really make things better? So, going forward, we’ll have to have some more functional tests and some more ratings of records, which won’t be 01, it won’t be do you have it, do you not have it? It’ll be – we need some things about how well does it actually work?

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

Great. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Great, thank you. It’s Paul Egerman. Just wanted to respond to the comments so far, I mean first, Deven, Deven McGraw raised a good point by her right, which is sort of to say, well, just how much testing is necessary? And that is a discussion that is a valuable policy discuss that we haven’t had. And I don’t think I could tell you exactly how much testing is necessary in any situation, we’re actually going to hear an example of testing this afternoon, when you present on the whole issue of 42 Part 2, and that was a valuable thing to have done, because we have some information.

But the comment is, there are many things in this 2015 edition that have never been used, I mean, just never been used. We can’t have something that’s been used when the implementation guide hasn’t been published yet. It’s just it’s very clear it hasn’t being used and there are some concepts that are totally new for EHR systems, like the unique device identifier. And all I’m saying is, it sort of relates a little bit to what David Bates is suggesting and – which is, you talk about integration of how these things are supposed work together, well you’re not going to find out how they work together unless you start using them in some real environments before you try to certify them.

And I also wanted to comment on what Gayle said about the use of certification for innovation. To me that’s like exactly the right issue to be raising, because what I see a lot in this NPRM, and a lot of desire of the people around this table are, is to come up with really good new ideas to sort of move things along. And that’s terrific that people want to do that, but certification is not the right tool, by itself, to do that. I mean, I don’t think the way – it’s a comment that Judy Faulkner made before, the way iPhone was created was not through a regulatory certification process. This is not how you create certification. It needs other vehicles first and those other vehicles have to include some sort of like on the ground, real world testing to find out if something works, before you do a nationwide rollout.

Once you’ve done a nationwide rollout, the expense is dramatic. The expense to all the vendors in this country to implement something is significant. And if you do that and then you say, well let’s see how it works out and next year we’ll try to fix it with another incremental change in case it doesn’t work, that’s a slow and expensive way to do innovation.

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

Thank you. Judy Faulkner?

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

I wanted to comment on innovation as well. I think Meaningful Use really helps with getting a baseline across vendors. You do run into, as we've been talking about, unintended consequences that could be hard to fix. Innovation, however, and I'm agreeing with what some of the other folks have said, is really not coming from certification. How do you do innovation? Innovation, I think, comes from two things. First of all, it's a new technology that comes out and you jump on it. So when the iPhone does come out, how do we work with the iPhone to jump on that and make that work with our software? FitBit comes out, okay, that's kind of cool, let's see what we can do with FitBit. We've been testing the Google glasses, those are all things that are innovation that start not from a committee, but start from somewhere, somebody doing something clever that we pick up on, and say, ooh, how do we make this even better?

The second place innovation comes from is when we meet with customers and we go over the software with them, sometimes they come up with a great idea that because we have gone from one customer to another to another, we can tell this one will work, that one might not. And so we then zero in on some creative ideas coming from customers themselves that we can evaluate, because of our gut feel having worked with so many. Those I think are the two places innovation comes from.

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

Thank you. Karen?

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thanks, Paul. This is a bit of a non sequitur, but related and I just want to be certain that the Policy Committee and those who are listening know that we are in a – we have taken on the important challenge of fixing our certification process. And that, to use Deven's words almost, it should be leaner and nicer as opposed to meaner. So, we're working on the timelines, the cost, the burden, all those issues and trying to understand how we are a much better of a regulator and supporter of the floor and/or don't get in the way of innovation, to Judy's point.

We have two hearings, they start tom – well, a hearing starts tomorrow and will continue on through Thursday, and so, maybe Jodi can help us know exactly how to find the information on the certification hearings. But we are actively receiving input in a formal and in this kind of a process. So, I've also been listening not just to the 2015, but to your comments about our rulemaking process, our certification process and so I just want to reassure you that we know that it could use some fixing and we've been working on that.

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

And just to let folks know, the hearing is here – tomorrow it is here and it's at 9 AM.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Same time, same bat channel. And is it a phone call in or no?

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

Yes.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Okay.

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

The public – for the public, it's on the FACA calendar like all of the other meetings, so the public number will be listed there.

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

Devin Mann.

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

I guess Judy's comment about innovation and Deven's thoughts about being focused but also pushing the envelope a little bit. From the operation side and kind of implementing things, I would say that there's probably a role for policy in innovation as well. I would say there is a third bucket to – I totally agree with the two that Judy brought up. But, in setting a bar higher in a certain area that we're not focused on, has really at least in my experience, generated a lot of innovation. Maybe not always through certification saying exactly how to innovate, I agree, that can be stifling, but setting a bar and saying we need to focus on this area, I've seen a ton of it innovation coming up trying to reach that.

And often it's not an area we would have thought to go first, but because that bar is there, and David brought up population health, and I think that's a perfect example. It just wasn't necessarily in our bandwidth, but because the bar is there and the vendors have started putting things together that are useful, we are now really pushing the innovation envelope on that side. Both on my research program and on the operation side, and clinically we're – I was in a series of meetings just last week in the primary care clinics, all the clinicians are sitting around saying, we need to do this and let's think of new ways to get there, that take the technology that's there, but also push it. So, I think there's probably an important role for us to kind of push that as well.

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

I think that's an excellent addition to the two that Judy brought up and an excellent example. And I could maybe piggyback on that in terms of disparities, something that was caused – recording variables that can be used to measure and stratify by disparity variables is very useful and then you apply population management. So, these are areas where we're setting a different bar, it was – it didn't happen naturally, but it is in line with advanced both care models and payment models. And so I think it's a really useful comment. And it goes back to focusing on the what more than the how, and I think that's one of the biggest complaints that the vendors had was, if we step in. And as Karen mentioned, we're in this hearing tomorrow and the subsequent recommendations would like to try to focus much more on the what and leave the how's alone, because I think that's where it's treaded on waters that have not only been frustrating, but somewhat stifling. Any final comments – oh, Art.

Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health

Yeah, thank you Gayle for bringing me back to look at legislation because I went back there and started reviewing the focus on reducing health disparities that Paul just mentioned, improving public health, increasing prevention, coordination with community resources. And I think that Judy's comments about innovation and the opportunities with these new technologies, are ones that were focused on the market forces that push us to consume some things that are then opportunities, like FitBit or the phone. But some of these items that are in the legislation really don't have those FitBits. Like, what's the FitBit for disparities or public health?

And I just think that at some point in making our decision about is it a complete EHR, or modules, that these outside the EHR ecosystem that we have to be thinking about. And in my community, in the public health community, we're trying to get up to speed, to be part of this Meaningful Use. It doesn't mean that it's about just the certification, it's about creating the environment that the certification can permit us to address these items that were in the original legislation. So, I look at this as the complete EHR is maybe ideal, but I think the modules and figuring out how to do what Troy was saying, how to get to testing this. And I understand the combinatorial issue is big, but we need to figure out how to do the interoperability. That's the piece that I hope that as we talk about the modules, we say, there must be this interoperability to move forward, otherwise this module's not really serving our needs.

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

Okay, this was really a rich discussion, very helpful. To answer Deven McGraw's question again, I think that if – I mean, I thought the words on the slides did a nice representation of the discussions you had in the workgroup. If we – append the comments, somewhere in the comments received in this committee, I think that expresses both the perspectives, but also sentiments that can help inform ONC as it goes forward. And that combined with what they hear from the hearings tomorrow.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

I'm just interested – this is Karen DeSalvo. I'm just interested Larry, was there as much discussion in the workgroup about the need for interoperability and certification and standards around that as there was around this table today?

Larry Wolf – Health IT Strategist – Kindred Healthcare

There certainly was. A lot of that came up in the context that we'll hear this afternoon on behavioral health, long-term post-acute care. So I think the workgroup members probably felt like we've been down that, we've been saying that, that one of the clear areas where certification has clear value is in interoperability, especially between providers, that's been a focus.

Paul Egerman – Businessman/Software Entrepreneur

I'd like to say, in the discussion about incremental rulemaking, we clearly said we liked doing things as related to interoperability and also in terms of data definitions, which relates a little bit to what you're suggesting Paul, Dr. Tang. Because some of these issues about healthcare disparities have to deal with like how you define different ways to sort of slice and dice the data to order to evaluate it. So we said yeah, that part is good. It was the major functional changes that people objected to.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Would you put clarification of things like race, ethnicity, gender, sexual orientation as a data definition or is that –

Larry Wolf – Health IT Strategist – Kindred Healthcare

So I think the sense for all of those were, they're important things to capture the data, that we wanted to focus on that the system should have the ability to capture it, but not necessarily identify, this needs to go into demographics or needs to go somewhere else. And there are some references in existing Consolidated CDAs to some of those fields, and so where there's already a method to move them, that we have some standards either identified broadly, as in a template or specifically in terms of a dataset for naming things that should be built on.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Um hmm.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Am I answering your question, Karen?

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Yes you are, thank you.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Okay.

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

Okay, Larry does that – do you think you have enough guidance?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yes, I do. And I'll probably be going over recording and the notes from ONC as I look to add some material to these, and my sense is, that's the desire back. That is, to update this with some of the additional conversation we had today, so that ONC can have a summary of not just where the workgroup was, but also where the Policy Committee as a whole was.

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

That would be perfect. Thank you.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Okay, and I'll get that circulated to this group, so where I've shortchanged something you think is important, you can have some input before we lock em up.

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

That'll be very helpful and I know they're expecting it very soon. But thank you Larry for guiding the enormous work that went behind this and guiding the conversation and presenting it. Thank you.

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

Okay, and our final update for the morning is Jodi Daniel talking about the FDASIA report that came out. And, as we mentioned earlier, there'll be a Task Force that David Bates will lead to provide a response, similar to this, to that report. I wouldn't call it an NPRM, but it's their report to Congress.

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

Great. Thank you very much. So, I just want to remind folks, particularly folks who may be newer to the Policy Committee that we had a – this Policy Committee and a very large workgroup providing input to ONC and the Department as a whole, that really helped to shape our – the draft report that came out. And so we thank you all and we look for your wisdom and guidance as we move forward in thinking about some of the specific things to implement, as well as finalizing the report.

So, the report was released last month and I mentioned it at the last Policy Committee meeting and folks were interested in a fuller presentation, so I'm back today to walk through the details of the report and what we put forward in collaboration with FDA and FCC. I also want to acknowledge that we did work very closely with the other federal agencies, it was a true collaboration with FDA and FCC. And Steve Posnack, who just walked out of the room, I'll probably be leaning on him, he'll jump in and help correct me, kick me under the table if I say anything or if he wants to add to anything I've said.

So just by way of background, and I'll try to go through some of this quickly. We started down this path because we obviously are focused on how we can leverage health IT to afford benefits to the healthcare system and to patients, more specifically, both in improving healthcare quality, reducing errors, reducing costs and increasing consumer engagement. But we know that whenever any new technology is introduced, there are great opportunities for improvements, but there also can be new risks that come from this. And we really wanted to make sure that as we're rolling out health IT on a – nationally, that we're thinking about what those risks might be and how we can mitigate those risks, as well as thinking about where there are opportunities to leverage health IT to improve safety. We kicked off an effort with the Institute of Medicine, where we have some representatives here that participated on that, to look at this for us. And they gave us a series of recommendations. And that was great background for the report that we did.

So, how we got to this report was that the FDA Safety and Innovation Act had a section in there that charged the FDA to work in collaboration with ONC and the FCC to develop a report that contained a proposed strategy and recommendations on a risk-based regulatory framework that does two things. It promotes – well, three things, promotes innovation, promotes safety and avoids regulatory duplication. And that was supposed to be for all of health IT including mobile medical apps. So, really small charge, no big deal, we just could do that in a backroom – no, not at all. We were – the legislation specifically said that we can convene external stakeholders and experts for input. We thought that that was a really wise idea and we wanted to leverage the great group we have here, the Policy Committee, to pull together that workgroup and to advise us.

So just again, refresher, the Policy Committee FDASIA workgroup, we had 29 members and 3 ex-officio agency members, the largest workgroup we've ever had, because we were trying to get as diverse a group as possible, but keep it as manageable as possible to actually get to some recommendations. David Bates was our Chair, did an amazing job of trying to pull together all of those different perspectives. We had three workgroups focused on taxonomy, risk and innovation, and regulations, to focus on the areas that we needed specific input on. And these were designed to be recommendations to the agencies as we put together a framework. We did not ask the workgroup in the four short months that they met to develop the framework, but really to give us input that we should consider in developing that framework.

We also simultaneously had opened a docket in the Federal Register to get public comment more broadly. So while all the meetings were open to the public and public can comment at each of the meetings, we specifically solicited public input. Some of that input if it was received early on, was given to the workgroup for their deliberations, but the agencies did consider all of that input in developing our framework. So this is our FDASIA committee membership. Again, thanks to David for his leadership.

And here are some of the key workgroup recommendations that went into the report. I'm not going to go through all of these, but highlight a few that really did help shape our thinking. First was that the scope should be risk-based oversight and based on functionality. And I'll talk a little bit more about that when I talk about what we put forward in the report.

The – also the recommendations included that the agency should address current deficiencies, ambiguities and duplications. There was an indication that substantial regulation beyond the current FDA regulations was not necessary, and we took that to heart, and you'll see that when I talk through the different categories that we established and the kinds of oversight that we're proposing. And lastly I want to highlight that there is a strong focus on creating a learning environment, which is also a key piece of the recommendations from the Institute of Medicine report. And this, again, was one of the areas of focus in our draft report.

Just a couple more, these were some of the public comments that we got, they were very consistent with what we heard from you all, but a couple of other things to highlight. The public commenters suggested that we categorize health IT into different kinds of categories, administrative, clinical and medical device, and you'll see that reflected in our report. Again they focused on functionality and a learning environment, and also they suggested that we should be – that the framework should be flexible enough to accommodate evolving technology. So not to be so precise and so prescriptive that as technology emerges, it's not clear what the right path is for oversight of that new technology, but to have enough flexibility for technology that develops, that we might not anticipate at this time, to fit within that framework. And we think we've – we've tried to do that.

A couple of side principles that we worked from in report was first that we employed a risk-based approach to mitigate patient safety risks while avoiding unnecessary regulatory oversight. This was a huge focus, both of the charge to us as well as the comments from the Policy Committee and the public. We wanted to leverage private sector knowledge, experience and expertise. So there are clearly roles for government in protecting patient safety, but there are also important opportunities and roles for the private sector. And we wanted to make sure we're leveraging that expertise, experience and knowledge and not trying to do everything by the government, but to figure out how we can have partnerships with the private sector.

We wanted to facilitate innovation, again, we focus a lot on safety, but in thinking about safety, we also wanted to think about innovation and how we can balance those two. Promote transparency on product performance and safety, this was again another focus that came out in the Institute of Medicine report that we focused on here as well as from the Policy Committee. And then finally, this is a theme that keeps coming up and that we believe very strongly is creating an environment of learning and continual improvement in order to have a culture of safety, and not just a regulatory schema for patient safety. So, first I want to highlight that report, I want to say this, let me say this like three times, is a draft. It is a draft that is out for comment. We are looking for input and we're providing many opportunities to do that, including through this committee, through public meetings, through a public comment process, etcetera. So, this is a draft for comment and we really do solicit and look forward to comments from various different stakeholders.

Okay, so, let me start getting into the meat of it. So as I mentioned, we talked about functionality, we talked about categories of health IT functionality. So, first is my FDA colleagues have said in the past in presenting this, no – any categorization is going to be imperfect, there are always going to be questions on the edges on what falls into what bucket, and that is a challenge. But I think it's also a reality when we want to be able to be flexible for new and evolving technologies. That said, if there are things in here that are unclear and that folks want clarity on, I encourage you all to submit comments on specific functionalities that we can weigh in on and hopefully provide some clarity. So please give us feedback on that.

So let me talk about the three categories. The first is administrative functionalities, this is admissions, billing and claim processing, scheduling, analysis of historical claims data and things like that. And in this category we sort of just put it off to the side and said, no additional oversight is required. We're not – there's very low risk and we sort of put it off to the side.

On the right side, the blue column, medical device functionality, this is the functionality that FDA has been historically overseeing through their regulatory process. So things like computer-aided detection software and remote display or notification of real-time alarms from bedside monitors, this is real-time alarms. Radiation treatment therapy planning software, so these are things that FDA has traditionally regulated, that they have products that are regulated currently and they will continue to oversee and regulate based on their current regulatory schema and authority.

So the report focuses primarily on the center bucket, this green column called health management functionality, health management/health IT functionality. This area we see as mostly being efforts that

ONC would help lead, in collaboration with the private sector and where we hope that we'd have public, private partnerships and collaboration to try to address these kind of functionality. So this is primarily the types of functionality that are part of our certified EHR technology. So if it's – so provider order entry, medication management, electronic access to clinical results, data capture and encounter documentation, the kinds of things that we primarily talk about in this room, in this group. And this is the proposed focus of our Health IT framework.

Now one point I want to make is that we are talking about function, not product. So when you look at the report, you won't see the word EHR and it falling into one of the buckets. The reason for that is that people use labels to mean lots of different things. There are billing functionalities that are part of EHRs, and that's in the red category, the administrative functionality. And there could be some functionality that's currently regulated by FDA that somebody combines in an EHR that people think about as a traditional EHR. The one important point to note is that just because there is something that is part of an EHR package that may fall in that blue bucket, in that medical device functionality, it does not make the entire product something that would be regulated by FDA. It does not, let me say that word again, and does not make it regulated by FDA. So we would look at it functionality by functionality and a functionality that falls in that blue bucket would go through FDA oversight and everything else would not.

