



HIT Policy Committee Final Transcript June 10, 2014

Presentation

Operator

All lines are bridged with the public.

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

Thank you. Good morning, everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is the 60th meeting of the Health IT Policy Committee. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. If you are tweeting, the hashtag for today's meeting is #HITPC. And I will now take roll. Paul Tang?

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

Here.

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

Sorry, I should have said Karen first. Karen DeSalvo?

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

Present.

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

Alicia Staley? Aury Nagy? Charles Kennedy? Christine Bechtel?

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

Good morning.

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

Hi, Christine. Chris Lehmann?

Christoph U. Lehmann, MD, FACMI, FAAP – Director, Clinical Information Technology - Johns Hopkins Children's Medical and Surgical Center; AMIA

Good morning.

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

Good morning. David Kotz?

David F. Kotz, PhD – Champion International Professor – Dartmouth College

Good morning.

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

Good morning. David Lansky?

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

Here.

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

Hi, David. David Bates? Deven McGraw, I know Deven will be joining us later. Devin Mann? Gayle Harrell?

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

Here.

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

Hi, Gayle. Josh Sharfstein? Madh Agarwal? Marc Probst?

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

Here.

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

Hi, Marc. Neal Patterson?

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

Present.

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

Hi, Neal.

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

Hi.

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

Patrick Conway? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Here.

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

Hi, Paul. Rob Tagalicod? Scott Gottlieb? Thomas Greig? And Troy Seagondollar? And so as you all may have noticed we have our three new members joining us today. So we have Dr. Chris Lehmann who is our first pediatrician on the Policy Committee and he will be filling the vulnerable population slot, which used to be Neil Calman's slot on the committee. We have Neal Patterson, who is the CEO of Cerner, who will be replacing Judy Faulkner as the health IT vendor representative. And we have Kim Schofield, who will fill the position of the consumer representative, formerly Art Davidson's position. She is a health educator and an advocacy chair for the Lupus Foundation, and she herself is a lupus patient. So I just want to take this opportunity to welcome our new members and we'll get to meet them all in person at the July meeting.

Also as a reminder, we're going to use the hand-raising feature for questions after our presentations. So, if you aren't logged into Adobe Connect, if could try to do that, we would appreciate it. If not, please either send me an e-mail and wait until after we go through the queue of questions and we'll take verbal responses for people with questions. And with that, I'll turn it over to you, Paul.

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

And I think I'll turn it back to Karen for any introductory remarks and then we'll get started with a review of the agenda.

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

Thank you, Michelle and thank you, Paul. If you all will allow, I just wanted to make a couple of high-level remarks and invite maybe folks for questions perhaps not during the meeting but afterwards, or if there are any pressing questions right now. One is for the Policy Committee to just make certain that I share that everyone – so that everyone knows that we undertook some functional realignment of ONC in the last couple of weeks. There's been – I think you all received an email from Jodi giving you some information and pointing you to a link where you can read more that's on the Federal Register Notice.

This is something that we've been talking about for months and is predicated on a need to begin to pivot out of the ARRA Era, it's hard to say, of ONC when we were largely a grant making agency and growing very quickly in other areas of our work around policy and coordination. And that timing means that some of our programs are beginning to sunset and we have an opportunity to begin to focus in a very systematic way on interoperability and on the implementation of a roadmap that we are working on developing internally and will want to do with the FACA.

This in particular for you all means that there have been some changes in the names, for example, of some of our units. The example would be the Office of the Chief Medical Officer, which we are renaming as the Office of Quality and Safety, since that is truthfully the work that they have been doing and it hopefully reflects better to the outside world where the right door is for those kinds of conversations. And we also took the opportunity to take the Office of Standards and Technology, which has always been with us, but split it from the Office of the Chief Scientist. So the Chief Scientist, Doug, can focus on forward-leaning and future innovations and the learning health system works that's going on with PCOR, as an example, as well as international work. And then the Office of Standards and Technology picks up certification, is led by Steve Posnack, who's been with ONC for almost a decade doing a lot of policy work, but also as a strong technology background to really marry those two concepts and work, as I said, on implementation in a variety of areas including interoperability. We retained all of our other portfolio, for example, the Privacy and Security, the eConsumer Health, which remains in programs where it's been and overall for the organization, removed some layers between the immediate office, the National Coordinator and the leaders of these areas.

And one final comment, which is that we did create a new shop that is designed to be a feedback loop between the development of strategic priorities for ONC for the federal HIT strategic framework and then for what we hope will become a national consensus agenda. And the performance measurement team and then the evaluation team, which Jen runs – Jen King, who you all know, as an opportunity for us to really understand the impact of policies and other work that we at ONC do, but that we all do together, and see how the field is moving forward. So for purposes of the FACA, specifically though, Jodi still has the FACA in her portfolio, that remains unchanged; Michelle remains unchanged and many of the faces I think that you all see are the same. But I do – I wanted to let you all know that you're going to be seeing a lot more of Steve Posnack in his role of running the Office of Standards and Technology and Kim Lynch, who runs Programs, which is our major outreach portfolio.

I'm just going to say the second piece and then if there are any big questions, I'll be happy to take them. The second is just that on the heels of that, we released an invitation to dialogue around interoperability that signals a couple of things. And that really is meant to essentially set a table and begin a journey that will move us towards a much more concrete and detailed roadmap around interoperability that we share with the private sector and with our other partners in the federal government. We want to make sure that we're looking towards a future that involves the query response in addition to the use cases for Direct. And be thoughtful about whether architectural suggestions like JASON have teeth and are something that might be a platform for moving forward, and also really make sure we're thinking through privacy, security and governance and other issues.

And I would say very broadly about this, too, this interoperability conversation we're looking forward to having is more than just about healthcare, it's about health. And how do we create a future where information can flow not just between the healthcare systems and electronic health records, but really create a platform that broadens our perspective on all the things that influence health including patient-generated data and opportunities for big data and research to do that in a way that is appropriately private and secure. So, that's the beginning of our journey, it's not desi – it's designed to be a visioning statement and we'll be working with you all and others on developing a concrete plan.

It's not that we're going to do it all as I say often, we can't, we want to do this in partnership with others and just make certain that there's a real collaborative consensus. And I just got passed a note because I did neglect to say that we – back to the reorg that Judy Murphy is taking on a new role in the organization as Chief Nursing Officer and she will be over the Quality and Safety shop, and I'm excited to have her be willing to take on that role. I think it's an important voice that is welcomed, along with all the other voices that we have at ONC and in the country. So, I'm going to stop there and if there are pressing questions, I will be happy to take them and/or hopefully you all know how to find me off-line and I'm always available to answer any questions or to provide more information.

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

Thank you, Karen. Any specific questions for Karen? Okay. Well thank you very much.

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

Thanks –

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

So, I want to open up – go ahead –

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

I just said thank...

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

So, I want to open up and welcome the new members and thank you for participating, thank you for your commitment to both the committee and the mission of the committee, in terms of advising ONC and HHS, who have been highly participating in this committee and we appreciate all of the volunteer effort provided by members.

Let me, before I forget, ask for an approval of the minutes. You had that distributed to you probably a couple of weeks ago and hopefully you've had a chance to look it over and ask for any comments. If not, I'll entertain a motion to approve the minutes.

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

So moved by Gayle.

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

Okay, thank you. And second?

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

Yup, second.

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

Okay, and any further discussion or additions. All in favor?

Multiple speakers

Aye.

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

Any opposed or abstain? Okay, well thank you very much. Let's look at the agenda we have. We try to alternate between in-person and virtual, partly as a cost-saving measure, so we'll open up with a data review from ONC and from CMS. Jen King has an update in terms of what's been experienced with the eligible professionals in the first three years. We've been asking for that to better understand what we know at this point. I'll present an update from the certification hearing and we do have some recommendations for approval by the committee, for discussion and approval. Then Larry Wolf is going to give us an update on the LTPAC and behavioral health update in the voluntary certification program. They will be updating us for – and then have final recommendations for our next face-to-face meeting in July.

Helen Burstin and Terry Cullen are going to update us on the quality measures, their work and their perspective or opinion on LTPAC and behavioral health quality measures. And then Deven and Mickey will be providing recommendations for approval in the behavioral health data segmentation topic. And we'll conclude with Jon White from AHRQ, presenting the JASON Report. This is something that Karen has asked for the HIT Policy Committee and Standards Committee to comment on. She talked about it in the context of interoperability. And then we'll close with the public comment. Any comments or additions to the agenda?

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

This is Michelle, just a reminder, if you aren't speaking, if you could please mute your line it would be appreciated.

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

Okay, well let's open up with Jen King and Elisabeth Meyers from ONC and CMS for a data update. Jen, I think you're probably going to go first.

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

Okay, great. Good morning everyone, this is Jen. Like Paul mentioned, we have some data today on the three-year experience of eligible professionals in the EHR Incentive Program from 2011 through 2013. So, we've been presenting a lot of this data over time as it's been coming in to you all on a monthly basis. But we're taking advantage of the fact today that we have had the opportunity to dig in a little bit more and understand in a little bit more detail, what's been happening on the eligible professional side, in addition to just sort of the topline statistics on overall progress.

So, on the next slide you'll see that we have three main questions that we are going to look at today. First looking at who has been able to achieve Meaningful Use in the first three years of the program. And then we'll take a look at who's been able to continue to achieve Meaningful Use year over year? And then lastly, look at how performance on the Meaningful Use objectives varies by key professional characteristics.

So first taking a look at who's been able to achieve Meaningful Use in the first three years. On the next slide, you see that's the vast maj – a strong majority of EPs have attested to Stage 1 so far, about 6 in 10, up until now. And if we dig into that group a little bit more to look at which types of professionals are more likely to be in that group that has attested to Meaningful Use? On the next slide, we took a look at attestation rates by physician age, specialty and group size. And we see here that younger physicians are slightly more likely to have attested to Meaningful Use than older physicians. We see that there are no real differences in attestation rates by primary care versus medical or surgical specialists, but we do see that physicians with behavioral health specialties or non-direct patient care specialties are less likely to have attested in the first three years of the program. And we also see that solo providers are less likely to have attested to Meaningful Use than physicians in larger group practices.

On the next slide, we took a look at variation in attestation rates by some key area characteristics. So first, looking at urban/rural practice location, we see that rural providers are just a little bit more likely to have attested to Meaningful Use. No real differences in terms of whether or not the physician is located in a primary care health care professional shortage area. And some modest differences in terms of some of the population demographics in the counties in which physicians are located. So physicians and counties with higher percentages of the population that are Hispanic or black or have incomes below the poverty level were slightly less likely to have attested to Meaningful Use in the first three years of the program.

And then lastly, on the next slide we took a look at the role that technical assistance and participation in some new models of care is playing in – and the association with attestation rates. And here we see by far the largest effect sizes that we've seen of any of the characteristics we've looked at. So we see that physicians who are participating in the Regional Extension Centers are significantly more likely to have attested to Meaningful Use in the first three years of the program. We also see that physicians who are – have certification as patient-centered medical home, through NCQA, which is just one of the many PCMH programs but sort of an indicator that we had data on here. We see that physicians participating in those programs were also significantly more likely to have attested to Meaningful Use in the first three years of the program. And a little bit more likely where physicians who are located in states that are attesting state innovation models through CMS, which is a multi-payer sort of comprehensive reform efforts going on in those states, and physicians who were located in Beacon communities. So we see strong relationships here between technical assistance provided through the RECs and some of the new models of care that are being rolled out across the nation and attestation for Meaningful Use.

So then, on the next slide, the next thing we looked at, like I mentioned, is the types of professionals that have been able to achieve Meaningful Use year over year in the program. So those that have been able to maintain participation over the full three years. So the next slide here shows you a snapshot of information that you've seen before, but this is sort of a visual representation of the providers who first attested in 2011 and their participation going forward over the next two years. So this shows you here that of the 58,000 or so professionals who attested through Medicare in 2011, the vast majority of them have it continue to attest in 2012 and 2013, but we do see some movement in and out.

So the orange segment of this chart down at the bottom shows you that about 16% of those EPs skipped 2012 and did not attest in 2012, but just under half of those professionals who skipped 2012, ended up coming back in 2013 to attest. And then that far bottom segment there, the 9% of the orange, shows you the segment of professionals who attested in 2011 but then skipped 2012 and also skipped 2013. So this group includes some professionals who have likely become ineligible for the program over those two years because they've left practice due to retirement or other reasons. Physicians who have potentially died, so we don't have full information on what's happening in that group and we would expect that some of that group are not returning for valid reasons such as those, but it also contains folks who started in 2011 and for whatever reason, have not come back in 2012 and 2013.

So to understand sort of who's in that group and who might be at highest risk of skipping multiple years, on the next slide we just took a look at whether or not there's any variation in key physician characteristics in terms of the likelihood of being in that group that has skipped two years of the program. And we see some differences by specialty practice size and rural/urban location. So we see that behavioral health and non-direct patient care physicians are little bit more likely to be in that group that has skipped two years, as are physicians in smaller practices. And just a small difference in terms of physicians in rural counties who were a little bit more likely to be in that group.

So lastly, on the next slide here, we're taking a look at how performance on the core objectives has varied by key provider characteristics. So the next slide here shows sort of an aggregate measure of average performance relative to thresholds on the core objectives among Medicare physicians who have attested in the three years. And we've broken this down by the year that the physician first attested in the program and then their performance over time as they've attested for multiple years. So you can see, for example the blue bar shows those providers who first attested in 2011 and in 2011 on average they were scoring 78% above the thresholds across all of the core objectives. And by the third year that they had attested, 2013, that had increased to about an average of 86%.

So we see some small changes over time in terms of better performance on the core objectives. And we also see some small differences in terms of when providers came into the program. So, for example, the green bar there shows that providers who started the program in 2013 actually had slightly higher on average scores relative to the thresholds in their first year of attestation than did the providers who attested earlier in the 2011 or 2012 cohorts. The differences are small here, but you see some trends in a positive direction.

So, on the next slide here we took a look at whether or not there is variation in performance on that measure by key provider characteristics and we didn't see many differences by some of the characteristics I've shown earlier. We do see that physicians in smaller practices were scoring a little bit lower on average on the threshold scores, but still quite high overall. And we did see that physicians participating in patient-centered medical homes had higher scores on average as well. But we didn't see any major differences by other characteristics like physician age or urban/rural locations.

So then moving forward to the next slide – I guess that wraps up the new data that we’re presenting today. Just wanted to give you a snapshot of next month in July we plan to present some – a little bit more in depth data on the early folks who have been attesting to Stage 2 so far and digging in a little bit more into their characteristics and some details there. And then moving forward to the next slide here, happy to take any questions at this point. But just want to sort of sum up by saying that these analyses that we’ve been able to do here sort of provide us some important information going forward about the types of providers that may be most in need of assistance going forward, that will be particularly important for us to monitor. Also really highlights the key role that technical assistance through the Regional Extension Centers has played in helping providers achieve Meaningful Use thus far and also sort of highlights the intersection between some of these new models of care and achievement of Meaningful Use thus far. So thank you all, I’m happy to take questions.

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

Thank you, Jen. Very interesting, I especially liked your green/orange graph, I mean it was – it’s very – it’s easy to interpret that and it does show sort of migration in and out. And I think all of the widths are proportionate and all the percents are absolute, so you can just add these together. So, it’s very helpful. I do have one clarifying question on the – when you quote a statistic on average performance above threshold, how do you calculate percent above threshold?

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

So, this was something that we – we were trying to come up with a measure that would sort of be one measure that we could easily look at performance across all the objectives, since CMS has been presenting the detailed data on objective by objective performance, so you all are very familiar with that. So what we did to create this measure was take, for each objective the threshold that is in place, so if it was a 50% threshold for example. We calculated – and a provider scored 80% on the measure, we calculated what percent above 50 80 was and then took the average of the provider’s score relative to the threshold across all the core objectives. So this is a way of taking a look at how far beyond the threshold the provider is participating – is scoring and gives sort of greater weight to those measures where the threshold is lower. So getting an 80% on a measure with a 30% threshold gives you a little bit higher score than getting 80% on a measure with 70% threshold, for example.

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

Thank you. So in your example, if the threshold was 50 and you scored 80, then you were 60% above threshold.

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

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

And likewise if the threshold was 5%, like in – 5% and you scored 10, then that would be 100% or 20 would be 400%, I guess. Is that right?

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

Well, it would be – so actually – so if the threshold was 5 –

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

And you got 20 –

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

– then you would have a potential of scoring 95 points above that. So if you scored 80 points above that it would be 80 over 95. Does that make sense? We debated whether or not to actually include a calculation slide there, which we probably should have done. So I'd be happy to provide sort of the details on the calculation and we can maybe add that to the deck that's posted.

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

Sure, that would be helpful. So just one example, if it was 5% and you scored 20%, what would that be?

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

So, maybe I can do that calculation while Beth is doing her update and then I can give the exact answer rather than trying to do it on the fly.

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

Sure, okay. Other questions for Jen? I think everyone is anxious to hear next, in July, the early experience in Stage 2.

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

Paul, its Christine, I just have a quick question.

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

Sure, go ahead Christine.

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

Jen, when you listed the different sort of delivery system models, I didn't see ACOs on there, is that underneath the state innovation models or was that not possible to look at?

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

So we are working on some of those analyses now, but we just haven't had the full data on that to be able to present that yet, but they're not included under the state innovation model specifically.

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

Okay, got it. Thank you.

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

Um hmm.

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

Any other questions for Jen? Let's move on to Elisabeth then, an update from CMS, please.

