HIT Policy Committee
Final Transcript
May 12, 2015

Presentation

Operator
All lines are now bridged.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology **Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee. As a reminder, today's meeting is being transcribed and recorded, so please state your name before speaking. Also as a reminder, there will be public comment before and after lunch and public comment is limited to 3 minutes per person. We have some new folks in the room today, which you will see when we go around the room. Coming up in future meetings also we are going to be asking you all to share if you have any conflicts of interest. We'll follow up with additional information, but please expect that starting at the June meeting. So let's start with David to do roll.**

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

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

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

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

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

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

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

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

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

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

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

Donna R. Cryer, JD – Founder and President – Global Liver Institute
Donna Cryer, Global Liver Institute.

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
And we missed Kim Schofield, who's back in the room. On the phone we have 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.

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

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

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare
I'm here.

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

Paul Egerman – Businessman/Software Entrepreneur
Here, good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Paul. Is Terry Cullen on the line? Anyone else on the line that I missed? Okay. Also, if you are following along via Twitter, the hashtag for today's meeting is #HITPC. And with that, I will turn it over to Karen.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Thanks Michelle; good morning everybody, thanks to those who are here and those who are on the phone joining us. Paul, I have a couple of housekeeping things that we need to do, some saying of good byes and saying of hellos and I thought I might first just start, since the question on the table is, what's going on with Karen? And just to tell you all thanks to everybody for well wishes and their support. The President did nominate me to be the Acting Assistant Secretary for Health. I do continue as National Coordinator and will continue in that role for some time; so I am here today and here in general.

I want to thank the team at ONC in particular for being so incredibly supportive and wonderful in the work they do every day. We have a lot to do still and into the future and I'm looking forward to continuing that pathway with you all, as is the Secretary. And I think it's really important for me to underscore again and re-emphasize her ongoing commitment and support not only to ONC, but more importantly to the work that we are doing. She considers the health IT portfolio to be essential to her major initiatives, delivery system reform, precision medicine, opioids and other items, but those three in particular. And so no matter, I will continue to be very involved in health information technology as her senior public health and medicine advisor and working on delivery system reform. So, we've got a lot to do, let's keep up the great work.

I do, I wasn't able last time to say my goodbyes to a couple of folks. So first, I know we sort of did that last time, and I hope I'm going to remember all four. So Marc, I'm going to start with you, you're on the phone. Good riddance, get out of here already.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare
Uh, I feel like usual, Karen.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Boy, I won't wax too long but just Marc to say, thank you for being brilliant, doing such great work out in Utah to show us how it all can be…how it all can come to life and how health information technology informs care and science and quality improvement. And it's just really been wonderful to have the chance to work with you and learn from you and I hope that that will continue and that you'll continue to be a part of the efforts that we have going forward.

David Bates has been trying to keep me straight for a lot of years and I want to thank him for his service on this committee and for his personal mentorship of me as I was a Fellow many years ago and then ongoing today and for his particular work in helping us think about safety here for this committee, but I think also for the world in general and I look forward to his continued contributions.

And for…oh Christine is not here. Christine, are you on the phone?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
I bet she's running late.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Is she? All right, well she's going to have to read the transcript where I'll just say that, we'll just have a consumer-facing API and we'll send her her data that way.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
She would appreciate that.

Karen B. DeSalvo, MD, MPH, Mc-National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
She would and she would be right to appreciate that because it's a good thing. The…I want to thank Christine for her commitment; her unwavering focus on making sure that the consumer's voice is not only heard that is listened to and that we continue to advance this agenda with them in mind and not making it for them, but with them and she is just a treasure and we really appreciate that work. And why am I forgetting the fourth person?

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

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Oh Charles. Okay, Charles Kennedy is on the phone? No, no Charles, he'll read the transcript also. And Charles, I want to thank also for his service. He has helped us to really understand where we have gaps and opportunities, at least in the time I've been with him, in thinking about how we're going to advance payment models and what that means to the providers on the frontlines and where we might be going straight or going awry and actually seeing that Health IT is supporting and enabling that and not getting in the way. So Charles, thank you for your wisdom in that and for what you're also doing on the ground to see it come to life.

So that was just…I just wanted to take a minute to make my personal thanks to those folks that we're losing, even though Paul did it last time. And I'm turning it over to Paul.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
No, I…and I'll just echo what Karen said and also I meant it last time when I expressed my appreciation for how hard and how long these four members have been both with us and working on these…the workgroups and the committee. So thank you all for your services. And I get the pleasure of introducing new members to the team and we have three out of the four potential candidates.

To my left is Kathy Blake. Now Kathy and I go way back, actually, I'm going to say that differently. Just yesterday we were residents at Stanford and she is the Vice President for Performance Improvement at the AMA and she heads up the quality measurement activities there. She also resides in both Chicago and Santa Fe, New Mexico. Now I'm going to make my assumption that it's not Chicago in the winter and Arizona in the summer, but that's one of her special traits.

Donna Cryer is no stranger to us, she's been in the Privacy & Security Workgroup. She is the founder and President of the Global Liver Institute in Washington and that organization facilitates collaboration between…amongst various stakeholders, patient advocates, policymakers, regulators , health systems and payers to solve the challenges of advanced liver disease and treating those diseases, but also she is a strong patient advocate or person advocate for all people who participate in the health care system. Thank you for joining us.

And finally, Brent Snyder, who is a CIO at Adventist Health System, a large health system in…based in Florida; he's also been a CFO and he's a lawyer. So I think he probably just gets too bored and so he's fortunately taken on the task of working with us on the Policy Committee to represent healthcare providers. I should mention that Kathy is representing health care quality measurement and reporting and Donna, of course, is representing patients and consumers. So welcome to all three of you and thank you for donating your time. You don't know how much time you're going to be donating yet; we usually tell that to you after you've joined. So thank you very much and welcome.

Okay, let me move on to business of the minutes from last meeting that was distributed earlier. I wonder if anybody has a motion to approve them.

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Thank you, Deven. And second?

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Thank you, Chris. And any further discussion or amendments to the minutes? If not, 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? And thank you very much. Okay today we're going to concentrate on two main areas; we're responding to the fairly recently released NPRM on Stage 3 Meaningful Use as well as the certification criteria and we're going to hear from a number of our workgroups with respons…proposed responses to that for the committee's deliberation. So we're going to start out with the Meaningful Use NPRM comments from the Advanced Health Models and Meaningful Use Workgroup along with others, which I'll mention in just a bit.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
We're getting some background noise; if there's somebody on the phone that could mute their line that would be wonderful. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay, and Joe Kimura; are you on the phone?

Joe Kimura, MD, MPH – Deputy Chief Medical Officer – Atrius Health
I am here, Paul.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Great; thank you. So Joe and I co-lead the Advanced Health Models and Meaningful Use Workgroup and we're going to report on some of the comments we had, the collective group and I'll mention the other groups that participated during this section. So…is this working? Okay, so here's a list of the workgroup members for Advanced Health Models. Thank you very much to the ONC staff and in addition, Samantha Meklir and Alex Baker, uh no, some maybe it needs a battery change.

So, we've divided ourselves…there should be another slide that talks about the process. So we divided the 8 objectives into…amongst 4 workgroups in a sense. The AHM Workgroup took apart some of the objectives and then the Consumer Workgroup, the Privacy & Security Workgroup and the Interoperability Workgroup also contributed. So, we'll…the first slide shows the subgroup, number 1 that dealt with the overall approach and ty…and somebody's…okay, for the folks on the phone, the slides are moving quite a bit now and we're going to settle down.

Okay, here we are. So we have the 8 objectives and key questions and we divided amongst the workgroups you see before us. Then we got on a call last week to try to reconcile these responses and we're presenting a summary of those responses to you today. Next slide, please. In the AHM Workgroup we divided ourselves into four subgroups, which you see before you. Next slide, please. Okay, and the first summary I'm going to talk about is from subgroup 1 which dealt with overall approach. Next slide, please. I lead it up with Mark Savage, Charlene Underwood, Shawn Alfreds and Frederick Isasi. Next slide, please.

So we look at the change or the approach, the different approach that was taken with MU3, Meaningful Use 3 proposed rule. And they fall into these buckets, to simplify the program, to reduce the burden and provide more flexibility. Next slide, please.

And the first one is simplification. One of the things is to uni…one of the ways they simplified it is to unify the stages to a single stage, which is Stage 3 and from then on, it would be one stage instead of multiple stages. We thought…the workgroup thought this was a great idea. It's a lot easier to understand, we don't have multiple people in different stages, even in the same organization and, it synchronizes one organization with its clinical trading partners. So that, we're in total agreement with that move.

The second point was to align the reporting periods; also makes it much easier to understand. It aligns both the provider side and the inpatient side…the eligible hospitals. So that also synchronizes both the internal and the external partner activities. It does create a bit of a bolus effect towards the end of the calendar year, but we thought that was…that the benefits outweighed the cost in terms of aligning reporting periods.

Second piece is to reduce the burden; everybody cheered that one, of course. The first approach to that is to reduce the total number of objectives to 8, concentrating on the more advanced functionality. We all recognize there was a little bit of fudging going on in the sense that some of these objectives had more than one measure. But all in all, we thought it was a great idea to sort of concentrate on a fewer number of advanced and highly valued functionality.

Also agreed with removing the duplicate and topped out measures, even though there's persistent value we didn't think that people would stop doing something they were already doing; so this reduced the burden of having to comply with it and to document your compliance with those; so that was good. And finally, to remove the paper counting measures that is concentrated only on things that are much easier to measure with less burden, which is that that's stored in the electronic systems.

For flexibility we had some more discussion on it. We in a sense agreed with the proposal in the MU3 document, but I'm going to give you some provisos in terms of discussion we had. One, the providers…so in the proposed rule it was proposed that 2017 would be an optional year for providers; if they were ready and chose to go to Meaningful Use Stage 3 and that everyone would have to be in Stage 3 by 2018. So providers appreciated that flexibility.

We did recognize, however, that any of these "ors" turned out to be "ands," for vendors. In other words, if the providers have the option of going to Stage 3 by 2017, then vendors need to make their products capable of doing that. So that does affect the timelines, we all talked about the lead time required for developing, testing, implementing, and teaching or training the new versions of a software. So we thought there were three options that may help mitigate some of that effect on timelines.

The first option is, as stated in the NPRM, which is to make 2017 optional and 2018 mandatory. That would require all the vendors to have full 2015 certification by 2017. The other extreme would be to accept the somewhat proposed in modification rule, the question was posed, should we just make Meaningful Use Stage 3 mandatory for 2018 and not have the optional 2017; still having full 2015 certification for the vendor products.

The third one is sort of a compromise or in between that is, keep the proposed timeline, optional 2017, mandatory 2019; but in some cases having…relying on 2014 certification of a product, instead of going to a 2015 certification. What that does is that frees up vendors to devote more of their time on the new functionality rather than ones that are being tweaked for example.

So that's…those are 3 options to consider. So once again, the workgroup in its voting did agree to propose that we keep the MU3 language; that is optional 2017 and mandatory 2018. But that these…the variance on that could help in terms of the time constraints.