The one piece of – one area where some more clarity is needed, and I'll talk about it at the very end, is clinical decision support. This is an area where FDA has some medical devices that could be called clinical decision support, again, we have a labeling – people use that label to mean lots of different things, and they are looking to provide some more clarity in that space. And there is a piece of the report that talks about some of that line drawing. The workgroup and the Policy Committee did recommend that some high risk – some particularly high risk clinical decision support should have some additional oversight, but that a large majority of clinical decision support would fall within this green bucket. So that is an area that some more clarity could be given.

So in looking at this, we identified four priority areas for that green – for that center column, for health management/health IT. The first is promoting the use of quality management principles, and I'll go through each of these in a little more detail. The second is, develop – identifying, developing and adopting standards and best practices. The third is to leverage conformity assessment tools and finally, creating a learning – an environment of learning and continual improvement. We also talk in the report about creating a Health IT Safety Center. This primarily falls in that last bucket of environment of learning, continual improvement, but there may be some aspects of the other priorities that could be supported by Health IT Safety Center, so that's why it's represented across the bottom.

So I'm going to go through these a little bit quickly, because I know we're short on time – we're short on time. So first is quality management principles, and this is something that is done – it can be used throughout product development – throughout the product lifecycle to help identify, track, manage, and mitigate issues, not just in the development process, but also in the implementation, customization and use of health IT. The proposed action we have here is for the agencies to work with health IT stakeholders to identify the essential elements of a health IT quality framework and leverage existing quality management principles and identifying areas where quality management principles can or should be applied. Again this is an area where it additional feedback and input from stakeholders would be very helpful and how we can leverage existing frameworks, existing quality management principles and standards to support these different areas of health IT lifecycle.

So the second priority area was standards and best practices. So, consensus standards, I mean this is something we talk about all the time and this group can provide requirement specifications, guidelines or characteristic to help ensure consistent use of processes and products. The conclusion that the report made in this draft report is that this is really an important area for us to focus on, to make sure that we have high-quality health IT products and services and that they're implemented in a safe way. There were five areas that were specified as focus areas within standards and best practices. First was Health IT design and development, including usability. And usability was something that the Institute of Medicine also spent some time focusing on. Local implementation, customization and maintenance, interoperability, quality management and quality systems and risk management. I'm going to talk about two of those.

So first is interoperability. So this was an interesting conversation I remember having in the FDASIA workgroup, was interoperability as a mechanism to both promote safety and promote innovation. That if you have true interoperability that it allows people to innovate on top of that. It also helps to ensure safety by making sure that the right data gets to the right place without being – with data integrity and the like. So this was an area where it – working toward interoperability can actually help both pieces of that equation. The proposed action was that – the agencies recommended that entities be identified to develop, test and validate interoperability, test product conformance with standards and transparently share results of product performance to promote adoption of interoperable solutions. Now of course we have – we do that through our own – through ONC and through our standards development processes and our regulations. And we're also looking at the private sector to see – to try to focus on where we should paying attention and who can help to do some of these things as well.

Next – the next one I wanted to focus on was best practices for local implementation, customization and maintenance of health IT. This goes to Troy's comments and the Certification/Adoption Workgroup discussion about integration of systems. And I think this is an area that could be really key to help promoting safety and helping to develop and have widespread best practices for implementation and use of health IT. And I think the integration of the systems could be an area where best practices could support as well.

The third category was conformity assessment tools. So the conformity assessment tools like testing, certification and accreditation can help provide assurance that when we have best practices and standards, that products and services meet those standards and best practices. So, how do we assure that not only we have the standards and best practices, but that we can demonstrate conformance to those either buy the products or implementation of those products? We concluded that the tool should be use and applied in a risk-based manner to distinguish high-quality products, developers and vendors and organizations from those that fail to meet a specified level of quality, safety or performance. And we're seeking public input on areas where non-governmental, independent conformity assessment programs could be developed to fill current gaps. We also, of course, have our certification program and that's something that we could leverage as well, but we're looking at how we can leverage the private sector to do some of this as well and again, there may be some connections with the Safety Center.

And the last category was the environment of learning continual improvement. So we – the Institute of Medicine report specifically encouraged us to think about health IT safety in the context of the entire sociotechnical environment, that it's not just is a product safe, but you have to look at how it's developed, used, implemented, maintained, customized, etcetera, to see how it's – to ensure its safety. And we also know that from the Institute of Medicine report and from our own information that we've gotten from other stakeholders, that we don't have great data at this point about the risks, about the opportunities, about mitigation strategies, what's worked and what's not.

The recommendation here that we put forward was that we wanted to have the public and private sector work together to help develop a culture of safety, to develop transparency and continual improvement and to develop a culture with shared responsibility and better defined accountability. So we proposed in this report the creation of public-private entity, a Health IT Safety Center, that would serve as a trusted convener of health IT stakeholders, government and nongovernment alike, identify governance structures and functions needed and to help create this learning environment and have better information and better communication about some of the best practices. We talked about the Safety Center doing three things, to focus on engagement, bringing the right folks together to the table to have those conversations, to have those folks who are implementing the systems, developing the systems and regulating the systems to be able to work collaboratively and thinking through the best way to promote safety innovation.

We also, as I said, there's – we have a limited amount of evidence at this point and the evidence is sort of dispersed throughout different organizations, systems, PSOs and the like, trying to get better evidence, trying to bring that information so with better knowledge, better analysis of data, etcetera, to help support the efforts of different organizations in improving safety. And then finally education, so where we see that there are some good practices or opportunities, how can we leverage a Safety Center to try to educate folks to follow those best practices, to understand the risks, etcetera.

Currently we do have some funding that we've been – some efforts that we've been funding on safety that I just wanted to highlight. Focused – two of them are focused on the analysis of information. We're working with the Joint Commission to look at their Sentinel Events database for health IT related events and to provide us a report on their findings, as well as to develop some educational material based on those findings. We also are doing analysis of health IT events in two large patient safety organizations, PSOs, and expect to get reports from them as well. And we've put out a tool called the SAFER Guides, which are evidence-based and provide basically serve as a risk assessment and some recommended practices on health IT safety in nine areas of known risk. We are finally directly on this point, at the Safety Center we have engaged a contractor to help us do a feasibility assessment of the Safety Center and help us think about how we might organize the Safety Center effectively, and we should have some findings from that soon, that can help advise us on our work going forward.

I'm not going to read through these, you have them in your packet, but I wanted to particularly highlight in this environment of learning, some of the questions that we specifically asked in the report for input and that we'd – of course welcome your input on as well as this committee. And the last thing I wanted to highlight, as I mentioned at the beginning is the comments in the report on clinical decision support, as this is, I think, an area where there's been a lot of confusion of who's in charge and what kind of oversight mechanisms are in place.

As I mentioned, this is an area where the Policy Committee had recommended to us that there may be some high risk clinical decision support that may pose safety risks and that we should have oversight of and other things that may not. This is what we put forward in the report, the two different categories, and I used the same colors here, the blue and the green for health management functionality and medical device functionality. At this point the way we have it proposed, health management – health IT functionality that would be called CDS. And therefore not within, again not within, FDA's regulatory oversight are things like clinical order sets – clinician order sets, drug-drug interactions and allergy alerts, drug dosing calculations, drug formulary guidelines, preventative care reminders, access to treatment guidelines and calculation of prediction rules.

Again – so I'm probably not going to be able to answer questions on, if you throw out specific type of functionality and where does it fall within these at this point. I encourage you to give us those as comments, so that we can bring it back with the FDA and have those conversations and try to provide more clarity. The FDA has specifically said that they do not intend to focus their oversight on the health management functionality piece of this, that they will focus on the medical device functionality and they are really looking for private sector input on how to draw those lines and how they can provide some more clarity in this space.

I will leave with our next steps, which is that there is a 90-day comment period, it ends I believe July 7, so please do provide formal comments and give us some specific examples that you'd like some clarity on. There is a public workshop next week, May 13 through May 15, is the agenda – Steve, the agenda is posted? Okay, the agenda is posted so you don't have to show up to all three days, you can show up to those days that you're most interested in. Fortunately for some or unfortunately for those downtown, it is up at NIST, which is up in Gaithersburg, so plan to spend the day and have fun with us. We will be there all three days. The workshop will also be webcast, you do need to register both for the webcast and for showing up in person, because it is a federal building, so if you're planning to show up, please do register so they will let you in the building. And here is the website that you can receive – you can get a copy of the report. And I will open it up for questions.

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

Thanks Jodi very comprehensive report of the draft. I have one quick – on usability suggestion, one – the color code you use, if you could do green, yellow, red it would fit cognitively, green is not touch, red is – The HIT Safety Center –

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

I don't know if the FDA wants there –

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

Okay, green, yellow, blue, I don't – it's just hard – every time you said it was hard to match, for some reason. The HIT Safety Center, you list – you didn't explicitly list – so a couple of things in the IOM report was the NTSB model, which gave them the ability to essentially mandate getting data, which I know you can't do. And the other part was to analyze the – to investigate and come up with lessons learned. I didn't see that explicitly here, you did mention Joint Commission doing some analysis, but is it your proposal that it incorporate that investigatory – the lessons learned kind of function?

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

So at this point, we, one that would require – that would probably require additional authority for us to be able to do investigations, that's not something that ONC has done. There were also some concerns about that role and how you would – how that would be done given the volume of potential safety events and the overlap with patient safety organizations, who do do that work. So that based on our proposed, we do have a proposal in our 2015 budget for a Health IT Safety Center, I don't think the level of funding that's proposed would necessarily enable a full investigatory process nor do we have – we believe we'd have the authority at this point to do that. So, that isn't contemplated at this point.

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

Okay, but it's something you'd be open to feedback on potentially?

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

We're always open to feedback, Paul.

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

Okay, Devin Mann was first.

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

Thanks Jodi, that's really a great overview and I agree with, I think, most of the principles, but one of the things that strikes me is this comes under the umbrella of patient safety and at the end of the presentation ends there with this Health IT Safety Center. But a lot of the functions you're talking about, I mean the initiatives are much bigger than safety. So when you talk about implementation principles and local customization and innovation, all of these things are things that on the operations side, goes way beyond what we usually define as patient safety. Like you have committees about patient safety, you mentioned JCAHO, patient safety – these are very much patient safety things. And I'm just wondering how that's going to tease apart because if you use that patient safety lens, and that's I think where this is all about. I just want to make sure that you're not then constraining the work that we do that's way beyond patient safety and trying to apply our larger innovation in practice redesign to safety standards? Does that make sense?

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

I think so, I think. It would be interesting to hear more about the specific concerns and what kind of specific pieces of what you're doing that you would want to make sure was not subsumed. I mean, this is focused on a framework for safety and innovation and it is – so I don't think so. But if there are particular concerns, I'd be interested in hearing what they are, to make sure we don't overstep or cause unnecessary –

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

Well in particular, some of the slides about like quality management principles –

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

Yeah.

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

– so that's a much bigger tent than safety in and of itself, we try to apply those things to lots of other development. You mentioned under standards and best practices proposed action, so health IT design, and development usability. We're doing research in agile development and all the kind of design principles, safety is not the number one concern in that development, and it probably shouldn't be, at first. There are kind of tensions there and I'm trying to figure out how – and if I felt that tension was under the umbrella of a Health IT Safety Center, the prioritization of what comes first, I think would be different than if it was in my hospital's kind of practice redesign group –

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

Um hmm.

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

– versus its safety group versus its research group and so a lot of these things you're talking about, local implementation, customization and maintenance is not always about safety issues.

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

Right, a fair point.

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

And so I that's – I don't know if it's a terminology issue, and it may be, but I'm interested to see how that plays out.

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

Okay, so maybe we just – this is helpful insight and maybe we need to be a little bit more clear and kind of putting some – around it.

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

Yeah, and if your point is to be just about safety, then I would make sure throughout that it's focused on safety. If you really mean to be bigger than safety, then we have to think about that word and how it's used.

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

Yeah, yeah, that's a fair point. I mean it is safety and innovation and – but that's something I'll take back. Thank you.

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

Right, and you mention the FDA, which is obviously a safety thing, that's what I associate with that –

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

Yeah.

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

– but then you use that word innovation again, which – safety is a piece of innovation, but it's just a piece.

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

And I'll just add a little bit, so the IOM report did include all of these dimen – the implementation and follow up as part of – a significant contributor to lack of safety.

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

Right, and so the question I have is, if you're saying there might be other things that are part of implementation that don't go to safety or innovation and you – might be separate, is that?

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

The principle – the kind of best practices for implementation are not necessarily always the best practices for making sure safety is there, first.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

This is Jacob Reider. Shouldn't maybe – and if I have a new idea for how to implement and it's inherently unsafe, doesn't that make that new idea not such a good idea?

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

I think it's easy to say, of course – it's like the patients come first. Yes, safety's always important. But in terms of more proximal indicators of how we start developing and how we start doing things, we obviously don't want to kill people, but I think we often can be constrained. So JCAHO's a good example, often we develop the JCAHO standards because safety comes first and you do exactly that. But often that same kind of safety can be had by taking a different approach and not focusing so much on safety first and actually giving us a little bit of space to innovate, and then always keeping safety in mind and then you'll end at the same place, but get there very differently, I think.

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

So does that argue for when we're thinking about quality management practices – best practice – quality management principles, best practices, etcetera, that we should be looking more broadly so that we're not limiting the thinking to just safety because you may need to balance some things? Like we're trying to balance –

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

Yes –

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

– safety and innovation or –

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

I think so.

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

Okay.

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

I think if that's important to you –

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

(Indiscernible)

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

– If you're trying to be broad, then I would include a broader tent of kind of principles. If you're trying to be specific to safety, then that makes sense, then just make sure that the language is specific.

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

Thank you.

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

We have two constraints to manage under, one is, we will have public comments before we adjourn for lunch or take a break for lunch. And two, we have to start by 1:15, because Dr. Koh has a time constraint. So, the discussion – we are going to have a Task Force, and you can volunteer to be on that Task Force, to respond.

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

Oh, there you go –

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

See, you love this committee, right.

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

Right, and you all know how to find me, so if you want to give me personal comments, I'd be happy to listen.

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

No, these are really good comments and this is – it's an open book, ONC will manage the HIT Safety Center and really do look forward to your comments. And as I said, please volunteer for the – either submit comments to Jodi or us or join the Task Force to submit formal comments. Is that true of David as well?

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

If you're interested to joining the Task Force, if you could send me an email, I'd appreciate it. Thank you.

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

There's only one person to send an email to and that's Michelle. And then it'll get done. Any other final words? Thank you, Jodi that was really helpful and a very comprehensive report. Okay, so like to open it up for public comment please?

Public Comment

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

If there's anybody in the room that would like to make a public comment, please come up to the table. As a reminder public comment is limited to three minutes. And if we could open up the lines as well.

Rebecca Armendariz – Altarum Institute

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

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

It looks like there's no one in the room, so operator, we'll wait for you if there's anyone on the line.

Rebecca Armendariz – Altarum Institute

We have no comment at this time.

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

Thank you very much. So we'll take a break until – we will resume promptly 1:15 PM, because Dr. Koh will be making comments to us and he has a time window to follow. So, thank you very much.

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

If everybody could take their seats. Thank you, everyone, welcome back from lunch, I'm going to now turn over to Paul.

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

Oh, okay, thank you. And thanks for coming back pretty much on time. So, Dr. Howard Koh is Assistant Secretary for Health at HHS and wanted to spend some time talking to us a little bit about behavioral health needs. Dr. Koh?

Howard K. Koh, MD, MPH – Assistant Secretary of Health – US Department of Health & Human Services

Thank you very much and thank you for having me join for a couple of minutes by phone and let me thank the committee for giving me this opportunity to just say hello to you. And to thank ONC, Dr. DeSalvo, Joy Pritts and also acknowledge my advisor here in the Office of the Assistant Secretary, Sarah Wattenberg, who helped to arrange this call. And I'm here to spend just a couple of minutes with you chatting about behavioral health and how it overlaps with HIT and just give you some perspective from where I sit as the Assistant Secretary and as a physician and as the Co-Chair of the Behavioral Health Coordinating Committee for HHS.

You may know that when this administration began, the Secretary charged Pam Hyde, the administrator of SAMHSA and myself to start a behavioral health coordinating committee because we all felt there are so many issues related to mental health and substance use that weren't being addressed department-wide. And we've been very pleased to do this over the last number of years in the era of health reform and we've been also very pleased that health reform has talked about truly transforming the health system and integrating so many parts of the system that have been fragmented up-to-date.

I'm a physician who has cared for patients for over 30 years and I've seen for myself how fragmented the behavioral health system or non-system is. We have almost 20% of American adults suffering from a mental health disorder, almost 10% struggling with a substance use disorder, most of them are not receiving the services they need and deserve. And so with the Mental Health Parity Act, the final rules being completed by the end of last year and of course the Affordable Care Act, we now may have some 62 million more Americans having access to behavioral health services. And that really represents a stunning transformation for our country. And we have people who are suffering from behavioral health conditions who have lots of comorbidity, high tobacco use, high obesity rates and often die much younger than the general population. And so these are issues that we're all aware of as Americans. Issues of mental health and substance abuse affect every family that I have seen, that's from the perspective as the Assistant Secretary, and especially as the Co-Chair of this Behavioral Health Coordinating Committee.

So that's why I want to chat with you for 2 minutes today, because I know that until now, behavioral health providers have been largely excluded from receiving incentive payments through the Meaningful Use EHR Incentive Program. And I know this department and many in the country would like to encourage behavioral health providers to adopt certified EHRs that are interoperable with the one's being adopted by the general health care sector. We want behavioral health providers to be included in the transformed health system. And then we want patients, most of all, to feel like they're being taken care of in a patient-centered way, not in a fragmented way that we have endured up to the present time. So I am hoping that this committee can weigh in on this and really talk about including Behavioral Health dimensions in their discussions about what's considered an interoperable system for the future.