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

Okay. Thank you. Hi, this is Elisabeth Myers from the HIT Initiatives Group at CMS and I just have a couple quick updates on our attestation numbers so far. Can you go to the next slide, please? And actually, one more. So, a couple of people had asked about just looking at registration year over year and month over month instead of how we had been presenting it before, so we put together just a slightly different version of the table. So you can see as year over year attestat – or I'm sorry, registration, this is to the end of April 2014 and you can see our totals are 316,303, 156,641 and 4727 eligible hospitals – next slide.

So our Medicaid payment totals, I just wanted to point out the MU program to date number on the middle of the blue line and the center blue line. You can see it's a 44,900, so that is a pretty significant improvement and we're excited to see that the MU performance numbers for Medicaid continue to climb. Next slide, please. Overall, we are at 383,072 eligible professionals and hospitals who have been paid through the program so far. The numbers for the year these are paid keep – just you want to keep that in mind, I'll get through to 2014 attestations a little bit later on. But unique providers paid in 2014 represents when the payments were made, not necessarily who has attested so far for this year. Next slide, please. Overall, we are at \$23,725,000,000 payments total made through the program. Next slide, please.

And I put in this estimate because there were a couple questions that we received about total payments made not by unique providers. So these are the estimates through the end of May 2014 for total payments made. The number of total payments made is just over 660,000 and you can see the number there that is 24 billion is because this one goes through the end of May, this estimate whereas the previous slide went through the end of April. Next slide, please.

So overall registered, we are at just under 95% of eligible hospitals have registered for the program. And next slide. We have just over 91% who have been paid for the program. Next slide. Overall registered eligible professionals we have finally hit a mark that is pretty exciting here, we are 88% of eligible professionals have registered for the program, so that's an indicator of awareness of the program throughout the country. Next slide, please. And we have – here are our numbers for paid eligible professionals, sorry, just under 46% who have been paid through the Medicare program, just over 22% who have been paid through Medicaid and then our MAO program at 2.3%. Next slide, please.

So just a program trends and highlights, to reiterate over 91% of eligible hospitals have received an EHR incentive payment for either Meaningful Use or AIU. We are at 88% of eligible professionals who have registered for the Medicare or Medicaid EHR Incentive Programs. We have 68% of the Medicare and Medicaid EPs have made a financial commitment by implementing an EHR. And over 380,000 Medicare and Medicaid eligible professionals and eligible hospitals have received and EHR Incentive payment. Next slide, please.

These are our attestations for 2014 through June 1. We have 1497 eligible professionals who have attested for the 2014 reporting year, 231 are new participants and 447 have attested to Stage 2 of Meaningful Use. There are 75 eligible hospitals who have attested for the 2014 reporting year, 21 of those hospitals are new participants and 8 have attested to Stage 2 of Meaningful Use. Next slide, please.

As you all are most likely aware, we've recently published an NPRM for Meaningful Use about the use of CEHRT in the program for the 2014 EHR reporting period. Next slide, please. Just wanted to give a very quick overview of that NPRM. CMS and ONC developed the NPRM and published it on May 20 proposing flexibility around 2014 use of certified EHR technology for just the 2014 EHR reporting period. And in addition, we extended Stage 2 through 2016 that should have been no surprise to anyone, we announced that we would be doing that back in December. If finalized, the NPRM would allow providers to meet Meaningful Use with electronic health record technology certified to the 2011 edition criteria or the 2014 edition criteria. And somehow, that got deleted from that slide, but it should say 2011 edition criteria, the 2014 edition criteria, or a combination of both editions of certified EHR technology for the 2014 reporting period. It would require providers to report using just the 2014 edition CEHRT for the 2015 EHR reporting period as had been previously outlined in the regulations. And again, it does extend Stage 2 through 2016, so Stage 3 would begin in 2017. Next slide, please.

The options, just a little more clarity around them, because we've received quite a few questions about what they say. The proposed options for providers scheduled to meet Stage 1 in 2014 using variations on the certified EHR technology. Provider who is scheduled to meet Stage 1 in 2014, if this proposal were to be finalized, would be able to use 2011 certified EHR technology to attest to 2013 definition of Stage 1 Meaningful Use objectives and measures and to 2013 CQMs. And by 2013 CQMs, we simply mean CQMs that were in use by the program during the 2013 EHR reporting year.

You could potentially use a combination of 2011 and 2014 edition CEHRT. To do so, you would actually have to choose a task, you would either attest to the 2013 definition of Stage 1 Meaningful Use objectives and measures and attest to 2013 clinical quality measures. Or you could attest to the 2014 definition of Stage 1 Meaningful Use objectives and measures and report on the 2014 clinical quality measures using the methods that are available for 2014, which include attestations and electronic reporting through the quality reporting program. You could also use your 2014 edition to provide EHR technology to attest the 2014 definition Stage 1 objectives and measures and the 2014 clinical quality measures. As previously stated, these would be in the methods that are already approved for the program from the 2014 EHR reporting period. Next slide, please.

Proposed options in the NPRM for providers who are scheduled to begin Stage 2 in 2014. Again, these are around the use of certified EHR technology and the functionality of that technology. This would allow providers to potentially use 2011 certified EHR technology to 2013 definition of Stage 1 objectives and measures and again the 2013 clinical quality measures they would have to be attested to, that is the clinical quality measures that were in place for the program last year. Ultimately a provider could potentially use 2011 and 2014 edition certified EHR technology to meet the 2013 definitions of Stage 1 objectives and measures and the 2013 CQMs or the 2014 definition of Stage 1 objectives and measures and submit the 2014 CQMs through the methods that were previously available. Or the 2014 definition of Stage 2 objectives and measures and the 2014 CQMs, as mentioned, either through attestation or electronically reporting.

And finally, they could use their 2014 edition certified EHR technology to meet the 2014 definition of Stage 2 objectives and measures and the 2014 CQMs, as scheduled or the 2014 definition Stage 1 objectives and measures and 2014 CQMs, again using the CQM methods of attestation or electronic reporting through the clinical quality program. These proposals were made for providers who have been unable to fully implement certified EHR technology due to the delays in availability for 2014 CEHRTs. Again, this is sort of the second arm of the previous policy that we had put in place using the hardship exception. The hardship exceptions are seen as a sort of safety net for providers to allow them to not be subjected to the payment adjustments and this proposal would allow providers to also continue to remain on the incentive payment track as well and meet Meaningful Use for 2014.

Again, this is a proposed NPRM. If we can go to the next slide. We are currently accepting public comment on it, this is not a finalized regulation. The NPRM is available on the Federal Registry, the link is available on this slide. The deadline for submitting comments is July 21, 2014. We do strongly recommend that you submit your comments early, to allow us adequate time to get through them so that we can finalize the rule rather quickly, if we are to determine that that finalization will happen. Next slide, please. So, are there any questions, I can take questions now. Again, I do want to sort of reiterate before we begin any questions that this is a proposed rule, so there is a limit to the questions that we can address on it, because it is out for public comment right now. We can clarify what the rule says, we cannot make policy interpretations at this time. So I'd be happy to take any questions.

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

Thank you very much, Elisabeth. Questions or comments from the group? Okay, well thank you –

Paul Egerman – Businessman/Software Entrepreneur

Actually, Paul, I had my hand up.

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

Oh, sorry, didn't – go ahead, Paul Egerman.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman and I say thank you Beth for another very good presentation. I had a couple of questions, actually. In your slides, you show something like over 400 eligible providers who made it to Stage 2, if I read it right, and I'm curious to know if you can tell me a little bit more about them, are they like individual providers or are they all members of the single group? Are they associated with any of the hospitals who made it to Stage 2? And my second question is, if I read your slides right, you have eight hospitals that have now attested to Stage 2 and my question is, based on that the CMS consider Stage 2 be a success?

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

So first off, for the first question, as Jennifer mentioned we are – we have a team that is predominantly run by ONC funded by CMS to actually reach out to all of the providers who have met Stage 2 and learn more about them. And figure out both who they are and any characteristics like specialty and so forth and so the characteristics of – from them. So you'll see more on that as that effort moves forward. Just a quick statement, they are largely individual providers. From the data that we do have on them, they are not necessarily associated with hospitals. And some of the data that we do have indicates that there is a higher is a normal distribution percentage of them that are using a cloud-based software system.

Paul Egerman – Businessman/Software Entrepreneur

I'm sorry – could you just – a higher what distribution? I didn't quite hear you.

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

So as Jennifer, I think she either last time or two times ago sort of mentioned that the distribution of vendor and vendor products over providers is actually a relatively small number of vendors who cover a rather large percentage of the providers. So we understand sort of what that market looks like, there is a larger distribution of cloud-based software among those who have successfully attested so far, than there is for the overall group. So it seems that the providers who have used cloud-based software have been able to attest early, for that group of eligible professionals.

And then in terms of the eight eligible hospitals who have attested to Stage 2, I will again state that our concern is not over the stage of Meaningful Use, although we are paying attention to the ability to meet the objectives and measures. Our largest concern is over the functionality of CEHRTs, that is our – all of our indicators and all of the checking that we have been doing indicates that that is the sort of primary cause of barriers to application so far, which again is part of the driver behind putting together this NPRM.

Paul Egerman – Businessman/Software Entrepreneur

So, my question was, is this successful, Stage 2 successful?

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

As I have said before, I don't think that we can analyze whether Stage 2 is successful, as we don't have data on Stage 2. Again, the indicators all show that part of the concern is the ability to have functioning software, which allows you to do either Stage 1 or Stage 2. The total number of hospitals is 75 that is a concern as well. So I think that you will see that the impetus behind putting together an NPRM that allows for flexibility around the use of software is an effort to attempt to provide providers with a method to be able to meet Meaningful Use for the 2014 reporting period.

Paul Egerman – Businessman/Software Entrepreneur

Thank you very much.

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

Thank you. Any other questions? Okay, thanks a lot Elizabeth and Jen.

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

Paul, this is Karen. I tried to raise my hand, but maybe it didn't –

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

Sure, go ahead. I'm sorry, no, you did, I – sorry.

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

I wondered if it might be helpful at the next Policy Committee to have some folks who have successfully attested to come and speak about their experience, could even just ask John Halamka to do it, for example, since he was one of the first or if not the first. Just to give the Policy Committee some sense of what's working on the ground and how providers are solving challenges together to meet the expectations of Meaningful Use.

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

Sure. I talked to – and Jennifer with you and we'll – we can see if they have anyone that they think would be really helpful with that.

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

So that would match well with our updates from Jen about early experience with Stage 2. That would be great. Thank you. Anything else? Okay, thank you. So now we'll move on to the next agenda item, which is an update I'm going to give on the certification hearing, if we can tee up those slides, please.

So this is a hearing that we conducted on May 7. This is in response to a lot of public feedback about certification, the process, the results and the effort involved in it. Next slide, please.

We had a number participants in this hearing in terms of from the FACA groups. Next slide, please. Our purpose is to understand what's working and where are the challenges with Stages 1 and 2 on the way to Stage 3. So this is a learning experience and see what the lessons learned from the experience that people had going through the certification process so far over the past three years. Next slide, please. We had four panels, one with providers of various types, two vendors, three the certification and accreditation bodies and four some other private sector representatives so we can get input from other certification programs. Next slide, please.

So, the first panel was on providers and you can see that it spanned the gap between a small practice like the pediatric practice there, to large, New York Presbyterian Hospital. And we had a couple of self-developed groups as well...I'm sorry, wrong slide, so, including public health – public sector like Indian Health Service. Next slide, please.

So what are some of the key findings? One, the notion that that everybody's interested in fulfilling the intent, but as – by nature, the way the certification program was implemented you have object – MU objectives, you have certification criteria developed based on that. And then you have testing scenarios that are based on the certification criteria. Oftentimes they may meet the certification criteria, the products that is, but the way they're implemented may disrupt the workflow of the providers and that's where a lot of the challenges come in. So while the functions may fulfill the intent of the criteria – well, the letter of the criteria, in other words meet all the test scenarios, it may not fulfill the intent.

So for example, if we want clinical summaries to be informative to patients an unwieldy report, because that may fulfill the letter of the criteria, ends up not being that useful to either the patient or the provider. Similarly, patient education the idea, the intent would be to have a very specific instructions for this patient. It's not as helpful if you have an encyclopedia discussion about a particular condition and that sometimes occurred. Another example is check the box, so in working through a function a vendor might have an easy way of fulfilling that function by having the provider check the box, doing med rec, for example. That may be easy from a vendor point of view and may pass the certification testing scenario, but that's not as worthwhile for either the provider or the patient.

Next thing was, because the certification criteria, the way it's tested basically reduces to a test scenario, and there may be one test scenario, the vendors may not have enough flexibility to say let me meet the intent without fulfilling only the specific scenario described by that test plan. And that's where we get the problem of the functionality is there, but it requires a very specific workflow that is, does not meet the needs of a particular provider. And then frankly, some of the providers said, gosh, we had certified products but they just don't work as stated or it may not work in certain states and the state of Alaska was one of those states where we had some changes. Next slide, please.

Sometimes – so, it's one thing to say we'd like interoperability, it's another thing to say, certify that this can interoperate, but can you really test for interoperability between any systems? Probably not, I mean that's a tall challenge and we know that. So although people would like to count on their systems being able to operate with any of the other systems of their trading – their clinical trading partners, it often takes a lot more work than just having certified products. Overall, I think folks, certainly on the provider panel and I think on the vendor panel as well, felt that the certification program should be less prescriptive, focus on the intent, and focus on the what and less on the how. Now the tension is, how do you test without having a specific scenario and how do you have specific scenario without essentially baking in the workflow. So that's a challenge that we just have to address in the certification program.

I think both providers and vendors talked about time and timing. Time – the amount of time it takes for development of the software, for testing, but on the provider's side, the time required for implementation. And providers were asking for more flexibility in terms of that timing and one example of the flexibility was what was just discussed in the NPRM for Stage 2. An ideal certification program, according to the providers, would not only talk about which programs are certified, but find some way – some transparent way of allowing providers to compare their functionality. So not just having a yes/no certified, but also having more details in a way that they can compare them, both for selecting products as well as frankly, giving the market a bit more information about the differences between one product and another. And maybe giving vendors a bit of intelligence in terms of what things seem to be working better. Next slide, please.

The next panel was of vendors and they were both small and large, cloud-based and more traditional, including two self-developed programs, from Intermountain and Beth Israel Deaconess. Next slide, please. Same kinds of questions, what's been your experience and how would you advise us going forward in future stages. So from the vendors we heard that the timeline was tight enough, they'd love to have a complete set of requirements with adequate time for the development. And by complete they talked about how you may have one set of requirements be available, but it relies on other requirements being available at the same time. And if they're not all available in their final form at the same time, that really doesn't start the clock in terms of how they can reliably develop the products. Because they've found themselves starting to base on the most recent criteria, then there'll be a change midstream and then they have to do some rework. So that was a big ask of the vendors.

Another is the alignment. So as I said, we start from the MU objective, then you talk about the criteria for the MU objective and then you talk about clinical quality measures that are trying to measure an output from use of the functionality described in the MU objective. They're not necessarily all aligned and then the final test is the auditing procedure, the requirements may differ from all of the other requirements and may differ from one auditor to another. Another thing that was brought up by vendors is the quality and reliability of the testing tools. So apparently, the testing tools were not in their final form, not necessarily completely usable by the time the vendors were required to start using them. And so that caused some delay and some rework as they tried to use these tools.

Next, the complexity of the program, so if you start – from start to finish, from starting to understand the MU objectives as they come out in the final rule. So understanding the certification criteria to working with the test system, each of those steps has its complication and isn't necessarily right first out of the gate. So a recomm – a specific recommendation was made that we really have a Kaizen process that looks through the entire process, the entire cycle and try to streamline it, but also sort of rationalize it and align it, so that everything from the requirements to the timing is well tuned. That would give the most chance of having a good start and having sufficient time to develop products, test them and get them implemented so one of the suggestions in terms of meeting all these, both a streamlined process and paying attention to the most important things is to certify only on the critical few. And the two that were suggested over and over by panelists, now that's both actually the provider and the vendor, are those criteria that deal with interoperability and clinical quality measures.

Next slide, please. Third panel we heard from the testing labs and the accreditation bodies. Next slide, please. And here they're talk – they mentioned some of the same things the vendors did, which is when you have new procedures and test tools, make sure they're pilot tested and some of the glitches worked out before they're put into publication and made available for use by anyone, by the vendors, by the testing bodies. Improve the consistency between testing labs, so should there – could there be pilot tests that are available to all of the testing labs and ACBs, so that they can all understand the testing procedures, understand the results they should expect and how the tools operate and provide feedback before its final publication. The testing tools, they asked for it to be more automated so that they can process more test cases, reuse test – am I still connected?

Caitlin Collins – Project Coordinator – Altarum Institute

Yes, Paul, we can hear you.

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

Okay. So, and have a much more robust type of testing methodology which includes testing of security of products. They also asked for the test criteria to focus on some key kinds of functionality, like interoperability and security testing and wanted to do less – .so wanted to have the functionality prescribed but less specificity or prescriptiveness of the testing themselves. Next slide, please.

And in the final panel, we looked outside of the testing bodies and tried to understand other perspectives dealing with EHR functionality. Next slide, please. So they reiterated the importance of having really robust testing procedures and testing tools that really helps the efficiency and decreases the burden and the frustration with the program. They commented how when you change – so if it's not quite right out of the gate and the changes in the middle really disrupt the overall program, increase the frustration, delay the time, increase the cost. One suggestion is, by one of the certifiers, is to make sure you include subject matter experts as you develop the program. Because that just helps, it takes into account the workflow as you develop the test scenarios, for example.