On this one year reporting period, there was also agreement on choosing the one year, full reporting period. If, however, CMS chooses to have…offer us a shorter timeline, such as in the past 90 days; the advice would be to keep the 9o days or whatever the shorter period is synchronous so that everybody is moving at the same time instead of letting each provider choose their continuous 90 days anytime throughout the year. What that does by keeping it synchronized, is it helps with things like interoperability where you need a transmitter and the receiver to be in synchrony.

On flexibility, we recognized that there was some flexibility offered in terms of reporting on all three measures, for example, on the three that you list…you see there, but only meeting thresholds on two of the three. So that seemed to be a good way of handling the flexibility.

Okay, I'll next move to subgroup number 2 which dealt with three of the objectives you see before you, eRX, CDS and CPOE. This was ably led by Mike Zaroukian with Deven Mann, Lisa Marsch and Marty Fattig participating. So objective 2 has to do with ePrescribing and basically it in…it increases the threshold from 80% for EPs and 25% for EHs. In general we agreed with the increase in objectives; we agreed with two of them and had some changes to another two, and I'm going to go over those in a little bit more detail.

So the first one is that we do agree with the increase in the objective; we note that 25% may be reasonable…and the slides keep moving for some reason...25% may be a little difficult for hospitals in terms of transmitting the prescription, because a lot of times, for example, either the receiving site, let's say a nursing home, may not have that capability to receive it or the patient may not know what pharmacy they're going to fill it in. So that's an example, but we do think that 25% is reasonable.

One thing that seemed potentially, you know, we recommend reconsideration is the querying for formulary because there are lots of times when the formulary may not be known either by the pharmacy or the patient or having the right…the up-to-date information in the system. So, that there was a lit…or a question whether that particular requirement adds value.

The second piece in terms of scheduled drugs, the suggestion was, we agree with including scheduled drugs, but right now the proposal is to include it for the full reporting period. If there is a time when you can meet it…when the permissible transmission occurs within a reporting period, the suggestion is to go ahead and accept it from that point forward.

The next thing…topic has to do with OTC medicines, over-the-counter medicines and the proposal is to exclude those. The group felt that since OTC medicines they're just a change…it's a change in formulary, a lot of prescription drugs go over-the-counter, they're still very important. They're important from an indications point of view, let's say aspirin. They're important from a drug interaction point of view, so there's no reason to exclude it, according to the workgroup members; it should be allowed for providers who want to keep track of those in their EHR, but not required.

The other recommended change has to do with prescription and the word that's used in proposal is refill; we think that what they really mean is renewal, a refill is a pharmacy transaction, a renewal is another order. And we believe that the order is important, for example, on discharge you may renew a medicine and you want that information to be captured in the eRX and also all of the things that go along with it. So those are the two changes that we would make and the rationale behind that.

Objective 3 has to do with clinical decision support; in a sense there's no change from Stage 2. So we agree with the overall measure. There are some details in it that we would like to get clarified, for example, there's a note there's a definition of high priority health condition that's not actually defined in the proposed rule and we think that that would be helpful. The other point for measure 2 has to do with enabling drug-drug interaction alerts. And the question is, is it enabling everything as delivered by the vendor, the knowledge-based vendor, drug vendor or can there be some changes made? So for example, it's well known that there's a high false positive rate in drug-drug interactions, so many organizations decide to filter out and just get the high priority one; is that considered "enabled?" It's a question like that.

Wanted to reinforce that in Stage 2, CMS did have to clarify their policy on licensed health professional to include externally credentialed medical assistants. So we just wanted to keep that top of mind and also to include behavioral health as high-priority area.

Objectives 4 has to do with CPOE, basically it's increasing the threshold 80, 60 and 60 for medications, lab and diagnostic imaging respectively. Comments here, we agree with virtually everything and I'll mention a little tweak to the last one.

So in the first one, the increase in the expanding the notion of diagnostic imaging, it went beyond traditional radiology; the question we have is, can it also cover other images such as dermatology images, so long as there's a result report accompanying that. Second comment has to do with limiting measures to those records that are in the EHR versus keeping track of the paper-based records as well; and we agree with the proposal just to…to allow people to just consider those…that information that's in the EHR.

Third, we agree with the notion that there certainly can be technology barriers; the caveat is, how would you define that? How would you define it in a way that would stand up to the audit. And finally the question of whether there should be allowance for a zero denominator in cases where a measure doesn't apply. We thought that yes, it's unlikely it may happen, but it's also covered by the exclusion of less than 100 orders.

We're going…next going to turn to the discussion of population and public health objective and Joe's going to take over from here and I'll try to advance the slides for you, Joe.

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

Great, thanks Paul. Good morning everyone, so I want to go to the next slide and just quickly acknowledge Art Davidson, Amy Zimmerman, Terry O'Malley, Neal Patterson and then ONC staff, Jim and Kim, who have helped us out tremendously in pulling this together. Next slide, please.

And just a quick start overall in terms of the overview of this objective. There are six measures that are involved, and this is really around the engagement with the public health and the clinical data registries. The objective contains these six measures with eligible providers needing to meet 3 of 5, with the electronic reportable lab reporting one being only eligible for hospitals and critical access hospitals. Overall measure 3 around case reporting is new. Measures 4 and 5 are closely related to concepts in Meaningful Use Stage 2 and 5 of the 6 measures also come with some new upgrades with respect to standards. So that's the context we have as we dive in. Next slide.

So quick current state summarization; ONC was great to put together this and around readiness around public health agencies to be accepting data. Again, gives a pretty high level view around immunizations and electronic lab reporting enjoying the highest rates with syndromic and public health registries trailing a little bit behind. Obviously we said that case reporting was new and that clinical data registry, there's some overlap there with specialty registries, and we'll get into that as we go forward. Next slide.

So in general at the top level, the workgroups agreed with most of the objectives and the measures that are involved and acknowledge the importance of improving health of patients and communities through the expanded use of data. We felt that the objective was also consistent, laying out things that were consistent with the interoperability roadmap. And it also started to set that foundation for population health type activities that extended beyond traditional providers. So overall the workgroup was pretty encouraged by the general direction.

The themes that came out in terms of some concerns; one were around timing and eligibility specifications. And it kind of came up repeatedly as we went through the measures. Timing was really around a lot of the readiness elements of things, given the heavy overlap with some standards for these measures and eligibility was also sort of an aspect around what sorts of registries would be considered eligible?

On the second side of it, the other sort of theme that came up a fair amount was around bi-directionality. There's a relative focus on just reporting out to the PHA, and the workgroup tried to take a frame where it was trying to figure out how these measures would really influence a meaningful clinical outcomes for patients and communities. And when we did that, we kind of came back to the bi-directionality element as a critical way for both providers and the public health agencies to take timely and clinically meaningful action. So you'll hear those two themes kind of repeatedly arise as we go through the measures. Next slide.

So the first is immunization registry reporting, and this is sort of a general summary of the measure itself. Go to the next slide. And our key points for immunization registries was that again, while this measure actually has it called out around the bi-directionality of submitting and receiving actions, it was the receive portion that probably received the most attention from the workgroup.

In particular, the concept of receiving forecasting information from an IIS system; the workgroup noted that provider EHRs may actually have more clinically appropriate forecasts and we're trying to distinguish in this proposed measure around, what was the expected display and what was the expected action that needed to happen with respect to information that was brought into a provider organization; and again, the major point being just getting some more clarification around that.

It was noted, actually, ONC did pull, Jim actually was able to pull some information around immunization registries saying that again, sort of there's more than a dozen EHR vendors that are currently supporting the bi-directional exchange and with six states reporting out and, I think New York City had a really high concentration with about 252 sites already doing this kind of bi-directional exchange. Next slide, please.

So measure 2 was around syndromic surveillance reporting and again, the clinical goal around trying to help public health agencies detect early indicators. This…oh, next slide. So the general comment here was that we definitely sort of agreed with the idea that urgent care settings be appropriate to be put together with the hospitals, but we felt that the measure seemed to try to lump public health issues of surveillance around sort of infections, violence and trauma with chronic disease surveillance around diabetes, hypertension and obesity.

And we actually thought that those were two distinct concepts, not just in content, but more importantly with respect to the required timing of data exchange in order for that exchange to be actionable and meaningful. And because of that, there was a general recommendation from the workgroup, if we're…is there a way to actually split the chronic condition surveillance portion out of this particular measure into a distinct measure, if that was deemed to be important. Next slide.

Case reporting, measure 3; so this was a new measure and again, sort of the idea was heavily supported by the workgroup. Next slide. And, okay, got it, yeah…and so, beyond the importance, I think this was a really good example where bi-directionality came up a fair amount in our discussion. Right now that's really described as a unidirectional case reporting into the public health agency, but the key area of discussion here that was really brought forward was around syndromic surveillance that the bi-directional exchange was really important so support the workflows of both the public health agencies and the providers to take timely action that would actually bring benefit to the communities. And so the lack of that sort of description around the bi-directional expectations again just led a little bit of the thinking around how this measure would drive towards that value towards community. Next slide.

Okay, and sorry we're blasting through this pretty quickly here. So measures 4 and 5 were the public health and the clinical data registry reporting measures and overall, again, the workgroup believed that this was an important set of measures and wanted to encourage the use of this exchange between public health registries and clinical data registries. Next slide.

And the single biggest sort of comment for these two measures was really around clarity for the rules for what counts as a registry. Currently with the way the rule is written, there are standards that are suggested for the public health agency registries like the cancer, the health surveys, the antibiotic uses but there really isn't a lot of standards for clinical data registries. And the linking of the eligible registries with what…how to satisfy this measure, actually raised some questions around whether or not some of the current specialized registries in Stage 2, would they actually count in terms of a clinical data registry reporting mechanism, in this particular measure. And so again, the lack of clarity was called out repeatedly and something that again, the workgroup would wish that was a little bit better defined in this particular measure. Next slide.

And measure 6 was around the electronic reportable lab reporting. And I think from this particular measure, most of the workgroup agreed with the principle of the measure and there wasn't a lot of changes from Meaningful Use Stage 2, so, this was actually pretty good general agreement. And I'm going to keep going because we have three global comments.

So the three big questions, specific questions around the overall objective; the first one was around the definition of engagement. And the rule provided three different options; option 1, complete just the registration to submit data; everything around that option the workgroup agreed upon.

Engagement option 2 was around sort of testing and validation. And for this one in particular, there was a comment really around defining what response meant in the validation phase. And we wanted to be sure that response really meant an acknowledgement and intent to fix within 30 days and not that the code changes and fixes would be implemented within 30 days of that request. I think again this sort of speaks to the timing elements of the clarifying elements of this objective.

Option three in production, there's is a similar comment that was brought forward, again with the idea that once a provider is engaged with a public health agency, if something happens operationally, how do you actually address the operational disruption and again, suggesting language around sort of the 30-day request to acknowledge that request and process for investigation being some of the bridge elements around sort of maintaining that engagement in option 3. Next slide.