Now I know there are many special dimensions to this in terms of promoting exchange of behavioral health information. I know there are additional privacy protections that have to be honored, federal privacy laws. And I know that there are also state laws in addition that limit sharing of information related to mental health and other sensitive health conditions such as HIV. I mean, we're talking about information affecting some of the most vulnerable in our society and we all recognize that. So we would love to have this committee not view that as an insurmountable barrier, but as an issue that can be addressed and overcome with a lot of collaboration, cooperation and working particularly with the ONC Standards and Interoperability Framework data segmentation for privacy initiative. It's my hope that if we do that in collaboration with ONC that we can explore inclusion of standards for certification criteria for EHRs that include the exchange of behavioral health information.

So as I close, I just want to thank you for this couple of minutes of time and just thank you for letting me share my perspective on this. It's something that I and many of us feel very, very strongly about and I hope you do, too. I mean, you really can't be healthy unless you have your emotional well-being as well as your physical well-being, I think everybody agrees to that. And the Affordable Care Act really represents a transformative opportunity to really change the way we care for patients and treat them as – in a really patient-centered way. Until now, we have not had a lot of progress on including behavioral health providers in this evolving system, I hope this is an opportunity where we can now include such providers to the benefit of the system and to patients themselves.

So I hope you can take this opportunity as an advisory committee to really tackle this issue head-on, give it your utmost consideration. Consider the standards developed by ONC as part of any certification that your committee would recommend in the future. And I just want to thank you for allowing me to express some thoughts with you today. Thank you very, very much.

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

Thank you, Dr. Koh. Did you have time for comments or questions?

Howard K. Koh, MD, MPH – Assistant Secretary of Health – US Department of Health & Human Services

(Indiscernible)

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

Go ahead.

Howard K. Koh, MD, MPH – Assistant Secretary of Health – US Department of Health & Human Services

I think that's about it.

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

Okay, well you introduced the whole afternoon for us perfectly.

Howard K. Koh, MD, MPH – Assistant Secretary of Health – US Department of Health & Human Services

Okay –

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

We are going to concentrate – yup. Thank you very much.

Howard K. Koh, MD, MPH – Assistant Secretary of Health – US Department of Health & Human Services

Thank you so much for your time.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thanks Howard.

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

So, he did a great job introducing this afternoon's topics and covering the two that he highlighted, one is interoperability being – having the behavioral health community providers and their data be part of a more integrated system and with the attendant privacy and security concerns to address the special needs in privacy and security for this type of information. Karen, did you want to add anything in terms of the voluntary program?

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Just to underscore what's been said, I mean I think from a health standpoint for our community, and more specifically for the goal of the three-part aim for HHS about lowering costs, giving better care and improving health. Being able to see through standardized ways the health of the population in behavioral health sphere and long-term post-acute care, dialysis, other parts of the healthcare continuum is really important. And so in response to figuring out how we can enable and support that, I think this afternoon is going to be talking a bit about some opportunities to use technology to do a better job of standardization of captured data. And doing it in such a way that's private and secure that meets needs and expectations and allow us to get a more holistic picture of the patient than we've been able to get heretofore. And so as we go forward, this is, I think, a real opportunity for us to make a difference more broadly in people's lives. Thanks.

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

Thank you. And we've always consider privacy and security as one of these foundational pieces and no more is true than – well, it's true in – especially true in behavioral health. And so we're leading off with the Privacy & Security Tiger Team talking about something that actually wasn't in the charge, speaking of our legislation, to look at data segmentation as a possible way of improving the privacy and security of this information. And – yes, please.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

I heard him say privacy and – I heard him say interoperability and then we have to recognize privacy and security. And as I heard him, and maybe I heard him wrong, I heard him say try to figure out how you still take care of the whole patient – honoring those rules, but you still need to take care of the whole patient and that's a good challenge.

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

It's a challenge. That's why there was a spe – yeah. That's why there was a special Tiger Team for this and it was called out as a special – recognizing that it's tough as a special challenge in our original HITECH legislation.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

But it does takes us different from saying, here are the rules, let's just figure out how we do them to, here are the rules, let's figure out – I mean I think there are two different mental approaches you can have to this.

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

(Indiscernible)

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corpora

We can talk off-line.

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

Okay. Okay, Deven McGraw and Micky Tripathi.

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

Okay, great. I am – Micky, are you on the phone?

Micky Tripathi, PhD – President and Chief Executive Officer – Massachusetts eHealth

Collaborative

Yes, I'm here.

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

Terrific. So just want to start off by acknowledging the members of the Tiger Team, who are a very consistent and hard-working group through the years. We have a few additional folks from when we just started, but a real nice core of people who have really hung in there through some difficult discussions, and this one is probably right up there with some of the more challenging ones that we've had to talk about. But we have never back down from a challenge, this is what we like to do.

'So what I'm going to do today is give you an update on discussions we've been having in the Tiger Team with respect to a conversation that began with a presentation from the Certification and Adoption Workgroup in our last committee meeting about certification to enable the exchange of behavioral health data. And for us, in particular, that's the issue of how do you provide the protections for that data while still enabling it to be exchanged in order to care for the whole patient. We're not asking you to endorse recommendations today, but we do want to give you a sense of sort of what we've seen, what we're – what the tenor of our conversations have been to date. Because we would be very interested in getting feedback from you all as we move into what will be the last two sessions where we will consider this issue and we aim to get you final recommendations in June.

So this is just a repeat of a slide that you've seen before from the – initially presented by the Certification and Adoption Workgroup where they had initially put on the table that – the idea of having a technical functionality to be able to honor rules around behavioral health data, ought to be present both with respect to any system that's used by a behavioral health care provider who's directly subject to those laws. But also subsequent providers, because in particular, and as I'll discuss in more detail in a minute, the rules around how you handle certain types of behavioral health data essentially attach to that information and flow down the chain and we have to try to figure out a way to honor that. So that question was teed up specifically for us to address.

So first I want to explain a little bit about what these federal rules are, we won't go into a huge amount of detail on them, but everyone should have a background level of information in order for you to understand both the challenges and the opportunities that we have here. So 42 CFR Part 2, otherwise known as Part 2, applies to federally assisted substance abuse treatment programs. So if you are holding yourselves out to the public as providing substance abuse treatment programs, you are more than likely going to be covered under this legislation. Because it even – attaches even if you're – the extent of your federal assistance is that you prescribe controlled substances, that you have the license to prescribe. But you also have to holding yourselves out as providing substance abuse treatment programs. So an ordinary provider with the license to prescribe schedule 3 substances, no; a provider holding themselves out as running a substance abuse treatment program with the ability to prescribe those substances, is covered.

In addition to anyone who is in fact receiving money to treat – from the federal government to treat patients with this disorder.

So it has a pretty broad reach and if it covers you, you need a patient's authorization in order to disclose identifiable information from one of these programs. And there are limited exceptions, but they're not the HIPAA-type exceptions, it's not a general treatment exception. You need to be able to get the patient's authorization to share data, even for treatment purposes. And then once that information is disclosed, the recipient of that information, even if they themselves are not a Part 2 covered provider, needs to also honor the commitment made to the patient that their information won't be redisclosed without further authorization from them. So it has a fairly broad reach and has an important set of rules that have been in place for many, many years.

The other thing to note is that if in fact you've got information that's disclosed among providers who are not covered by Part 2 or let's say the patient introduces this information from – either verbally or sending information from a PHR that did not originate with a Part 2 covered program, so it isn't covered by these Part 2 rules. Now having said that, you may be provider operating in a state where you have state law constraints that provide sort of additional – that set up additional requirements for requiring the patient's specific authorization to share a certain type of data. Mental health data is commonly covered by state law and what that means – now, usually those laws don't necessarily have redisclosure pieces to them, but if you're exchanging within the same state, you're essentially exchanging with providers who also have to abide by that obligation with respect to when they disclose that data. So that's generally the sort of a very small snapshot of the legal environment that we're dealing with here.

This is not the first time that both the Tiger Team and the Policy Committee have thought about the issues of sensitive information requiring additional consent and how you handle that with respect to health IT. Way back in the early days of the Tiger Team, when we were considering issues of consent generally, in 2010, Paul will remember this, I called it the summer of consent. We started to address this issue and we also had a hearing on data segmentation technologies and found at the time, that the technology at that point was promising, but still in very early stages. We urged ONC to make this a priority to explore further in pilots, which they did. And in the interim, there were lots of opportunities for education, both of consumers and providers with respect to execution of consent decisions, what does that mean for the patient. Are they making these decisions in a knowing way? Do they sort of understand both what the implications of that are? And similarly on the provider side.

So now I'm going to sort of take you through some observations that we're beginning to make that are informing some of our discussions here. The lengthy discussion that's in that 2010 letter, which I just summarized for you, it also acknowledges the very sort of difficult issues that arise in this space from a policy context. Clearly, the need to provide coordinated care for these individuals to treat them, to treat the whole patient, not to sort of have separate silos for one part of their health information versus another, or at least have coordination where the silos can talk to one another, is incredibly critical. And I won't reiterate the very eloquent words of Dr. Koh and also Dr. DeSalvo about how important this issue is. And we knew that back in 2010 and we fully acknowledged it.

And the requirements that are in these will laws that require the special consent are not aimed to make people's lives miserable or to make things difficult, but to in fact to ensure that with respect to sensitive conditions, the patient's trust the system enough to go in and seek care, which might be very stigmatizing to them. And so they are given additional controls on how this information can be used and disclosed, so that they will not avoid seeking care because of concerns about who's going to see that information and how it might be used and how widely is it going to get out to people.

However, of course, the ability for patients to withhold consent to disclose any information relevant to care is of great concern to healthcare providers. Providers want to provide the best care for their patients and they have concerns, which both stem from their professional and ethical obligations to their patients, but also their concerns about possible liability, about incomplete or in the words of one of our Tiger Team members, Swiss cheese records. And there certainly is no difference in the technology enabled records environment where patients, for years, have not necessarily told you everything when they're sitting in front of you and your treating them. But there – I think we have to recognize that in an environment where we're using electronic health records, there may be heightened expectations about just how complete the information is in those records, even if that is not necessarily a match with reality.

So where is this data, the technology? Where – what was piloted? What does this technology look like? Well we took a look at this technology and it's essentially – it's called Data Segmentation for Privacy, or DS4P, was an initiative of the S&I Framework. There were 6 pilots that were launched to test this technology and so it wasn't a small initiative, it was actually quite substantial. And we wanted to understand a little bit more about how it worked and what have been the experience in implementing it so far. And so we had – we didn't have a hearing, but we invited a number of people to talk to us on Tiger Team phone calls, this is the list of folks that we heard from. Two – in particular, you'll see two vendors up there from the – from two of the pilots, a representative from a particular health information exchange that's dedicated to behavioral health information and then we were aided by staff from the Substance Abuse and Mental Health Services Administration, otherwise known as SAMSA.

So what did we learn? So what happened before all these pilots came about, what did providers do before the wonderful age of technology? Well, in the paper world, there were always – providers always made an effort to honor patients' rights to consent consistent with the law, by basically redacting the information or just omitting it from any record that would be sent where it was possible. This was less than perfect, inferences from other data are always possible, that will probably also be true in an electronic context as well. Leakage, data that's in notes, but not necessarily in the standardized data field that is probably mo – that's no – I mean, standardized data fields are in technology, but certainly if there – even in the paper world there was information in notes that might've been redacted out of sort of a summary document.

Some HIEs will not accept information from Part 2 providers, we've heard this actually fairly consistently across a number of issues where we've had health information exchanges talking to us, because they have concerns about the ability to honor the legal requirements. And so we are seeing these sort of private health information exchanges that consist of largely behavioral health care providers so that they can at least – they and providers who might not be covered by those rules, but who are very interested in receiving that data, becoming part of an exchange that enables the sharing of this data.

So how does this work in terms of DS4P technology in particular? Well, the behavioral health care provider, the entity providing the substance abuse treatment services subject to Part 2 and the enhanced authorization requirements, obtains the required authorization from the patient to disclose the information to another care provider. This gets honored in the technology through a tag that's on the C-CDA or if there happens to be just an individually disclosed data element, the tag can apply to that data element as well. So that when it's coming from the behavioral health care provider, it'll be noted in the payload and/or the metadata that the document is restricted and cannot be redisclosed without further authorization from the patient. So the authorization comes from the patient, yes, it's okay to send. And so the behavioral health care provider has what they need under the law to send the data and they send it, but they, per requirements of Part 2, tag it with the restriction that the data can't be redisclosed without the patient's further authorization.

On the recipient side, if that recipient provider is using the data segmentation for privacy standards, they have the capability to view it, so read-only. But the C-CDA or the data with a tag on it cannot be automatically, and here's, pick your verb because people use different terms to describe this, it can't be parsed, consumed or interdigitated within the EHR. In other words, the data can't be picked apart and sent to decision-support. It can't be picked apart and sent to the various elements of the EHR because doing so would risk the possibility of being able to redisclose it without the opportunity to obtain the authorization for that to happen. It's also important to note that if you are a recipient provider who doesn't use this DS4P technology, you can't even view the information.

So we also found that the – to date the implementation of this standard has either been all in or all out with respect to disclosure of information from these behavioral health Part 2 providers. So again, the restriction is going to apply to the entire document, so whatever is in the document with the restricted tag on it's either all in or it's all out. The vendors that we talked to talked about the possibility of making it more granular by just not including data that the patient might want to hold back while sending everything else. But that of course raises the Swiss cheese problem of the record's coming over, it's incomplete and there isn't really a way to indicate that the information is not complete, at least not with the technology. And that also raises privacy issues, something's missing, what's missing?

Some of the things that the technology companies are working on next in terms of sort of iterating on the functionality of this is to enable behavioral health providers to be queried for the information. So that the querying entity sends the authorization, rather than the exchange being initiated by the behavioral health care provider, enabling that parsing that we talked about, so that decision support can actually occur on this data in a way that still honors the need for confidentiality. So in terms of sort of where we have begun our discussions on this, we acknowledge right off the bat that this is not a perfect solution, right, we ideally would want that parsing. We would ideally want something that is more than view only.

But we also heard from one of the vendors where their pilot is not just a pilot, but has, in fact, been operational that providers appreciate – the ones that they’ve worked with, appreciate just the ability even to have this data and to see it. And to see it in advance of a patient coming for a visit so that they can prepare. And probably important, very important from the behavioral health care provider’s standpoint is that it enables them to share electronically in ways that have not been possible for them before. Because they are always required to honor Part 2 with respect to the data that they’re sharing. So the inability for them to have any functionality to send documents electronically meant that they couldn’t send documents at all and they were sort of stuck with paper-based ways of exchanging.

So then we get to the question of, okay, so what does that mean? If it works really well for behavioral health care providers, can we get to a point where we believe this should be part of a voluntary certification program for them? Okay, so that’s one set of questions. But then the question that was initially teed up for us by the Certification and Adoption Workgroup is well, we need the recipient systems to have this technology, too. And as I just acknowledged, you can’t read the document if you don’t have this technology on the recipient side.

On the other hand, given that you can’t parse that document when it comes in, there may still be providers who are reluctant to accept a document that cannot be incorporated into their record. And we have a lot of questions that have gone back to the vendors about well, what happens if you have a recipient provider – how do they indicate they’re not open for business? What happens if the document comes in and can’t be read, where does it go? Does the mere receipt of it create liability? And we hope to have some of those questions answered in the next section.

But what – given this sort of – all the conversations that we had about certification earlier, we have the legal requirement for this data, an imperative for behavioral health care providers. But on the recipient provider side, we have little bit less experience, other than in the pilots, about how that data gets received and what does that mean for certification standpoint? On the other hand, if you want to reward providers for accepting this data as part of care coordination, if they can meet their Meaningful Use care coordination objectives by receiving data from behavioral health care providers. And they are interested to have – especially those who have a significant portion of their population that are served by behavioral health care providers, the lack of a functionality to be able to view the document again keeps those patients sort of locked in the dark ages of paper records once again. And these are – again, these are the conversations that we are currently having that we would like to get your feedback on.

Education of providers and patients on these issues is always going to be key about sort of what the limits of the technology are. And we also think that there – and here’s where I think we’re reasonably close to consensus on this, because we can usually very easily say, we need more education without much argument. But in the case of the guidance that goes out under Part 2, you’ll recall that when I talked about the scope of Part 2, you have – the guidance is incomplete. You recall that when I spoke about the scope of Part 2 earlier, information that’s sourced from a non-Part 2 health care provider or from the patient, in fact doesn’t have – doesn’t get protected in the same way that data that comes directly from a behavioral health care provider would.

And so that raises the question of, okay, let’s say you’re a recipient health care provider, you agree you’re going to get this document and you’re reading it, and you’re seeing all sorts of things in that document that you know you want in your EHR, so that you can do medication reconciliation. That you can check for the possibility of adverse reactions for combination of drugs, you can check all sorts of decision-support software. And so that various parts of your healthcare system can work on this information. If it’s not parsed in the EHR, it makes it incredibly difficult to do that. Can you, for example, have a subsequent conversation with the patient when you see them, in order to get this information in your EHR and essentially get authorization from the patient at that time? We’ll, it’s a little complicated because what the SAMHSA staff were very clear that they didn’t want is just a process where the patient would be provided with the C-CDA and just asked to verify that it’s all correct.