So part of the – a collateral to that recommendation is that there would be increased collaboration between the private sector and the federal government as you develop both the procedures and the testing tools and the scenarios. Because the more feedback as found by one of the testifiers, the better the end product, the more robust it is out of the gate when it's available for vendors to use. And once again, we have the advice to focus on a critical few. There's so much work, there's so much – it takes so much effort to make robust tools and to have the criteria set right, that the fewer we work on, the more likely we are to get it right. Next slide, please.

So, the overall summary, people were all – no one was disputing the intent, the benefits of executing the Meaningful Use objective, but the rush, the pace in terms of product development, testing and eventual implementation by the provider was pretty hurried. So the concerns include that the specificity of the certification criteria, and particularly the test scenarios, may inadvertently lock in a workflow in order to carry out the scenario. Because the vendors may program for that scenario and that sort of determines the workflow, and that does not give the provider enough flexibility in what's most efficient either in their practice or their style of practice or actually even their specialty. When the products – when the tools are incompletely tested, it causes delays and rework. That when the interpretations are inconsistent with all the folks involved, the testing lab, the certifiers, the auditors, that creates a lot more rework as well.

We all know that certifications doesn't guarantee an integrated product or interoperability, much to the dismay of providers, you'd sort of like to pick something off the shelf that has a seal of approval and it will work magically with every other product. That's actually both very hard and probably impractical, so, as we all know that we have modular certification that certifies each functionality. But it doesn't necessarily certify that the functionality works together even with one vendor and certainly the interoperability problem amongst vendors just magnifies that issue.

There's – another big suggestion is to have a mechanism for timely feedback from the vendors. So let's say this testing tool is not working as you expect, how do you feed that information back in a way that it can impact, it can improve the products in a timely way. That's the notion of can you have pilot tests? Can you have more subject matter experts participate in some early version, get the feedback and then produce your final let's say testing tools available for everybody to use.

Then finally, we heard the comments about certification and the pace of certification, the time required, certainly it does take time. Even – it's not necessarily, as we heard either from providers implementing it and using it is one thing, documenting that you use it well is another. And sometimes the same thing is for vendors, implementing the function is one thing, documenting and proving that it's working is another effort and all of that efforts combined may crowd out time that they could use for doing innovation. Next slide, please.

So in consideration of this, came up with two major recommendations from the group. The first, the motivation is – fort this first recommendation is that the current process is inefficient and burdensome and all of us would like to get the waste out. So the objective is to have coordinated, integrated, well-understood certification process with a minimum burden. Sounds like a good objective. And really, as we heard from everyone about various components, it became clear. I'm sure it's clear to ONC as well that if we got everybody together and really looked at the whole certification process, end-to-end, starting from the translation of the Meaningful Use objective all the way to doing the test and the audits, we would all learn something about where – all the people that are involved.

And it's common with these Kaizen's you'd see a lot of areas where you can eliminate redundancies, eliminate waste and come up with a more streamlined process that also is more rational. And I think everybody was bought in to trying to help with that. That does require having broad stakers involved from providers who end up having to use these things that are certified to the developers and the testing bodies and the auditors, who are all part of this process. And so if we establish the certification roadmap and timeline, what's coming down the pike, that'll help everybody plan. So that one-time Kaizen will get a lot of the thoughts, the recommendations to streamline the process and to get the waste out and to right size it, but we want to also have a continuous PDCA mechanism to provide feedback and continuously improve this process. Next slide, please.

So the second major recommendation, it won't be a surprise given that we heard it from every panel, there's a feeling of being overwhelmed. We're after a very good goal, and no one disagrees with even the objectives – the Meaningful Use objectives in the goal towards measuring and improving outcomes in new models of care. But the pace is pretty overwhelming and of course, we live in a world where it's not just Meaningful Use, but it's all the other changes that are going on. So the objective here is to focus on the critical few. Over and over people mentioned interoperability, clinical quality measures because it is so important to measuring and improving outcome, and I'll just also say, the right clinical quality measures, but we have to do some work there, and we can't lose sight of privacy and security. That's sort of an underpinning infrastructure we need and needs to be part of certification.

So, these require a cross-organizational collaboration and in addition sort of to – data interoperability, we may need policy interoperability so that we can rationalize and harmonize all the different processes and policies that are involved, and of course somebody mentioned states as well. Need the alignment of standards, the measures and the programs, having some overarching governance so that someone can guide how do we keep this process efficient, how do we keep it effective and how to minimize the burden. And the people thought that a public/private collaboration where we involve a lot more subject matter experts could help with these goals. Next slide, please.

So finally, let me open this up for discussion and any further comments by members of the group, and I don't know whether Mike Zaroukian, who was Co-Chair of this hearing, is available. Open up to – and Paul Egerman has his hand up.

Paul Egerman – Businessman/Software Entrepreneur

Yes, thank you very much, Dr. Tang. In participating in the hearing, I do have a couple of observations that weren't, I didn't quite think were captured in your slides. One was from the vendor panel, there was a universal view that the costs of certification and the cost to develop the programs was out – was not stated accurately and the difference was dramatic. So that EHR Association and one vendor said, it was off by an order of magnitude. Marc Probst on a self-developed system, did not give a specific number, but said it was off by multiples. And so that there is a feeling that ONC has dramatically underestimated the cost and to the point where vendors are actually laughing at what the cost section says, that it's just nowhere near close. And so that's an area that has considerable concern, and also an area of where there should be some work.

The second thing that's hard to capture, I mean, you did a great job, Paul, in trying to summarize a complicated thing. It's hard to capture the intensity that came out from the vendors and some of the providers, I mean, people are very unhappy is what I would say. Very unhappy with the process, the idea that there's a moving target, that they're being put through hoops to do some things that they find it all very frustrating. So those are just some comments.

I do have a question about the recommendations, the recommendation to reduce scope, which is a good recommendation. The question is, does that recommendation apply to Stage 3? Does it apply to the 2015 proposed certification? Does it apply to Stage 2? And that's an important question to address because if the answer to that is no, it's not going to be applied to any of those things, then we don't really have very much of a recommendation here.

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

I'll try to respond to that last question which is, what does it apply to? I think these are – this is feedback and recommendations to ONC about the certification process. Probably it certainly applies to Stage 3 going forward, don't know whether it – well, it's up to ONC to decide whether there are some changes. For example the Kaizen, that could apply to any stage that could apply as soon as we can do that. So I think that's an example of something that can be taken as quickly as it can be under – whose results can be affected as soon as we can undertake such a process. Christine?

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

Thanks, Paul. I had a couple of questions. So first, I think a lot of the recommendations are really good. I think it's a great idea to set up a more timely mechanism for vendors to provide feedback on the process. I also think Kaizen event idea is good. I wanted to check on a timeline for that, in other words, if the recommendation was accepted and ONC pursued it, how long of a process that typically is and confirming whether we would keep the current process in place until a revised one is available. So that's my first question.

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

Karen might be able to unders – answer that more than I can. So these are recommendations coming from this group. Don't know about the timing. From our own organizations, you can actually get to – organize this process fairly quickly and there's a lot of results that vary from low hanging fruit that could be implemented very quickly to things that take more time to develop and work through. Karen, do you have any comments?

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

I'm sorry can you repeat the question.

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

Sure. I was asking about, I think the Kaizen event is a good idea. I wanted to check on, if the recommendation was accepted, how long organizing and getting through that process might take. And what I heard Paul say is, if you take it up quickly, it's generally a process you can organize fairly quickly, I'm guessing it's a couple day in-person thing with some planning time. But what I'm really wondering about is, and perhaps it's maybe not a question, as I hear your answer Paul, as much as a recommendation that I want to discuss and hopefully add. Which is making sure that the intent would be to keep the current process in place until such time as the redesigned process might be able to be fully implemented.

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

Actually, if Jacob's still on the line, might ask him to address it, since he is point here at ONC, along with the rest of the team on making improvements to the certification program. I think as I've shared with this group before, and I know I shared at the hearing, this is an area we believe there is opportunity for improvement in the approach, the program and we're absolutely open and willing to taking lots of tools to make that happen, Kaizen being something that could be an option. There probably are a lot of steps to getting it set up and quickly is the word I hesitate to use. But Jacob with his experience with what we have been doing with CMS, might be able to give us some sense of what that timeline would look like if we wanted to undertake it and then any other things that he wanted to share.

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

Karen, this is Michelle. I think we lost Jacob he was on earlier.

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

Oh, that's too bad. Well then, what I'll say is that I'll get with the committee about how long the setup would take if we were to undertake it. But a general notion of creating not just one-time improvement, but a culture of continuous improvement for the certification program is a high priority for us.

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

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

Great. So I guess Paul, my suggestion would just be that we add something that acknowledges that the new – that the current process would need to continue to be in place until such time as improvements can be made, whether those are incremental improvements, as you suggested that could be done quickly. Or whether they – it's a wholesale redesign of the process that maybe takes a little bit longer. I just – we continue to experience many, many delays and we heard from a vendor in the Meaningful Use Workgroup hearings that those delays were not helpful for their process as well. So I'd like to suggest that we add an acknowledgment that the current process would need to be in place until it can be changed.

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

(Indiscernible)

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

If I – this is Karen, again. If I could just underscore one thing that you did say, which is, where we can make iterative improvements now that can make a difference, we will, while we continue to work on broader improvements that may need to happen.

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

Thank you.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman. I guess I would disagree with what Christine just said. I mean basically having sat through the hearing, we have a process here that is broken, people are extremely unhappy and we should not continue to have our foot on the accelerator while we try to figure out what's wrong. We need to stop and absorb all this and do it right. It goes back to my question, what are we going to do in terms of reducing the scope? If all we're going to do is say, well, we're going to spend a few months trying to analyze this thing, in the meantime we're going to finalize the 2015 edition and we're going to – all of Stage 3, then it seems like we're just wasting all of our time.

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

Well I think in case we need a very clear understanding of what the impact of pausing any current processes would be, particularly since there's a statutory requirement to use certified EHRs, what are the options there if you do pause the current process? I'm very concerned about that, I mean, I understand the need to change the process and perhaps there are iterative improvements that mean that the program could be significantly improved in a very short term without a pause. But, I just want to state, I'm not in agreement that we just sort of stop everything and take several months to redesign it. I don't know that we know the implications of what that would mean in terms of timing and people's ability to attest. And then whether that allows the vendors to come back and further delay delivery of product for current market conditions and things like that. So I think we don't understand enough to know whether stopping is a good idea.

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

So this is Paul Tang and I just want to point out that the previous Paul, it was Paul Egerman, it's hard for the transcript. But let me sort of digest what I think I heard Karen say, and what she's said in the past, which is, so we had a lot of feedback about individual components of this process. And I think ONC has expressed a willingness, and the whole reason for them having this hearing is to improve each one of those components. So for example, the robustness of the testing tools as it comes out. I'm sure – I'm guessing all the work is going on to improve each of those components. I think the major recommendations as we heard from the various stakeholders is that it would be useful to have this Kaizen meeting where you have all this stakeholders looking at the end-to-end process. So that's sort of a new recommendation, but I don't think that says – that that's saying the organiz – that ONC currently is not working to improve the components. That's what at least I hear Karen –

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

Paul, this is Jacob and I was away from the phone for moment when Karen called on me. Would you like me to go over briefly what it is that we're doing to improve the efficiency of the program currently even short of the Kaizen?

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

Yeah, that would be very helpful and address the questions from the floor.

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

Very briefly, what we've done is we've looked at what the testing procedures are and how it is that we are causing perhaps unnecessary pain to those who are bringing their products to certification. So we've worked a lot over the last couple of months with the certification bodies and had some interaction – have had some interactions with the vendors to better map out some of the life cycle. As we get towards something like a Kaizen, and I think it's a good recommendation that the committee had to bring all the stakeholders into a room and walk through it. But there's also work that we can do ahead of time that can make that process much more efficient.

So, the first piece is what are parts of this process that could become more efficient? And we've looked at a lot of the test procedures and the development of the test procedures themselves. We heard loud and clear at the hearing that many of the test procedures are more prescriptive than they may need to be. And so this is a difficult balance because the more prescriptive they are, the easier it is for the test labs to test them, because it says do A, then B, then C, then D. And if we're not as prescriptive, then the test labs say, well what's a pass and what's a fail? And it's a little bit more ambiguous, kind of like taking your driver's test when you're 16.

And yet we think that there is a happy medium between the 40-page prescriptive test procedure. And something on the order of four to five pages that is perhaps less prescriptive, more flexible, yet gives some clear endpoints that need to be met to assure the purchasers of these products that they do the things that those who are selling them claim that they do. And that's the key endpoint here is that the certification program is meant to confirm that the products do what they say they'll do and they do it consistently and they do it in a manner that aligns with regulations that we put out.

So that's the – I don't want to talk too long, but that's the thumbnail version of what we have been doing and what we are in the process of doing now is relooking at those things. And so for upcoming certification iterations, we hope that everybody is going to see shorter and cleaner certification test procedures. And then by extension, the test scripts that the test labs put out in the testing process will be more fluid and potentially it will be less of a unit test and more of a scenario-based testing. So that you don't have to have these artificial unit tests where it's as if what you're doing is isolated in a clinical workflow, so you might actually test a handful of different things at once by testing one – area. So is that what you were looking for?

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

Yes, that's very helpful, Jacob. Neal Patterson?

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

And Paul, I had a second question, so –

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

Okay.

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

– when you –

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

Why don't you put your hand up and then I'll make sure I keep you in the queue here. Neal Patterson's next, please.

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

Yeah, this is Neal. I just wanted to make a counter comment here. I don't think we are extremely distressed or unhappy with the process. I like the direction you're heading, I mean the comments you made, Paul, better coordination between public and private, a desi – end-to-end design and focus – with a clear focus on interoperability, quality measurements and privacy and security. So all of – I think the continuous improvement is a very good direction but I'm going to speak for our side, we're not extremely dissatisfied or upset about the current process.

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

Thank you. Christine?

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

What other question was related to I think actually something that Neal just mentioned as well, which is the recommendation about the limited scope for interoperability, CQMs and privacy and security. What does that mean in terms of what does not get certified and standardized?

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

Can you state that a different way?

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

So if the scope is limited to just those three areas, then what are the remaining areas – functional areas that would no longer be certified like secure messaging or view, download, transmit or patient education or some of the care coordination elements, maybe care planning for example, after visit summary. Are those things sort of out of certification for future iterations or new functions that maybe fall in to some of the other areas that are outside of interoperability, CQMs or privacy and security. So in other words, if we're limiting the scope that it's sort of the inherent – my take-away from that is that there are things that would no longer continue to be certified and I'm just trying to figure out what those would be.

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

Ah, yes. I think it – so one, it's saying in the way we view certification now to limit it to those three areas. It probably does leave as an exercise to all of us, and maybe this is something we need to follow-up on, is, what would you do? Do you have to certify to each Meaningful Use objective? There's a theory that did connect the two, is there a way to continue to have Meaningful Use objectives and behaviors that are measured, for example, through – well here's one we've talked about in the past is everything is migrating towards just measuring the CQMs. And you need the functionality in order for you to deliver good outcomes. And we rely less on a certification program that sort of prescribes how an EHR, what functions an EHR has and must demonstrate and make more the emphasis on how do you use this tool, EHRs, HIT to deliver better outcomes.

That's where – that was the original vision so I guess what the corollary, and that's what you're asking about, to this recommendation is that you have specific technical certification of products in these three areas and the others, you have the vendors respond to their customers so their customers can deliver meaningful CQMs and CQMs that show improvement. That's one way to answer your question, but yes, the direct effect is that you'd have – the recommendation is saying you have less certification of products to do specific functions, outside of those – outside of a critical few, and three were mentioned.

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

So if Meaningful Use, just trying to understand further, if Meaningful Use were to add a new objective that – something like patient-generated health data, for example or a new kind of decision support, would vendors then need to create the functionality but they wouldn't have – they wouldn't have to do that based on any standards? Or would they no longer have to create the functionality and therefore Meaningful Use itself would be limited only to CQM, interoperability and privacy and security?

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

I think that's something we'd have to work out, but it – maybe the scenario is that yes, the providers are required to meet certain objectives under Meaningful Use meaningful and that it's up to the market to ask the vendors to do that without a separate certification program. That's all – I'm just – pure speculation, but we'd have to work –

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

This is Jacob. Just a question, maybe since I have my federal hat on. Is your suggestion and is the advice that you're giving be that ONC focus only on certification with respect to the Meaningful Use Incentive Program?

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

I don't think so.

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

So I guess that's where I'm concerned and the concern is a little more magnified. If we're – so if we have an ACO, for example, or a state innovation program or any new model basically say, look, we really need the functionality to do X and it doesn't cleanly fall within those three areas. Then we would have to rely on the fact that they're a big enough market share to be able to pull the vendors away from universally – the priorities that they have and investing in these three areas and try to get them to develop these other functions or features, I'm concerned about that. And I'm not sure we understand – I heard you say, Paul Tang, that we'd be sort of speculating about the impact of a limited certification scope.

So I'm worried that we don't understand fully the impact of this particular recommendation and I'm wondering if we instead should let a recommendation like this come out of – in some kind of Kaizen process – I'm just not comfortable making a recommendation without really understanding what does it mean for providers who need particular functionalities like patient-generated health data? They really want to do that but – and the market isn't there yet, how do they have a voice in this?

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

So maybe – I don't know that we need to work all this out in this particular meeting. Maybe one way to modify the recommendations – the recommendation still would be to limit the scope of certification, it may not be prescriptive say, and it must only be these things. It's sort of the major recommendation is limit the scope of the certification, it doesn't mean limit the scope even of Meaningful Use, but limit the scope of certification and here are things that – here are three things we heard about consistently.