So for the idea, one of the key ideas within this objective was to create a centralized repository for all of the registries from the national, state and local PHAs around their readiness to sort of accept. And the big theme that came out here was again around timing and the fact that the workgroup would like to suggest that that the clinical repository, or element registry is better, are submitted into this clinical repository, be submitted within 12 months prior to the reporting period. And really the importance for that was to give provider groups time to actually gear up to be able to engage in those particular registries rather than just learning on day 1 of the reporting period which potential registries are eligible.

This did lead to some conversation around making sure that once registries are placed onto the repository list, that they can't really be removed, given the timelines for providers to try to set up capabilities to be able to exchange with those registries. So timing was a big issue with respect to the repository. But again, strong support that such a repository, well-structured and well-documented would be a tremendous resource to the providers, next group…and vendors. Next slide.

And this is our last one; again, sort of the objective also allowed with respect to the 3 of 5 for EPs and 4 of 6 is for hospitals and critical access that you can actually satisfy this objective by reporting to multiple PHA registries and multiple CDR registries to fulfill this objective. And the caveat or the recommended sort of addition was that the workgroup recognized that you can send the same data to multiple unique registries and if you did that, as long as the data is satisfying that unique registries criteria and purpose, that the provider is eligible sort of providers, hospitals and access hospitals, should be able to get credit for that, even though they're actually sending that same data. And so that was just one additional point that got brought up here. I think that concludes our…this section.

All right, so Paul, I think now might…

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

I can't move the slide, can you move it up? There we go. Thank you.

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

Okay and so I'll move now on to the quality measures group and this is a group that was led by Cheryl Damberg, Ginny Meadows, Norma Lang and Sumit Nagpal, and I will try to do it justice to that workgroup; and again with a quick overview in the very beginning.

So the three questions that were really raised were that one, was the number of CQMs that vendors must certify to, and there were three options. Option 1 that EP vendors certify to all of the clinical quality measures. Option 2 is a phased approach and option 3, the EHR is certified to more than the minimum of CQM's. So that's the first question.

Second question was around alignment of CMS quality measurement programs and trying to get the Stage 3 NPRM basically trying to further align EHR Incentive Programs with all the other CMS quality reporting programs and also encouraging alignment of all the measurements across multiple care settings to demonstrate Meaningful Use.

I think there's the third question on the next slide; and then finally, creating a requirement for health IT to record structured data sufficient to be able to enable sort of flirtation of quality measurements by subpopulations and particularly as a mechanism to reduce disparities of quality and care across these subpopulations.

So, with those three questions, next slide. Current state summary really goes through and says that so for most vendors certified to all CQM's, basically to be able to allow their sort of customers to meet the myriad of quality programs that were in play. However, that noted in particular that delays in the release of fully tested and accurate measure specs and CEHRT tools, really created some challenges for the vendors and providers and this was highlighted a fair amount by the workgroup.

Third point that the CQMs…not all CQMs are obviously relevant to all providers, particularly around a system supporting clinical specialists that serve a very narrow subset of particular patients or diagnoses or conditions. And then finally, sort of a positive note that says that lots of EPs and EHs were really involved in innovating and creating locally derived eCQMs to really address quality improvement opportunities within their own individual health systems. And that was something that the workgroup highlighted as a really good thing that should be encouraged.

So going to the next slide; so within the three options, the workgroup wanted to recommend option 1 that vendors certify to all EHRs…certify EHRs to all CQMs, but really conditional upon two things, one was around sort of innovative measure development and the other one was around timing. And the innovative measure development really was to push the Policy Committee to promote the pathways to test, share, implement these new measures in order to address some of the aspects around certifying these quality measures to the level and degree that I think that the workgroup was hoping.

And that…providing that pathway for innovative measure development also sort of tailored in with the aspect that for all CQMs, that there would be adequate implementation time of about 18 months, to allow for vendors to implement, certify and roll out with respect to the providers; so again, new types of measures as well as timing.

Improved alignment was strongly agreed upon by the group and again supports all the efforts to align the EHR Incentive Programs with the quality reporting programs not including just the content, but again on measure specifications and reporting requirements; so being sure that that alignment goes all the way down with respect to the quality measures and then finally in agreement with the clinical quality measure filtering criteria as something that should be done. Next slide.

So a couple of deeper comments on the aspects around the number of measures. Again the workgroup commented that the phase approach to them didn't seem to reduce the burden so much for the vendors, but that they again really highlighted that the inadequately tested eCQMs really could be very disruptive and so the need to ensure that the eCQM specs and CEHRT tools are accurate, complete and fully tested prior to release was emphasized. And again, this lead time for making sure that before these things are actually deployed out to the frontline that there is adequate time for these things to be fully tested. Next slide.

In addition, sort of this aspect around, again, certain CQMs not being relevant to specific sort of specialists, thinking about some flexibility to allow the EHA vendors to certify specialty EHRs with CQMs specifically relevant to target sort of customer or the relevance…clinical relevance of that target customer. And then finally again, this aspect around really emphasizing this innovation pathway and the workgroup noted that this is a concept that was actually also a part of the July 21 transmittal letter from last year and so again wants to encourage this as a pathway to begin to really help providers really use their HIT technology for meaningful quality measurement. Next slide.

With respect to alignment, I think overall alignment across the CMS programs was encouraged. There was a point around aligning across private and public payers around quality measurement as well, to try to reduce that burden on providers. And again, the third bullet around really making sure that it's not just sort of the top-level content alignment, but for alignment around the specifications and the data collection requirements, reporting formats, standards, etcetera, for measures that are sort of reflecting the same concept and making sure that it was standardized all the way down.

And then this fourth point, which is also pretty important, around standardization of data elements. And this actually was highlighted in the sense that as you expect these data elements and interoperability going forward, the implementation of new measures and their specifications would be…and the effectiveness of doing that, is really dependent on again getting clean, standard data elements that are pretty important.

And the next slide actually also speaks a little bit to this in the sense that the support…sort of the measure filter criterion was very much sort of supported, but as you can see on the slide, the collection of the disparity-sensitive data elements in a structured data format using standardized variable definitions in health IT systems would be able to support this. And I think the underlying elements link back to that previous comment again of those data elements having to have some kind of specification, standardized specification, for it to be really useful going forward. Next slide.

And so final closing comments; overall again, on this first element, really was, the workgroup was commenting on acknowledging some of the operational…downstream operational impact when the stability of quality measures is disrupted by updates. And this first bullet point, I think, is sort of the key around saying that the workgroup would like for CMS annual updates to be limited to changes that do not have a significant impact on clinician workflow or provider implementation time or require extensive software code changes or recertification of EHR software due to the compressed time between the release of annual eCQM updates and the required use of measures in an EHR.

If an eCQM requires more extensive modification, and for any new CQM introduced to any program, then the scheduling of such changes should provide ample time to accommodate these activities. And I think again sort of it's talking around the disruption, the downstream disruption, particularly if these measures are again tied to accountability type programs of what provider workflow needs to change? Vendor workflows need to change? The use of those IT tools that would need to change to be able to again match the expectation of the point of those particular measures and again, that disruption was highlighted pretty significantly. Next slide. Next slide.

And the last two slides again speaking a little bit more to the expansion and the encouragement to the Policy Committee to start encouraging again the advancement of quality measurement that span care processes. And on this slide in particular, to really emphasize the availability of standards to further interoperability because that interoperability will allow capture of information across various continuums that will allow again better, more patient centered improvement and measures to drive that kind of improvement going forward, so it was an encouragement here.

And then the next slide, and final slide, is again this aspect around electronic quality measures really trying to look across a longer period of time utilizing more data sources and considering care in multiple settings as the direction that we should be trying to promote to actually expand the scope of quality measures in a way that's again meaningful for accountable care organizations and other types of accountability programs and value-based payment models. And I believe, that's the final one.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
All right, thank you. So we'll open it up to comments or questions from the group on this section.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Apparently I'm on deck; David Lansky.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
Thank you. Thank you both, really great reports, great work everybody. I just want to follow up on the last points that Joe was making on behalf of Cheryl and the team. It feels like we've been to this movie before and we've been talking for 3 or 4 years about the importance of taking advantage of the expansion of the EHR environment to capture quality measures that would really support a lot of purposes. And the last several slides exhort us to give more attention to the opportunity for longitudinal data collection and so on.

So I really want to suggest that we, in our comments, make this kind of a primary theme. Certainly as Karen is very involved in leading our efforts toward…shifting toward value payment generally and there's a great, pressing need to capture information that documents value, everybody in this country will be paid increasingly based on a calculation of value. And the ability to discern value is going to be based on these electronic health records and the interconnections between them. So if we're not able to build a…some measurement of longitudinal health improvement from the electronic health record in the next three or four years, according to the HHS timeline, we're going to be at a terrible disadvantage in rewarding providers based on not very good information about their quality performance.

So, I think this is the time to really make this a priority element of the recommendations for Stage 3. And some of the themes that are throughout the slides about measuring outcomes, capturing patient centered data, patient-generated health data and patient reported outcomes, I think have to be elevated to priority elements of the strategy if we're going to satisfy the national objectives around improving value in the health care system.

There are a couple of places I think we could do that; for example the registries item under measure 5 that Joe talked about is a place where registries could be given more opportunity to capture that kind of data. They are inherently designed to capture data across the span of care and including patient-generated data and many conditions, many specialties. So if we could give that a little more oomph in the ability to satisfy those requirements by capturing this kind of information that would be a great opportunity. And I think there are other opportunities throughout the recommendations where we could do that.

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

I mean I'll respond by saying we couldn't agree with you more from the time that you chaired the original Quality Measure Workgroup, this has been a theme. I think what's changed now compared to even two years ago, the IOM recent report on vital signs really has community at its heart, continuum, longitudinal measures and health.

As you know, Robert Wood Johnson, speaking of health, is…works on culture of health and if you think about…it was one of the…another mechanism that has come about just even in this past year is NQF now has an incubator where they can, instead of just relying passively, waiting for folks to…organizations to come forward, the folks can get together and work on some of the measure gap. So I think there is a lot that has changed in the environment, but I think without the movement, the push to say, let's take advantage of this, I think we may not move fast enough.

But what you heard is, there's…everybody wants the right measures and then ought to be consistent across all the payers and all the plans; there's a lot of just unaligned measures that causes wasteful work. But we really do need to do it now, just as you said, so we couldn't be in agree…more in agreement. And actually part of the workgroup, the Advanced Health Model Workgroup is to take that and run with it as well.

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

Great; thank you David, thank you Paul. I think on the phone we have Paul Egerman and Anjum and then Troy. Paul?

Paul Egerman – Businessman/Software Entrepreneur
Yes, thank you and thank you for a terrific and well thought out presentation. I have a comment about the most recent slide number 11 in the deck, in which you talked about the annual CQM updates and trying to limit the changes. I of course agree with this in terms of what is written here and to any extent that I would comment on it, I would actually encourage ONC to make it even stronger.

It would seem to me that if there's going to be continually updates to these CQM measures and to other things, that they should use the data that is already being collected. The constant changes of data and additions of new data elements, besides upsetting physician workflow, is actually counterproductive to the quality intention of the quality measures, because it creates, by itself, safety hazards that you have new things to figure out how to test and new places for physicians to either make mistakes or to get frustrated.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Great; thank you Paul. Anjum?