On the other hand, if there's a conversation that takes place with the patient where the patient sort of fully understands sort of what the – that the provider wants to incorporate the information in the EHR, but what that might mean in terms of getting consent for possible further disclosure for treatment purposes. That that might be something worth considering for future guidance, but there – but that's not sort of the state of where the guidance is today, but could be very helpful. And the sense I got from talking with them is that certainly if we were to accompany our recommendations on the technology functionality with some additional recommendations with respect to how providers can implement this and still be able to care for the whole patient with all the data, that that would be well received.

So that is sort of where we have progressed to date. Very much want your feedback again, both on the sort of – I think the question that was presented to us was really a technology functionality question, right. What – where did the DS4 pilots bring us and what does that mean for certification for us in two ways? One is with respect to the voluntary certification for behavioral health that for the most part has been considered very thoughtfully by the Certification and Adoption Workgroup group and that Larry will be making a presentation to you all on later today. And then a secondary question with respect to how can we best enable recipient providers to receive that information if they want to and they are desiring having all of this information, even if they can only view it at this point. And how then do we also improve our understanding of the policies around this so that it's very clear what the environment is that we're working under.

So Micky, I dominated this discussion, as usual. Did I leave anything out? Is there anything you want to add?

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

No, I thought that was gripping. No, I thought that was very complete. Thank you.

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

Yeah, so I actually had two more slides but I basically summarize them. So, there we are, I forgot they were on slides.

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

Good. Thank you, Deven. Questions from the committee or comments? Oh, Paul Egerman.

Paul Egerman – Businessman/Software Entrepreneur

Great. Thank you, Deven and Micky for a great presentation. This is very complicated topic and you did a great job, Deven, of explaining it. I have both a question and an observation. First, the question is, for these pilot organizations, still need a little more, what kind of organizations there are? What kind of healthcare organizations they are?

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

Well, they're all – the pilots are launched by, I mean I'll get Joy's help on this, but by vendors in particular, but they serve a certain population. So for example, the pilot – I have to go back – pardon me for the people who are viewing this on line, I hope that's not too fast. So for the – oops, that's not even it, where is my –

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

You went a little bit past it on the – one more I think. One more, there –

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

Thank you, thank you all. There we go. All right, so the VA SAMHSA pilot, for example, was a pilot involving VA facilities. The two vendors that we heard from were Netsmart and SATVA. I actually, beyond sort of knowing that they were – were there behavioral health and other providers in there, I'm going to let Joy hand this.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Netsmart serves a behavioral health – primarily behavioral health clientele and they share the information – their pilot involves sorting the information through Florida, I can't remember which county it was, but it was the 211 system. So what it did is, it allowed the information to go from behavioral health care providers to other government agencies that provided service once those patients were discharged from the hospital. So it enabled the transition of care from a behavioral health care provider who was covered by 42 CFR Part 2 to one that was not.

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

Great. So here's my observation, which is – like I said, this was a complicated issue and to link this discussion with the discussion we're about to have about LTPAC. I wanted to sort of think about the transitions that occur when a patient goes from an acute care facility to an extended care facility and to think through the issue, for the minute, of gee, you're dealing a patient who is ill, maybe older and can that individual really give granular consent to anything? And my suggestion to you is to look at that transition and perhaps a few other transitions, and to perhaps talk to HIM people and look at the entire administrative activity that goes on when a patient moves from acute care facility to an extended care facility, in terms of all the consents and everything that has to happen. And then also look at what is the impact of the patient on all of that stuff?

To speak exactly to what Dr. Koh and Dr. DeSalvo were talking about is to look at the patient as a whole. And to try to understand does the administrative activity benefit the patient in that particular transition or is it a burden that delays the transition, which I know frequently causes a fair amount of stress for the patient and the family. And where I'm going for – going with this is to sort of suggest that perhaps one way to impact this whole situation is to find certain classifications of redisclosures that really should be exempted from Part 2, that that could be something that could be very helpful to everybody. If you could sort of say, well when the patient originally agreed to go to the acute care facility and agreed to disclose their information to that, they also agreed to whatever subsequent healthcare organization they get transferred to, and that's not a redisclosure. And I suspect if you could find a way to carve out some of those, that would be helpful to the patient.

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

Yeah, I think – so I think what your comment suggests is a couple of approaches. One we've already acknowledged which is to urge SAMHSA to think about what kind of helpful guidance they can provide, which they have done before in health information exchange contexts, but that doesn't change the law. And the other piece would be if in fact we were to say a re-examination of the law, we might consider that and get there, but that would take a lot longer to achieve than guidance that might actually be able to be issued within a relatively short period of time.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Just very short, there is a statutory requirement so when Devin said re-examining the law, it's not just a regulatory change –

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

So, Congress would have to act.

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

Okay, I have Art, Alicia, Judy, and Gayle. Art?

Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health

Thank you, Deven. This is a pretty difficult topic. I'd like to just understand a little bit better about this tagging.

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

Um hmm.

Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health

So there's a tagging that could apply to its use in an EHR, right? Does the tagging also apply to seeing the document that is being shared? I mean, if we have this transition of care document that could be in a PDF, too, does it encrypt it somehow that unless you have the key to untag or the matching key that you won't be able to read it?

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

Yeah, you can't read it without the software because I'm not sure if encryption is exa – I don't think encryption is the technology that's used, but it is essentially cloaked with a protection that you could not read it as a recipient if it was tagged with the DS4P, unless you had the key to at least read it. But then it's read-only, meaning it can't be parsed into and consumed by the rest of your EHR to be used in decision support. And some of those the ways that providers – that an EHR would act on information would qualify as a use and would be covered under the original consent to disclose to the provider in the first place. But there may be, and this is almost getting back to some of the accounting of disclosure conversations that we had fairly recently about what constitutes a disclosure and doesn't, and we would have to dive into how that's defined under the Part 2 rules to see if there's any wiggle room. But suffice it to say, the pretty full explanation of what the law required when they developed the technology, so that it would enable behavioral health care providers to able to still exchange data electronically while honoring their obligation, which is that it cannot leave their facility without that.

Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health

So – out the EHR reading this and let's say I am capable of at least reading visually the document and I see that the patient is on a certain medication, I put that into my note. And then that note then gets combined into a transition of care document, when they're going to the next site. Are they violating Part 2?

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

If they haven't asked for the patient's authorization to disclose that data and it's sourced from that Part 2 provider, which was the case in your scenario, yes.

Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health

So, if I had to make a choice about a drug because of the medicine that they were on, I would not be able to substantiate the reason I made that choice. Because that's the piece that I need to get permission share, is that – I just – I want to get the – because there's a reasoning why someone might select a path, based on the current medications they are on for behavioral health reasons, and that would not be represented in the transition of care of document without the permission of the patient.

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

Yeah, I believe that's the case, Art, but we are trying to have one or two of the vendors come back for our next Tiger Team call, and I will get that sort of reinforced. But I think the other operative question that I want to make sure the committee considers is what if the information never came over to begin with?

Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health

Well then you would make the cho – you might make the wrong choice, yeah.

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

Right.

Arthur Davidson, MD, MSPH – Director, Public Health Informatics – Denver Public Health

Okay. Thank you.

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

I have my virtual card up after Paul Egerman, and I was going to wait until the end, but since Art brought up that point, I wonder if I could ask my question that's related. So you talked about how you could transmit, with patient permission this information, but yet it could not be parsed and incorporated in the new EHR. Now is there some indication in the receiving EHR that such information exists? The reason for asking is, in the early days of AIDS, California which is prone to writing legislation, came up with a mechanism that asked us to put a sticker on the paper chart at the time that said there's protected information in there, but you were not allowed to disclose it was abnormal. So it wasn't too soon after where people could figure exactly what was going on. So is there – what is the sta – in the receiving EHR, is there an indication that there is information available or not? If there isn't, then how would a person even fi – so, is there an indication that there's protected information that is somewhere there?

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

You know, that's a really good question, Paul. That's related to some of the – in the backup slides we have a whole list of questions that we've sent to the vendors for follow-up. And I think we get a little bit to the edges of that, but not in precisely the way you've described. So I think it's a really good question. My assumption, based on what we have heard, is that again, it's read-only it's – but I don't know whether there is a document that – whether there is something that pops up in the EHR that says there's a read-only document for you in this folder. I don't think so, but that's a good question.

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

Okay. And then I think I had Alicia and then Judy and Gayle.

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

Deven, sorry, this is Micky, can I just add one thing?

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

Yes please Micky.

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

That is, I think one thing I think we should all keep in mind is that DS4P is a particular approach and is a particular instantiation in these pilots. But as we think about the general question of – which was the question that the Tiger Team was asked to look at, related to behavioral health communities desire to have some kind of certified system. There may indeed be lots of other approaches and as we're talking about innovation in the morning, there may be other approaches and that could be a Standards Committee discussion about what some of those other approaches might be.

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

Thank you. Alicia?

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

Okay, so I guess – I was just looking for clarification, I guess, on the tagging. I'm sort of interested. Is that – are you looking – the way that you're setting up is that treat it as almost like a partition in the record or a partition in the whole system that would have this information? Because I guess getting to some of the questions that have been asked, if you're like, here's a read-only document, that you're sort of signaling that there's additional information and aren't you thereby disclosing – you're sort of indicating?

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

Yes and the – well, so for the initial transmission that has been covered by a patient authorization.

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

Okay. Alright.

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

So it comes over, it's read-only but the patient has already authorized –

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

Okay.

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

– that particular – it's subsequent ways that it might be disclosed that is the piece that doesn't allow the information to be parsed. But I assume that if it comes in, it wouldn't be sent to you if it wasn't authorized, you've got it, you have to at least be able to store it. Whether there's some – whether you get the popup window or some other way of knowing that it's there or how that gets alerted, how that gets filed, I think is a little bit more of an open question. But it's the subsequent – it works very well, I think, for the behavior health entities that couldn't share data before, right, they get the ability to send this data electronically with the restriction communicated on it, per the rules that apply directly to them. And they've been able to help facilitate the coordination of care for a patient that they have treated. It ge..it's on the recipient end that they can read it to facilitate that care, because the consent already came, but then in terms of sort of subsequently whether that information could go elsewhere, they would need to get additional authorization from that point forward. Does that make sense?

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

Absolutely.

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

Okay.

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

And I guess just to reiterate then, the key to the whole process is really in the disclosure or at the very beginning of the process and how that communication is made to the patient in terms of the disclosure policies and procedures if you will?

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

Yeah, that's one of the key communication elements.

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

Okay, thank you.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Deven, is it like in a financial or an HRE system, where based upon your sign-on and your permissions, you would or would not see certain levels of data, is a built like that or is it really just a flat file that's –

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

It's the whole document. So they don't have the ability to be granular within the document, it's the whole C-CDA, or, if you were, the vendors said – you want to go ahead Joy?

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yeah, they have the ability to tag within the document, nobody has implemented it that way. They are implementing it at the document level. When the document comes over, it has been tagged with a notice that shows up before people view it that says, this is your notice, as required by law, this is your notice that you are receiving protected information. If you're not willing to protect this information, according to law, like don't open this notice. So the patients already authorized it to go over and then the two that we have seen, they are able to view the document. The document, by design now, is put into a separate, as Alicia was asking, it's put into a separate file.

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

Okay.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

It is not, by design right now, not incorporated into the EHR.

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

Right. One of the –

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

– role-based access is not – has not been one of the functionalities that has been associated with any of these pilots.

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

Right. And one other thing that was in the slides, but that I forgot to mention, was that 90% of patients whose data is covered by Part 2 say yes when they are asked for authorization to disclose for treatment purposes.

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

Do they generally say a blanket yes or by – ?

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

No, it's not a blanket law. You have to ask for authorization with each disclosure.

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

Okay, Judy?

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

I have a couple – a few clarifying questions, if 90% say yes, do you know what percent are asked ?

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

They all have to be asked.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

They all do, okay. Two, and you said that you're not allowed – the patient can't authorize it to be redisclosed?

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

Well, they can at the – as long as the authorization meets the authorization requirements, right, so you can't sort of generally say, would you authorize to disclose it and do you then authorize to disclose it for any purposes whatsoever? My understanding of the law is that it requires a specific authorization of where it's going and for what purposes.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Okay. So then – because I like it being read-only and not discrete, because that removes any ethical concern from the EHR of, I know there's a contraindication, but I can't say anything and the liability that goes with that. So I think it's safer for us to have it view-only. My second question is, who's the provider? And by that, we've been using provider to be the healthcare organization.

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

Um hmm.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

And we've been using provider even to be the OCA.

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

Right.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

So if the behavioral health organizations sends something to OHSU, University of Chicago or whatever, and they are each an OCA, does that mean that the provider means it's okay within that organization for the appropriate people to look or is it – or in this particular case, is the provider just an individual clinician?

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

Right, well this gets to the definition of disclosure and it may be, in fact –

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

We're having a side conversation, I do apologize, with all due respect. That's why I was asking about the role-based viewing because in the medical home team, I'll use that example, if you have a med psych and a psych team, you want them to have access to the information. But not everybody on the medical home team needs to see all that information about – in spite of that provider's tax ID number, it'll vary quite a bit based upon...

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

So this is the issue of what is defined as disclosure, right. And Judy, you're using the OCA, organized healthcare arrangement language that comes from HIPAA, which is different than Part 2. So what we will do on the Tiger Team – on our Tiger Team calls, is get clarification on what constitutes a disclosure in the Part 2 world and that will inform our policy discussion around all this. But I think it's also important to remember that even if there is some – use is allowed because that was covered by the original authorization, you still have the problem of whether you can control for disclosures if the information is parsed into the EHR. And that's the piece that is the subsequent piece that the vendors are working on, but hasn't sort of yet been sort of tested. And so that's why at least currently it's read only. But that's a really good question and we should pin that down. Joy?

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

There's actually been quite a lot of guidance given by SAMHSA on this issue, not taking it from the perspective of whether it's a disclosure or not, but as to the breadth of who the patient designates as the potential – as the authorized recipient of the data. And we can give you links to that and we can give you some more information on that, but they've even considered it within the HIE continuum as like, can you just say, I give my information to the entire HIE or does it have to be more specific than that. So that has been – there's been a lot of discussion on that already to date.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

To the ICU in OHSU or is it to the individual Dr. Smith?

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

It does not have to be an individual doctor. That we know from prior guidance.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Okay.

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

Okay, we're towards the end of time so we have Gayle and David Kotz as our final questions/comments.

Gayle Harrell, MA – Florida State Representative – Florida State Legislator

Thank you very much. This is Gayle Harrell. Most of my questions have been answered but I do have kind of a technical question in how it works into the entire system. If – first of all, do we have the ability to tag each discrete element of it and does the system in place have the ability to recognize each of those is discreet elements. For instance, if you have specific medications that are psychotropic medications, does it tag individual elements? Does it tag not just the CCD, but the en – the specific element. And then of there is the technical capability to allow the release of those elements that are already parsed, because they're individual elements, to be able to actually use them with very specific consent that is then being able to transfer that consent to another level.

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

So, as Joy mentioned earlier, the capability to tag individual data elements is the piece that hasn't been fully piloted and tested yet. So what has been tested is the capability to tag the C-CDA, right. So that means that when it comes in, it's read-only and so I don't think I quite understand your second question about parsing, because today the standard doesn't permit that. But if it were already in your EHR and essentially what came over from the Part 2 provider was reinforcing that information, then the source of that information was not Part 2 and information that's already been in your EHR, if you're not a Part 2 provider isn't covered by these rules. If that – I don't know if that answers your question or not.

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

A clarification on that, but if you ask the patient specifically, you read the doc – if it's not, and you're telling me it's really not parsable, that although you could tag it, it's not coming that way now, that perhaps the technology could be developed to later do that.

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

They are working on that.

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

They are working on that, so the capability is there. But if you, and this is where I get a little cloudy, if you then confirm with the patient that they are on a specific medication, a psychotropic medication for instance, and you confirm that after having read that in the unparsed document, can you then enter it into your record and then disclose it further?

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

So this is the piece that we – that probably will be a topic of a recommendation we will make as a Tiger Team because there isn't SAMHSA guidance – written guidance on this topic today. And it is an area where additional guidance on when data is sourced by the patient and when you are permitted to sort of enter that into your records and then not necessarily be subject to Part 2, even though the patient – your knowledge of the information may have originated from a Part 2 Program. How do you sort of parse all of that out?

The concerns of the agency and I understand this is that people will do an end run around the protections unbeknownst to the patient by just asking them to confirm information, without necessarily explaining to them what the confirmation of that information means when it's been subsequently entered into the record, right? They were – they found it much more appealing when it's framed as a fulsome conversation with the patient about what it means to sort of have that information in the record and can I put it in my EHR and that may mean it could get disclosed without your authorization. But always in accordance with privacy law like, whatever is the conversation, it's two very – in the eyes of the agency and I understand why, two very different things. But we don't have guidance on this today and it seems as though some guidance on how information is sourced from the patient and then can be put into the record appropriately without running afoul of the law, is an important area to pursue.

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

Absolutely. Thank you.

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

David Kotz has the last question

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

Yes, thank you and I apologize for missing the meeting in person today. I may be thinking a bit beyond the standard and beyond perhaps even our scope here, but there's a lot of interesting research on the use of mobile technologies for monitoring behavior, monitoring substance use and providing treatment or prevention interventions in the moment. And it seems to me that that's going to be producing a lot of data about patients behavior that they might consent to provide to their behavioral health provider, maybe consent also to provide to other providers. And I guess what I'm wondering is, are we considering only these fairly discrete C-CDAs handed off from one EHR to another or should we be thinking ahead to some of these more continuous data flows of behavioral data?

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

So two things on that, it's a really good question. So one thing is that we are at least initially trying to confine our recommendations to the question that was presented, which is actually in the context of behavioral health certification. And an idea from the Certification and Adoption Workgroup that we really ought to have pair certification, right, behavioral health care providers and the recipient providers both having the capability to at least send and receive and read.