Paul Egerman – Businessman/Software Entrepreneur

And this is Paul Egerman. Perhaps it would be help if I gave also a few other examples which would be, as part of interoperability, the implementation guides could say specify for example format for date of birth or the format for a ZIP code or the formats for vital signs. And people would think, well that's enough, you don't have to also specify how those data elements will be entered, all you need to do is look at it in terms of how it looks when you do the information exchange. And you don't really have to worry about anything else other than that that would be an example of being less prescriptive.

Similarly, you could say on the CQMs, well gee now, you've got to break it down by say race or sexual orientation and you can specify what those breakdowns might be. But similarly, that would be enough, you don't have to say race and sexual orientation have to be included in demographic data. So those would be some examples, they're very simple, as to how you could be less prescriptive and more a concept of focusing your eyes on the prize in terms of what you are trying to accomplish.

This issue is at the core of the entire discussion. People did feel in the hearing that our current system is broken, that they are overwhelmed by it. That the timing estimates are way off and if what we do is say we have an improvement process and we're going to focus on scope, but not really limit our scope and we're not really going to do anything different, then we really haven't heard the message from the hearing.

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

Yeah, and I understand that and I really do hear the message from the hearing. I think it's just that this recommendation is so broad as to not be very clear in terms of its impact. And so, as I was listening to you, Paul, I think – Paul Egerman, I think it was really important for us early on they have standardized data elements around race, ethnicity, language, and even coming up around sexual orientation and gender identity or disability status. But we didn't – we tried to use for SOGI data, a certification process that would say, here's how these data need to be able to move around, but you don't have to record them if it's not relevant to your practice. And I think that's good, and I think that's what you're saying.

Paul Egerman – Businessman/Software Entrepreneur

You're misunderstanding what I'm saying, I'm saying, if you need to move it around, specify that.

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

If you need to include them in information exchange, the transition of care document, specify that, but you don't have to say these are demographic items, you have to enter them as part of the demographic – as part of demographic data and we're going to test that. Because that's not necessary – that's a logical way of implementing it, but it may not be the only way to implement it –

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

Okay, I'd like to –

Paul Egerman – Businessman/Software Entrepreneur

– and it doubles up on the – it simply adds extra testing that is unnecessary.

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

So I'd like to end this particular detailed discussion, we have other people and we are over time, so let me move to Chris Lehmann, please.

Christoph U. Lehmann, MD, FACMI, FAAP – Director, Clinical Information Technology – Johns Hopkins Children's Medical and Surgical Center; AMIA

May I just say one word? This is Chris Lehmann .

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

I know, I'm –

Christoph U. Lehmann, MD, FACMI, FAAP – Director, Clinical Information Technology – Johns Hopkins Children's Medical and Surgical Center; AMIA

As a representative for vulnerable population who may need special functions to support their care in the EHR, I have some fundamental concerns about weakening or undermining the certification process and I just wanted to put that on the record.

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

Thank you, Chris. And David Lansky, final question?

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

Thanks Paul, I just wanted to add, I think this also raises questions about the long-term role of the federal agencies in the private market, and that's a good discussion to have as part of the strategy discussion. I think it goes beyond the technicalities of some of the issues that have already surfaced. And as we think about where to put this larger issue it taps many of the longer-term strategic roles of the Policy Committee and of ONC, so I would actually elevate this to a bigger discussion.

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

Thanks, good point as well. Thank you. Okay, this is a proposed recommendation to go to ONC as a result of these hearings. So there were two major recommendations, one was Kaizen to go – an end-to-end Kaizen to streamline the process, get the waste out and rationalize it. And the second was the recommendation to focus – to limit the scope of certification. We can modify that to talking about three areas that were brought up and not necessarily limiting it to those three. But these are two recommendations that I'd like to have a vote from the committee in terms of moving that forward.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul, I just want to know what I'm voting on. So on the second one, are you saying it's no longer limiting the scope to those three, in other words, are you changing what was on the screen?

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

I'd be open to people's thoughts more broadly but the major recommendation is to limit the scope of certification. These three came up repeatedly –

Paul Egerman – Businessman/Software Entrepreneur

Is that what we're voting on right now?

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

It would be – that's one of the two recommendations.

Paul Egerman – Businessman/Software Entrepreneur

Okay.

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

If you want, we can take them separately but so there were two recommendations that came out of the group, out of the hearing that the group had in response to the hearing. And those are the end-to-end Kaizen and the second is to limit the scope of certification to critical few. So let me take them one by one and I'll – the second one we can ask for different options.

Okay, so the first one is an end-to – a Kaizen covering the end-to-end certification process. And is there a motion to –

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

If you need it – I'll support that.

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

So, you're moving that.

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

Yeah.

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

And is there a second?

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

Second.

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

Okay, thank you. Any further discussion? All in favor?

Multiple speakers

Aye.

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

Any opposed or abstain? Okay, that carries. The second one, if you'll move to the next slide, please. Let me – I'll put it in two possible options. The first option is as stated which is, limit the scope of certification and these are the three that are part of the recommendation. And I can give a second option of limit the scope of certification and these are three that should be included, but it doesn't limit it to just these three. Anyone want to move the former option, the first option, which is in front of you?

Paul Egerman – Businessman/Software Entrepreneur

I'll move it. Paul.

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

That was Paul Egerman. Second?

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

Second.

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

Okay. Any further discussion on that that would be any new points? Okay. All in favor of this?

Multiple speakers

Aye.

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

And I guess I'm going to have to ask for any opposed or abstain?

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

Yeah, its Christine; I do not support.

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

Deven, do not support, prefer the other option.

David F. Kotz, PhD – Champion International Professor – Dartmouth College

David, prefer the other option.

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

Okay, so that's three.

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

David Bates –

Christoph U. Lehmann, MD, FACMI, FAAP – Director, Clinical Information Technology – Johns Hopkins Children's Medical and Surgical Center; AMIA

Chris Lehmann, do not support.

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

Okay, so let's see. Let's get a tally of the supporters, Michelle? So why don't we get a roll? Actually, let's do a roll call one or two – option one or two.

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

But Paul, that doesn't, I guess, leave any room for people who don't like either option.

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

Yes they can do zero, one, or two.

Paul Egerman – Businessman/Software Entrepreneur

So Paul, we just have – not to be overly formal, but we just had a motion and we counted up the number who opposed, let's count up the number who are in favor so that we can understand whether or not this motion passed.

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

Yes, okay. Let's go ahead and do that –

Paul Egerman – Businessman/Software Entrepreneur

If it didn't pass, it's valuable to know what the variation in numbers are.

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

That's right. Okay, Michelle, do you want to just do roll call please?

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

Sure, based upon who's on the phone – Christine, we know.

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

Opposed.

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

And Chris Lehmann is opposed. David Bates is opposed. David Kotz?

David F. Kotz, PhD – Champion International Professor – Dartmouth College

Opposed.

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

David Lansky, opposed.

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

Opposed.

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

Deven is opposed. Devin Mann I don't believe is on. Gayle?

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

Yes –

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

Kim Schofield?

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

Opposed.

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

Marc Probst?

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

I swear number one.

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

Neal Patterson.

Neal Patterson, MBA – Chairman of the Board and Chief Executive Officer – Cerner Corporation
Opposed as stated.

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

Paul Egerman – Businessman/Software Entrepreneur
Yes, favor.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Scott Gottlieb? I'm sorry, Scott doesn't vote.

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

Next. So that recommendation fails. The second option was the same as this, limit scope of certification including the following, interoperability, CQMs and privacy and security, but it does not limit it to this. But the notion is that would be more limited than the current certification program. Anyone want to move that?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
This is Deven, I so move.

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

David Lansky, MD, PhD – President & Chief Executive Officer – Pacific Business Group on Health 3719
Second, David.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
And we've heard the discussion. Anything else to add? Okay, so let's have a roll call please.

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

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

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

Christoph U. Lehmann, MD, FACMI, FAAP – Director, Clinical Information Technology – Johns Hopkins Children’s Medical and Surgical Center; AMIA

Opposed.

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

David Bates?

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

Opposed.

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

David Kotz?

David F. Kotz, PhD – Champion International Professor – Dartmouth College

Support.

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

David Lansky?

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

Favor.

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

Deven McGraw?

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

Support.

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

Gayle?

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

Support.

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

Kim Schofield.

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

Support.

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

Marc Probst?

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

Support.

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

Neal Patterson?

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

Support.

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

Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Opposed.

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

And I think Karen and I still get a vote, right?

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

Yes. Do you support, Paul?

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

I support.

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

I think I'm going to abstain.

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

So what's the tally, Michelle?

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

Very close. I believe it's approved, based upon the vote.

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

Well, what's the actual count?

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

I had nine approved, nine for.

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

Nine to four?

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

No.

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

Sorry?

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

Nine/six, nine for it.

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

Okay, so that's not a super majority for sure, it is probably a clear majority. Now the question is, we can move forward with this with additional comments about those who oppose it. If someone wants to make a counter proposal, I can open it up – I'm nervous that we have gone way over time, certainly appreciate this is probably one of the – this is a major topic for ONC for sure. Is there a counter – another motion that would reflect those who oppose this one?

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

Paul, its Christine; I think my suggestion was that we suggest that we include that in the Kaizen or whatever process that ONC undertakes and allow the whole discussion of limiting and the impact to be part of that work. My concern is not about limiting to specific areas, my concern is that we don't understand, or at least I don't understand what it would mean to limit the scope of certification really from all sides, other than reducing burden. But I just don't know what all that means, so I would propose that that discussion and that recommendation really be part of that Kaizen process with a broad group of stakeholders who could be thoughtful about it.

Christoph U. Lehmann, MD, FACMI, FAAP – Director, Clinical Information Technology – Johns Hopkins Children's Medical and Surgical Center; AMIA

I agree, I think we should look at what functionalities should fall by the wayside and what the impact of such a decision would be before we pull the trigger on it.

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

May I offer a friendly amendment? I think imposing this really major policy decision on the Kaizen for process would probably be distracting. I think it's worth the discussion, it may have to be in one of our workgroups and possibly actually the Meaningful Use Workgroup or the new workgroup that includes Meaningful Use to figure out, on a policy level, how to deal with that.

Christoph U. Lehmann, MD, FACMI, FAAP – Director, Clinical Information Technology – Johns Hopkins Children’s Medical and Surgical Center; AMIA

Yeah, that’s probably correct, a Kaizen is not the place to look at that.

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

So this is Gayle, I’d like to offer also that that Kaizen event should never make a policy decision for this committee. We are the ultimate recommendation...this committee makes – is charged with making recommendations to ONC, not a subgroup, not a Kaizen event –

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

Yeah, it’s Christine I agree with that and I would like to clarify, what I was suggesting is that this be a topic that be considered so that a broad range of stakeholders can provide input, whether it’s the Kaizen process or any process. But ultimately, it’s not even this committee, in my opinion, it’s ONC that makes this decision. So I just want to be, I think it was Chris who said, just thoughtful about what the impact is and have a forum, whether it’s Kaizen or something else for doing that. But ONC needs to – I think would benefit from receiving multi-stakeholder input, but they do need to make that decision, I agree with Gayle on that.

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

So may I reflect on the motion that was approved to include a discussion that the concern that folks who voted against it was primarily around looking at the implications of limiting scope, to lessen the MU objectives. That’s certainly something we can act further on in terms of looking at the ramifications of that. This is only a reflection of the majority vote and ONC has heard all of this discussion. They don’t – they make their independent decision on how to act on it. That fair.

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

Yes.

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

So in other words, this would go forward with majority vote, indicating what the minority opinion was and I think we’ve teed up saying, we need to do further work in this committee and workgroup to flesh this out. Okay, well thank you everyone. Let’s move on to the LTPAC and behavioral health update from the Certification/Adoption Workgroup, and Larry Wolf is presenting.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So, good to be back with everybody today and the conversation we’ve just had, I think informs some the recommendations coming out of the workgroup because we met several times after the certification hearing. This is intended to be our last presentation of individual recommendations and we will present the full package at next month’s hearing, recognizing that there have been various comments made at the prior Policy Committee meetings and we want those reflected in the final set of things we bring forward. So the intention is, this is sort of the last of the detail components and then we’ll have wrap up, as it were, in July. And again – so let’s go to the next slide.

So a big thanks to all the members of the workgroup, this has been a long ongoing discussion we've been having. Also thanks to the ONC staff, Liz Palena-Hall, Elise Anthony, Jennifer Frazier, Michelle Consolazio, who have helped us stay on track and have been very effective in pulling together the comments and discussion in the workgroup and reflecting them in the slide sets. Let's go on. So today we're going to give you report out on a listing session that we heard and response to a blog post, so some written comments as listening session with hearings and presenters.

We have some specific recommendations around LTPAC and behavioral health in three areas. One is the LTPAC patient assessments that are mandated by various CMS programs and making sure that they're aligned with the broader standards, that ONC has been working on in support of interoperability. In behavior health we have sort of the flipside, of there are not a set of broad assessments and so we have some comments about that. And finally, some recommendations on ONC doing – taking on the job of tracking the trends in these care settings, because data on what's actually implemented is very soft and uses different definitions. And then finally, mostly in an appendix we have some more detailed comments about certification criteria that would apply to selected subsets of LTPAC and behavioral health providers. So, that's our overview.

Next slide, please. So, it seems like a year ago, but it was only May 22 we had a listing session with three panels. We put out a request in a blog post and heard from folks that had not been previously been part of our discussion, so it was very helpful to have done that. We also had six written comments. Next slide, please.

We're going to walk through the summary of what was heard and I think it's useful that in some ways I wanted to argue with some of the folks in what they said. But that didn't make their perspective and their experience any less relevant, so, we left a lot of this as is rather than trying to drill into well what really was the underlying issue. So for example, we heard things about problems that people had getting Direct set up and it wasn't clear exactly what those problems were, but it sounds like there's a fair amount of complexity and multiple Direct addresses being set up for providers as they deal with receiving transition of care documents from acute care settings.

So it's an area, I think, that needs more exploration and it was an example of the kind of things that we were hearing, I think goes to the earlier discussion as well of the need for broad stakeholder input as we rollout these programs. You can see there's quite a variety of specifics here and I'm not going to go through each one of them, other than to say that we did hear a pretty broad range of both support for building on things that are already in the certification and the Meaningful Use Program as well specific needs in these care settings. Next slide, please.

So, some major headlines, so transitions of care continues to be a really hot topic and the court for certification with the intention that it improve interoperability and being able to send and receive the transitions of care. And I think also a fair recognition that the transition of care is a process that happens over time, it's not just at the moment of discharge. So some information is useful in making a decision about where to transfer a patient and whether the location their being transferred to has the services and can meet the needs of the individual. And what those specific needs are so you can be ready when they show up. And then supporting any late documentation that comes in from the discharging location to the new site of care. I mean it's not uncommon for lab work or other information to be made available at that earlier setting after discharge, but it's important to continue to pass along.

We heard various ways in which people were using tools so that, for example, while we mostly speak about use of Direct as a way to send a CDA document that's the care summary at the point of discharge. We heard use within one of the RIOs where they were being used as general secure communications and attaching various kinds of documents, including PDFs of the information that were then sent using their Direct services. And then we heard comments about what's in the CDA documents may not actually be the actual information that's needed. And that the process of creating it might be relatively straightforward, but the process of receiving and incorporating the information is challenging both for clinicians and also for vendors and the products, which kind of spills over into the clinical reconciliation piece.

So it was felt to be – it's a critical thing to do, we didn't get a lot of comment about ease or difficulty of doing the reconciliation, but I think there's a pretty broad understanding that this is a new process for organizations and for clinicians. It has intended to happen in a very focused way around medication reconciliation, but with the CDA documents, there's the opportunity to do it more broadly.

As far as the patient assessments, we heard more support for standards to establish crosscutting quality measures so that things could be done consistently across settings. And that there actually could be good measurement, because one of the hot topics and a broader policy issue is, how do we move forward with healthcare reform and various discussions of setting neutral payment if we don't have consistent measures across the settings and actually can assess what's happening in different settings. And the notion of further standardizing data elements within those assessments so that they could actually support the clinical decision-making that happens both by people and by technology. Next slide, please.

We heard various discussions about CPOE and I think the big thing about any of the ordering processes is that there are actually several participants in the ordering cycle in ways different from ambulatory practices and acute care hospitals. That is more of a multi-wave relationship between the physicians who may or may not be on-site, the nursing facility staff primarily led by nursing that receives orders and manages the execution of the orders within the facility. And then the outside provider, whether it's a pharmacy or lab or other ancillary that's providing the service and maintaining that communication so that all parties stay coordinated as the orders happen, as they get clarified and as they get executed and reports come back. Broad discussion about clinical decision support, already touched on some the issues with ePrescribing and lab results. Next slide.

Advanced directives continues to get discussion and visibility is something that's really important and a topic area to move forward and ways in which things could be standardized but still left sufficiently open that they actually capture both particular state requirements as well as the intent of the individual who is making the advanced directive. At the same time, it has to be clear enough that the providers understand what's being asked of them. So, it's an area where we've got a chance to look at what's helpful in terms of standards, but also need to recognize the complexity of what's in the advanced directives.

A comment on immunizations about the states are really not consistently implementing any way to receive information or to send back information on immunizations. And that certification might be the easy part of actually getting this to be a useful workflow and information exchange. We heard some comments on wanting more information about past history on somebody and a comment about data portability. Next slide, please.