Anjum Khurshid, PhD, MPAff, MBBS – Director, Health Systems Division – Louisiana Public Health Institute
Thank you, good morning. Thank you for the…person as well. I couldn't…public health supporting measures and first of all, we are very glad that there are these 6 measures now under the public health reporting and I couldn't agree more in terms of the comments that were made by the workgroup around clarifying the differences in roles of public health registry reporting and clinical data registry reporting on measures 4 and 5.

One of the issues of concern that has been shared with me by other public health professionals as well is measure 5 around clinical data registry reporting in what ways, if it is not linked to, you know, public health entities or organizations that are involved in directly public health services, in some ways can this affect the kind of progress we are seeing in measures 1 and 2 in terms of focus on promoting more involvement of public health reporting under Meaningful Use. Any comments on that?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So the last part you said, so maybe, can you repeat that last sentence in terms of measure 5 versus measure 1 and 2?

Anjum Khurshid, PhD, MPAff, MBBS – Director, Health Systems Division – Louisiana Public Health Institute
Right, so I mean, yes seeing good progress in measures 1 and 2 when they were part of Meaningful Use requirements that people have achieved that public health reporting measures; but measure 5 includes cases where the registry may not be used for public health or linked to public health organizations. Does it in some ways weaken the overall emphasis on public health reporting for that purpose?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
I'm not sure I fully understand the question.

Joe Kimura, MD, MPH – Deputy Chief Medical Officer – Atrius Health
Well I can try a little bit here. So, I think it's an interesting point there. I think part of the challenge for us too was around 5 and what actually would entail sort of a clinical registry that would be eligible here. I think as a workgroup we definitely tried to think through what's the mechanism by which sort of exchanges…exchanging this information with this registry would lead to benefit to patients and the communities and tried to sort of articulate that a little bit more.

I think it does raise some questions. I think within an individual registry you could say that providers can absolutely benefit the populations that they're serving by exchanging information, getting benchmarks and other kinds of information to help drive system level quality improvement. But to the broader element around public health, if there was not that kind of exchange, essentially the provider would then have to be exchanging it with the PHA kind of agency, if there wasn't any kind of third…sort of three-way exchange of information.

So, it's…I recognize that that could be an issue, I don't think this goes into that level of detail. So I wouldn't say that it's a barrier yet, I think we're still looking for a little bit more clarification on how we would actually interact with these clinical data registries.

Anjum Khurshid, PhD, MPAff, MBBS – Director, Health Systems Division – Louisiana Public Health Institute
And so that was exactly the point I was making and so I think it goes back to really clarifying measure 4 and 5 in more detail that would be helpful. Thank you.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Great, thank you. Troy?

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Am I on? Yeah, I guess I am. The one thing that really comes to mind, I mean, I look at Stage 3, we're at the final stage here and I keep looking at what the World Health Organization defines as health and I'll just read it to you. It's actually the, let me see here, I lost it unfortunately; the state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmary.

I'm wondering, you know, looking at what…dovetailing off what David said earlier about, you know, the need for robust definitions. I really look at this whole thing, at some point, I mean, we need to pull it together and what I see is a lot of areas where we have structured data, but then other areas where it's really loose and still kind of out in the open. And one specific thing that always comes to mind is the definition of care plan. We really haven't nailed that down, I mean, we need, from my point of view, I mean we need something a little bit more solid in definition of, what are the key components of a care plan?

We have the minimum data set and we've taken those from Stage 1 and Stage 2 and we've rolled them up into other aspects, primarily the C-CDA and we've left a placeholder for care plan. But there still really is no definition of that. As I look at Stage 3, and we really are talking about the sharing of information among the interdisciplinary teams, really what we have is just a lot of pieces, but there's no conglomeration, there's no aspect where someone from public health or some other aspect who's looking at the grander scheme of things, they can't look at it and get the picture of what health means to the individual.

And I champion, you know, Christine, I mean I just love her passion about making everything patient-centered and I still haven't seen that yet in Stage 3 and I'm hoping we can get there by really looking at the definition of the care plan and moving forward from there. Umm, other than that, I mean, I think that the rest of it looks really good in that framework. Thank you.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Great, thank you Troy. Other questions? Anything on the phone?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Maybe I'll just point out one, there was a listening session conducted by ONC on, and the question was what to call it, was it a care plan or health management plan; but, so there is activity going on to further that work. So there's been some S&I activity from a standards point of view, but also reco…they, ONC invited the various stakeholders so it's not just technology, for example, it's certainly not only the professional societies, but the teaching organizations that sort of would move a coordinated, shared plan moving forward.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Yeah, and maybe…this is Karen, maybe just to bring it to ground to, clinically that's what we hear a lot from the frontlines, that they need to be able to see that shared note, the shared information and back again to David's point about this opportunity to pay for value and population health necessary to have that more fulsome picture of the person's health, including their view. Agreed.

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

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Just to…thank you, just to follow on. Thank you for your kind words, too, Troy. So I know one of the things Paul that we've been talking about is this care plan component and it actually was on the work plan for the Advanced Health Models group, but I think it was sort of pushed too far later this year; I'm not sure about that. And I just was wondering about the timing of that, if there is an opportunity to push that up because I think we know a lot, but we haven't really coalesced it in a way that we could make some decisions, make some recommendations on policy and find those levers that we can pull to move it forward in more of a consensus way.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
No, you're exactly right, Christine. I think we were overtaken by events, the flurry of NPRMs that came out, so we're finishing that work and then the two topics actually that are high on the list, one is advanced health models…or it's three topics; 2 is "care plan" or shared health plan and three is what David mentioned which is, how do we deal with…how do we push harder on the measures of doing good from a health point of view.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
And if the Consumer Workgroup can help, particularly I think there's been a lot of work done for consumers on care planning, but not really with them. So if we can help in that respect, we would be delighted.

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

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
This is David Bates. I think also that the care plan is going to be a linchpin in moving forward. We just have done a big trial in which it was a core part of what we're trying to do and that has convinced me that there's a lot more work to be done to figure out, you know, what should be included? And what providers and patients will find most helpful? And so we really need some support for people to do research on this. This is…one other thing, I feel like we're not ready to say what the standard is for it because we don't…we still are working out what should be included.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So maybe we should bring back the report from that hear…that listening session back to the full group. Great; thank you. Okay, so the next report out is going to be with Micky Tripathi and Chris Lehmann.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Good morning. So we're going to go through quickly the objective 7, health information exchange NPRM comments and I'm going to walk us through this, just in the interest of time, since we've been allotted 15 minutes, but wanted to make sure that Chris certainly has the opportunity to weigh in at any point as well and certainly during the discussion as well. So, why don't we get to it and hopefully I'm going to go through just certain highlights for each of the measures. I will point out that our presentation was a part of batch 3 out of 7, so hopefully you've had some time to read it. We're striving to get to batch 1, so sometime before the end of the year Chris, let's try to make sure we're in batch 1.

Uh oh, what did I just do? Oh, here we go. So we were asked to look at objective 7 which is health information exchange and also there were some specific questions from the NPRM including questions on HIE governance and those sorts of questions that we addressed as well as we went along the way. I will, before I start, I want to thank the group and thank Chris also for very engaged participation, this is very much a forced march over a very short timeframe and lots of complexity and you know, it's very hard for people to volunteer their time and do this on these timelines. So, we appreciate all the engagement we got.

So objective 7, just to refresh your memories, has 3 measures in it; it's health information exchange broadly. The providers have to meet only 2 out of 3 in terms of threshold, but they would be required to report on all 3. So we've, sort of in very simplistic terms I would say, measure 1 you can think of as send; 2 was receive, 3 is reconcile. So send…the proposal is that the electronic summary of care record would be for 50% of outgoing transitions and referrals.

Measure 2 would be to receive and incorporate a summary of care record for 40% of incoming transitions or referrals. And I would just point to this as being sort of a signature moment in interoperability as it relates to Meaningful Use because it's the first time that we're having any proposed measure or a measure that would be upon receiving of information, which is sort of the first step toward the query kinds of…kind of architecture that all of us would like to get to with interoperability. So this is a real signature moment here as we think about this. And then third is clinical information reconciliation and the proposal is for that to be for 80% of transitions or referrals for three types of information, as we'll describe.

So I'm going to dive down into the details here in a second, but we just note that these measures are somewhat interrelated. My ability to send depends on people being able to receive. My ability to receive depends on people actually sending things to me. And then finally my ability to efficiently reconcile something depends on my first getting the information and the quality of information I get. So in some ways we do need to think of these as interrelated and not lose sight of that as we think about it.

So, in general the workgroup agrees with the direction and goals of the objective 7 measures; very important for quality and safety and HIE functions, we note, are gaining traction in the market and these objectives are good to keep good impetus to keep things progressing.

We are concerned, though, with the setting of higher…of high…thresholds that we think might be too high in certain cases, not because we're opposed to higher thresholds, we very much support higher thresholds, but we don't want to have to backtrack on the threshold as has happened with view, download, transmit, as we know and we certainly want to motivate providers to "own the problem," so we don't want to take that off the plate in terms of accountability. On the other hand, we don't want to be penalizing people for things that are genuinely out of their control. So, that's the balance that we sought as we worked our way through these.

And one of the things that we would note, because you'll see this in some of our recommendations, is that you can balance threshold with judicious allowance for exclusions. So you can set a high threshold as long as you allow some appropriate exclusions along the way. Correspondingly, if you get rid of all the exclusions, you probably need to lower the threshold in order to accommodate the real world variation that exists out there.

So first thing that we asked ourselves as we thought about thresholds is, well what's been going on with Stage 2? Two out of three of the measures actually have a direct connection to a Stage 2 measure, so we thought, well let's take a look at that, just to see what would be appropriate. For measure 1, and as it turns out that for two of the measures, so measure 1, which is the send, remember and measure 3, which is the reconcile, those have direct connections to a Stage 2 measure. As I pointed out, measure 2 is genuinely new so we really don't have anything to go on there from Stage 2.

So for measure 1, for the Stage 2 results so far for 2014, what we see is that by and large the results are that the reporting is at 30…40% for EPs and 36% for EHs as opposed to a 50% recommendation from CMS. So you might think that well, that's going to be 2 years from now, so maybe that suggests that they're well on the way to being able to do it and that's a good stretch goal. Right that might be a…one way to interpret that and as we'll discuss in a second, there may be some caveats in thinking about it that way.

The second, as you look at measure, that says measure 2; that should say measure 3, I apologize for that that would be for reconciliation. As you can see, the demonstrated performance of those who actually are attesting to that measure for Stage 2 is at 93% for providers and 87% versus a proposed threshold of 80%. So that would suggest that, okay that ought to be something that people should be able to accomplish.

We would note though that Stage 2 required only med reconciliation, is the point that we're going to get to in our recommend…in our comments. Stage 3 requires an uptick from the 50% to an 80% threshold but also expands the scope to not only be for medications, it also requires medication allergies as well as problems. So you're increasing the threshold and increasing the scope, all at the same time. So, we'll get to that in a second.