But the other thing that's relevant for some of those other sort of data streams is that when the patient herself collects the data and shares it with the healthcare provider, the patient has done so with consent and the patient isn't a Part 2 provider. So now that covers the Part 2 cons – situation with federal law – it actually doesn't necessarily cover state law, because once the provider has that information in her records, then she may have some state law considerations with respect to redisclosing it to other healthcare providers. But it's partly – it's not a great answer to your question, David, because it kicks you right into reflecting what a sort of hodgepodge of sort of legal requirements we have here and how confusing it can be.

But I think that if we do confine our recommendations to what's on the table, we will serve the question at hand in a timely way. But I think we should, David, I think you raise a really good point that we should not – we should make sure that whatever we establish through these proceedings, doesn't close the door to the broader range of sharing of information by patients and others that is sensitive, through tools that are becoming more and more widespread use and that we want to acknowledge and encourage in many cases.

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

Right. Thank you.

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

So I think we're going to have to move on because we have other topics that we actually need approval from this committee. So thank you so mu – and Deven and Micky are coming back next month to present their final recommendations.

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

Yeah, we really appreciate the opportunity to get in front of you ahead of time. It just helps us because it's such a complicated topic. So, thank you.

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

Well, we appreciate it as well, I mean, this is sort of the fun part where we're dealing with really new frontiers. When they dreamed up Part 2, they didn't imagine EHRs, HIE and VDT, for sure. So, these are important issues, we want to both treat patients holistically, but protect the information sensitive.

So our next presentation is about the voluntary certification program in long-term post-acute care and behavioral health. These are recommendations that we're asking for approval from the committee.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So, good to be back in front of you guys. It's only been a few hours, seems like years. So, let me begin again with some thanks. So, wouldn't be here without help from some ONC staff, so Liz Palena-Hall has been supporting this area for a long time and recently we've had support from Elise Anthony and Jennifer Frazier, more so on the behavioral health side. But I think those three have really worked together very well to move this forward and help the workgroup continue to move forward.

So most of the slides here you've seen before, so I'm going to try and zip through those so we can get to the substantive ones at the end. So, our great workgroup members, the charge that we should look broadly at certification beyond the Meaningful Use Program, specifically at other care settings. And what would we do about certification criteria for a couple of particular areas. So we've reported back on the first part, that's our five-part framework and we're working on the second part, which is LTPAC and behavioral health.

So, let's just keep going here. So we did have some hearings and a couple highlights out of the hearings, and I think the main point here is that we want consistency. So whatever certification criteria exists for a certain function in – for one set of providers under one federal program, we'd like to see consistent set of requirements for other providers in other federal programs. And I would say that the piece that I've sort of been adding to my rap here is, it started with the perspective of the providers, that we want the providers to have stuff equally, but as we pursued that, it became clear that a lot of is driven by various federal initiatives and those initiatives need to be aligned.

So if one agency asked for data reported in one format and that format is different from what other agencies are requesting. Or is different from the exchange formats that have been set up for reporting to public health or set of for providing information to other providers, that we're not focusing on one standard we're creating many standards and many transport technologies, which adds to the complexity of costs and creates more fragmentation. So some of this is not just getting all the providers on the same page, but getting the federal agencies on the same page, so, that emphasis is not necessarily in the slides because that's one of those sort of daunting realities of when you talk about this enough, some other things surface.

And as was mentioned this morning, a lot of emphasis on interoperability, exchange of information, continuity of care, this is about providing good care for patients as they transition from one care setting to another. And also, consistent support for modular. So particularly among providers that aren't getting incentives for their adoption and don't have other regulatory requirements to have software. The easier it is for them to pick up pieces of technology and implement those pieces, gives them a lower threshold to starting to incorporate things that would help them do a better job of exchanging information or providing new enhanced functionality within their own setting.

We went through these principles last time with you folks and they're unchanged and they really span some of the – most of the points I've hit on already. Maybe adding a reminder of, even within these provider groups, there is huge variation. We heard this particularly among behavioral health providers that many which could be individual practitioners, the LTPAC, long-term post-acute care settings and tend to be institutional settings that by their very nature have more staff and more infrastructure and historically have had more systems. But that that spread of providers is very real and when we use these umbrella terms it's everything from inpatient settings, outpatient settings, large providers, small providers, individual practitioners.

So we put forward sort of three big buckets and most of what's up on the slide we'll be back in June with more information. But two particular things we're giving you sort of our final update on, hopefully final update on this time and that's in the red box for all providers, transition of care and privacy and security. We did get some comments about what does "all" mean and I think this is sort of really telling, actually of we're expanding a program that was originally developed with a very clear focus, a legislative mandate. And we're now saying, there are parts of this that are valuable to other providers either because of other federal programs or because of the actions of those providers.

So what we're looking for are the things in the red box that say, this is the part of the level playing field. This is what we think is useful for everybody, it encourages information flow at transitions of care. But as Deven was trying to get us to pay attention to, there are nuances in there where things that appear to be symmetrical might not actually be symmetrical. So, nothing is easy but fortunately, that one the Tiger Team has offered to take leadership on.

Okay. So, transitions of care, so this is a little bit modified from the last time you saw it. The first piece is consistent, that we're looking to take the existing Meaningful Use Stage 2 certification requirements and roll those forward and say, those we mean all providers. If you want to accept or receive transitions of care documents and your system is certified to this, it should work. Sort of the floor piece that was talked about this morning. The second piece is changed from last time and mostly around discussion of how mature are the standards. And so there's a subsequent slide that sort of lays out some of the pieces here.

But the question is not would it be useful to have more information and more structured information in the transitions of care document, but is that – are those standards far enough along that we could build on them for a national certification? And as you'll see in the box below, in the grid below, this was a piece that the committee asked us to come back and do in following the footsteps of the Meaningful Use Workgroup of assessing what is the provider use effort, how mature are the standards and what's the development effort. And because of the workflow implications here, because this is new activity, the provider effort is going to be high. There's existing paper process, manual process to facilitate transitions of care, but the electronic one what is new.

And we're beginning to see this in Stage 2 as acute-care hospitals roll out their Stage 2 and get ready to use Stage 2, they're tapping the shoulders of their downstream providers saying, we'd like to send you CDA documents, can you receive? And even if you don't have the technology to receive, can we help you acquire the technology to receive? And even if that is zero cost, let me assure you that it's not zero cost to receive, there is well, now what's my legal obligation if I'm getting this? Let me make sure my lawyers all sign off. And how am I going to use it? What's my workflow going to be? Who's going to look at this inbox? What are they going to do with what they find? And is it just receive or can I also send? And if I send, do I have other obligations about what it is I'm sending? So even building on things that are there have effort.

On the development effort side, clearly if you're already a Stage 2 2014 edition provider – vendor, you've done it. The development effort is over. If you haven't done it, what I'm hearing from a lot of people creating CDA documents, in fact, going back pre-HITECH is they're not particularly easy documents to create. So you need some experience and practice to create them and you need the right vocabulary and code sets in place so that actually can transmit to the standards. So there's effort on the developer side, there's use effort on the provider side, and then there's a place where you may, in fact, be having some undertow of ongoing subscription costs, because you might be paying for that standard vocabulary, beyond just having the ability to send and receive documents. So I'm going to skip ahead to this slide.

So these were some additional comments about transitions of care. So, to the slide we were just on, not the one I skipped over, so we want consistency here with all providers. We want to point to the additional work that has been done on transitions of care by HL7, that was a 2013 activity for them. And some of that was done with the intention of getting the standard available for use in subsequent ONC certification. But the assessment of the workgroup is that very little has been done with that to date. And we have very little experience even with the Stage 2 exchange of Meaningful Use documents using Direct, even if just in a read mode. So really asking pretty hard the question of how mature are the standards here?

Okay, the other piece for all providers is, these are the elements of the 2014 certification requirements that address privacy and security. We felt these should be brought forward, that they're not particularly new, that they're good practices that have been in place for a long time. And so we felt that both provider effort and development effort was relatively low and that the standards and were pretty mature. There is an asterisk at the end of all those sections of ONC certification because we heard what could be seen as some confusion among providers on what it meant to have certified software with regard to privacy and security and the requirements under HIPAA.

And we've had this conversation before with other providers that just because you have the technology, doesn't mean you're HIPPA compliant, right, you need policies and procedures. You need to make sure that they're being followed. There are a lot of things you need to do beyond just having the right software in place. And so this was a reminder of that and the suggestion that, as we go forward that there should be additional outreach that says if you're buying software that is certified to these things, you've got to still use it well. You've got to still train your staff.

So, I think that's – nope, some have some work to do. So part of what we had was a request from ONC and from the Policy Committee was to go back to the things we had previously reviewed and say, so what's the effort to do these things? Where are the standards? What's the development effort? What's the provider effort? So we're looking to gather some more input around that. To that end, we have a blog going out early this week, so it might even be out as we're speaking. I've seen drafts, if not today then certainly tomorrow and we will be having a listening session next week, right? The 13th, read the slide Larry.

W

Next Tuesday.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Next Tuesday, 5/13. There's too much of my slides. So we'll be have a listening session and the blog is asking for people who are interested in being part of the listening session, they have the opportunity to sign up. And depending on response, we may have the fortunate situation of overflow and not have everybody who wants to present, present. But we're hoping to get a pretty good diversity of folks who choose to sign up and talk to us during a listening session.

There will also be the opportunity to, off the blog, to respond electronically and so we can capture things from people who won't be able to present at the listening session. And then we'll be reviewing this response and getting back to you in June to wrap up all of this stuff.

There are a couple of other things on here that the workgroup is doing, we have certification hearings has already been mentioned tomorrow and Thursday. And then we'll be reviewing that and getting ready also for our listening session. I think, that's it.

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

Good, thank you Larry again. Dr. DeSalvo?

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Larry, thank you guys, thanks to everybody who's been working on this. I just wanted to get a point of clarification to make sure that this is what your intention is, which is the following. That as we at ONC are evolving the certification expectations going into the future, the next couple of cycles, is the intention for these expectations around ToC and privacy and security to marry up to those, not to be static?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yeah.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Okay, static, so the language should say, to meet the expectations and these are the ones that are in place now are being contemplated, but as those evolve at ONC that may also evolve. Is that right?

Larry Wolf – Health IT Strategist – Kindred Healthcare

That's probably a useful thing to put in explicitly –

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yes, that was the intention, not to lock it into the current, but to move in sync.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Right, I'm thinking for example about the ToC as the technology and the opportunity for query, for example, evolves, we want to make sure that that is an option, if that makes sense, going forward.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

So you remind me of something I didn't say during the slides, which I think is important. So we're evolving from a time when we really focused only on the HITECH incentives for Meaningful Use. And we're broadening the programs that may be asking for certified software and certainly broadening the thinking about what providers are using certified software, whether or not they're getting payment.

And so the suggestions been made to me that the terminology of non-MU certification is actually putting those other providers in a funny place, because it's defining them as a negative. And that sort of in the spirit of celebrating diversity, we should think about the attributes we want to attract and identify things that way and name the programs in the certification that way. So it may make sense, these things we've labeled all providers to think about, so how would those be framed independent of the Meaningful Use Program, in way that's clear that these are really for everyone. And yes, they're part of an HHS program, CMS program is going to pay you if you are using them or penalize you if you're not using them, but you may be outside that program and these could still be valuable to you. So to think broadly about how these things get identified. Particularly as we start rolling in things, because the CHPL, as many people have commented, is already kind of overloaded, and think about how to structure it in a way that you could slice and dice it and actually find the things that would be relevant to you as a provider.

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

So to summarize, the action being requested of this committee today is to approve these two recommendations, i.e. to extend what already exists already and will track with Meaningful Use Stage 3 over to those who can't participate in it, the LTPAC and the behavior health, both vendors as well as the – well, it's mainly the vendors, it's certification. The motivation is so that we can consider the holistic patient that includes the continuums that were not expressed included in HITECH.

As part of that, Larry, in your first one, the second one seems like a no-brainer because it's all – it's got the right attributes, it's fully mature standards and low effort. The first one is – does take effort, but in fact, it was requested by the people who are – to expend that effort. You did include a new thing, which is to track the care planning standards, which are acknowledged were not mature, not in use and vis-à-vis this morning's discussion, is that still part of the recommendation you want to bring forward ?

Larry Wolf – Health IT Strategist – Kindred Healthcare

So the recommendation here got softened from where it was last time. So last time it was, let's go ahead, go with the new standards. And the consideration the workgroup was saying, but they're not really ready yet.

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

Right.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So we're asking for a further assessment during the regulatory process of where are they? And at the point where they're deemed ready, that they – it's this, when standards become mature piece. At the point where they become ready that it would be reasonable – again, that they apply broadly and in terms of drivers, a lot of the drivers of more information in transitions of care came from the post-acute space. It's a very active S&I Framework group that was – that spun up by the community, not spun up because of ONC. Although ONC did supply some support, but it was created out of the community saying, we want to make sure that when we get one of these documents, it's useful to us. And so there's a lot of effort put in to say, so what other information do we need and that – some of which is included in the stuff that was balloted, the extended C-CDA work that was done.

But to the point of this morning's discussion, there's not a lot of field testing of that. And the notion that there is a care plan that is supported across multiple providers is conceptually tough, right. You get it and that's great, as soon as you go to modify it, well then what happens with it then? You have to cycle it back to the folks who sent it to you. Do they have to agree to the revised plan? How do we actually make this useful? It isn't like we all have some shared record in the sky that everybody is contributing to and is dynamic and real-time. No, these are isolated records by individual providers, we're trying to coordinate them through documents, that's a tough thing to do.

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

So, is your lang – just to clarify, is your language, which says when standards become mature, is that sufficient or vis-à-vis this morning's discussion, is it mature and tested?

Larry Wolf – Health IT Strategist – Kindred Healthcare

So maybe it needs to say mature and tested, because we are including a maturity that has been tested. Okay.

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

Okay. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Yes, I actually have a simpler suggestion, which is picking up on what Dr. DeSalvo said about somehow marrying the LTPAC and behavioral health to what's going on with Meaningful Use. Because I think transitions of care should just be what the 2014 edition says and then whatever happens with the 2015 edition and subsequent, happens to LTPAC also. And I think that that's simple to do, we get past all of this other stuff and also it's important to remember there are vendors who do both right now. There are vendors who sell to the Meaningful Use side of the world, but also sell pretty much the same software, maybe not identical to the LTPAC. So, that's another reason why we should go ahead and just keep them in sync. So that would be my suggestion and I know there are some people who are really excited about some of the stuff that's proposed for 2015, but if it gets accepted, well, okay, that's great or married to the 2014 thing and the same rules will apply in terms of whether or not people will migrate to it.

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

Any further discussion? I'll entertain a motion to approve the recommendation for these two functions?

Anyone second? Okay. Any further discussion? Go ahead, Troy.

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

I'm sorry, again, I mean I still have to reflect on, I understand transition of care, the care planning standards when they become mature, the ambiguity of that just concerns me.

Paul Egerman – Businessman/Software Entrepreneur

So maybe I should ask the committee about picking up Paul's suggestion – Paul Egerman's suggestion, which is that we actually strike number two as a recommendation that we reinforce number one with we don't want to lock is in and never move beyond the current certification requirements. We want this to track with the current – with the certification requirements as they change over time. And then allow those transition of care documents and other CDA documents to evolve and to be applied broadly. Would that – does that address your concern?

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

Yes, yes it would. Yeah. Thank you, Larry.

Larry Wolf – Health IT Strategist – Kindred Healthcare

We'll clean these up in a final version.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Do we need a formal motion for that?

W

I'll second.

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

Or is that an amendment to this first one?

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

I don't know –

Paul Egerman – Businessman/Software Entrepreneur

I move to amend the motion.

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

Yeah, so – so or one possibility is just to amend that motion yes?

W

Or make an amendment.

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

Yes. So –

W

(Indiscernible)

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

If he'd – you already called the question, though.

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

I haven't called the question yet. So the person who, I think Christine moved – so would you entertained a friendly amendment, which is basically to strike number two?

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

Yes. In fact, I'll amend it myself.

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

Okay. Any further discussion on the amended motion?

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Yes.

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

Yes, Judy.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

If you amend it and then care planning is taken out of that sentence, then what is left? Isn't what's left just C-CDA documents?

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

No, he's saying that number one would basically become a little bit expanded to say that it should track Meaningful Use always, so the standards may evolve in Meaningful Use, whether – including the edition of the HL7 ToC and care planning standards, if needed, so just to track what happens there.

W

– care planning.

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

– which was part –

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Trying to figure out – for the programmers –

Larry Wolf – Health IT Strategist – Kindred Healthcare

Right, and it needs to be stronger, I think, than just Meaningful Use. So the extent to which ONC has certification for transitions of care that it should track those standards for all providers as the certification requirements – certification criteria change over time.

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

So the original motivation is so that people not involved in the HI – not called out as meaningful users would participate in the same system – ecosystem and be able to have systems and data interoperate with each other. So originally, the thought was well, we just take Meaningful Use and apply it everywhere and that's Larry's first presentation, which the colored slide summarizes. Oh, but there's this, that and the other. So we're starting with what can be just a simple adoption and tracking of the original Meaningful Use, which only one of these two, it turns out.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Well, and will we set ourselves up by tacking on number two, which was really extending it –

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

Right.

Larry Wolf – Health IT Strategist – Kindred Healthcare

– in our enthusiasm.

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

So, we saved you. Thank you.

W

From yourself.

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

From yourself, right. Were you going to say something? Okay. Troy, are you still up or –

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

No, no, I'm just listening.