We continued the discussion with some information about DSM-5, which is the primary diagnostic scheme being used in behavioral health and the need to align that with other codes required for billing and reporting. And the need to have consistency across those. We also had some further discussion about data segmentation and consent management, including some suggestions that patients might be able to segment who their information gets sent to. If you look at using the example of MyHealthVet and the ability of an individual to choose what information they did the download and transmit on, so they could be selective in what information they sent. But that introduces the risk of incomplete data and there's nothing in the data set that indicates the selection process that used to create the data set. So, the recipient of the information doesn't have a flag that says, information's been limited. But again, a focus on that this is an important topic. So this was really the input that we received during the listening sessions and the blog comments.

Next slide, please. So what did we make of all that? A lot of that was consistent with some of our earlier discussions and what we have here are specific recommendations for behavioral health and LTPAC. So, let's go on to the next slide. You'll remember the framework we set up last time with a focus on transitions of care, privacy and security and data segmentation and consent as issues that affect all providers. Things that are specific to the care settings that we were asked to focus on, long-term post-acute care and behavioral health and then a few things, actually many things – a great many things that span a mix of providers.

And I think I'll comment on the blue area because most of that, in fact almost all that material has been moved into the appendix. In some ways, it speaks to the discussion that the committee was just having on how – Meaningful Use and certification criteria. And these were examples of things that are in the current certification program and the functionality is used in some of the long-term post-acute care and behavioral health settings, depending on the setting. We did not do an in-depth analysis of how to align these particular criteria with particular settings. We also felt that given sort of the priorities of really looking to enhance exchange that there would need to be other drivers for these to be pulled into a specific certification program.

So, in the sense – continuing the sense that we want to be as aligned – as fully aligned with Meaningful Use certification program as possible. And the fact that there are certification criteria in these area and that the program under the modular certification supports vendors selectively certifying to each of these measures, that that was a model that seemed to be working okay. And would also allow other programs that needed to reference specific certification programs, specific certification criteria to do that. That they'd be out there in the domain of things that existed that could be certified. So if there were a CMS program focused in one of these areas that it could identify for this program you need software that meets these specific criteria. But separate that kind of driver, we didn't see a need to move these forward as specific recommendations.

As far as the all providers box, we've talked already and brought forward recommendations on transitions of care, on privacy and security. And we've also asked, and the Tiger Team on Privacy and Security has already taken up the question of data segmentation and consent management. So we continue with that piece. And the quality measures, as they affect this area, has also been passed off to the Quality Measures Workgroup, so there's activity happening in the all providers' space. So we'll be talking today more specifically about the things in the green box, the LTPAC specific settings and behavioral health setting specific certification. Next slide. Thank you.

So, the overall recommendation here is really around the policy opportunity. In the LTPAC space, there has been a long history of mandated patient assessments and these have been drivers of health IT adoption among those providers, in order to collect the information needed for the assessments and then transmit them electronically. However, those assessments, because they have had such a long history, were built in many ways before the current era of certification and the current standards that ONC has been moving forward. So it feels like there is opportunity here to really do some alignment among federal programs around the data that's being collected, the quality measures that are being developed as a result of that data and the standards that are being used. And the goal here would be to not only allow for data reuse, but also to increase the interoperability among providers by looking where information could be of value in all the care settings. So the various acute care settings as well as the post-acute care settings.

And as was pointed out that people in all of these settings have behavioral health issues, so where we're moving information, collecting information under various federal mandates that we should look to opportunities to leverage that information. And further, that it be done in ways that build on provider workflow, on the patient care process and minimize the requirements for after-the-fact analysis in generating this information with an eye towards assessments in this space that are like the eQuality measures that actually are derived directly from the care being provided. So this is really a request really that ONC take this on as a unique opportunity really at this time to move forward on the federal landscape. Next slide, please.

So in terms of specific recommendations, and this format is one you may remember from our earlier presentations. So the new bullet here are reflects the policy opportunity and that we're looking for ONC to advance health IT standards for the patient assessment data to support reuse and administrative use of that information. So this is not a specific – should show up in certification, but should, in fact, drive the federal work to standardize the data in these assessments. So the future work here of harmonizing the federal content and making the CMS data elements, which CMS has already stated the intention to make these available as a data element library, to further link those with the broad national standards that ONC has been supporting.

We were asked to look at level of effort and standards maturity for this. And we believe on the provider side, that the effort is medium that these assessments are already in place. They represent a fair amount of effort to take on, but they are already in place and so we felt that adjustments that would result in changes to the assessments would have some impact on providers, but not huge. That the standards themselves are at various levels of maturity, there's already been exercise by HHS to create some of the maps between the assessments and standard vocabulary like SNOMED and LOINC, but that work needs to be completed. And the standards themselves are not widely adopted in LTPAC, so there would need to be – it's sort of the provider effort would, in part, need to address that. As well as moving to the developer effort, that the impact here is likely to be high, because these standards are not broadly in place today. And reuse of information, in some ways has even been constrained by CMS guidelines, because the survey process that uses these assessment tools really requires that you answer the question the way it was stated in the tool. And that if you're reusing information and computer system is making the analysis of how to answer the question, but that's not actually following the intent of the assessment tool. So, some of that would actually need to be addressed in a policy and regulatory way, as well is in software development. Next slide, please.

Behavioral health was much more an open landscape. So we actually recommended beginning the vocabulary standardization progress to support behavioral health patient assessments and to look at the standards that are already out there. We heard some states already have some pretty well defined assessments that they require, but they're not widely used outside of specific settings or specific states. So it's a much broader area where there are not a lot of existing assessments to build on. So that addressed the two specific setting recommendations and then...next slide.

So tracking trends in a national survey, these could be combined, we put them separate but I think you can see the intention here is to really understand better what is the level of health IT adoption in this space. We saw a huge variation in level of adoption as reported by various surveys. It's not clear how much that reflects differences among survey tools, differences among definitions of what is an EHR – excuse me, and level of response to the surveys themselves. So we'd like to see that better tracking of the trends happen and that ONC look to move forward some definitions that could be applied broadly across all the different initiatives and so we could get consistent reporting and focus the effort on collecting information in ways that actually gave us a clear view of the landscape. Next slide.

So, I think we've got a couple of short things – next slide, yeah, so I've already commented on this. This is about the some care settings piece, that we have many different care settings covered by these two broad headings of long-term post-acute care and behavioral health. And they range from very high acuity inpatient settings to residential settings with various levels of support provided to the people living in those settings, to outpatient settings, from large organizations providing the care to individual solo practitioners providing care and so a very broad landscape.

And the fence here was that matching up certification criteria to specific parts of that landscape could make sense and where they do, to really build on existing certification criteria, to continue with the modular and voluntary approach that's been part of the program. And again pointing out that there have been vendors that address both of these large markets that have used the certification program to date, even without a mandate that there's some sense that it gives them some market differentiation and may actually help their customers by helping focus on what actually is included in the area.

And again, alignment with federal and state programs, so that there's programmatic reasons driving adoption and that in those cases, certification might make sense and would serve as a floor. So there's a reminder of the really certification being a floor for functionality. And in general, we continued the discussion about where's the value of certification. And it was generally felt that outside of specific drivers that certification in and of itself didn't move things forward, but there was no final consensus reached by the workgroup on that topic. Next slide.

So that wrapped up where we are. We do have again some slides that you've seen earlier in the appendix that looked at specific areas in that other category, in the "some" category and identified where they fit in various aspects of long-term post-acute care and behavioral health. But I don't plan to go through those in detail, especially because our recommendation is that they be chosen selectively as needed by other programs. So, comments and discussion from the workgroup – from the Policy Committee, rather.

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

Thank you, Larry. And to summarize, your request for recommendations for today is what, the two new – well, it's almost only one, right, the LTPAC specific one on dealing with the subset of patient assessment data?

Larry Wolf – Health IT Strategist – Kindred Healthcare

So I guess – so, let's back up a couple of slides and I'll tell you specifically what we're bringing forward. Let's see, it would probably be helpful if I give you a number, let's back up to around 12 or 13 and I'll see where we are. Okay, so this is the description, 13. Next slide, please. So yeah, this is the specific recommendation around LTPAC patient assessments for support the use of a subset of the data with some future work. And then the behavioral health one that follows and then the recommendation that ONC trends what's happening in the field and do the fieldwork or support the fieldwork to collect the right information. So the next two slides – so these three slides together with are the core of what we're recommending.

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

So previously talk about the transition of care as an important part of essentially mandatory certification, right?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yes.

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

And privacy and security and then we're going to hear from Deven about the data segmentation piece. And as part of the, I think you would consider this mandatory certification, would be work on a subset of the patient assessment data. And the other two –

Larry Wolf – Health IT Strategist – Kindred Healthcare

So –

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

Go ahead.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So right, so Paul, mandatory in the context of voluntary, right?

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

Mandatory – core voluntary, in a voluntary certification program –

Larry Wolf – Health IT Strategist – Kindred Healthcare

These things –

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

– you would have core...

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yes. Yes.

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

– transitions of care, privacy and security and patient assessment data or some subset of patient assessment data. Then you're recommending two actions for ONC, future work on behavioral health and on tracking the trends.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Right.

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

Did I summarize that correctly? Okay, so the new action for today really is, from a core point of view, is the slide in front of us and then the additional recommended action.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yes.

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

Okay. So comments from the committee or questions? Paul Egerman.

Paul Egerman – Businessman/Software Entrepreneur

Yes. Thank you for your presentation Larry. So on this slide 13 the patient assessment data, when I listened to the workgroup discussion there were some concerns expressed – concerns expressed was that there is already a requirement to electronically submit patient assessment data to CMS and there's like 90% compliance with that. And so, this appears to be a new interoperability concept where now the assessment data will be electronically submitted from basically one provider organization to another. And the concerns that were expressed were whether – were first about the utility of them, what would it look like? Would it be 37 pages long?

And also how does this patient assessment data relate to the transitions of care document. If this is really important data, why isn't it just part of the transition of care document? Why do we have now two documents that are being transmitted and how do they relate to each other? And so I thought those were all good comments and I looked down on the sheet here, it says development effort high and it says standards maturity, there's some mapping has done, but it seems like this hasn't been done before. And it just – I just have a concern that this becomes like another variation of our experience with the transition of care document. We put some effort into this, but it either doesn't get used or if it does get used, perhaps doesn't have the utility that we expect.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So, I think that's a really good set of concerns to raise, Paul. I think the intention behind this was to as much as possible to align at the data level so that the elements that are in transition of care documents, for example, would begin to show up as the data standards used by CMS as this information is collected for these assessments. And you're correct that the current assessment is a very large – assessments in general are very large and that we're not necessarily mandating or requesting that they be mandated to be sent from care setting to care setting.

We've seen the example with the Pennsylvania KeyHIE program where they've have developed a tool that takes in the current assessment, maps it to the standard vocabularies for some key areas and then builds the transition of care document that's been populated. It's a relatively circuitous process, so in part we're looking to streamline that process and not require a lot of machinations behind the scenes to sort of square up the data.

Paul Egerman – Businessman/Software Entrepreneur

But this seems to go farther than just data definitions, there's interoperability of patient assessment data and perhaps I'm understanding it wrong. But I got the picture of this is like more independent of the transition of care document that would be transmitted from one provider organization to another. Do I understand that wrong?

Larry Wolf – Health IT Strategist – Kindred Healthcare

So no, I think that that in fact is part of the intent here, that other information is needed beyond what's in ToC. That one of the thoughts is that these providers, as patients move from care setting to care setting, that if they could have the assessment from the prior care setting, it actually gives them a basis for future assessments in their care setting. So there was some intent around these assessments themselves that they be more interoperable.

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

Anybody else have any questions or comments?

Larry Wolf – Health IT Strategist – Kindred Healthcare

I think to the discussion about maturity of standards and the risks of getting out there ahead of the standards. The reason that the wording here is as open as it is, is that we feel that work needs to be done to bring these things into alignment and not arbitrarily say the current assessments need to be sent as is and just map the data and we're done. A fair amount of work needs to be put in to actually make that a usable, useful process and not just add to the data flood that seems to be happening out there.

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

But nonetheless, you're recommending this as a core certification in this voluntary program?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Umm, so we're recommending it, but what we're recommending is that the data be standardized. So in some sense this is separate from – this is pre-certification if you will, there's work to be done on the standards level.

Paul Egerman – Businessman/Software Entrepreneur

And this is Paul Egerman, again. I don't have any trouble with the standardization of the data, I can see huge benefits of that. As I recall the workgroup discussion, I did not think that there was a strong assessment though for a strong consensus for turning this into an assessment document that would be easily transferred among organizations, that there were some – questions that I raised were simply a reflection of questions I heard at the time.

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

So this is Paul Tang. So how would you differentiate, Larry, between you recommended further actions let's say in behavioral health, this might be more specific action that is, work on the standards.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yeah, so this is an example of in LTPAC, the assessments exist, they're in use, and they are being transmitted today.

Paul Egerman – Businessman/Software Entrepreneur

– to CMS.

Larry Wolf – Health IT Strategist – Kindred Healthcare

However, have to be transmitted to CMS today, but they're not being transmitted among providers today and they're not infor – and broadly speaking, they're not informing the transitions of care information, for some of the reasons that Paul Egerman brought forward. The assessments are very large and unless you're intimately familiar with the assessment, you might be scratching your head at exactly what this yes or no answer is telling you because you don't have the 20 pages in the assessment manual that tell you what that question is getting at.

So actually, having these assessments play into the flow of information is a nontrivial exercise, it's not just a standards mapping exercise. And we're trying to recognize that the maturity is lacking for that right now, but we feel that there's a real opportunity to take this on, that these are assessments that are widely used. They're necessary for receiving Medicare payment, they've driven a lot of IT adoption and so we should be smart about looking at these as opportunities to improve interoperability and system use.

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

Okay so let me make sure that we have the specific ask for what you need approved and Michelle, can I ask about the annotations that the final package approved at the July meeting – is there another approval that's required next meeting?

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

No, we had just originally said that the whole package would be brought forth, but if we can finish everything up today, I'm sure Larry will be happy with that.

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

Okay, so the whole package being the “for all,” the transition of care and privacy and security –

Michelle Consolazio, MPA – Federal Advisory Committee 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

In addition to the – okay. So do you want to state your ask Larry and maybe somebody can move that?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Okay, so, let's see if I can do this right. So there are three things on the agenda to move forward. One is interoperability of LTPAC patient assessment data. And given that the workgroups understanding is that this is not mature enough to move forward into the certification today, that we're recommending that the work be done to standardize the information so that it can play into the general flow of patient information that is sent from provider to provider. And that's work that would be ONC and CMS work primarily, but clearly affects providers and vendors.

The second piece is around behavioral health where standard assessments are not in place today, but where that was felt to be valuable in the care settings. And so we're recommending that work be done to do that, identify the data that would be useful for those assessments that could be passed from care setting to care setting and that be coordinated with other initiatives, other federal initiatives in the area. SAMHSA expressed that they are doing a lot of work to improve the use of information systems in substance abuse and treatment programs.

And finally, to get better reporting of what's in the field, better understanding of what the state of adoption is. Those are the three. I apologize that it's sort of rambling.

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

Okay, does somebody in the committee want to move that?

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

So moved.

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

Okay. And the second?

M

Second.

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

Okay. Any further discussion or clarification? Okay, people are ready to vote on this. Now the other thing – then we did not vote on the ToC and the privacy and security, is that right Michelle? Is that part of the “package?”

Michelle Consolazio, MPA – Federal Advisory Committee 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. So you'll recall from the last discussion, the workgroup wanted to sync up, i.e. make the same as part of this voluntary certification, the transition of care certification from Meaningful Use for the Meaningful Use eligible providers, as well as privacy and security, so that these programs – this voluntary program for behavioral health, LTPAC would be consistent with the MU compliant program. And then we're going to hear from Deven about the data segmentation part. So is that the complete package? Larry, is that the complete package?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yes, so other than we have six months of discussion and input, yes, those whatever it is, five or six points are the complete package.

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

Okay. The people who made that motion, would you include the previous recommendations from last time in your motion?

Paul Egerman – Businessman/Software Entrepreneur

I'm sorry, the previous recommendations are just on privacy, security and –

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

– transition of care –

Paul Egerman – Businessman/Software Entrepreneur

– on transition of care document.

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

Right, making those identical to the current MU.

Paul Egerman – Businessman/Software Entrepreneur

Okay, so it doesn't include anything that's like clinical decision support or ePrescribing or any of that stuff.

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

Correct.

Paul Egerman – Businessman/Software Entrepreneur

Okay.

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

Are people ready to vote on that motion? All in favor.

Multiple speakers

Aye.

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

Any opposed or abstain? Okay, well very good and thank you for all that hard work, Larry. I know that was many, many meetings and calls. And I'm sure that these segments – the LTPAC and behavioral health providers and vendors appreciate the work. Thank you very much.

Larry Wolf – Health IT Strategist – Kindred Healthcare

My pleasure, thank you.

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

Okay, we'll proceed on to the LTPAC and BH quality measure update from Helen and Terry.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Hey Paul, its Helen. I don't think Terry can be on, she had to jump off –

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

You know what Helen, I can be on for just a little, thanks.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Oh great, well why don't you start then. I'll stay on as long as I don't get – off.

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

Okay. Both Helen and I have other conflicting things, so we appreciate this time to do. And it's very good we're following up on Larry's presentation. And I would refer you, just so you're aware to what Larry presented on 12, 13 and 14, because summarized in there is basically where I think we ended up in terms of the Quality Measure Workgroup, this is a follow-up to the presentation that we gave at the last meeting.

So the next slide, and we did not copy a lot from that last presentation, so hopefully you have it for reference, but I can go through it. As you know, we were asked to look at quality measures for both LTPAC and behavioral health for voluntary EHR certification. We did present our draft recommendations and then listened to the feedback we got from you and from others after we did that draft presentation. In addition to that, we had held listening sessions and solicited public comments on the voluntary certification, specifically related to the quality measure recommendations. So the next slide.