The concern that we have about basing too much on these results is that as it turns out, there is enormous selection bias in the data so far. Of the people who are scheduled to attest for Stage 2, it turns out that 76% of eligible providers and 35% of hospitals got out of having to do it through hardship exemptions, leveraging the flex rule or they just haven't attested yet and so we don't have the data yet.

So for eligible providers in particular, only 25% of those scheduled went forward and actually had to attest for Stage 2. And then when you look at the measure 1, which is the send requirement, it turns out that of that 25%, 86% of them qualified for an exclusion, so you only had 14% of the 25% who are actually reporting on the send. That boils all the way down to only 8000 eligible providers who are actually attesting to the send measure for Stage 2. And as you might imagine, those are probably by and large, you know, ahead of the curve in terms of their adoption capabilities. So we're just pointing out that we ought to sort of take that into account as we look at these measure thresholds. So, the experience suggests that the Stage 2…that the Stage 2 thresholds are higher and perhaps significantly higher, given the small sample results to date.

So why don't we dive into the measures then. So what I'm going to do is I will, in the format here, is we'll have one slide that just tries to boil down in as simple terms as we can what the measure 1…what the measure is and what the specific CMS proposals are for Stage 3. And then on the next page, we'll sort of give a little dashboard of where we agreed and where we suggested recommendations…recommended changes and then I'm only going to pick a couple of the key ones to explain further. And then happy to discuss any other ones during the Q&A.

So the first thing, measure 1 is to send electronic summary of care records for 50% of outgoing transitions, as I said. It increases the Stage 2 threshold which is from 10% up to 50%, okay, so that's a pretty big jump. It requires electronic transport but doesn't specify the use of a standard or participation in any particular HIE arrangement.

So you may recall Stage 2 had a requirement that said you had to send via the Direct protocol or, according to the Direct standard, which had a couple of options. This removes that, or you could do it under governance mechanism that was approved by ONC. This removes that requirement and says you can do it via any electronic means, as long as it's electronic.

Three, it allows the inclusion of patient self-referrals. Why is that important? Because this is your transition of care or referrals, many cases, as we know, the patient just shows up; if you didn't include self-referrals, then nobody would be able to get any credit for that. So it has an allowance for that under a certain set of terms.

Number 4, it allows the inclusion of transitions or referrals to providers who are on the same EHR, which is a little bit of a weird allowance, so called selfies. I'll describe that in a second. It allows that in Stage 3. In Stage 2 it ended up allowing that, but originally there was some ambiguity in the rule, people asked questions and CMS responded and said, those are allowed, that's what happened during Stage 2. Now they're basically saying, we were going to instantiate that now in the rule to allow those.

Item 6, it allows the exclusion if zero transitions or referrals are in the…if you don't have any transitions or referrals in the reporting period. This is actually a key difference from Stage 2; in Stage 2 if you had fewer than 100 transitions, qualifying transitions or referrals in that reporting period, you could be excluded from the requirement. I believe that the reason that this is now set to zero is because, as I described to you, 86% of eligible providers last year were able to get out of this requirement.

We would point out, though, that that ended up being just sort of an artifact of the fact that the reporting period got shrunk from 12 months to 90 days during last year, as a part of the accommodation of looking what was going on in the market. But there wasn't a corresponding decrease in the exclusion; the exclusion, if you were going to do that, you know, to do it correspondingly, you would have reduced that to 25. What happened is, that stayed at 100 so there were a lot of people who within 90 days were able to get in the exclusion of 100. That's why they're referring…reducing that to zero now, I think. Finally there's an allowance for an exclusion for providers who are in counties with low broadband penetration.

So our overall dashboard here, and the only ones I'm going to discuss are, in general we agree with two of them around allowing any electronic transport; we'll get to that on our comments on governance…HIE governance as well and allowing the patients self-referrals, so I'm not going to talk about that any more. The ones that I will spend a little bit more time talking about are lowering the threshold to 40%. We recommend lowering the threshold to 40% from the 50% and about the do not allow selfies would be our recommendation, rather than allowing those and allowing some flexibility in the CCDS payload or the payload for what needs to get sent.

I will as a general comment say that on number 7, this comes up on the next one as well, there was an exclusion allowed for low broad…for being in an area where there is low broadband participation…penetration. We think that that's not appropriate for providers. That was originally for patient engagement kinds of measures where you could imagine in a retail, you know, broadband market that perhaps that's an issue with the patients being able to engage, but we think provider to provider, most providers are going to have access to broadband so we actually would remove that exclusion for providers.

So number 1, lowering the threshold to 40%. Stage 2 data, as we pointed out, suggests that the average provider will be…could be well below 50%, based on the selection bias and the data as well, because of that 2014 exclusion allowance. We do want to keep the rate high to motivate forward progress; so we're not saying, let's reduce it down to 20%. And I should point out that there was some disagreement in the workgroup around this.

There were many providers who were very concerned that 50% was too high, there were some providers, who I'll point out and we'll get to this in the other comment that we have which is that the C-CDAs themselves they find not particularly useful. And so some clinicians reported, my concern is not about being able to hit 50%, it's about being able to push around 50% of stuff that is not useful to me. I mean, I'm already getting 10% that isn't useful now, why would we increase it to 50%? I'd rather get 10% of stuff that's really useful rather than 50% of stuff that's not useful.

So with that in mind, though, and looking at the fact that even though we have a small number of providers reporting, they're at 36% for eligible providers and 40% for hospitals; we felt like we couldn't come in with a measure that was below the experience from last year. So that's why we're saying 40% would be our recommendation rather than 50%.

Next one I'd like to discuss in greater detail is the not allowing selfies. So just so everyone is clear, this is the case where I'm an integrated delivery network, let's say and I'm on an EHR system both on the inpatient and my ambulatory provider, my employed ambulatory provider's on that same system so we're literally on the same system and we can look at all the same patient data. We're on the same database and we do that.

CMS allowed during Stage 2 for the hospital to send a CCD discharge summary for example, to the employed ambulatory provider and get credit for that…for the measure when in fact that ambulatory provider could have just looked in the EHR and seen exactly the same data. So as we discussed this in the workgroup, we felt pretty strongly that this disproportionately favors integrated delivery networks and what we'd like to do is suggest that that not be allowed, even though it was allowed after the fact in Stage 2, we would suggest that not be allowed an exclusion so it will force those integrated delivery networks to do…to take those as an…take it out of the denominator and the numerator, which was the original suggestion there, and then force them to get their 40% outside of their integrated delivery network.

Number 5; we would allo…we would suggest allowing flexibility in the CCDS payload and this relates to this issue of C-CDA bloat, as I pointed out earlier, people feeling like they're getting things that are not useful to them because there's just too much in there and not particularly focused on the particular clinically appropriate information that they'd like. So right now people are finding that it's not clinically beneficial to use the, you know, to have data that's the meaningful use common data set, let alone the expanded CCDS.

So what we would suggest is that provider discretion be allowed so that the sender can actually have some discretion based on the clinical appropriateness of the transition to decide a little bit what they are going to include in that rather than saying it has to be all the CCDS data elements that are available. And there is a little bit of a precedent for that because the rule does allow, in certain cases, labs, clinical notes, problems and there's one other category for clinicians to have discretion over how much they send in that category. So it does say that they can have discretion over which labs to send. We're suggesting taking it one step further to say, give them a little bit more discretion on which data elements to send if they really think that it's not appropriate for the receiver.

Finally, the last one is to allow the exclusion for fewer than 100 translations or referrals. As I pointed out, this may seem somewhat ironic given that I was just pointing to the huge selection bias and so many people were able to take the exclusion. We think that if you have 12 months reporting that it actually makes sense to have the exclusion for fewer than 100 referrals. Because if you bring it down to zero as CMS suggested, you're getting a lot of providers who really have very few transitions or referrals to make an investment in technology that is really an opportunity cost for them and they're making an investment in something that is taking away resources and attention from other things that are probably going to be more beneficial for patient care.

So, for those who are in that category, we would recommend having that exclusion, but making sure that if you adjust the reporting period again, let's not have this loophole where you don't adjust the denominator of the exclusion.

So now we move to measure 2, which is the receive and incorporate. This is a new measure that has a 40% threshold. There's another element that says that you need to "incorporate" the summary of care record. It allows for what's called active or passive receipt, meaning that I can query to get something or it can just come to me as a part of measure 1. For example, transition of care, it just gets pushed to me; that would count too, as long as I Incorporated it. And it also allows any type of query, meaning I don't have to do an electronic query, I can call someone, I can FAX someone, as long as it comes back to me electronically, that's fine. And it can come via any electronic means.

It restricts the applicability of it to transition or referral episodes and that's a specific thing that we'll talk about that in our recommendation. So it means that it only counts if I get information related to a specific episode of care that was a transition or a referral, nothing outside of that. It allows an exclusion for encounters where information is unavailable, but it does force me as a provider to go and ask for the information, but if I didn't get it, I have to go and ask for it and then get the report every single time that it's unavailable in order to be able to have that exclusion.

And then there is a question there about whether so-called utilization alerts, which would be like an ADT alert of an event, should be allowed to count for this. I'll just jump right to the end on that one; we recommend not allowing that for a variety of reasons. I won't go into the details unless anyone is interested in the Q&A. But what I'd like to focus on is a recommendation…our recommendation to lower the threshold to 25% from 40%.

The allowing provider discretion in what to incorporate, I won't go into that in detail except to point out that it's identical, our reasoning there is identical to what I just described for the send. That we think providers should have the discretion to incorporate only things that are clinically appropriate from their end.

And I would like to spend a little bit more time on 6 and 7, which is allowing for queries outside of a specific transition referral episode. So in this case what we're suggesting is that you ought to get credit for getting information that you request, even if it isn't related to a particular transition or a particular referral, and I'll describe that in a second. And then finally, allowing the exclusion for transitions and referrals from entities not…who are not using CEHRT.

So our suggestion is that the threshold be lowered from 25% to 40%. Umm, first our biggest concern is that this is just a brand-new measure and as I described, sort of novel territory nationwide and so we think that it's inappropriate to raise it too high and have 40% as such a high bar. On the other hand, we think it's a very important measure, so we recognize and really applaud CMS for taking I think a creative approach to saying how do we make a step forward in query without having a full blown, ubiquitous query ecosystem out there in the market.

By allowing some flexibility in how it's done, through some of the exclusions that we're suggesting, we think that 25% is something, though it is a high bar for a new measure, but it's something that can be accomplished. And we do point out that it needs to be somewhat aligned with measure 1; my ability to receive really depends on people sending stuff. So we did want to sort of have that linkage there as well.

So let me jump ahead now to two of the bigger ones. One is for allowing for queries outside of specific transition referral episodes. So we just note, you know, as a workgroup that first off, population health management is increasing demand for information outside of discrete episodes of care, and indeed in the advanced health models presentation that we did last week, someone in that group did point out to us that we probably need to move away from this concept of episode of care, because as we think about care coordination, they're not linked to particular episodes, they're linking to be able to manage patients at large. And so we just note that that is sort of a general trend and something that we're all pushing for in value-based care and other kinds of models.