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

Okay, so now we have – would you restate the motion, Christine, please? Oh, Joy.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Joy.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

You can't direct things.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

I'm getting tested because I'm trying to draw the proper line between participating in a discussion and raising an issue I think needs to be raised. So, I say this with that caveat. When we do this for behavioral health, the recommendation, the result would be a behavioral health EHR that's certified?

Larry Wolf – Health IT Strategist – Kindred Healthcare

So that's a whole other question, right? We haven't talked about the lowercase "P" packaging of this to these other providers.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Well the question is that from what we've seen is that this transition of care, you raised this earlier, Larry, is as people think they're buying a HIPAA-covered product.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Right.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

They would think – behavioral health care providers would think that this might satisfy their special requirements and it will not.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Right, so we have – so on this piece, we're very aware of that, so it shows up in two places, the expansion to all providers and the note that consent management is a specific issue in behavioral health. So it think, Joy your point is – needs to be well taken as this goes forward that just because you have ONC certified transition care document, may not meet your requirements for enhanced consent, enhanced privacy.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yeah.

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

We really need to start communicating what is a certification under HITECH or Meaningful Use and specifically, what does it mean? So that it's the buyer beware kind of a thing and – because I think we even get confused and that certainly raised its head this morning. If we understand, these are floors to accomplish certain programmatic objectives, it could be Meaningful Use, it could be a condition of some – participation in some other program. I think that would give some clarity to what we're – to our purpose and what our goals and objectives are, I think.

And so that would help if we reinforce that message, what we're saying is then it would be ideally interoperable with other meaningful – other ToC certified systems in the Meaningful Use Program, no more. Yeah, I just think we're probably not really clear on that and it would benefit us –

Larry Wolf – Health IT Strategist – Kindred Healthcare

And I think also, to some of other discussions, given that there are state regs, state laws that might be more restrictive in how information gets shared, it doesn't address those that all.

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

So to Joy's point, it also specifically does not implement the privacy and security for this protected information. This is no guarantee, this certification is not –

W

It gives you interoperable –

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

It gi – with one class of products, it's basically Meaningful Use certified products.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Right. And it might be very valuable if the behavior health providers could just receive those documents.

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

Right.

Larry Wolf – Health IT Strategist – Kindred Healthcare

And potentially even incorporate those documents into their EHR coming from the other providers.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

So the behavioral health and the post-acute care software development vendors, is there any teeth to this?

(Indiscernible)

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

It's just kind of a request?

(Indiscernible)

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

So, the only –

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

The thought was that there were going to be market teeth because the customers, purchasers were wanting this as part of their reassurance because they wanted to interoperate with the rest –

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Where it might have some teeth is those vendors who are also in the non-EH – non-behavioral health who extend out to them, but it would focus on – then does it have – then is it a requirement or is it not even for that?

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

So program is voluntary beyond the Meaningful Use eligible providers and hospitals. I think as we've all acknowledged here, the goal for the nation is that we have an opportunity to standardize the capture of electronic health information for everyone in ways that are private and secure, both at rest and in motion. And so to do such a thing, to really see this vision of everyone's information being available, if they so desire and if we need to see it for appropriate purposes, etcetera, and I – etcetera lightly, it's important, but that we have to start creating an opportunity for other providers to have some standardization of what they're buying.

And they're asking us and SAMHSAs asking us and others are asking us to find a way to structure that so there are some guideposts about where they're going and what to build. And that this is – that for me the importance is that we make certain that that Meaningful Use expectation around the functionality and requirements of those products evolves, because it's going to, that we make sure that this marries up to that so that in the right circumstances, that information can communicate. That's all. But it would be a voluntary portion, but it would be a seal of approval, maybe I could say it that way, as an opportunity for that provider to know what it is that they're purchasing.

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

I think Larry also acknowledged that it's possible SAMHSA and other granting agencies could use it, this voluntary program, as a way of accomplishing program objectives.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yeah, we heard that specifically during our discussions that SAMHSA is seriously considering as part of their grant program. Saying that – and they didn't say in what way the grant monies would be tied to certified technology, whether it be a bump up or whether it was a baseline requirement or they didn't indicated at all how they would use them. But they said they did have interest in having these as something they can reference for their grantees.

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

Josh?

Joshua Sharfstein, MD – Secretary, Department of Health & Mental Hygiene, Maryland

I'm just going to say that I think that there's also a good chance that changing financial incentives for behavioral health providers and others could play a big role. In Maryland, we allow behavior health providers to get the ADT real-time updates, secure messages when they're part of our health homes. So they're at – sort of at risk a little bit for – they get a benefit if they can help control the medical costs of patients who are seen very frequently in their clinics. And it's been extremely popular, we have about 5-10,000 patients in the health homes and their providers, not just their medical providers but their behavioral health providers find out immediately if they go to the ER for something, and it's really popular.

And I think that eventually we're moving to a system where hopefully they'll be at least at a certain level, bonuses and other things. When the medical costs are controlled in patients who are seen frequently in methadone clinics and psychiatric day programs and other things where they're seen so frequently in behavioral health but they're diabetic or have all sorts of other medical conditions. So I think that that's pro – that may even be without SAMHSA grants, in terms of a financial incentive to – and an interest in getting records that can allow people to be successful under those circumstances.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So maybe with a sense of continuing the discussion, so allow the post-acute care providers and long-term care providers are getting a lot of requests from their acute-care partners of, you can't be a black hole any more. When we send someone to you for care and then they're transferred to us, we need to know what happened. There's a long history there of, well, we don't trust anything that didn't come from us and so there's a little bit of a not invented here data trust issue, but I think the ability to have a closed loop on the information flow is really critical. And so having consistent standards in place allows that to happen, even among the providers that are not in a particular program.

Joshua Sharfstein, MD – Secretary, Department of Health & Mental Hygiene, Maryland

And just to add, in Maryland we're moving away from fee-for-service payment for all hospital care, all payers, and that has huge implications for the relationship of long-term care facilities. And so there's a huge demand for sharing of information in that area.

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

Sort of a – this is a credit to success I think, that we have a community that's asking to be brought into the fold. So, that's – we need to look – okay, so the motion is that essentially the functions, the two objectives that are brought forth, transition of care minus the care planning on number two, and the privacy and security that are the same and would be married to the Meaningful Use Stage 3 objectives is being proposed for approval.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

And moving forward.

Larry Wolf – Health IT Strategist – Kindred Healthcare

And moving forward. So we're starting with what we know about already, we can only recommend what we know about, I think to Paul's point, and that we want to track.

Paul Egerman – Businessman/Software Entrepreneur

And starting from Stage 2.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Right.

Paul Egerman – Businessman/Software Entrepreneur

Because that's what currently exists, you said Stage 3, starting point is Stage 2 then moving forward from there.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Just in this specific area though, right?

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

Just in these two specific areas.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Yeah.

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

Okay.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Have you talked to the software developers at all, are they – you said we have a group behind it, I'm just cu – are they behind it, too?

Larry Wolf – Health IT Strategist – Kindred Healthcare

So, to be fair, they recognize that tracking these takes effort, some of them have already spent that effort and have gotten modular certification, a couple got complete certification. Others are looking to support their customers in creating standard documents, but haven't gotten certified. So I'd say among the vendors, it's mixed, the level of support that's there for doing this, but we certainly see some have already jumped into the voluntary program.

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

Okay, ready for a vote? All in favor?

Multiple speakers

.Aye.

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

And – thank you. And all opposed? Or abstain? Okay, it's unanimous. Well thank you very much, Larry, and we'll look forward to the rest of it next month.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you, Larry.

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

Okay. Our next and final presentation is going to be related to – your final discussion, is going to be related to quality measures that support the programs you just heard about. So the Voluntary Certification Program, like with Meaningful Use Program, has – is proposing to have a quality measures associated with it and so presenting some draft recommendations for our discussion, but not approval this time, are Helen Burstin and Terry Cullen from the Quality Measures Workgroup.

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

I just want to note, it's not clear on the agenda that they're presenting two items today, and so my apologies. But the first is related to LTPAC and behavioral health and then there is another separate presentation.

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

Ah, okay.

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

– hi, sorry, we're cognizant of the time, so I'm going to so the Quality Measures Workgroup for LTPAC and BH and Helen's going to do MU Stage 3.

So we were requested by the CA workgroup to look at quality measures related to these two areas. So we're following up today, as you can it tell, a trend behavior health, long-term PAC, what's the impact on quality measures and we're going to go over that with you. Before we go with what we did, we also, just like Larry, want to thank the staff who made this work. It was pretty difficult getting a ton of people together, you see them up there. We had experts both from the LTPAC arena, as well as behavioral health. The experts included both federal people as well as outside people and they helped inform what we were doing.

So we had a couple asks, we actually did not address all of these. One reason was we had one meeting for each of these and then we had a lot of dialogue. There was a huge ask and we're going to show you what we ended up doing. I think what you're going to hear, however, is an echo of what you've heard earlier today, throughout the day, the need for data standards, the need for interoperability, the need for data sharing, the need to adjust behavioral health security. And we're going to end up with a slide that looks like it's recommendations, but it's really food for thought and our understanding is we're coming back in June to go over those specific recommendations, Paul, that was done in conjunction with you.

So I'm not going to read this, you can see what we were trying to do from the ask. The final thing, I think though, that we addressed, or at least talked about was certification versus incentives, what drives uptake? And you're going to see some slides that have already come to this committee in the past. So you see why that last question is so important. Future vision for quality measurement, I'm sure you've all seen this before, really at that end is this intercha – interoperable exchange of information across care settings. However, what you're going to see today from our recommendations is that we're following this curve that we're going to ask really for this data elements, data sharing, and then interoperable exchange.

So why are we doing this? What's the value? The CMS states and payers have a certification platform already that provides a helpful foundation for quality measurement, and we're going to show you what that is in both of these arenas. Our understanding, and what we learned from going through this is what I think we already knew going into it was that we really needed to address data elements and figure out what the assessments are of what the most value and where standards related efforts were already underway or needed to be accelerated. And that we were starting with these sub settings, and these sub-settings are obviously behavioral health and long-term care.

What we know is that transitions of care is important and we just got done talking about that, the certification to transitions of care is an important building block. To share information, long-term care and behavioral health are both the settings where people go in and out, there's a lot of bi – potentially of bidirectional data flow and that we needed to focus on that as we look at quality measurement. That any effort towards quality measurement and incorporation of the ability to produce quality measures required the platform that supported that ability to share the information, so that there was no way that either of these two areas could be addressed as a silo to in terms of information. You're going to see that both of these areas, however, start at different points.

The long-term care area is influenced by standardized assessment data that's already sent to CMS. CMS helped inform our dialogue, they were present on the calls. CMS already calculates measures for these providers based on data that they submit. It's clear that that data uses some standardized data elements, it may not use standards that have been endorsed in the Meaningful Use standards up until now and/or standards that are ubiquitously recognized throughout the health IT arena. But there are standard data elements in that everybody is reporting on the same data element, whether it's mapped to a recognized SDO approved standard or not.

Behavioral health settings, on the other hand, have had fewer arenas where there's traditionally exportation of quality measures to the external bodies, and you see them on this slide, both in Medicaid for ambulatory care settings and inpatient psych hospitals. However, beyond that we weren't able to identify a large area where there was routine reporting, unlike on the long-term care area where we see routine reporting to CMS.

So we'll go into the individual LTPAC findings. This is a slide you have seen before and I think that this is one of the drivers for the dialogue. We see ranges from 6% to 43% on people that are using, in this case uncertified electronic health records. Larry's group had reported on this previously and you can see the difference between hospitals all the way up to intermediate care facilities, where there's unknown data in that area. However, this, I think, points out that there's a large opportunity to have tremendous impact in adoption rates for electronic health records and for health IT if we are able to do it.

So remember, we had a meeting and the results are what you're going to see here. So this is what our experts told us, that common definition for data elements are important, that there is need to have semantic interoperability, so while there may be ongoing reporting to CMS, I harken back to well-child assessments. What we know is that element "A" in form "A" may not be the same as element "B" in form "C," or it may be the same element, but there's no mapping, so this need for the semantic interoperability. That there's already significant patient level assessment data that's coming in to CMS, but once again, is that – is there a way to normalize that data and/or map it to standards?

And what we did here from people is that that was a recognized need in the LTPAC community. That there was this recognition that without the standardization of these elements to each other, but also to standardized vocabularies that were in use throughout the health IT systems, that this emphasis on quality measurement would languish, because that was critical. The data elements from the assessment tools were collected seamlessly and needed to be collected seamlessly through the EHR at the point of the care. And once again, this transition of care, what we know is we've heard that all day, transitions of care, transitions of care, this longitudinal view of care. And you're going to see that when we come to behavioral health and we will also be deferential to the previous discussion about sharing of behavioral health data.

So, what was the recommendation that came out of that, and remember, these are just being presented here, they're not for a vote, that there – one possibility was to certify the LTPAC data submission module. This is similar to something that CMS is doing. They have multiple patient assessment submission tools that we could say there is a data submission module for LTPAC. That there would be recognition of a small number of data elements for a small number of measure domains that we know are important in this community. And that coupled with that there would be the recognition of a small set of the data elements that were then standardized, and we don't have that word up there, but actually that's the major thing is that the common data elements become standardized. We know that there is work in this arena from functional status, cognitive status and other areas you're going to see in behavioral health.

So you'll see similarities between here and there, but the difference is that the LT community is already reporting to CMS, a large number of data elements, whether they're standardized or not. And that's why you see the second bullet here, which is really this recognition of the role that CMS plays in this arena, that CMS could consider certifying their free, CMS patient assessment submission tools, and those could then be used to perform these functions. However, if that happens, those data elements still need to have that second bullet done, common data elements that are standardized across. There were other considerations and barriers that came from our workgroup.

And there was this recognition that we needed a new electronic clinical quality measurement for the timely electronic exchange of interoperable ToC data documents, consistent with what you guys have already heard today from many of the workgroups. That ONC should consider the current specifications and requirements of the CMS long-term care program as they move ahead with any recommendations because we don't want to have rework done. But that finally then, this harmonized version of these data elements with the C-CDA and other standards already established for MU. That's work that has not been done that would need to be done, some of that work may actually just be discovery, where a lot of this may already be done but we obviously did not have the time to do that, when we were going through.

So now I'm going to quickly go to behavioral health, and you'll remember, we had a different group of people that informed the behavioral health dialogue. Once again, this is a slide that you've seen in the past. You may harken back to that other – the long-term one where you saw 46%, here you see 21% as your high, you see 2% as your low with – given that we have unknowns here. However on that 21%, these are community mental health centers, we see 65% that have adopted some form of EHRs. So the assumption is that these EHRs may or may not be specific for behavioral health, but there is definitely an adoption going on in the community mental health centers of electronic records.

So what did we find here that's – we went back and we looked at our clinical quality measures that we have in MU2, we believe some of these are already pertinent. Remember, our charge was clinical quality measures and how can we get that data to make a difference. However, there once again in this arena, are opportunities to align data elements to standardized vocabularies, a theme that we kept hearing and you've heard before, too. What we want to present to you are just this crosswalk of the electronic measures that we did in conjunction with the people that were our subject matter experts.

These are measures that are in MU2 and/or in development, and I'm going to go to the next two slides because you can see a cross-walk. The highlighted in MU2 – the highlighted are the measures in MU2, the others are developmental measures that have been proposed, and we'll be talking about MU3 and clinical quality measure in the next presentation. So you can see there's significant work already in this arena, the assumption is that these measures already have detailed data element specifications that are linked to standards. Meaning that some of this work could potentially be accelerated for clinical quality measures in behavioral health for electronic reporting. These are then once again the pediatric mental health arena, which we wanted to ensure we paid attention to here. I will posit that when we talked predominantly about long-term care, that was predominantly a focus on the adult arena, not that there aren't children in long-term care, but most of that presentation was focused on adults.

So what happens here then? What do we say from an eCQM arena related to behavioral health? And we're going to give you a few possibilities, and this is related to what we are understanding is of the state-of-the-art in the behavioral health domain. And you can see that there – we believe there are a couple of options, they obviously build on each other. The first is to collect and send the data elements, a small set of defined data elements. The second would be to have the health IT system collect, calculate and send the clinical quality measures. And then the third would be to have the health IT system have the functionality to capture a small set of key patient assessments. So obviously what you can figure out from this is you start with the data elements and calculate, you send measures and then you calculate and send key patient assessments. So there's obviously a dependency across here.

What we wanted to do, and we're going to show another slide in just a few seconds, was to really recommend option 2 in the short term with the recognition that we need to start work in the standardized common data elements related to behavioral health. So while many of data, the clinical quality measures that you saw previously, that are already in MU2, have some standard common data elements. What we know is that we need to push on this a little. There are other areas of measurement that are critical to the behavioral health arena that need additional extension of the data elements and/or identifications of different standards that can be used.

The other considerations and barriers and once again we've spent a lot of time today talking about this 42 CFR Part 2. I'm not going to rehash any of that. Suffice it to say we were attentive to that. We know that data privacy was critical. The reporting of behavioral health measures obviously has a dependency on ensuring that the allowing of data transfer can occur if we're going to hold a facility that is only behavioral health accountable to report on clinical quality measure that may have dependency on measures that have been taken at a non-behavioral health facility and vice versa. So – and the allowing of the data sharing for quality measurement is critically – is a critical dependency for the ability to be able to segment data and/or collect the data.