The feedback we got from the HIT Policy Committee, or our interpretation of the feedback, really focused on the belief that the quality measures that we had indicated in our initial presentation for behavioral health would not outcomes measures and that's accurate. They were not outcome measures, they were much more process measures. We heard concern from the Policy Committee that the recommendations promoted infrastructure, and you may recall we did promote infrastructure. We talked specifically about what we thought were going to be needed in the IT system in order to get at the clinical quality measures. And there was a sense that there was an unclear value proposition at that time, perhaps because we were focused on some infrastructure issues and not specifically on measures.

And in addition, there was expression that the industry, and we had heard this from our listening session, too, that the industry could build innovative solutions if we didn't lock them down into some very specific things. What you heard from Larry on the previous presentation was really this focus on data and how important the data elements are and the need for common data and that actually reflects what we'd also heard also. The public comments really supported the intent of our recommendations and really the sense that we needed to focus however on standardizing common data elements. I think this is consistent with what you just heard from Larry, that there's a lot, a lot of groundwork, if we believe that standards and terminology is groundwork that needs to be done prior to our ability to move to quality measures.

And we heard that loud and clear and on the next slide, you'll see the results of us hearing that. We believe at this point that the recommendations, and you may recall we had recommendations about certifying functionality to collect and send data elements, certifying functionality to collect, calculate, send data elements, certifying just the ability to have functionality to capture the patient assessment. But they're not ready for the short term and the reason why they're not ready for the short term is really reflective of what Larry suggested, is that there's a real need to do some basic patient assessment data harmonization, make data elements available, identify vocabulary standards and data definitions.

So at this point, what we are presenting to the workgroup is that we do not believe we can make a final recommendation for quality measures because there's too much basic work that needs to get done. We believe that ONC needs to continue discussions with the federal agencies and for many of these, especially for the long-term, it's the CMS work that's been done for years that is really marvelous. But needs to be transitioned into some standards that have already been endorsed so that the policy and the standards readiness for voluntary certification for quality measures can be met.

And that's it, we do have backup slides that we're not going to go through. I would reference you to these slides, however, if you have questions because they include what we presented before, which was long-term PAC voluntary certification draft stuff, really once again reflecting the need for common data elements. And very similar to what Larry suggested, which was, working with the CMS data element library to make it publicly available and linking its content to nationally accepted standards. So when we put this draft together, we had not looked at Larry's draft. However, looking at what Larry presented today, I think our group would endorse what Larry presented and just indicate that right now, until that other work is done and we can figure out how to go from process measures to outcome measures, we do not have specific recommendations for measures. And Helen I don't know if you want to share anything?

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

No, I think you captured it really well it was on to the last discussion as well, the similarities are really striking. I think we are all in the same place. Thanks Terry.

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

Well thank you to both of you and to Larry. So this was an ask from ONC about making recommendations about voluntary certification program. You've heard the extensive work that Larry presented and now what Terry and Helen have looked at the issues surrounding quality measures in this same space. And I think the upshot is, it's not ready for a certification program, at least at this point. But further work needs to be done, particularly around data standards. Have I captured that accurately?

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

That sounds right.

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

That would be accurate, yeah, from our perspective that is, right. And Larry did a great job, I think, including in his recommendations they actually subsume what we would have come up with in terms of data and standards. And we didn't recommend them, because we assumed that Larry was going to do that.

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

Okay. Questions, comments from the committee? Okay. So there are no recommendations to approve and thank you so much for looking into the issue and soliciting the public comment and then coming to your conclusions and recommendations for the committee. Appreciate it.

Helen Burstin, MPH, MD, FACP – Senior Vice President for Performance Measures – National Quality Forum

Our pleasure.

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

Thanks.

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

Okay. We're ready to move on now to Deven McGraw and Micky Tripathi on behavioral health data segmentation from the Privacy & Security Tiger Team.

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

Great. Thank you very much –

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

(Indiscernible)

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

– Paul, can everyone hear me okay?

W

We can.

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

Okay good. Let's go with the next slide, please. As always, we like to start our presentations by thanking the members of the Tiger Team for their consistent good work on these difficult issues, and this one was a bit of a doozy. As you all got a picture of – or a snapshot of when we initially gave you a presentation on some of these issues at the meeting last month. Next slide, please.

So our agenda here is to present you with recommendations for your approval regarding certification to enable the exchange of behavioral health data. And these are recommendations that initiated with the good work done by the Certification and Adoption Workgroup in looking at vol – criteria for the voluntary certification program for behavioral health providers. And then how one could facilitate the exchange of information by these providers with some concomitant requirements in certification for the general certification program, which we started by shorthand calling the general provider certification program. And apologies to all for that shorthand, but it helps to distinguish between the two different programs that are being set up.

One of the things that because we took some time out of the Policy Committee last month to lay out in pretty full description sort of the range of policy issues that are at stake here, I'm not going to go over that again today. But I'll remind the committee of a couple of things. One is that the behavioral health providers, particularly the ones that are governed by the federal substance abuse program rules, have some very specific requirements that they need to abide by, a good portion of which are in statute and not just in regulation. They are required to get the consent of their patients in order to share any data that potentially identifies the patient as having been in the substance abuse treatment program or have been a substance abuser.

And they need to pass along, if they sha – if they get permission to share that data, and the data is then shared, they need to pass along the fact that that data is subject to restrictions. And the recipient of that data also is required, under federal statutory law, not to redisclose that information without the consent of the patient. And unlike HIPAA, these are consents that apply, even for treatment. HIPAA, as I think most of you know, does not require consent when you're sharing data for treatment purposes. These rules are different, they apply to federal substance abuse treatment providers and then subsequently end up applying to any provider who receives that data in terms of requiring protection.

And so we really tried to focus in our discussions on the narrow question of whether EHRs, both on the behavioral health side and the general provider side ought to be certified to have some capability to enable compliance with these Part 2 requirements. We didn't – lots and lots of policy questions and a rigorous policy debate could ensue about whether this is an appropriate policy. But it is policy and its congressional policy on part of it and then regulations to implement it that have been promulgated by the Substance Abuse and Mental Health Services Administration, otherwise known as SAMHSA. So with all of that backdrop in mind, let's get right to the heart of the matter with respect to what we're recommending here. Next slide, please.

So we have sort of two initial framing slides for you that sort of set out in summary form a kind of technology glide path, and this is the sender side glide path and frankly it's much simpler. Because it assumes that what we're talking about for senders are those senders who are covered by those Part 2 substance abuse treatment privacy rules. And at level zero, which is really where we're at currently, they don't have the capability to send patient information electronically because they don't necessarily have a technical capability to indicate that the information is subject to these restrictions on redisclosure. And ideally, even if they were able to send it, they'd need to have some degree of confidence that the receiver could properly handle that data.

Level 1, which is sort of the next step in kind of technical capabilities here, is to enable them, assuming they've got authorization from the patient to send it in the first place, they could send a C-CDA, which is the coordination of care document that's part of the certification. But it would be tagged in a way that would indicate that it was restricted and subject to the Part 2 restrictions on redisclosure. And frankly that's the capability that they need in order to comply with their Part 2 obligation. Next slide.

The picture is a bit more complicated for the recipient side. And these are providers who by and large are not going to be covered by Part 2 because if they were covered by – but even if they are covered by Part 2, essentially the recipients have a sort of much bigger load to carry here. The current state for recipients is that they don't have the capability to receive the Part 2 covered data. And so the way, if they're getting this information for care coordination at all, they're receiving it in paper or by fax or they might be subsequently collecting it from patients as part of sort of an initial treatment interview.

Level I, and this is the technology level that has been piloted, is what we're shorthand calling a document level sequester. It enables the recipient EHR to receive and recognize that a documents coming in from a Part 2 provider and it's tagged as being restricted to cannot be redisclosed. And to prevent inadvertent redisclosure, essentially on the recipient end, their capability is just to be able to view that data. It does not get parsed or interdigitated or consumed into the EHR where software could act on it, such as clinical decision support software, for example. It just provides that sort of very basic level view that the provider can see what's going on with the patient and then be able to treat the patient accordingly. It is far from ideal.

We've mapped out sort of two other levels in the glide path here, but we don't have the technical capability to reach these yet. So in some sense what we're – what this chart overall represents is an ideal state, a glide path for reaching all the way to level 3. And a level 2, for example, might involve the ability to sort of parse or interdigitate or consume the data that's received from a Part 2 provider in a local EHR, but be prevented from redisclosing it. And then subsequently, the last level would be yes, you can redisclose it and we can be sure that that redisclosed data is also tagged with the redisclosure prohibitions. And so it has a sort of more complete sort of set of protections around it without necessarily this sort of disutility that's created by the sort of view only or stop only at the local level steps to this process. So, but really as you'll see when we get to the recommendation slide, which are next and you can go ahead and go there, what we are trying to do here is to get the field from zero to 1. Next slide, please.

So with that in mind, we recommend that ideally for Meaningful Use Stage 3, and we have – we framed it that way because we recognized that from a timing perspective, it may be difficult to do so, but we still think it would be ideal to proceed with Stage 3 with these recommendations if it's possible to do so. You would include the level 1 send and receive functionality in that voluntary behavioral certification for the behavioral health providers. So it's – as Larry mentioned in his previous presentation, what we're recommending here is a required certification criterion that would be part of a voluntary program.

The behavioral health EHRs are also going to need to be able to control the recipients that they're sending these documents to because to, forgive me for using a sports analogy here, but the senders need to know th – the throwers of the of the data need to have catchers on the other side, right. And so they need to be able to both technically – from a technical standpoint, be able to send these C-CDAs in compliance with their policy, but ideally they need to know that there's a recipient on the other end who can receive it. And this is both a function of sort of doing the work to know that there's a provider on the other end who wants this data.

But that provider's going to need the technical capability to be able to at least receive the information and at least to view it. And that's where this second bullet recommendation comes in, which is to say, there should be level I receiver functionality to be able to get that restric – the document C-CDA that's tagged as restricted and at least be able to view it. Only here we're not recommending that this be a required criterion for certified EHR technology, but instead we're recommending that it be voluntary. That way only those recipient providers who are interested in being at level I and being able to receive this data digitally, even though they are only permitted to view it. They won't be to consume it in their EHR and take advantage of the software capabilities of their EHR to really fully be able to use that data. And so given those limitations in the technology, we are recommending that this be voluntary criteria.

And that means, for those of you who can actually see that tiny little asterisk, we're not suggesting that there be a Meaningful Use requirement to use this technology. But instead, the exchange of these documents could be counted for meeting coordination of care capab – requirements that are already in existence in Meaningful Use. And those providers who have a significant population that they are treating that come from substance abuse treatment programs are going to want to have this capability in their systems so that in fact they can count those transitions of care in some way, shape or form for meeting care coordination objectives.

And fully recognizing that this is a bit of a baby step, frankly, from a technology standpoint at least it moves from the status quo, which is zero digital exchange of this data to this sort of very initial level. But in order to get there, you really do need the catchers to be empowered to at least receive the data and be able to view it. As I mentioned earlier, levels 2 and 3 are really beyond where we could go for Meaningful Use Stage 3. But the Tiger Team felt strongly that we would be far less likely to progress to these higher levels of functionality without at least laying the foundation from – for taking that initial step and moving from level zero to level 1, for both behavioral health providers as well as the general provider community, the recipients. Next slide, please.

Was that you Micky? Did you want to – am I – is there anything you want to add before we get into the policy and best practice piece?

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

Umm, no and I think you laid it out nicely, Deven. I guess the thing that I would just emphasize is that as we were going through these deliberations, we tried to take into account that this is a very complex area. And while, as Deven said, we're kind of taking – proposing a baby step here, that's in recognition of the extreme technical complexity of this, as well as from a business clinical workflow perspective, there's a lot of complexity as well. Because these laws that are sort of enshrined in statute, as Deven said, were really made for a paper world. And – but we have to live with them, so, really in recognition of that and we had a lot of deliberation looking both at the business workflow aspects and didn't – we're not tying this to the DS4P technology. But we used that as a window into the technical feasibility of being able to accomplish these general kinds of incremental steps that we're proposing here. So hopefully that's reflected there that there was a lot of thought here to try and take into account the complexity, but also try to set at least a meaningful framework for moving this forward. Because it's an area that there hasn't been much forward progress in the last few years.

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

Yeah, good point, Micky. Perhaps I shouldn't use the word "baby" because it did take a lot of effort just to get from zero to 1, it just looks so small in terms of the grander scale that we hope to get to. But you don't get there without taking that initial step.

So in terms of the policy, I mean, we do think and recommend that there continue to be pilots of this technology, particularly with respect to how the recipients can handle that data when they get it. Because just – moving from zero to 1 was one set of Herculean effort, moving from 1 to 2 and then even from 2 to 3 will take additional work and that work should continue to be supported and encouraged. And we have sort of a number of sort of sub-prongs here. What could we do to make sure that that data doesn't go from a Part 2 provider to a recipient who doesn't want to receive it? Are there technical mechanisms that can be put in place or do we still need the human response of knowing that the provider is ready to receive it, either by calling them ahead of time or through established referral relationships.

What are the sort of unanticipated workflows and consequences that result from this level 1 functionality and are there ways to sort of ease that burden from a technical standpoint? How do we move from part one – from Stage I to Stage II where you can at least locally consume the data, if not redisclose it and then how then do you get to Stage III? Education of providers and patients is going to be very key. The obligations that come with this data and clarifying it is not well understood. I recall we had a lot of questions in our initial presentation to you all in the Policy Committee about whether for example the disclosure by the Part 2 provider needed to specify the specific doctor for example that the information was going to. And did the EHR receiving systems need to find a way that to make sure that only that physician saw the information?

And we got some clarification from SAMSHA that in fact as long as the consent that the patient authorizes, authorizes it to go to the entire physician practice, for example or a particular healthcare entity. That that would not be a violation of Part 2 rules to have it be received by an entity and then subsequently forwarded to the relevant physicians. But it's not clear that that kind of sort of clarity is fully out in the marketplace. There's a lot of misunderstanding about what the rules do and don't provide. And frankly, we think that there is a lot of room for the Substance Abuse and Mental Health Services Administration to take a look at the statute and think about what they could do with the regs or with more guidance to clarify how the exchange of information can occur in a digital environment.

And in fact, shortly after we began having these discussions, SAMSHA announced that they were going to have a listening session on this topic, which will take place next week I believe and –

M

I believe it's tomorrow, isn't it?

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

– or maybe even later this week and they are inviting comments on clarification and amendments to their rules that might be able to be made in order to facilitate greater exchange. And so for example, Paul Egerman, I recall your question about whether it would be possible to sort of define redisclosure in a way that would enable patients to authorize care for treatments – for any treatment by any provider as opposed to having to sort of execute an authorization that would have to be done each and every transition of care. And that very well may be something that's possible, but it will require SAMHSA examining the statute and thinking through how their regulations might still be consistent with the statute and yet still enable patients to have the capabilities to provide broader authorizations for data sharing.

M

(Indiscernible)

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

Another issue that came up a lot in our discussions is what about data that is in fact sourced from the patient as opposed to data that comes from a Part 2 provider? And how – is there a way for recipient providers to be in compliance with Part 2 and yet still be able to talk to their patients and explain to them what the consequences are of not having information that can be parsed or interdigitated into the EHR? Next slide and this is, I think, the last one. It is.

We do think that the sta – that it will be up to the Standards Committee to address the particular type of functionality that would be part of this certification process that we're recommending. So for example, they should address, is the data segmentation for privacy standard that was tested in the pilots, or any other standard that might be out there, is it mature or feasible enough for the behavioral health EHR voluntary certification. And if so, at what granularity. And the same question really applies in thinking through the voluntary certification criterion for the general mandatory certification program. And again, at that level of granularity. Micky, was there anything that I left out of that as we covered the slides?

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

No, I think that was great Deven.

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

Okay. Yeah, so the bottom line is what we're recommending is a voluntary capability for general EHRs at the sort of level 1 data segmentation level of functionality. And then a required criterion for the voluntary behavioral health certification program that enables them to share segmented data and be in compliance with Part 2.

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

So, the second part was required for the BH, what did you say about for the general EHR?

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

Voluntary. A voluntary certification criterion. So for example, the general certification program today has a voluntary criterion for complying with accounting of disclosures. And that has been a voluntary criterion for both the first stage of the EHR certification as well as the 2014 criteria. It doesn't get picked a very much by vendors because we're still lacking the policy clarity on how to implement the changes to the accounting of disclosure standard that were required by HITECH. And for those of you who have been on the Policy Committee for quite some time, you'll recall that we put forward a set of recommendations for how to implement that program, but it's not in effect yet so it's not surprising that a voluntary criterion for that particular functionality has not really been taken up by vendors.

But there is a history of having voluntary criterion for the required certification program. And the reason why we're saying it should be voluntary is because we recognize that a lot of healthcare providers might not be comfortable with a technical functionality that enables them to receive data from the behavioral health provider that they then can't really fully utilize within their EHR. And so they don't want to receive that data at all, they don't want the functionality. Versus other providers who believe that receiving it in view only is better than nothing – voluntary criterion enables them to do that. And frankly, it might even enable us to get some field experience with how well the – how much uptake there's been and how well it's working, even if we – even if our recommendation to continue to pilot is adopted or not adopted.