So we'd suggest including information received from queries outside of specific transitions or referrals, because…both because it will encourage the use of advanced HIE functions; so in places where people are able to do electronic query and response, it encourages them to do that and gives greater incentive for people to adopt those functions. But it also promotes cognitive activities, such as care planning and care coordination. It does raise the question though, of well, how do I do my measure definition now? How do I determine the denominator for discretionary queries, right; because technically the denominator of the universe is infinite?

What we would suggest is that for the measure that we allow EP/EH discretion on which queries are clinically appropriate and included in the numerator and denominator. I mean, in a way we are saying that we're only going to grade you if you get the answer right. On the other hand we would just point out that this is only one of three channels that they can get that information; there's the query, but they still are going to be getting information related to, you know, so an episode of care for transitions or referrals.

And we would also suggest that within an EP practice, because it raises the question of, well wait a minute, what if a care coordinator just generates that query, how do I give credit? Well, you could give credit, either give credit to any EP who has seen the patient, which would be relatively easy to do in the system, or to the PCP or to the last EP to have seen the patient; we're not making a specific recommendation on how to do that, but we're just suggesting to CMS that there are ways of figuring out a practical solution to that denominator question.

Number 7, we would allow…we would suggest allowing an exclusion for transitions or referrals from entities who are not using CEHRT and let me explain that for a second. The current denominator for measure 2 includes every transition or referral, regardless of whether the transition comes from an eligible provider or eligible hospital. However, we just note that in order to meet this measure, the receiving entity has to incorporate a C-CDA summary of care. The only people who are going to be able to do that are people who are on CEHRT, right? By and large right, 99.9% of the time, it's going to be someone who is on CEHRT and thus will almost never be available from an LTPAC provider, for example, since they don't qualify for meaningful use.

So unlike measure 1…and unlike measure 1, it's not possible to bootstrap easy technology solutions here. So for measure 1, many of you…who are in this day to day in the market may know that in many of these cases you just have had the ability to receive something and so what a lot of larger provider organizations did is they purchased web portal solutions for long-term care facilities, for example, so that they could receive a Direct message and just see it in essentially secure Gmail. We don't have that option here for measure 2, because you need the sender to be able to send it to you and there are no easy fixes for that kind of technology.

So, the information unavailable exclusion could cover this, but what that would require, as I pointed out earlier with that exclusion, is that every single time I have to make that request for each transition. So every LTPAC provider…patient who comes to me, I have to call and ask them, do you still not have the ability to send a C-CDA; oh, okay, now I get credit for it, right? What we're suggesting is that we allow an exclusion for known entities that don't have CEHRT, rather than…that for each transition, because that will ease the workflow and it'll also offer the opportunity for automated filtering on the receiving end by that entity. And it'll be the provider's responsibility for taking into account of, well that LTPAC organization did get CEHRT half-way through the year; well that would be the provider's responsibility to take that into account. But we think that that would make it a little bit easier to make this measure sort of adopted in the market.

I'm going to jump now to measure 3; this is reconciliation of clinical information. There is a recommendation, as I said, to increase the threshold to 80% and to increase it to include med allergies and problems, as well as medications. It's required for transition referrals and any encounter with new patients. There's a question there of automated versus manual; CMS is asking whether they should require automated versus manual, right now they don't specify. There's a question about allowing credentialed MAs to perform med rec, like is allowed with CPOE in the proposed rule. And then finally there's a question of should this be uniformly applied to specialists as well as primary care physicians.

I will…what I'll discuss is our recommendations on 2 and then…and on 6. So at a high level we agree with setting the 80% threshold for medications and medication allergies, so even though that is big jump up, given the experience that we've had and the clinician input that we had during the workgroup, we feel that those are, you know, are very good sort of forward progress and we think it makes sense to push everyone toward that.

We do suggest lowering the threshold for problems to 10%, and I'll discuss that in greater detail. We suggest removing this so-called never before encountered patients from the denominator. That's basically if a new patient comes to you, having that as a requirement, because there just seemed to be a practical issue of what am I reconciling against if the patient is new, I mean, the only thing I have is the patient information, so we suggest sort of taking that out.

We recommend, also in line with what CMS has proposed, allowing either automated or manual reconciliation because of the, you know, sort of the high variation in the quality of data right now that we're getting. We do recommend allowing credentialed MAs to perform reconciliation, which is not a part of the role right now, they're asking the question. We recommend allowing that. And then finally I'll discuss in greater detail the exclusion for some specialists; and I'm going to move quickly through this.

In the lowering threshold for problems to 10%, this was an area that the clinicians in the workgroup in particular felt particularly strongly about. We're concerned about expanding the scope to problems at such a high threshold. As I said, for meds and med allergies, we agree with keeping it at 80% and indeed, we had a discussion about whether it should be 100%. And one of the things that we were concerned about is, well, there are cases where it just doesn't make sense, so it's hard to set it at 100%.

But the problem reconciliation is operationally difficult because of the different nature…because it's really different in nature from meds and meds allergies. Patients can report meds and med allergies to some level of competency, but it's much less able to reliably report on diagnoses. There's ambiguity in coding conventions, umm, many cases of multiple ICD codes covering single experience of illness; so you could have different people reporting different ICD codes for the same experience of illness.

And then finally, there's lots of variation in the way providers do problems; there's the lumpers versus the splitters. There's the active versus inactive. There's the clean desk versus the messy desk. I mean, there's all sorts of different ways of doing it and there seemed to be too much variation to require this be done 80% of the time.

On the other hand, however, we do think it's really important and we note that this is the last stage, so what we didn't want to do is present a problem to CMS by taking it off the table that might then pose a higher threshold or a higher, you know, sort of barrier for them to be able to include something new in the future. So that's why we said, let's put it at 10% now so it's in there and then allow CMS sort of the opportunity to create a ramp over time to increase that.

The only other thing I would spend a little more time on here, and then I'll jump to the HIE governance, is allowing exclusions for some specialists. And the only point I would make here is that a number of clinicians in the workgroup pointed out that there are just some specialties that just don't…they're low prescribers or they're orthopedists who it doesn't make sense for them to have to do meds, meds allergies, you know, all of the time and so it seemed to make sense to specify certain specialties where that might be the case and to allow some kind of exclusion. We're not making a specific requirement on how to do that, we're just suggesting that CMS take a deeper look at that; that was a question that they asked, should we do it? We're saying yes, and suggesting they take a deeper look at that.

Last section here is on the NPR…is a question on the governance. So the NPRM allows any electronic means, CMS poses the question, should they have a requirement for some kind of electronic means or, particularly related to HIE governance that would be in line with governance mechanism that ONC establishes or might establish in the future.

The workgroup agrees with the current approach, which is to allow any electronic means and not tying EHR incentives to a governance mechanism that may be established by ONC. We believe that providers should have the flexibility in which electronic means they use to meet the objectives and we do note, however, that at some point in the future, a more assertive federal government role may be required if HIE doesn't progress sufficiently, safely and equitably according to objectives and meaningful metrics. We'd just, you know, we encourage ONC and CMS to develop those metrics so that we have good nationwide metrics along those dimensions. And then we also note the JASON Task Force did recommend a series of escalating, non-regulatory steps to strongly get the market moving forward, you know, short of sort of direct intervention in HIE.

That concludes our formal comments. I hope I haven't been over time.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
That's wonderful. Thank you, Micky. Comments and questions? Karen.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Thank you Micky and thank you Chris. I just have a clarifying question. I wasn't certain I understood what you were getting at around measure 2, number 6; that's about querying for transitions or episodes of care?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Yes. So that would be the case where let's say we're doing some care planning for a particular patient. It's not connected to a particular transition, so it's not that the patient was transitioned last week. It's not that the patient was referred to me last week. It's at some point down the road as a part of our management of our risk contract and the patients who are in that risk contract, we're doing a care coordination activity and we'd like to get a little bit more information and we have the ability to query another system and get something electronic back.

Under the current rule, that wouldn't…we wouldn't get any credit for that but what we're suggesting is that you ought to be able to get credit for that because that's encouraging people to do things that we all think we want them to do, they are performing a query and getting information back and it encourages them to use the advanced HIE functions that would enable that kind of capability.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
I see, so you're talking about a patient with whom you may have an existing relationship that you're doing care coordination or care management…

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

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
…in between visits or episodes…

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

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
Yeah, accountable care organization that might want to proactively address something with the patient population.

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

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
So, I just wanted to disagree with your recommendation about referrals and integrated delivery networks and not counting those. I think it's not in touch with the realities of sort of where things are within accountable care. If you look at integrated delivery systems, and I come from one, 85 or 90% of the referrals are actually within the network and at the end of the day, I think what you want is most referrals to be electronic and to be moving back and forth and including electronic information. If you look at the ones that are outside of the network, it's only 10 or 15% of all the referrals, which is a small minority, and most of those are really very different. Many of them are self-referrals, many of them are clinically inappropriate and I just think it creates problems to exclude the vast majority of what you're doing.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
David, may I ask you a question back at this point? What do you propose is the benefit of including the referral within your institution? What does it clinically improve that you don't already have? You already have, within the organization, access to the electronic health record and by counting this in, you do not improve the quality of data that's being sent or the amount or the accessibility to it.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
Well I respectively disagree. We did a study in our own network and half the time when providers got a referral within our highly integrated network, the question that the provider had for the specialist was not included, which the specialist found to be problematic. And in addition, when we then asked the primary care providers, did they get their question answered by the specialist, they…the primary care providers said that over half the time they did not. You know, even in integrated systems, our referral processes, I would submit, are fundamentally broken and we have a ways to go, even though everybody has access to the information. As a specialist, I really want to know what the question is and as a primary care doctor, I want to know what the answer to my question was.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right, I guess the only other thing I would add and point out, and we're certainly happy to take this back to discuss further. So it is just that we're talking about speci…we're not talking about any IDNs, we're saying that when you're literally on the same EHR. So everyone is literally on the same EHR system, and would just point out that it may be that if those issues exist that having alerting kinds of systems within the EHR is probably the better way to develop that, I would argue, than having this kind of rule that really gives a disproportionate advantage to people just to qualify for Meaningful Use. But it's probably not the best technological solution for doing to it, it's just getting them to do it this way…or they're doing it this way because Meaningful Use forces them to do it this way and they can get credit for it. But we're happy to take it back and discuss it with the work group again.

Paul Tang, MD, MS – Vice President, Chef Innovation and Technology Officer – Palo Alto Medical Foundation
Next, Troy?

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Umm, David, just to clarify; when we discussed this what we were talking about is the denominator, right? So it really had to do with how many of those transitions are countable. So I'm from an IDN as well and we truly do have an unfair advantage over the top of this so we're trying to level set this with other provider networks and things like that. But, it had to do with how we count the denominator, you know, if you can count those of 100% of those that are, umm, sent to an outside…outside of our EHR platform, if those are countable, then yeah, we meet the criteria for this measure; but, that was part of it. So I just wanted to…kind of the context of the conversation we had about this.