Also our experts volunteered repeatedly that without incentives, voluntary certification may have low uptake. It's hard to know exactly what the reason is behind the low uptake on that slide that you'd previously seen C&A Workgroup related to behavioral health. But we were repeatedly cautioned that incentives could play a critical part in the uptake of health IT systems. There was a need for a central organization or stewardship of behavioral health measurement development, I don't think that's unique in the area of behavioral health, but we did hear this over and over. Clinical registries should have a capability inherent within health IT, the word specialized here is critical. Because what people were talking about, I think, and this was some of the way that to address 42 CFR Part 2 was to have, for instance, a behavioral health clinical registry, a mental health clinical registry that could perhaps have constraints on it in terms of who could access it or not access it. But the belief was that the health IT system needed to be able to promulgate and support the creation of clinical registries.

Finally, the other consideration and barrier and we've heard this before and once again we heard it repeatedly is that non-traditional determinants of health are critical for, in this case it was behavioral health arena, that endorsed standards needed to be identified, developed if they weren't available to be identified, for many of these factors, psychosocial factors and housing. And the reason for that was the impact of those factors on behavioral health and behavioral health outcomes. Because obviously in our dialogue, the discussion while it was focused on the measures, the real focus was on the decrease in health disparities, the achieving health equity for a population that may be more at risk because of behavioral health diagnoses.

So overarching notes, we believe that our discussions could inform a broader framework for certification around quality measurement for other settings. So what you saw – what you hopefully have seen today is that we have tried to do this compare and contrast. Where could we start – where could we look at this so that we had a framework that people could use for other areas, but obviously then with a drill down to the long-term and the behavioral health areas. That there are commonalities that could be applied across any setting and they're the themes you already know, data standard, semantic interoperability, interoperability of – sharing of data and then, as has been highlighted before, this transition of care.

The current state and role of health IT adoption, and you can see this right here, should guide the health IT pathway for these particular settings. If you think of that last bullet up there, it's really related to the options we gave you for behavioral health. Where can you start that makes sense so that your delta between where you want to go, can be incrementally attacked and you can move along that pathway that we showed earlier, which is the arrow that we all know so well. So, let me just go back, for this discussion.

So while these are recommendations, they're really not recommendations, they are points for discussion that we wanted to bring up. And these were where we came to, as a group, that certain proposals would include that the certification of the LTPAC data submission module, and you can read that here, you've already seen this slide. That CMS consider certifying the free CMS patient assessment submission tools, to perform these functions, this would be for long-term. And then as we go to behavioral health, you've seen this slide, I just presented it, that your options would be 1, 2 or 3, a combination of 1, 2 and 3. And then what you saw from us is really a combination of 1, 2 and 3 is that for that short-term for the eCQM, you would recommend option 2, which is the ability to collect, calculate and send the quality measures. As opposed to, I'm just going to flip back really quick, as opposed to just collect and send the data elements. However, the dependency on that is that there has to be standardized common data elements that are available.

What we know is, once again, I go back to the slide we showed you with the MU measurement, we know that some of those data elements exist. We did not have the wherewithal to go in and do a mapping on those data elements and what was common and what wasn't. What we heard repeatedly, however, from the behavioral health community is that they felt that there were more data elements that would need to be standardized in order for us to really do eCQM measurement from the behavioral health arena. And with that, I'm going to stop. Do you want to – Helen?

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Nope.

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

Okay. And I don't know how much – I went fast because I know we have one more presentation.

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

Why don't we open up for discussion on this section of it and then we'll close discussion by 3:30 PM, if we haven't completed it, so that we have Helen's discussion of Stage 3. So then, I see David Lansky?

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

Thanks, Terry. I had a couple of questions and then maybe a comment, depending on the questions. On the slide that had the options for behavioral health, I don't know if you can still get that back. What do you think we mean by a small number of clinical quality measures? That's one and the second is, I didn't see an explanation of what key patient assessments meant in number 3?

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

So small, you mean how many – what's the number of measures? We didn't have that discussion specifically.

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

Okay. And then on option number 3, that you didn't particularly recommend, what was meant by key patient assessments?

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

So, what was meant by that versus how clear I can be are two different things. So what happened was, dur – the behavioral health people said the key assessments would be like for instance in the behavioral health arena, and remember it's mental health as well as alcohol and substance abuse we were looking at. How well a patient was doing 30 days out would be a key patient assessment. And we know that that data is difficult to happen, it's not clarified, so what does it mean to be doing well?

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

So, my comment, given that answer is, I think the list of quality measures that we're working from made me kind of nervous because an awful lot of them were measures of processes that people in that sector think are valuable, some of which are tied to outcomes and some are not tied to outcomes. And I would be reluctant to see us encourage an infrastructure build around capturing process data across a sector in industry where the value is not as clear and we're in this voluntary sensitive mode.

And this seems like an opportunity in a voluntary mode to really highlight, report your outcomes, you build whatever infrastructure you need to manage your processes in a very dynamic field, which is what we always said Stage 3 was about, not that it's directly the purpose of this topic. But it's an opportunity for us to signal that and that's why I was wary of the number, I could easily imagine satisfying the requirements that are implied here, once you define the small number of data elements getting bigger and bigger and bigger as you do that drill down you said we haven't yet had time to do. And that just made me nervous that for this kind of a program we should take a much more thin and elegant view of what becomes necessary for a voluntary adoption program.

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

And my one other comment is that during our dialogue, we did discover that there is some reporting going on and we did not delve into exactly what are those measures that are currently being reported. Because it may be that that thin, elegance may already be there for a subset that's already doing reporting.

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

Yeah, I think for me the patient assessments is actually a – number three, is a preferable direction for me. That we focus on the PHQ9 and the – and whatever other assessment tools are in common use, and get them accessible to the provider spectrum, rather than worry about all those individual processes that are listed on the eMeasures side.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Just one more comment, a lot of the measures that are listed on those slides that are highlighted in yellow are actually MU2...

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

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

So they're process measures that are kind of the baseline we're starting from. Some of those include like the PHQ9, which are great and need to get even further into use. But I think that there's definitely a movement towards away from some of those measures as you'll see, I think, in the next discussion.

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

Gayle, please.

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

Yes, thank you very much. Gayle Harrell. My question deals with what levers CMS already has in place, especially in LTPAC because I know, for instance, in the Medicaid program in Florida, 65% of the people – of the patients in our long-term care facilities are Medicaid recipients. So we already have levers in place and I would think that you would be able to do this certainly in coordination with ONC. But there are things that you could already – that CMS can already be doing and the coordination needs to happen, but, is that what you feel and see? And then, what process and progress are you making on that?

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

Gayle, that is what we heard, we heard it repeatedly from the long-term people that were on our call, including the people from CMS, they're already reporting. Their concern and other people's concern is that they may not – that reporting may be occurring – well, in many places is occurring independent of the health IT system. So, they are reporting on data that they are collecting to satisfy a CMS report and those data fields may or may not be standardized and may or may not be part of their health IT system, if they're running it. So some of this was a push to move towards electronic clinical quality measures that would be standardized and could be hopefully passively extracted from the health IT system as it got more sophisticated.

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

Thank you. I think that's the key, if you already have that lever in place and you have quality measures in place that people are already reporting, you don't need to do duplication, you need to start with what is required now and then build on that, that's a good way of starting a voluntary program, because there's already a need there. So if the quality measures are established, you've got a framework already, that's where you begin.

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

Yes, we would agree with that.

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

Great. Troy?

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

I think Gayle echoed a lot of my thoughts, is that – I had a couple of questions and you answered a couple of them is, what's being collected now? How is that being transmitted and to whom? Many of these things are done in secondary systems, things that you have to take it from the paper and enter it into something else. Sometimes you just submit it paper. So my question is, as we begin to build this and say okay, you need to submit the CQM data electronically, is the recipient ready to receive it? I mean we've run into that a lot of times with our immunization data that we need to share with our counties, they're not ready to receive it. So, I don't want to get the cart before the horse. So much like what Gayle was talking about is let's take a look at what we're doing now and what tools are we using to actually make that happen. And really add more to it, but make it easier for them to submit that data in an electronic format instead of having to transfer it to something else.

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

Yes, we would agree with that and what we heard from our CMS associates that were on the call is that they're already receiving that data, so people are reporting data. You're right, it sounds like a vast majority of that data is from a secondary system, which would be consistent with the use of health IT in those settings. So if we know there's not a lot of health IT, obviously they're submitting from some kind of secondary data set that they're collecting.

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

Right.

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

I would say that the need for the semantic interoperability and the data standardization, so for instance are they using SNOMED or ICD-9 or ICD-10. That came – that dialogue started on that call and was reinforced by either the fed – by both the federal and the nonfederal participants, that there was a sense that that hadn't been done. I would also, in full disclosure, tell you we didn't go in and look at those measures and we didn't do the crosswalk to the data standards and say, these are the 200 data elements that we think need to get standardized right away. I think if there's a sense that there's a push in that community, the long-term care community to move forward with the eCQMs, that would be the logical next step to do.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

And just to build on that, most of the, just the nursing home example, is built on MDS, the minimum data set 3.0 from CMS. It is standardized in terms of what nursing homes need to collect, but they're not doing it using the electronic health records.

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

Right.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

So I think the question is, how do you make it – make that reporting the easy thing to do because in fact, it would incentivize them to actually want electronic health records to make that data collection both easier, but also being able to get to the better measures they probably can't do currently. And especially with the connectivity back to the hospital, to the care tool, another one of the electronic tool sets CMS is developing, you can begin to see why you'd want to actually incentivize that use, because it will make better information available and it should decrease their burden over time. I agree.

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

In the conversations, did you have any vendors in the room that could say yes, we could do that? Was there anybody there that really said, oh yeah, it's not a problem, I mean, we can communicate with the CMS and do eCQM for you, not a problem?

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

No, we mainly had CMS and those who understand, for example, the MDS –

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

So it still needs to be explored is –

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

– so, it's really a question of handing it off, I think, at that point to those who could, maybe the Vendor Tiger Team could take a look at that as a next step potentially. Good thought.

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

Were there any thoughts about everything – we've had so much conversation about behavioral health and the nuances, that belong to behavioral health, you separated it subtly in the document, is that what you did in real time, is you separated it out, the LTPAC and the behavioral health?

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Yes.

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

Yes.

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

Okay, wonderful. Okay. Thanks.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Different groups.

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

Okay.

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

Judy?

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems Corporation

Yeah, I don't know if you've looked at what's going on overseas at all, but we see in some of the countries overseas that they have pretty strong social care programs that they are computerizing and they include behavioral health, mental health, maternal health and a number of other areas. And I think so that we don't end up with silos, it might be a good idea, if you're interested in that, to look at how they're doing the whole thing together, it's pretty comprehensive. Now I don't think there are systems yet that meet that, so that's going to be the challenge, but the concepts have been worked out and that might be of interest to you.

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

And we heard that repeatedly from our SAMHSA representatives on the behavioral health workgroup, this recognition that we really wanted to get to a holistic, coordinated care model. There was recognition that the Institute of Medicine was looking at non-traditional determinants of health, how to pull them in and then the transitions of care, how you would do bidirectional. So, we didn't look at that Judy, but obviously, and I think Helen will get to this when she gets to the quality measures for MU Stage 3. The work we had previously done with the ACOQM, we that repeatedly, too, that the really goal was health as opposed to health status, but it was really achieving health for an individual and a patient population and those other factors needed to somehow come into the fray of data that we were collecting and sharing on a regular basis.

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

Good. Thank you. Speaking of Meaningful Use Stage 3, it's quick?

Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator for Health Information Technology

Yeah, this is Kevin Larsen, just one quick clarification from CMS. They did tell us that they have a project that is nearly completed building a set of common data elements across long-term care settings. And that project is to map those to standards and to map those to a CCD, so that was something that the CMS representatives at our committee meeting talked about and was, I think, in alignment with the recommendations.

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

Okay. Helen, do you want to talk to us about quality measures for MU3?

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

All right, so continuing on, I realize I'm between you and leaving. So, just briefly we wanted to return to talk a bit more about our recommendations more specifically around MU3 measures and specifically the measures that – reflecting the stepwise progression. I think you've probably seen this slide many times today, so far, but really emphasizing that there was an expectation that MU3 would somehow be different. And that it would actually move us closer to outcomes, closer to building on a foundation of interoperable exchange, reducing the burden, getting to some of the key areas where we have not been successful in getting very many measures, like care coordination and incorporating that longitude view of the patient over time and settings.

So, as you'll see, some of this based on previous recommendations. For many of the concepts that were completely new, the workgroup has recommended developed – looking towards measures that have been developed for MU1 and MU2, as a first step. But some of these early process measures, as you'll see subsequently, have actually informed what we'd recommend for the development of the next age of measures. So, really building on what's happened in MU1 and MU2. And we specifically reviewed the measures under development by CMS. Some of these measures are – will be fully specified by the Fall of 2014, some are actually already out for public comment, and a link in the slides there for you to those measures that are already out for comment. But some are going through a fairly lengthy feasibility and validity testing process.

The last two items reflect on the NQF role, so I'll just briefly mention depending on the timing of when they're completed, it's not clear that they'd get through fully the NQF process in time for the MU3 NPRM, but we actually have just approved our new pa – a new optional pathway for eMeasures, which is trial use. So the idea would be measures that are otherwise would meet all the NQF criteria, including evidence, have gone through e-Measure feasibility, have a reasonable plan for usability and feasibility, of course. Would then move through our process with an expectation that they're implementation ready at the end of that, to go out and get the testing they need for reliability and validity. And we've, in conversations with Kevin as well as CMS, think this is a very viable option for new eMeasures, where the field really wants to get their hands on some of them and more quickly move them through the process before they've actually had an opportunity for full testing for reliability and validity.

You've seen this slide from us in the past as well, this is the measures concept crosswalk across some of the key domains in measurement. And you can see here the very simple red, yellow, green, where we have multiple concepts already in development or fully developed. And areas where we continue to have areas of red, where currently there are not measures, as you'll see, very few measures or no measures to date. For example on efficient use of facilities, some of the goals around self-management, patient experience or patient self-management, EHR safety, effective care planning are not ones that you're going to see reflected in the pages to come, although we do think they're critically important. I think the issue is as times some of them may be developed in other forms, it's not clear where the tether it is back to IT for some of these, like patient self-management.

So I just quickly will run through each of these by subdomain. As I mentioned, efficient use of facility, there are currently no concepts under development. Assessment in appropriate medication – assess appropriateness of medication and treatment, again none specifically listed here, although again, there are many others being developed for other applications and hopefully will move their way into this MU over time. Efficient use of diagnostic tests, some of these are listed as measures that are already under development, trying to get at some of the issues of overuse here, specifically listed here for breast cancer, headache and DEXA scans. There are specific recommendations the workgroup made to try to get to measures of overuse that move beyond imaging, and specifically think about measures that also reflect potential overuse of different levels of care like ICU care versus other settings of care.

This is a very broad domain around population and public health. Again listed out here by subdomains, we specifically italicized what the new versions of measures that are being developed, but are based on previous concepts. So not completely new, but also building on what's already been done to date. Healthy lifestyle behavior is listed there, for the most part all new, really getting at some of the annual wellness assessments, some counseling around alcohol and to partner violence. Effective preventive services is a very, very broad set of measures already developed clinical eMeasures here in this space. There are additional ones here both being developed on the prior concepts like prescreen vision in the medical home, and then some that are completely new, including some new dental measures that I know ONCs working closely with the Dental Quality Alliance on.

One note here is, we strongly believe since this is supposed to be about population health and disparities, that measures should be stratified by disparities and special populations whenever possible for those measures where there are concerns. And then in terms of recommendations for future development, there is also interest in making sure we can assess time to access language and interpreter services, measures that have already been developed for pen and paper, but again, an opportunity moving forward to think about how we can build them into the EHRs.

Patient and family engagement, patient health outcomes here, hopefully moving more and more towards these patient reported outcomes here. Specifically measures of functional status assessment, improvement for hip and knees, improvement in pain among children and a couple of outcomes for ADHD that build on prior concepts, honoring patient preferences, again, getting at both functional status assessments as well as goal setting for patient with a wide variety of chronic illnesses such as asthma, COPD, CHF, RA and chronic pain. And in terms of future development, very much strong interest from our workgroup of thinking about how ONC might partner with NIH on how to better utilize the PROMIS tools for both specific and global measurement of patient-reported outcomes. We have heard some examples, for example from Northwestern where they have already been taking the PROMIS tools to their patients who are doing and directly feeding them into their EHR. So, I think there are some nice opportunities there for future synergies and development.

Care coordination concepts by subdomain, effective care planning trying to get a sense of goal setting and risk reduction, a new measure specifically looking at continuity assessment. And building out a prior measure on closing referral loop, which actually was the critical information communicated with the request for referral, so getting to the first half of that loop. And finally looking at timely follow up of coordinating care with emergency departments. And the note here is the workgroup does really feel strongly there needs to be ongoing work to create more of a robust set of care coordination measures, specifically on closing the referral loop from the patient and provider perspective rather than just the providers. Does the patient get the information they need? Did they get the appointment? Were they seen as well as what has already been measured at the provider level.

Patient safety, this continues to be an area that is heavily oriented to the inpatient setting. We've had some discussions about the need for definitely more advance specifically in safety issues in the outpatient setting. I will note that those first two measures on adverse drug events are both hypoglycemia and hyperglycemia, were de novo eMeasures that just went through the NQF endorsement process with a full eMeasure feasibility assessment. It went very, very well, so very pleased to see finally some measures that are not sort of re-tooled old thoughts, but really what can be done using the better platform of what EHRs can bring to the table.

A list of other adverse drug events here, they do continue to be, and I know this is an issue David has raised in the past, they continue to be fairly specific to different therapeutic areas as opposed to a more global issue and I think that's an important issue going forward. But I think certainly begin to get at some of the key areas, around medication management and safety in particular. And lastly, there are hospital associated conditions, looking at a measure on rate of re-admission to the ICU within 48 hours. So recommendations for the future development, thinking how these potentially drug-drug interaction measures, either within eCQM space or perhaps even just linked to clinical decision-support and then really trying to get at this issue of more so global measures of safety, of medications rather than sort of everything being by therapeutic area.