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

Okay questions or comments from the committee. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Thank you, and thank you Deven and Micky for a very good presentation again on a complicated issue. First I wanted to comment Deven, since you mentioned my name on the issue of whether or not patients can give consent. My actual intention last month was to suggest that patients should be able to give consent in the way that we call a cascading series of consent. So if the patient consents to – for the information to be used by say an acute-care hospital. And during the course of the stay at the hospital, it's determined that the patient needs to subsequently go to an extended care facility or perhaps to a different hospital, because of the intensity of what is required, that you would not need to get additional consent because it was all related to the same incident of care. So that was my question from last time.

My more – the question that I want to ask this time is, we talked a little bit about testing last month, in terms of the piloting that has occurred on this process. And Micky very appropriately talked about some of the complexities of the workflow when you do this, where you don't really consume the data in the EHR systems. So it's not really being used for decision-support, it's not being used for medication administration. And I was curious to know from the pilots, this sort of level I capability, how many patients have been involved with these pilots where we've used this for the redisclosure process?

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

A good question. Is Joy Pritts on the line?

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

I am but I do not have – I am not privy to how many patients. I do know that they have actually implemented in real life, not as a pilot, they have moved to, I guess it's beyond production, they are doing this in real life, at least in a few of the instances.

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

Right, and how many organizations were involved in the pilot? There were like at least – I mean we talked to two, but there were a few more, were there not?

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

Well the entire pilot – the pilots involved a total of six – there are six different pilots, but I think Paul's question is more drilling down really into how many patients were involved with each of those and I couldn't possibly tell you that right now.

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

Okay.

Paul Egerman – Businessman/Software Entrepreneur

Because the number of patients, even though it was multiple facilities, it's only the number of patients involved with the substance – federally sponsored substance facilities. We're somewhat conflating segmentation with Part 2 and we really...this entire pilot process appears to be only on Part 2.

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

Well the reason – Paul, if I can jump in, the reason that the pilot process focused on Part 2 was a result of the – was an S&I initiative. And Part 2 is actually an issue that's faced over – across all 50 states. They recognized while they were doing this that there is a similar issue under many state laws.

And as to the number of patients, I do think it's important to recognize that the population in at least one of the pilots was predominantly, if not exclusively, from behavioral health care providers to transitioning them to other types of care, like through a 211 system in Florida. So, it was not one or two, it was their major – the people who were using this – organizations using this were using it in the manner that Deven has described, with their patient – almost their entire, probably, patient population.

Paul Egerman – Businessman/Software Entrepreneur

So roughly are we talking about thousands of patients?

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

Yes.

Paul Egerman – Businessman/Software Entrepreneur

Tens of thousands?

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

I don't know about the tens of thousands but it certainly was not hundreds. I can't tell you right now the magnitude, we can try to get that information for you for later in this – today, if you want.

Paul Egerman – Businessman/Software Entrepreneur

Well, at least for me that is helpful, because I look at the slide that's on the screen where it says, the Standards Committee should address though maturity of the standard, and I don't 100% agree with that. I mean, my view is, a technical group like the Standards Committee can definitely tell us when something is not mature, in other words, if they were to say it's not mature, I would agree with whatever they – anything they said is not mature. But to say it's mature, we really need to understand a little bit about to what extent – it's really a policy issue, to what extent it's really been used, to what extent people have thought through some of these workflows that Micky talked about, in terms of, again I'm using the example of clinical decision support. If you can't consume the data, just how is it that people are operating? Especially if it's in an inpatient basis and if they can't consume the data, how are they doing medication administration? And so to understand it, well maybe they found workarounds for that that would be useful to know, to make the decision that it's mature.

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

Well the entities that were involved in the pilots are used to dealing with this data, they – the pilots were conducted with behavioral health care providers and their established partners, or, I don't want to use the term partners. But the established other entities that they do business with on a regular basis, the people and organizations that they refer individuals to. So they have established relationships and they exchange this information in paper format and use it.

It's not – in the past, before they initiated this pilot, they were not exchanging any of this information electronically, they were exchanging all of it in paper format. What they've moved to now is step one, is exchanging – at least sending the documents electronically when they refer a patient to an outside service or another provider. And it has cut several days in their ability to – if not weeks in their ability to provide care to the reci – to the patient when they moved outside of behavioral health care context.

Paul Egerman – Businessman/Software Entrepreneur

Thank you.

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

Okay, any other comments or questions? So I think Deven you're asking for approval of the technical capabilities, this level 1 ideally for the Meaningful Use Stage 3 in a voluntary way for behavioral health and some of the other actions, right, like –

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

Yes. So if certifica – voluntary ba – for the voluntary behavioral health certification program, the level 1 functionality should be included.

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

Okay.

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

And for the general provider certified EHR technology, it should be a voluntary criterion. And there should continue to be pilot so that we can move from one to two and then ultimately to three. And clarification from SAMHSA and education about – clarification on the law and education. And those are sort of the – that’s the four-legged stool of the recommendation.

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

Thank you. Any member of the committee want to move that.

David F. Kotz, PhD – Champion International Professor – Dartmouth College

So moved, this is David Kotz.

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

Thank you. And second?

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

Second.

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

Okay. And any further discussion? All approve?

Multiple speakers

Aye.

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

Aye, this is Deven.

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

And oppose or abstain?

Paul Egerman – Businessman/Software Entrepreneur

Abstain, Paul.

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

Okay, Paul Egerman.

Paul Egerman – Businessman/Software Entrepreneur

Yup.

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

Okay. Motion passes and thank you again, Deven and Micky, always tackling these tough, tough issues and coming up with a cogent argument for some recommendations.

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

Well, thanks to you all and of course to our members of the Tiger Team and to the public that we heard from on this as well, it's very helpful.

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

Thank you.

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

Okay. And on time, we are going to hear from Jon White on the JASON Report. I'm sure he'll explain who these JASONers are and talk about the report. And we're going to be asking for some volunteers to join a Task Force to provide ONC with some feedback in conjunction with the Standards Committee. This Task Force will report out in August, so –

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

Thank you, Paul. Paul, this is Karen and if I – Jon, if I could jump in for one minute. Just to put this in broader context, I think you all saw this report come out a couple of months ago. And it is going – what you all share with us about your thinking of the JASON Report will be incredibly helpful as we're developing a roadmap at ONC that then we'll work with you all on refining through the Interoperability Workgroup and beyond. And so we really appreciate the opportunity to see this in the broader context. And we do recognize that there are some things they didn't touch on in the JASON Report, like for example governance, but we look forward to having other opportunities to work with the Policy Committee on understanding how the country might move forward in those areas as well.

And I just want to thank Jon for taking time both at Standards and at Policy to make this presentation. He's been going around sharing the information so we can really do what we can to get feedback and make sure the appropriate subject matter experts plus others have an opportunity to weigh in.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Perfect, I couldn't ask for a better lead-in. Hey everybody, this is Jon White from AHRQ and I assume I'm audible.

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

Yes.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Excellent. Very good. All right, so thank you so much for your time. I will do my best to not blitz through this presentation, but to speed through it because I think the more time that you have for discussion is better. So we are here discussing a report that AHRQ received, which is some expert analysis. The title of it is, "A Robust Health Data Infrastructure," and it's a forward-looking report. I think that it's – AHRQ does a lot of different things in terms of building the evidence about how health IT improves healthcare. A number have used in our grantees doing research about that. We do various other things like systematic reviews and some demonstrations. This is different than those, this is expert analysis is probably how I would best characterize it. So – and I think it's got some interesting ideas, so looking forward to the discussion. Next slide, please.

Thank you very much. So the report was funded by AHRQ, it was not done by AHRQ staff, it was done by JASON, and I'll talk about them in a second. The report was sponsored in collaboration with staff at the Office of the National Coordinator and also at Robert Wood Johnson foundation. JASON is a group that is relatively new to healthcare, a number of us have been working in the health IT space for a fairly long time and JASON has not been there before, so who are they? JASON is an independent scientific group that provides consulting services to the US government on matters of science and technology. It was established in 1959.

At any given time, there are somewhere from 30-60 JASONS. Over the years that they've been consulting for the US government, they've issued about 700 reports like this one, they've done a number of these over the years. Largely JASON has worked in the defense and intelligence communities and provided work for them. So well over half of the reports are classified and therefore are not available to the public. However, a number of them are publicly available and if you Google JASON, Federation of American Scientists, you can actually see a listing of their reports, and this one is included on there. Because of the work that they do for intelligence and defense, JASONS do not name individuals amongst themselves. There was a nice article in the Journal of Nature a couple of years ago, in 2011, that if anybody wants a copy I'm happy to share with them, that describes some of the JASONS work in the past and who they are. So, next slide.

So these are the charges or the questions that were laid before JASON to try to take a look at and again, I'll characterize this is forward-looking. JASON's compri – has a number of different disciplines amongst their members. There are physicists, mathematicians, biologists, chemists, physicians and computer scientists; there's a fairly wide array of expertise within JASON. And so they were asked some very broad ranging questions and again, kind of forward-looking. I've laid them out here, the bolding is mine, it is not from the report itself and I'm just going to – I'm not a big fan of reading slides, but I'll just call out a couple of these charges here.

How can the complex data handling techniques and Internet-based technologies be applied to healthcare to promote the development of real time integrated data sets at a scale seen in other industries? How can the various users of health data in the clinical research and public health communities be presented with tailored and highly specific data views in near real-time based on routinely collected health data? As health data grows from megabits to gigabits per individual, what fine-grained analytics should be made available to patients and healthcare providers? A question about fundamental data management capabilities and national security consequences, these questions are probably familiar to many of you. As we've gone from – applications in the hands of providers, patients, and health systems to try to get a handle on their information and their data and to try use it in the delivery of care. Now recently in the past several years, we've grown towards saying, okay, now that we have this data, how do we – how do you use it to improve the care that we are delivering and how can do we understand that better?

So we'll – before I get into some of the findings, I do want to point out that this report has been published both on healthIT.gov and healthIT.AHRQ.gov. It does not necessarily represent an official position of ONC or AHRQ. This is a again, I'll say an expert analysis, and there's a lot of stuff contained in the 65 or so pages of the report. The report is slightly less than the notes for this particular meeting, but it's still a fairly long document and fairly lengthy. So this report is – the slides that you're getting are fairly heavily excerpted. But I think that even though it's not the official position of AHRQ or ONC, you certainly heard interest from Karen and also from the rest of us – in some of the ideas that are expressed in here. And at the end, I'll talk of little bit about some of the interesting things I've heard since the report was published, from the private sector. So, next slide.

The way JASON studies work is, charges are laid out to the JASONS, a number of briefers with expertise in the questions that they've been asked are asked to come and brief the JASONS. And these are the organizations that had briefed them, that's also laid out in the report. Next slide.

So JASON identified several challenges to achieving the goals that were stated in the study charges. There are 15 of them listed out here. JASON said they did not have expertise to address all of these. If you could hit the next arrow, I want to know if it jumps to the next slide. Okay, so if you could do that six more times. So the underlined challenges are ones that JASON tried to address in the report that's been published. So, next slide.

So there are several findings, these were the ones listed as the key findings. And again, I want to read them to you for clarity sake. The current lack of interoperability among data resources for EHRs is a major impediment to the unencumbered exchange of health information and the development of a robust health data infrastructure. Second, interoperability issues can only be resolved by establishing a comprehensive, transparent and overarching software architecture for health information, and that is a term that we will get to, it's on the next slide. The twin goals of improved healthcare and lowered lower healthcare cost will be realized only if health related data can be used in the public interest for both clinical practice and biomedical research. And finally that will require implementing technical solutions that both protect patient privacy and enable data integration across patients.

So those are the key findings, again, I think some of you will find that there is some resonance to this, those of us who have worked on interoperability over the past decade, myself included, have struggled with some of these issues. So, on to the next slide.

So architecture is a term used variably by different people. So the report is very specific about when it – what an architecture is, and it bears repeating. For the purposes of this report, a software architecture defines a set of interfaces and interactions among the major components of the software system that ensures specified functionality. And particularly the functionality that we're getting at are the ones that were laid out in the study charges. So, next slide.

So JASON proposed an example architecture and they elaborated a number of principles upon which that architecture was based. Now I list them out here, and there are probably two that I will call out to you in particular, I won't read all of them to you. The two that spring to my mind, I think probably bear some discussion are the first one and the last one. The first one was a principle is that the patient owns his or her data. Now I think many of you probably who have not read report yet, have probably just thrown up your hands and like, that's not right. So what I'll – let me be clear, you're right, that's not right. Right now the person who generates the record owns the record, okay.

I think that this principle though, is ignored at our peril because I think what it represents is the growing sentiment that not only do patients have in currently defined law, rights to copies of their information in an electronic form. But that also that they have some standing with regard to their data and how it is used. And we'll talk about that a little bit when we get to privacy bundles, but I think that this sentiment is worth discussion.

The final – the other one that I want to call out to you is the bottom principle, which is that the architecture should provide a migration path from legacy EHR systems. That could be read to indicate that we need to move away from legacy EHR systems. For what it's worth, that's not how I read that principle, the way I read that is that we need to figure out how to enable the interoperability to achieve the kinds of capabilities and resources that were laid out in the charges and that we're not getting them with current EHR systems as much as we want to. On to the next slide, please.

So, this is the diagram that describes the example architecture. There's a lot more detail, of course, in the report itself, but let me talk a little bit about what the different components of this diagram represents. On the left is the box with the stovepipe legacy systems, these are EHR systems as currently installed across the country. Stovepipe in the sense that they comprise a lot of the layers that are in the middle, user interface, search and index functionality, chart and record data, so it keeps those within that system. So the question is how do you get from current systems to the rest of the architecture as described here?

So let me start with the bottom of the described architecture. The bottom of – the foundation of this the architecture are the data. Both the storage and the transport are defined here both in physical forms of the wires and the hard drives where they rest, as well as the logical handling of where – how the data are stored and transported. The report recommends that the data be encrypted both in rest and in transit. As we all know, data are encrypted currently in transit, but not necessarily at rest.

So moving up to the middle section of the architecture diagram, the layers to the stack, top is user interface, there's a middle layer, of course and then there are semantic and language translation layers, search and index functionality. And then they split out both chart and record data, as well as atomic data with metadata. And those – I think in – what those two boxes represent is recognition that while atomic data are desirable for the purposes of analysis and combining data into the large data sets for better understanding of what's happening in the healthcare system. But data are created as a record for both patients and there's a very – that's a very important purpose for the data.

And then finally, in the upper right corner of layers that span the stack that's in the middle, okay. And these relate to privacy and security and identity and authentication. So the box on the left there shows identity and authentication authorization, the box on the right is key and certificate management and then in the middle is this concept of patient privacy bundle management, and we'll discuss that a bit in the next slide. But before I get to that, so a key recommendation that I'll lay out towards the end here, are the dots that are between the current systems and the layers of the stack. And those dots are published application programming interfaces and that is really a key recommendation that we'll get to here, but I just wanted to recognize that its – part of the architecture. Okay, on to the next slide, please.

So, one of the charges laid out is how do we handle the privacy concerns when we're trying to achieve these goals of large data sets to be able to improve healthcare. And the recommendation from the JASON Report is that we try to get this through something called patient proxy bundle. This is a concept that has been around before, it's not brand new, but as it's laid out here, the patient privacy bundle is a collection of fine-grained settings of default permission and inheritance settings for access privileges to electronic health data. Both atomic data and metadata must be associated with permissions. The patient controls access by electing a privacy bundle. And that a fine-grained permission system is flexible and can accommodate many different types of security policies.

And then finally in terms of risk, the choice of a patient privacy bundle implies that an assumption of different levels of risk by the patient in return for different benefits for both for themselves and society. The point here is that there are lots of different types of health information and people have different feelings about the different types of health information. Some of it they're pretty easy to sharing and recognize the public good in it. And there are other kinds of information that may not be as good about sharing – as interested or willing to share. And that we ought to enable people's ability to choose about what is shared and what is not. So, I won't get too much into that, I know there are people who are far more expert in this than I. So, next slide, please.

So again as well with findings, there are a number of recommendations that were proposed in the report, I've selected two here for discussion. I'm certainly open to others if folks want to bring them forward. But first is that within 12 months ONC should define an overarching software architecture, as defined by this report, for the health data infrastructure. And the second is that the EHR vendors should be required to develop and publish APIs that support the architecture of the health data infrastructure. And those are quite pertinent to things that you all have been talking about for a long period of time. Next slide.

So the three topics that I thought were worth your time to talk about were what do you think, should ONV define an architecture this year and then to discuss the patient privacy and related risk managements vis-à-vis patient privacy bundles. And then finally, that the architecture should be supported by openly developed published and tested APIs. So, before I just – before I turn it over to you all, I would add the following. So it was mid-April when this report was published by us at HHS and there's been a lot interesting reaction. Most folks tend to take a quick look at it and go, huh. And then they read it through a second and they go, what? And then they read it through a third time and go, hmm, interesting. Folks I think accurately recognize that there's a lot of this that's pretty ambitious. There's a lot of it that doesn't necessarily reflect a go – a deep understanding of the way systems are currently developed or deployed or architected.

There are, at the same time, folks that say, there are a lot of good goals here, good aspirations. And what has been most interesting to me is that over the two months that this has been out there, what has come to my attention is that there are a lot of folks in the private sector who are working on aspects of this. APIs are not new, Blue Button and Blue Button Plus is something that you all have been working with for a long time. But – and there are other API initiatives, within the current health IT vendor community. So, some of these things are not new, I think they're actually being worked on now. They're not necessarily being worked on in a coordinated way.

I think it's an open question for you all to discuss about whether – how if there are things that you think should be worked on, ONC can promote those. I think that current programs are one potential way of doing it, but you may have good ideas about other ways of doing it. So I think that, like I said, there's a lot of information in the overall report. I've done my very best to try to encapsulate it and I really look forward to your thoughts. Some of you have already offered me thoughts and they've been really great, so I hope you all enjoyed the presentation and have a good chance for discussion. Thanks.