But, that wasn't the reason I had my flag up. The one thing that has always concerned me is the reconciliation, and we spent a lot of time talking about adding the additional components to this. Med rec has been problematic in and of itself and then adding the problems and the allergies, huge benefit to it; however, the person that does that really needs to be well defined. The credentialing, the credentialed MAs, I had questions on the meeting we had prior to this about what exactly does a credentialed MA, what does that mean? How do we do that? Is it an institutional level credentialing or is that a state-level credentialing? Who defines their scope, their standard of practice, things like that?

So those were some questions that I had that I'm still seeking information on. In the process, looking deeper into what a medical assistant can do versus what a provider can do, I mean really the definition of reconciliation is to create the most accurate list. Now the only one that can really make it accurate is somebody within…that has the scope to add, modify or delete from whatever that may be. And if it's a problem list, you know, the adding of a diagnosis is extremely important in the aspect of decision support as well as any other public health and continuing care aspects.

Allergies, there's always confusion as to is it really an allergy? Is it not an allergy? Is it just a sensitivity? And again, I mean the medical assistants whether they're credentialed or not, I mean they have a difference of opinion as to what that might be. Now the medications; what we have done in our process is we've allowed our medical assistants to add medications to a list, but it must go to a provider for the reconciliation; they need to bless that and say yes, this is a truly an accurate list and I'm going to add, modify or delete it, based on my professional practice, my professional scope.

So I think, again, I mean it's another layer of clarification as to what do we mean by reconciliation? Is it truly the accuracy of the list or is it just a review of the list or adding components to the list? But who is responsible for doing that when we're talking about adding in this other layer of credentialed medical staff or credentialed medical assistants, and there were two layers in there, in that portion of it; one of it said credentialed MA and then it said credentialed medical staff. So it either needs to be split apart of further refined.

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

Donna R. Cryer, JD – Founder and President – Global Liver Institute
First of all, thank you for such a comprehensive report and piece of information. My…I had two points, the first of which, I believe, really follows up on the issue that David raised and I think Micky, you actually began to answer. My concern around the disallow of selfies is sort of the reports from the real world of how care i…happens and perhaps I would phrase the issue as, how would a doctor know to look?

How would a physician, even within a, for the sake of argument we'll call it an integrated care system, know that a patient has met with primary care and then gastroenterology and then nephrology? How would the various physicians know that those visits happened and that they need to look to the record where there may be additions or other notes? And so that's my concern if sort of selfies were not allowed that there wouldn't be…that the other physicians involved in the care team would not be notified to be able to look into the record for additional information.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
No, I…and I take that, I think it's a very good point. I guess I would just ask and, you know, that if that is a big concern, is the biggest concern, if we asked Neal and all the engineers at Cerner is this the best way to solve that problem? I suspect that they would say, absolutely not that the best way to solve that problem is not for us to generate a CCD and sent it externally back to our own system and have that be the way to alert, that we can engineer something within the EHR, Neal, maybe you're going to tell my I'm wrong, but engineer something within the EHR to solve that problem. And I think people are doing it this way just because of the Meaningful Use allowance.

And I think it has the other down side that it, you know, sort of stops them from reaching out into the community and doing as much as they can in the community outside of the EHR system, which I think is what this measure in Meaningful Use in general is trying to accomplish.

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

Donna R. Cryer, JD – Founder and President – Global Liver Institute
And I…go ahead.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
I'm sorry, and one additional item. Members of the workgroup, especially representative from EPIC were concerned that this would provide an unfair advantage of large delivery systems over others who would not have to struggle because this is something that's automatically integrated in their system and wouldn't put them at an advantage in being able to achieve Meaningful Use as compared to smaller systems or individual providers. And that perception of fairness played very strongly in the discussion.

Donna R. Cryer, JD – Founder and President – Global Liver Institute
Thank you. My second point, and I'll raise this quickly, was about the exclusion of various specialists, so it is…you are not at this point making recommendations as to specific specialists to include and I just wonder, to exclude from the medication, allergies and additional information. Are you providing information about what criteria would be used to make such an exclusion, such as potential for patient harm?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Yeah, no, I think that's a great question; we haven't gotten that far but I think we have two more meetings before we're going to give our final recommendations, if I saw the timeline right. So we can certainly take that up with the workgroup to go one step further.

Donna R. Cryer, JD – Founder and President – Global Liver Institute
Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Let me just clarify that last statement. So…

Micky Tripathi, PhD – President &Chief Executive Officer – Massachusetts eHealth Collaborative
I mean internal meetings. Sorry, go ahead.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay, so I'll make a comment about our process then at the end.

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
And Neal, if you're…we'll take you out of turn if you're going to tell Micky he's wrong.

W
Or whatever.

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

Neal Patterson, MBA – Chairman of the Board and Chief Executive Officer – Cerner Corporation
I don't know if I…

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Neal, I just said you guys could do great things, you're going to tell me you can't do great things?

Neal Patterson, MBA – Chairman of the Board and Chief Executive Officer – Cerner Corporation
I'm going to agree with them and then to some degree say, you know, to both David and Donna that, I mean, I think we shouldn't come to Washington DC to set up the rules to kind of define how an integrated delivery system works. I mean, so if you're an integrated delivery system, you should be able to, inside your own organization make sure the specialist gets the right information when it's referred inside the network. So, I'm totally in agreement with your comment MIcky, and then the exclusion of selfies.

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

Paul Egerman – Businessman/Software Entrepreneur
Yes, I wanted to comment on the topic everything else is commenting on about the selfies. I mean, I have two observations; one is just because the organization is an integrated delivery network does not necessarily mean that everybody's on the same EHR systems. It's very common that you'll see physician offices and neighborhood health centers and a whole assortment of organizations that are really part of the organized healthcare arrangement, but have separate EHR systems. So that's one comment.

The second comment though is a little trickier which is, in the 2015 certification criteria are rules about segmentation, data segmentation as it relates to the CCD. And so the suggestion I would make to the workgroup is if you are going to re-examine this issue, you should also re-examine it from the context of does the data segmentation concept have an impact? Does that give a different reason for why the self-referrals might be very important, because the data might be segmented in such a way that a referral to some specialist within the organization has different data on it than the referral to another specialist?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
So on the second comment, if the…if my memory is right, I mean the segmentation requirements related to certification are for DS4P specifically and that is an optional requirement not related to Meaningful Use. So it's…particularly it's related to behavioral health and it's not required for Meaningful Use; so I'm not sure how that would fit in here.

But on your first point Paul, you know, as I said before, this would not…what we're proposing, the exclusion that we're proposing or removing of the exclusion would not apply in the cases where it's an integrated delivery system but they're on different EHR platforms. This is ver…this is something very peculiar in the Meaningful Use rule that says that it's for people, we're talking specifically about the case where they're literally on the same EHR and the ability to send a CCD to themselves, as it were, even though they're on the same EHR. But I agree with you in cases where they're on different platforms that absolutely ought to count toward the measure; that makes all the sense in the world.

Paul Egerman – Businessman/Software Entrepreneur
Micky, I'm not sure I know what you mean by different platforms? I mean, it's not uncommon that you would have the same vendor, but two different EHR systems.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right, in which case that would be…

Paul Egerman – Businessman/Software Entrepreneur
…because they have different platforms…

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
…because that would also not apply in this case; what it literally means is you're on the same database instance.

Paul Egerman – Businessman/Software Entrepreneur
Okay. And then on the second issue, I would encourage you to consider that just because the certification criteria is not mandatory for meaningful use, the assumption is that there are going to be some agencies that are going to make that mandatory and so there will be some vendors who will be providing that and I'm just curious to think through, I don't know the answer; but I think it would be good to think through, how does data segmentation, if that exists, change your view of the self-referrals.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Okay, we can take a look at that.

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

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So my comments go back to David's as well and have to do with referrals and our experience in a now more than a year and a half long project has been that we have to be thinking about, what is it that we want to achieve in terms of referrals? And often times, in fact more than 50% of the time, the patient who is referred, either within a system or to someone outside the system does not even make the appointment, does not show up and have the visit take place.

And so if we're talking about exchange of information, the…shall we say the failure to appear might be step 1 for the group to consider and then when we look at the issue that's been mentioned about, do you know what the question is that needs to be asked? I would argue that even in an integrated delivery system, when you have an enormous amount of information in an electronic health record, it may be very difficult for the receiving physician to be able to sort through all of that and to know exactly why the patient has appeared.

And our experience also in our project called Closing the Referral Loop is that often times the…in addition to the referring…or the receiving physician not knowing what the question is, neither does the patient. And so you end up having three sides of I would call it an isosceles triangle, where there are loose connections all along the way. So I'd urge the workgroup to think about how can this be tailored in a way so that a patient receives…actually has the referral that they need, knows the question, the consultant knows the question to be answered, and the primary care physician receives the answer they want. And I'm not sure this is getting us to it; so I would include the integrated health systems.

And then lastly also, just as something to consider as you deliberate on this further, we are, certainly at AMA and it's been done based on work supported by the American Board of Internal Medicine Foundation, looking at ways increasingly to move aspects of care outside of the office altogether and outside of the official transaction; so medication reconciliation, determination of allergies is done in pre-visit planning. And I would want to be sure that those kinds of activities could still quality, even if they do not occur on the same day as the patient appears.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Okay. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer Palo Alto Medical Foundation
I'll just observe…I hope I'm not stepping into this, just observe on this selfie issue. It sounds like we might be conflating a couple of issues; one is on care coordination/close the loop referral and the other is on exchange of information. So at the very least, maybe we can figure out how to disentangle that and try to understand…the motivation may be the same but I think we're actually talking about two different functionalities. Christine?

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Thank you. So I have two things and I wanted to go back to the slide 9. So the question that I have is about any electronic transport. One more…there it is. Perfect. So it's that number 2. I'm not sure if this is a policy recommendation or a standards recommendation or something that kind of touches both. But what I'm a little bit worried about is that in Stage 1 what we heard was the challenge with creating and sending the summary of care was that there were no standards specified in the certification rule.

Then there were two standards that were, I think, if I recall correctly, that were specified in certification for Stage 2. We are having some challenges, as you reported a couple of slides earlier, lots of exclusions, etcetera. So is this recommending remov…one of those standards was Direct; is this recommending removing those standards and are we going to create a problem where we still don't have systems that talk to each other or is this more focused on transport? I mean, I'm just worried about..

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Yeah. No, it's a great question. So the certification rule still requires that you be certified to the Direct standard. So from a technology perspective, you're still going to be required to have the system to allow Direct standard types of transaction and indeed, they even do require certain refinements of Direct to provide some of the, you know, sort of fill at least some of the little gaps that we've seen in the standard itself. But the rule is suggesting that as a provider, you're not required to do it via Direct, even though you need to have a technology that has the capability of doing it via Direct.