So broader recommendations and needs, one I just mentioned is, perhaps there are some process measures are they more appropriate to be as CDS rather than necessarily linked to an eCQM and perhaps have more of the outcomes within the eCQM space. A question, and I think a need to think about how we may better measure patient experience of care coordination through CAPs and what's the connectivity back to the electronic data, the electronic health records is an important issue. More measures that get at global composites, measures and standards that will allow us to support the transport of data elements, including care setting, care coordination, goal setting, thinking more about what that platform would look like and how to actually make collection and use of patient reported outcomes more likely and the link to PROMIS. And then building in –

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

Patient-generated health data.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Thank you, patient-generated health data into measures. We've had two days of re-admission measures, I had no idea what that acronym was for a moment, down the block. So, I think those are the recommendations at this point and I think all felt there were more – we wished there were more available, that we're I think getting closer to I think what we hoped would be more around outcomes. But I think you can clearly, at least, see the progression from MU1, MU2 to MU3 and I think we'll – that will continue to improve. Anything you want to add, Terry?

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

Good, thank you. Questions, comments? Let me open up by looking at some of these measures and even in the pipeline, and as you acknowledge, there's mostly process still. Just a few – a couple sections and is this – so Stage 3 was where we wanted it to happen and we still have a little bit of lead time left. Is this an opportunity where we need to do a little pushing rather than waiting? And I don't know quite how to do that, but –

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

And we've talked about this certainly with Kevin. I think there's also an opportunity to do more prospecting for measures.

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

Right.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

There are health systems, there are groups like TBGH who are using measures now that potentially we could think about bringing forward and trying to get ready for MU3. Look to who else has measures, I think not everything has to be a de novo, let's start from, a concept, find the evidence. The current measure development cycles are still quite long, and how do we jumpstart that perhaps by finding out where there are examples of successful measures have moved the needle, and try to build on those rather than everything starting from the ground up.

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

And I think that one other thing Paul, was related to, I hate to bring this back up, interoperability. There was this real sense of maybe the push should be in how to, and I think that that's what you're seeing on this last thing, patient generated health data, but not just patient generated, externally generated health data. How do you develop a me – perhaps the focus should be on a measure that somehow is dependent upon incorporation – receiving and incorporation of all that data into a measure.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thinking about the interoperability piece and the VA, for example, and so Terry, I'd ask you about your experience within the VA system of the kinds of measures they use and how they map to this list that we've been generating?

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

Well, so right now from a VA perspective, especially with DoD, what we're bringing in is we're bringing in seven domains and we're ensuring that all that data is mapped, the typical domains, the normal suspects, and then using that to trigger clinical decision support. So I think if you go back, some of these are really – well, you see it right here CDS in lieu of or linked to a measure. So is there a way that you can push the envelope by saying, you have to bring in, and this is the multiple things you can get, you have to bring in external data. That external data has to trigger the clinical decision support and then you have to show improvement. The problem is that those get fairly – they may, even if you can do them, they get fairly difficult to assess whether you've done all those multiple steps and it's almost multiple reporting and I think that that's what the workgroup struggled with.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

And it's also probably worth going back to the recommendations we had brought forward as part of the –

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

ACO –

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

– ACO Workgroup, which we ultimately combined because we thought those were the recommendations for the future. And a lot of those were about saying specifically pick measures that require that working together across silos, requires interoperable data as being some of the key thoughts of what you'd move forward with. This is predominantly what's already in development, given the timeline rather than, I think, what could start now or where you could find something to begin.

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

So were those the ACO QM recommendations in theory represented here? Because they reported up to your group, right?

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

Yes.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Yeah, so we actually ultimately decided that we liked those as a workgroup and we thought those were though initially sort of brought forward as the ACO Workgroup, that we really did view them as sort of the future of measurement and thought they were the right approach. And I still think we would agree, both Terry and I, that those are still the right approach in terms of what the future of quality measurement and performance measurement should be. I think what we've given you here is more so what we know is already in development among the key domains and where we think we need to continue to push.

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

Maybe I'll just conclude that thought and then – is there way in the push approach that we can incorporate more of that language in your final recommendations that you bring back next month –

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Sure.

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

– so that at least we can expose where we're headed, the trajectory, the glide path that when we talked about patient enga – you talked about giving people information and should we start measuring their understanding about the next steps. And I understand that they don't under – that these aren't in existence yet, but I'm a little nervous that at the end of Stage 3, if we're not at least having that in our language the recommendations that go to CMS and ONC, it won't surface again. That's my concern, I guess.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Just one thing, and I think we'd be delighted to actually combine those two and bring them back. I think one concern is to remember how many of the slides of our presentation were about the barriers to doing that and the lack of a platform to make them so. We'd be delighted to say, here's the idealized state, here's what we think we should do, here is where we are, but I think we can at least try to make it more oriented towards what – how to get towards the idealized state.

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

Right.

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

And I would totally agree with her. I think our reticence was the acknowledgment of where we are, how much we have to do just for interoperability. But I do harken back to what I mentioned is that our goal was health, when you looked at what we did with the ACO QMs, we kind of changed the whole framework. We basically said it's not health status, it's not disparity, it's the achieving of health, which we know has a dependency in there. We did lots of work in there and we can – obviously we would love to bring those back, but I think we just were cognizant of that it's a big push, which we would be more than willing to share with you, again.

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

Well I just don't want the language to get lost on its way to transition and in fact, the combination in the workgroups in the future would be sort of Advanced Health Models and Meaningful Use. And we just want something to hand off. Because it's sort of – when David Lansky had the Quality Measures Workgroup two or three years ago, they had these concepts, we tried to hand it off to the existing group and we just want to make sure that we don't lose sight of that where – what measures that matter to both the consumers and patients. That's all. David Lansky?

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

Have you thought or started to articulate what the translation of the measures might be into the requirements in the rule? Is it going to be core and menu and how many of each and how these might actually be deployed from the user point of view? And the reason I'm asking is I'm wondering, to get to Paul's point, if there's a place to update the approach we have taken in the past to a flag a PROMIS measure or something – some of these things that we think are – or the longitudinal measures that Terry described. Where to satisfy the measure you've got to pull some data from two or three places. That evolution of capability would be a win toward Paul's point of being able to say, okay, we got to 2017, and now at least the leading providers, who have chosen, whether it's off a menu of a different incentive or something. They got a gold star because they were able to move to the next generation of measures in a couple of targeted areas instead of leaving it a fairly flat menu which nobody picks the interesting things and the vendors aren't really incented to build those.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

We did not –

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

No, we haven't done that David, but it's a really helpful insight. So let me ask you something since you did this for a really long time. Do you think it would be helpful for us to go back and say these are – not that we want to do workgroup work right here, but that there are three core measures. Because it just seems like as long as we make them optional, we run the risk of nobody, like you just said, doing that really hard work.

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

Yeah, I think Paul's old concept of exemplar measures, if we could find the magic, maybe talking intensively with the vendors as well as providers, what would be the thing that would be a modest increment of programming and design engineering that would give us a new capability, like patient-generated data or PROMIS or some other element of integration. Or claims data, bring the ability to bring cost data into the quality measure, that – any of those things would be feature – improvements. And if we could find the one elegant lever, that would be ideal.

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

Vis-à-vis the point about core metrics in this sense is what you said – there is an IOM study going on right now on core metrics and it's due to report out I think in the fall, or late summer at any rate.

W

– be the summer.

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

I think – actually. Christine?

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

And report out on what, Paul? Core metrics?

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

On core metrics. Is ONC a funder, is that –

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

No. I don't think we are.

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

Okay, well at any rate, no, I think it's NIH.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

We're a participant, but I'm kind of counting on that.

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

So actually, so there is this IOM committee and there's a report out later.

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

So my main question actually was what David said. So I hope that the workgroup can take a look at the structure of the Meaningful Use quality measure requirements and how it could evolve since it's more of a stepwise process. We did actually did start with three core measures in Stage 1 and I don't think that approach worked very well, because we moved away very quickly from it, because it didn't apply to everyone, right. But anyway, so, like you said Terry, we don't need to do the workgroup work here, but I think that would be terrific and thank you guys for all of this. It's really good stuff.

So the other thing I was going to just ask and maybe clarify is, connecting patient experience, care coordination, I assume you mean CAPs questions on care coordination back to the EHR. We had done work, the work that David led in 2009-2010, where we came up some of the measure concepts that you guys have built on and now are getting to eMeasures, which is terrific. And one of the recommendations we made at that time was that HHS should really look at creating a common platform for patient experience data collection. Because the economy of scale, when the federal government is able to do that would be significant and could be potentially very meaningful and really get patient and family experience measures off the ground for many, many settings that can't always afford to do measurement the right way.

So – but in this case, obviously that recommendation didn't go anywhere. So I just was going to flag for you that one of the benefits and strat – it was strategic in Meaningful Use Stage 3 recommendations that including a patient experience – I'm sorry, patient-generated health data capacity was so that people could actually use it for – it would be an informal patient experience data collection tool. That they could use to focus on whether people thought their care was coordinated, etcetera, etcetera. So is that the way you're thinking about that second bullet there?

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

The second bullet on this slide? Yes. But we were not thinking – I was not aware of what you said you had proposed before about the federal – HHS becoming – developing the platform for reporting on that. But it was, how do we incorporate what in many cases is a de facto standard, not to say that CAPs is, but a de facto tool that many places are using into the electronic health record. Similar to what David was saying about, so where do you push on, do you push on fiscal data, do you push on patient experience of care data and then how do you link that back.

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

Yeah, and I think that's a challenging question that frankly I've struggled with for the last several years. Because when I look at patient experience and the connection to Meaningful Use of health IT, unless you're talking about HIT CAPS Module, which there is one, it's sort of like, yeah, there is definitely a role, there's a link, but it's not as direct as I think you would want. In that case, the way I viewed it is to really look at the EHR as a way to make the right thing to do the easy thing to do. So how do we use the EHR as a tool for providers who want to, to collect patient experience data a little bit more informally, because they want to use it for quality improvement as opposed to reporting, for example. Even though Meaningful Use isn't a performance program, I think getting people accustomed to using patient experience data for quality improvement purposes is really valuable, but whether it should become part of the bigger quality measure reporting requirements for the program, I'm less certain.

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

And I think the other thing that we're aware of is we don't want to get in a situation where we pick, and David, this kind of goes to your point, where we pick 1-3 measures, and people hard code those 1-3 measures.

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

Right.

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

Remember, the goal once again is to expand the capability of the system. And so the issue is, is there some generic way to say, you must incorporate blah, blah, blah and so that expands capability as opposed to just expanding then all of a sudden you're just including this one element from a survey in there. So I think we struggled with that.

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

Karen?

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

– David. Did you have something else David? Oh, all right. Well, recognizing how much work you guys have already put in, I just have this question about, that relates back to the prior presentation talking about common data elements in the LTPAC arena, for example. So in thinking as we go forward, years to come, I'm going to get back to the VA as an example. So the veteran who lives in rural Nebraska may also need to go to Omaha for their care, but in rural Nebraska they may be seeing a private provider and you want that information to move with them if they move through the system. And both of them would want to know about blood pressure control as an important outcome variable for them.

And so I guess I'm thinking about, as you all have been talking and is it rolled up on these slides that we need some common data elements that are collected, that are standardized, blood pressure, smoking, etcetera. That just relate to the core of things that we might want to translate into other information, but that would also relate back to other huge healthcare systems or payers like VA, DoD, etcetera and only be applicable in the private sector.

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

So I can just give you our experience. We focused on domains, seven domains, but within those domains that's where you get in trouble. So one would assume that vitals would be pretty easy, right, like how hard can vitals be? Well vitals, it turns out, is really difficult to do a crosswalk and one person can have 13 vitals and another one can have 22 vitals. And while you may have this – you may know what a blood pressure is, you really may not know what a blood pressure is. So I would agree with you, Karen, this is really critical work and the next step is not to just say, you're going to use – what code you're going to use, but you have to that next step, so you get to this really granular level, so you can do clinical decision support with it.

Obviously the VAs in the midst of this, as you know, as we're trying to figure out how to share more and more data with the Department of Defense. But we don't have a minimum core dataset. Now if you look at long-term care in a sense, because of what – and Kevin shared this, they actually have some long-term minimum data sets that are available. The problem is that they may or may not be mapped to specific standardized codes that have been endorsed by ONC through the standards subcommittee. But I think the goal of the measures and the electronic clinical quality measure is, in a sense, to create this de facto minimum data set, because you have to have "X" number of data elements in order to report on those eCQMs.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

As Jacob and Amy would say, give us the fundamental building blocks and you can almost build anything if we get the common data elements right.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Right and I think certainly if you look towards what's already been done through HHS quality measures counsel to pick measures that work across all the different agencies, well that would be a pretty logical place to start, in terms of at least making sure you've got those data elements. I think the challenges is, as we said in one of the earlier presentations as well, the problem is that for some of the measures you really want, those data elements that don't exist. So we can say these are the measures we really want and then unfortunately we're still at a state where many of the EHRs just can't capture those yet. But it would be nice to have the ones that are also the ones on the "to do list" to make sure they get standardized.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

And I have one more question about hospital acquired conditions. Has the CDC been engaged with you all in this? I'm – Chesley's gone, unfortunately, I don't know what they're measuring to track?

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Yeah. the CDC uses NHSN, which is a standardized approach to collecting all the data around healthcare associated infections. I know they've moved towards trying to have more and more of those available through EHRs, but I think for some institutions, they're not there yet.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Not there. Okay. Thank you.

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

The one thing – the one follow-up Karen on that is, how do you – how do we use the federal resources of ONC and the Standards Committee within ONC to drive to the next level? So I'm just going to pick on homelessness here, because it came up on behavioral health, it comes up on lots of places. I actually did a V-code search the other day, because we're supposed to be pulling our demographic data and sharing it with DoD, well homelessness was a critical thing. We don't have a homelessness field, but there are ways to get at homelessness, but they're all backdoor ways. So my think somebody's homeless may not be consistent with SAMHSAs saying they're homeless and so there are some known – I don't want to say it's low hanging fruit, because I don't think it's low hanging. But there are definitely predictors of health that we know about that we should figure out how to collect. And if we could push on it through an electronic quality clinical measure, I think we'll give you the measure.

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

Maybe one final follow-up and this is actually feeding – reflecting back to some things that you've said in the past. I guess I'm trying to put it all in one document, and you said some of this because it's sort of a hand-off, and that was the innova – you used the term prospecting again Helen. And the innovation track, where the theory was if CMS allowed one out of let's say six measures to be something that you already have experience with and you find this to be useful, well by golly share it and we'll give you credit for that. And that becomes an alternative pipeline for CMS and others, or even NQF to prospect for other measures. It's something you did in NQF, of course.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Right. I mean it sounds like what you're asking for going forward is kind of us doing a bit of a final report –

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

Yeah.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

– of going back through the various presentations we've made, pulling together all the different threads of where we think this needs to go. We'd be delighted to do that, that would actually be, I think, a nice way to wrap this up. But we'll continue to harp on where there are aspirations without infrastructure, but I think that's still really an important thing for ONC to continue to hear.

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

It's a bit of a connecting the dots, because those answer the questions, some of which we've – either you've raised or we've raised and if we could connect the dots in this way, it sets a little bit of a blueprint for the country. Even if it all doesn't happen in 2017. Any other questions or comments? This was wonderful, thank you, thank you very much Terry and Helen. And we'll open for public comment.

Public Comment

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

If there's anyone in the room that would like to make a comment. Just a reminder that comments are limited to 3 minutes. And operator, can you please open the lines?

Rebecca Armendariz – Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-6006 and press *1. If you are listening via your telephone, you may press *1 at this time to be entered into the queue. We have no comment at this time.

Donna Dunefsky – National Association for the Support of Long-Term Care

Hi, I'm Donna Dunefsky, I'm with the National Association for the Support of Long-Term Care, NASL. Our members are the IT vendors and providers in the long-term care space. They provide software and system support and everything. So we'd be happy to work with you on any of the things you've covered this afternoon, in particular the quality measures and the LTPAC related information. So, we are a resource for you. Thank you.

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

Operator is there anyone on the phone?

Rebecca Armendariz – Altarum Institute

We have no comment at this time.

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

Thank you.

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

So, during – one, this was, I thought, a really useful and productive day, in terms of the conversation. I think it was wonderful to have diversity of opinions and perspectives represented in the room, which is just by design and enjoyable. We talked about a lot of things that we said were at the leading edge, sometimes the bleeding edge, but it's one of the things that we need to help think about, and it's better if we think about it than let it happen to us, we'll be in dire straits that way.

Another thing is that all the workgroups got to thank their – the ONC – tremendously appreciated. And I want to talk about someone who's workgroup wasn't represented today, but who is a part of every call and is the lead staff for the Meaningful Use Workgroup and, by the way, is the one responsible for shepherding and herding this group – .

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

And standards.

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

And standards, and that's Michelle Consolazio. And thank you so much, Michelle. It's amazing, right, I actually don't believe one person does this, but at any rate, thank you all for a wonderful day and we will see you virtually in June. Thank you.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you.

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

Can I make quick announcements, a little plug.

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

Yes.

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

So tomorrow we have our certification hearing, just a reminder. We would love for people to participate, that starts at 9 AM. There are a few other things that we've discussed today. There's the Certification and Adoption long-term post-acute care and behavioral health listening session on May 13 and Meaningful Use is also holding two listening sessions May 20 and May 27. Thank you.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you.

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

Thank you.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you Paul.