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

Thank you very much, Jon. And let me open it up for comments or questions from the committee.
David Lansky.

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

Thank you, Paul. And thank you, Jon, I think it's a really interesting report. I enjoyed it and did read it three times so I followed the recommendation. A couple of thoughts, one is that they did not include purchasers or payers, other than John from Kaiser, among the briefers. And they also didn't clearly include any consumer users among the briefers. So I think the report reflects a point of view or a level – a scope, I guess that is limited. And that's fine, I actually think the report's very valuable as is and most of it would still apply to the other audiences that I'm thinking about.

But it also raises for me the – whether there is an opportunity as this work potentially proceeds and to include dimensions like public transparency of health data, public policy uses of data, public safety uses of data. The accountability issues and transparency issues in general of the public investment in health IT among the use cases that the report and its architecture should speak to, or however we all progress with this. And I'm also thinking this architecture seems to apply mostly to the clinical care environment, data capture architecture and not, per se, to the longitudinal linking aggregation and computation of data, which are the applications that those other users are mostly concerned about, in terms of getting transparency view into the performance of the health care system.

So, I just wondered if you have or others in our committee, had any thoughts about how we extend the JASON strategy, if necessary, maybe it's adequate as is, to address those other uses. And particularly thinking about the longitudinal aggregation question and the integration of patient-generated health data into the construct. Again, this seems rooted in the clinical experience and obviously we've all been talking about the collection of data from patients as an important part of the evolution of the architecture. Thanks.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Hey Paul, its John, can I briefly respond?

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

Absolutely, yes.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Okay, thanks. David, excellent comments and observations, part of the report that I kind of glossed over was the recognition that while there are current clinical information sources are as you stated, that there is a huge volume of data that is being generated now and even more that is just over the horizon. So I did gloss over that a little bit. One of the things that I hope maybe Deven will comment on a little bit was some discussion about how providing patient's access to their information through – or meaningful access to more of their information than they currently get through APIs might be one approach to achieving that longitudinal view of an individual and their health.

I think it's something that can be enabled, I think it's something that the committee certainly ought to discuss more. The final quick thing that I want to say, and then I'll shut up is, that this expert analysis, it's good for what it is. I think that Karen's and my interest in bringing this to both the Standards Committee and you, the Policy Committee is, and you are really the right next thing for this. So, these are some good thoughts being brought to you all and you all are the formal advisors to the ONC and the department, so we really appreciate your perspectives on that. Thanks.

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

Thank you. Deven McGraw? Might be on mute.

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

Oh, I am. I'm sorry. I don't know how long your queue is Paul, because I have the advantage of being on the interoperability workgroup or least I think I am, that will get us to discuss this in more detail. So I could either hold my comments for that process or go ahead and share some of them now.

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

Go ahead

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

So my – when I first read this and unlike David, I've only read it once, I probably need to read it a couple of more times. My first thought was, okay this is PCAST Part 2 and this is the second time that we are being advised by some renowned scientists that this sort of trajectory that we've been going on with respect to the technical piece of implementing health information exchange isn't right. And we need to shift to a strategy that makes the data more open and more available, but subject to privacy controls that are largely dictated by patient choice.

But I had a – I actually, and I do – and I would criticize this report as similarly having in some ways a fundamental misunderstanding of what the role of a provider EHR is and what it was initially sort of d – facilitated to address. And that to create a set of expectations that it would do more is a bit of a – is not only a technical change, but a radical cultural change. Having said that, I do think that the sort of ability to create a more open environment for data that is provided to the patient. For the patient to use and make choices about how to share could, in fact, be the way to sort of get the longitudinal record to be able to enable more robust data sharing both for care purposes as well as for analytics.

And it will be something that I will raise in more detail in further discussions about this. Because we've been sort of stuck, I think, with the architecture that we've created. And it's very hard to do a hard right turn from that, but it should be less difficult to do that in the sort of patient-facing environment where the tools are much more built on the kind of software architecture that's recommended in this JASON Report. And that frankly was – is very similar to what is recommended to us previously by the President's Counsel for Advisors in Science and Technology. So there may be an opening here to sort of freeing the data, but in a responsible ways through the sort of patient access route.

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

Jon did you want to –

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

Paul, this is Michelle. Can I just clarify one thing? I just want to note that we are actually forming a joint task force to respond.

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

Oh, okay.

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

And it will be between the Standards Committee and the Policy Committee. Micky has agreed to lead it from the policy side and David McCallie will be leading it from the standards side. And we will be asking for volunteers, so Deven, I'm assuming you're volunteering, so thank you for being the first one.

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

Okay, well okay then. Well since Micky will be tied up with this too, it probably makes sense that I – yes, you can count me in.

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

Okay then, maybe I'll piggyback a little bit on what Deven just said. I certainly recognize the overlap between this and the PCAST, both the scope and the recommendations. I want to ask maybe a question for Jon. The group certainly recognized that we have to weigh the privacy decisions and they took it at an atomic level with the benefit to the individual and to the public. The question is, how much knowledge is required for an individual to make an informed decision either for their own benefit or for the public? So that would require essentially almost at the atomic level for each and every patient to have that knowledge to make an informed choice. And then the implications, you did call it ambitious and how much did they weigh the feasibility and the cost involved in this major shift versus the benefits, so both the overall – the sort of the global cost-benefit as well as on an individual level, the cost-benefit of sharing each atomic data element? Was that robustly discussed or yeah, thank you.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Yeah, no, that was just a great question. So the analogy that I've used before in terms of population benefit is vaccination. There is some protection that is conferred to the individual when I go get my MMR or my tetanus shot. But really, the main benefit of doing vaccination is for the herd immunity, so something doesn't rip through the population like wildfire. So yeah, there's some benefit to vaccination, but there's really it's a population benefit is why we – vaccination. In a similar way, there's going to be some benefit that people get for themselves, but they also – people do need to recognize that when they share their information for the purposes of analysis and other things like that, that not all that benefit gets conferred to them. It gets conferred to the population in the form of new findings, more efficient care and stuff like that.

So in most discussions of the report, the more fine-grained you get, the more complicated it is. So, I don't think it's reasonable, and JASON didn't think it was reasonable either to expect everybody to understand every nuance of that. An approach they suggested to that was to have trusted organizations like say the Palo Alto Medical Foundation, right, or somebody else to say, okay, we recommend that you use the privacy bundle TANF. Because that will – and the broad brushstrokes are that it'll let you – your information be used for research, that it can't be tracked back to your house, that sort of thing. So rather than have individuals try to understand all the different aspects of that, that they wo – that the trusted organizations would recommend different privacy bundles. I think there are other potential approaches, but that at least was what was kind of described in the report. Did I get your question completely, Paul?

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

Yes. Yes, so what you're saying that yes, this was discussed and what you offered was one of the examples of how you could do this in a practical way. So, appreciate that answer.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Oh you know, actually you asked a second question which was, did they consider the cost and other things like that. They did not. They basically – again, they were given the charge of how do we achieve these kind of ability to generate large data sets and to be able to do fine-grained analytics on it. And what they proposed was the technical approach to doing that, they did not get into some of the other implications of it.

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

Ah, that's important, too. So that's very helpful context, thank you. Next is Paul Egerman.

Paul Egerman – Businessman/Software Entrepreneur

Great, thank you, Paul. First I want to partly agree with what Deven said. As I read the JASON Report, I saw it as like the sequel to the PCAST Report, it seemed like it was the PCAST Report again. And I would make the observation that when the PCAST Report was published, the Policy Committee had a workgroup that evaluated it. I was the Chair of the workgroup, we produced a report that was many pages long that was approved by the Policy Committee that talked about a lot of the kinds of issues that are being discussed right now. In terms of privacy, in terms of well gee, what really is the role of the data and is it really correct to use this data for research in this way.

And so I would hope that the new Task Force that David McCallie and Micky Tripathi are chairing would also read through that report, it was done about three years ago. And reflect upon the recommendations made in that report and reflect upon what has happened in the past three years in which ONC actually did a pretty good job, somewhere between pretty good and very good job of implementing a lot of what was in the PCAST Report, in terms of having metadata tags and establishing an architecture. And to understand that the PCAST Report and the JASON Report really only represented a very small setting, one type of information exchange that by itself is not a solution.

I would also make the comment that when you read the JASON Report, an interesting thing that I've noticed is it refers to EHR systems with the term legacy. They call them legacy EHR systems although it does not use that term as it relates to the Microsoft HealthVault. But with the exception of Microsoft HealthVault, EHR systems are called legacy systems and that's a fairly critical expression. A legacy system is sort of like something that like an archaeologist finds, it's like, it implies old and out of date when compared to what's in the report, which is supposed to be new and exciting.

And I would just make the comment that any time you take what you call legacy systems or what people called legacy systems, I call operational systems. And these systems that are operational, any time you compare an operational system with an intellectual report or a system on paper, well the paper system – the intellectual system always wins, always looks so much better until you actually have to put it into operation. And so those are my comments.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Hey Paul, its Jon White. Listen, those are good comments. I think they're all absolutely worth taking, especially going back to PCAST. I'd add two extra things, the first is that I felt like this report went one technical level deeper than the 2010 report PCAST report that started to get into some of the practicalities of how you enable the kind of things that they were charged to do.

The second piece that I think is probably worth adding for the look, as the Policy Committee and Standards Committee move forward with this, is taking a look at the PCORnet's projects that are under way now. There's both the patient powered research networks as well as the clinical data research networks and I think that those were brought into being since this report was generated. And I think that they probably have a significant amount to add to the conversation about how we're trying to get at this and what the current experience is with that. So thanks for your good comments.

Paul Egerman – Businessman/Software Entrepreneur

Well, yeah and I just have to say, though again, if you go through our response to the PCAST Report, one of the comments that was made by a lot of the researchers was that the data model for research is not the same as the data model for treatment. And that when you start to make a data model that tries to accomplish both, that there is a lot of complexity and it's possible that treatment is harmed. It is very interesting that both the physicians and the researchers did not like the idea that there was somehow going to be this one massive universal architecture for data that both would use for both purposes. And so that's an observation, but it's an observation as it relates to the idea of what's in the JASON Report is a theory, what the EHR systems have right now is operational, even though JASON calls them legacy. It is operational and it does work.

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

Okay. Any other comments or questions? As Michelle pointed out, we are – Karen has asked us to provide feedback on this report. It certainly deals with the infrastructure and especially the interoperability. And as you know, this is a priority for Karen, ONC, and HHS. So she's asked for our comments, there's going to be a Task Force formed jointly between HIT Standards Committee and this Policy Committee to provide feedback. And that'll meet over the next couple of months with a report back out in August.

So please volunteer, Deven would like someone else to join her on this report. And David McCallie from standards and Micky Tripathi representing policy will co-chair this Task Force. So please let us know if you're volunteering. Okay, I think – anything else – Karen, anything before we go to public comment.

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

No, I'm good. Thanks everybody.

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

Okay. Let's go ahead the public comment please.

Public Comment

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

Operator can you please open the line?

Caitlin Collins – Project Coordinator – Altarum Institute

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

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

While we wait, just a reminder, all public comment is limited to 3 minutes.

Caitlin Collins – Project Coordinator - Altarum Institute

We do have a comment from Shelly Spiro.

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

Go ahead.

Shelly Spiro – Executive Director - Pharmacy e-Health Information Technology Collaborative

Okay. Good afternoon, my name is Shelly Spiro. I'm the Executive Director of the Pharmacy HIT Collaborative representing over 250,000 members of the majority national pharmacy associations and key pharmacy organizations involved in health IT. On December 12, 2013, I testified to ONC HIT Policy Committee's Certification and Adoption Workgroup regarding the pharmacists and pharmacy clinical perspective on voluntary EHR certification for long-term post-acute-care settings. Pharmacists are highly trained as medication management experts. Over several years the collaborative and its members have been working with the National Council for Prescription Drug Program's NCPDP and HL7 on standards that will assist pharmacists and standard structure documentation of patient care services.

These are – examples would be, medication therapy management as required by the Medicare Part D Program, some Medicaid and also private insurers. One such standard is a joint project between NCPDP and HL7 for structured documents using clinical document architecture for the consolidated CDA. And also to meet some of the CMS required Part D take away documents for an annual comprehensive med review.

The Pharmacy HIT Collaborative worked with NCPDP and HL7 in the development of an ANSI-accredited pharmacist, pharmacy, provider EHR functional profile designed to facilitate and captured clinical medication related data at the point of care in a single logical health record. This functional profile specifies the requirements needed to support messages among prescribers, pharmacists, or pharmacy providers and other healthcare entities benefiting from medication-related information.

The LTPAC and behavioral voluntary EHR certification program can assist with improving medication management and the collaborative supports these efforts. We also ask that ONC supports a similar focus by providing guidance for pharmacists and pharmacy to implement voluntary EHR certification in all practice settings. Thank you.

Caitlin Collins – Project Coordinator, Altarum Institute

Thank you and we do have another comment. Corinne Rubin, please proceed.

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

Are they still on the line?

Caitlin Collins – Project Coordinator, Altarum Institute

Corinne, your line is live, if you are on mute, you need to take yourself off mute.

Koryn Rubin, MHSA – Assistant Director, Federal Affairs – American Medical Association

Thank you. Sorry, I got the operator got on the line. This is Koryn Rubin from the American Medical Association. The AMA has been deeply engaged and involved in quality measure development and educating physicians on reporting. Therefore we are seriously concerned with the lack of transparency and engagement from ONC and CMS around the development of clinical quality measures for Stage 3 Meaningful Use. One of the biggest challenges we have seen with the quality reporting program, in addition to the need for more measure reporting alignment and to move to a yearly rulemaking cycle to ensure quality measurement is following the most up-to-date evidence-based medicine, is having the opportunity to meaningful comment and inform the measure development process for the Meaningful Use Program.

Despite making numerous requests of ONC and CMS staff on how to put forward a request for a measure and for a status update on the possible ONC CMS contracted measures, this process remained opaque and elusive. Given this elusiveness, we are concerned that Stage 3 will still miss the mark with meeting the needs of physicians to meaningfully report quality measures. We learned by accident as we were reviewing the CMS website that there were several measures out for comment, consideration for Stage 3 Meaningful Use and the comment period for those measures recently closed.

Over the last several months we have reached out to CMS staff requesting more information on the availability and progress of Stage 3 clinical quality measures, which is why we were surprised to learn that there were several measures that were out for comment but no formal solicitation for input. Many of these measures are new measures that have not been utilized in any other quality program or have been re-specified from the existing measures. We are deeply concerned with the scientific and statistic validity as we've been unable to review the full measure specifications.

We are also concerned with the re-specified measures as our experience with measure development is that the numerator and denominator is not exactly the same between the two measures, the measures are not equivalent and need to go back to the drawing board with specifying and testing. Many of the proposed measures assume interoperability and the advanced stage of Meaningful Use the seamlessly in place. Therefore it is incumbent that before any of these measures go forward, there's real world testing in multiple types of physician practice settings and sizes to ensure the EHR can capture and calculate the measures without putting an undue burden on providers.

We are troubled by the amount of time and notice available to the public to provide feedback. Unless more time and opportunity is afforded to comments, prior to the proposed rule, we will be left with little if any opportunity to help meaningfully shape the clinical quality measures for Stage 3 and potentially left with poorly designed measures. We are also unsure the scientific rationale between the crosswalks made for Stage 1 and 2 measures to Stage 3. We recommend for ONC to maintain the existing set of measures so physicians who are entering Stage 1 of a program have the opportunity to participate and are not held to a more advanced statement of measurement before having a chance to get used to reporting quality measures and...

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

I'm sorry Koryn, your time is up.

Koryn Rubin, MHSA – Assistant Director, Federal Affairs – American Medical Association

All right.

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

Thank you. Any other –

Caitlin Collins – Project Coordinator - Altarum Institute

We have no more comment at this time.

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

Okay. Well thank you everyone, I know that it's harder to attend a meeting, particularly if it's a few hours on the phone, but really appreciate the robust interaction and the engagement of those folks on the call. So really appreciate that and appreciate the time of the presenters. And we will next meet in July, I believe July 8, is it, but whatever the date is, it's in person.

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

July 8.

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

July 8. Thank you everyone and see you in July.

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

Thanks Paul. Thanks everyone.

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

Thank you.

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

Bye.

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

Okay, see you in July.

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

Thank you.

Meeting Attendance						
Name	06/10/14	05/06/14	04/09/14	03/11/14	02/04/14	01/14/14
Alicia Staley		X	X			
Aury Nagy					X	X
Charles Kennedy		X	X		X	X
Chesley Richards		X				
Christine Bechtel	X	X	X	X	X	X
Christoph U. Lehmann	X	X				
David Kotz	X	X	X	X	X	X
David Lansky	X	X	X	X	X	X
David W Bates	X	X				
Deven McGraw	X	X	X	X		
Devin Mann		X		X	X	X
Gayle B. Harrell	X	X		X	X	
Joshua M. Sharfstein		X	X	X	X	X
Karen Desalvo	X	X	X	X	X	
Kim Schofield	X					
Madhulika Agarwal		X	X	X	X	X
Marc Probst	X	X	X	X	X	X
Neal Patterson	X					
Patrick Conway						
Paul Egerman	X	X	X	X	X	X
Paul Tang	X	X	X	X	X	X
Robert Tagalicod		X	X	X	X	X
Scott Gottlieb	X		X	X	X	
Thomas W. Greig	X	X	X			X
Troy Seagondollar		X	X	X	X	

Total Attendees	15	20	17	18	19	16
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