We think that that's appropriate because the issues with Direct are that yes, there was a standard, so Stage 1 said there was no standard. Stage 2 came with a standard but the standard was developed; essentially in the federal government and dropped on the market and there was no market ecosystem around it and those were the challenges we've been having. There are still market ecosystem issues so that's why we think that flexibility is important.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Okay, I mean I agree that conceptually and I completely agree with giving credit to those who have other kinds of information exchange capabilities or an HIE interface. I just, I think there is…I just want to encourage you to be very clear about it because there are a lot of other components where…or policy levers that people are pulling and saying, well if you have a certified system, then we assume you can, and I want to make sure you can, right?

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
So that's, I think that's important. So the only other comment that I have, which isn't necessarily, I think, for you guys as much as, I'm going to look at Paul here. A couple of slides earlier, you had a mention about the consequence of a reduction in the reporting period, going from 12 months to 90 days, without a corresponding adjustment to, in this case it was an exclusion threshold.

So I just wanted to flag that; I think that challenge affects a lot of different measures in that there are definitely measures in the Stage 3 element where, for example, if I think about secure messaging, if it becomes finalized where it's 35% of, you know, send; right? So its provider sends to 35% of patients, if suddenly you only have 90 days to do that, from a patient viewpoint, we're going to get spammed, right? So, I wonder if it's worth adding kind of a general comment that says, look, there are measures that if yet again, because we have this pattern, right; you go, which I don't support, but if you go from a 12 month to a 90 day reporting period, we've got to look at those things, because otherwise consumers are going to be really adversely impacted. Thanks.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
We have that as one of these bullet points in one of our recommendations, that general comment that you're asking for.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Great. And that's not just specific to the HIE…

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
…objective is what I want to make sure.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right, it wasn't; it was just in general. But I can make sure that it reads that way, too.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
I mean, they provided a lot of really great data that helps show the consequences…

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Right.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
…unintended consequence. Any more questions? Want to thank you so much for a won…a very, very clear presentation and for discussion. So let me comment here then on process.

So we're going to try to achieve consensus and where we can, let's say in certain sections, vote on agreement, perhaps with some tweaks like we normally do. Here where there looks like there were some issues that came up that want further exploration by the workgroup and they may come back on our call to have that explained and then we can take a vote on that section at that time, if that's okay.

Okay, so the next on the list is, I think its Privacy & Security and this is Deven and Stan.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Great. Thank you all very much. We have them combined in one deck here a set of comments on the Meaningful Use NPRM as well as a set of comments on the Certification NPRM. We're going to skip the front of the deck and have that after lunch in the certification section. So we need to move to…they did, oh, okay. Well the, let's just get going.

All right. Here are our workgroup members; my thanks to all of them for hanging with us through this process. Here, we're going to talk again about two pieces…two particular subjects for the Meaningful Use Stage 3 NPRM; one is the particular objective on protecting health information and the other one is an issue that we were asked to address about what are the additional privacy and security issues that arise with patient access to data either through the traditional view, download and transmit capability or through the new open API infrastructure that is allowed for in the NPRM and called for in certification?

So starting with the issue of…okay, this wasn't the first one that we had, but we'll go with it; the issue of privacy and security risks to patients using, again VDT or APIs. There are risks that are risks that the provider experiences because they're being asked to connect in to potentially a new set of technologies that could cause security risks for them; they may have some uncertainty about how HIPAA Security Rules applies and what kinds of steps they need to take to credential patients, for example, which is a topic that we've gone through before.

Paul Tang, as a matter of fact in our previous…Paul Egerman, in our previous meeting talked about, you know, what if the patient wants to connect something into the provider's EHR either through an API or through a transmit to a device, something that raises security risk for the provider system, what do you do in those circumstances? Similarly though, on the patients side, there are some risks that the patient will bear. We've talked numerous times on the committee about the fact that HIPAA provides comprehensive privacy and security standards that apply to healthcare providers and health plans, but don't apply to consumer-facing technology.

So if a consumer is using an App that they want to use to hold their data, that…the likelihood that that is covered by HIPAA is going to be very small. And so some uncertainties about whether the patient's aware of what the privacy policies are of the App that they might be using. Whether they were even able to understand what those policies are or find them and whether the patient's really in the know about the fact that, you know, once that data transfers over to them as part of a transmit or a download or through the use of an API, that the patient is then responsible for how that data then gets used and for choosing wisely, in accordance with the patient's own preferences about how they want to share that information with others.

And in general we are very supportive of empowering patients through greater access to their data; there's absolutely no doubt about. But certainly having some mechanisms for addressing these additional risks is going to be helpful. Patients will be at varying degrees of risk tolerance in terms of whether they care, maybe not at all, to caring a lot and needing to navigate the space that could be very confusing to them and maybe for a lot of them not even realizing that this data may not be subject to legal protection.

And so we do have a number of steps that we recommend taking, but they all really fall into the area of guidance. And frankly this is something actually that the Health IT Policy Committee addressed previously, back in August of 2011 when we first took on the issue of what are the risks to patients with this new view, and at that time it was just view and download capabilities. We're sort of going to be dropping on to patients a lot of really valuable data that's going to be both valuable to them, but valuable to all kinds of third parties who may be eager to grab onto that and get patients to use their devices for the purposes of being able to get that data. Do patients sort of fully understand that environment?

We came up with a set of best practices for view and download that frankly are extensible to the environment of where that data is transmitted to another party and we're recommending essentially that that same sort of best practice guidance that we called for in 2011 that hasn't really been produced yet, at least not directed towards this particular effort, really needs to move forward. This is not something you can fix through certification; it is definitely something where guidance is going to be enormously helpful.

We have been informed by workgroup members that are from the feder…who sit on our working group from the Federal Trade Commission, as well as our colleagues at ONC, that there already is an effort underway to develop joint guidance on managing privacy and security risks of mobile IT Apps and APIs. And this is then guidance that would go to consumers, it's guidance that would go to providers who are hoping to make patient access through these tools more easily accomplished; and of course, guidance for the vendors. If you want to do this right, what are some ways to do this right?

You know the Federal Trade Commission has put out guidance on consumer privacy generally, all of which touches on healthcare but none of which is necessarily directed at helping people navigate this particular space where there's going to be much greater access to clinical, you know, very rich and very valuable data that patients are going to be able to access. That is all good, but helping people manage those risks is going to be very helpful.

And a checklist was suggested on an earlier call that we had, and that's a really good idea. You know, what should you be looking for as a patient? And it's also helpful, frankly, to give this guidance to providers, too because who's the patient going to first ask about what should I do in this space, probably their doctor or the nurse in the office or a health coach. So, you know, so providing this guidance in sort of language that can be…that is useful to the different audiences; the vendors are going to need something that is much more specific and directed to the types of issues that are going to be important to them.

We also had prior recommendations around identity proofing, authenticating patients and how do you counsel patients who want to make family members, friends and legal personal representatives have access to data, either through again VDT or an API.

We also think it's pretty critical for ONC to work with the Office for Civil Rights to have guidance that specifically addresses the intersection between the Meaningful Use Program and HIPPA and the patient access requirements. Because I think there's a lot of confusion out there about sort of what are the baseline HIPPA requirements? What's required for meaningful use? And to…and what is the intersection between the two of them? I've heard a lot of questions, for example about, can patients be charged for access through an EHR? And a lot of sort of defaulting to, well what are the requirements under HIPPA? Where did those come into play when you're using your portal or your open API infrastructure to give patients their HIPPA rights to access data?

Similarly, on the issue that Paul Egerman raised in the earlier meeting where we discussed the security risks for the provider in accepting patient technologies through a sort of direct link into the EHR; what are the providers' security rule obligations with respect to making sure that they're not introducing security risks into their system? And what is their right to tell a patient who's saying, you know, I want you to connect with this App and the provider perceives a…legitimately perceives a security risk, to what extent can the provider say no, I won't connect with you through this mechanism, but I will connect with you through all of the following mechanisms.

So there already are, at least for the provider side of this, some responsibilities that providers have with respect to security. How does all of that interface with what's being requested as part of VDT and this…and access through APIs? And the…just more specific guidance that has some specific scenarios and FAQs that providers can then use in order to get over the hiccups in deploying this.

And then finally we do think that there might be room for a voluntary effort by…that includes industry to certify patient-facing health Apps that have…that adhere to a set of best practices around privacy and security. This is not something that we think the federal government should stand up, but we think that the various agencies that we've mentioned here, FTC, ONC, OCR, can play an advisory role in terms of sort of guiding an industry, and frankly it should say, you know, consumer involvement, too about what sorts of criteria should Apps meet in order to be sort of really following best practice guidelines with respect to privacy and security.

And the Federal Trade Commission have the authority under their authority given by Congress to crack down on deceptive trade practices that if you have a company that has voluntarily agreed to adhere to certain guidelines, then they can be held accountable for doing that. So there is sort of potential power in that from a regulatory standpoint, but only if there…the guidelines are formally adopted by industry. So industry really does need to be involved in shaping them and frankly, the Federal Trade Commission won't be that interested in enforcing them if they are not robust.

So we think that…we recognize the concerns in this space. We think they are manageable, but providers and industry are going to…providers in particular are going to need some help. Patients are going to ideally need some guidance for those who have particularly high privacy sensitivities and making good choices about Apps. And certainly industry, the vendors who create these Apps, the electronic health record vendors that are trying to help create these…the possibility of these connections to be provided with some suggestions about pathways that they can go down that will reduce the risks that we talked about earlier. So we had guidance written all over this. It's a pathway we've been down before, but we…but it hasn't really been addressed yet and so this is our opportunity to sort of underline it and stick yellow highlighters all over it.

In terms of the actual criterion, it's one criterion, in the Meaningful Use NPRM around protecting data, umm, nope, I don't know where it went, I'm going to have to verbally do this. So there is one objective that needs to be met in meaningful use with respect to protecting data, and that is to do is security risk assessment and to adopt safeguards to address deficiencies. This is been the criterion in the Meaningful Use Program right from the start.

We had previously as a committee said, this is exactly the place that meaningful use needs to emphasize, but providers need to understand that this needs to be a comprehensive risk assessment that is akin to what you need to do under the HIPPA Security Rule, but applied to your certified EHR technology. And so what's been proposed in the NPRM is some clarification that what providers need to do as part of the security risk assessment is to adopt not just the technical safeguards that frankly come in the EHR technology that you get from your vendor, but also look at administrative safeguards and physical safeguards. So those are the sort of three-prongs of the Security Rule and apply it to the certified EHR environment.

So it isn't just, you know, did you check the box and buy all the stuff you were supposed to buy from your EHR vendor it's, did you do the risk assessment in accordance with HIPAA that's much more comprehensive. That's made more clear in the NPRM; we gave it two thumbs up and had no additional comments.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer- Palo Alto Medical Foundation
Siskel and Ebert and Paul Egerman has a comment on the phone.

Paul Egerman – Businessman/Software Entrepreneur
Yes, thank you Deven, as usual, a great and concise and informative presentation. On the issue of these Apps, these mobile Apps, I just had two observations; one is, the issue still intersects with the sort of political hot buttons that exist right now around data blocking and there are, just the security issues are a good example of why providers need to be able to block some interactions from some sources.

My second observation is that I think that a lot of people do not understand how these mobile Apps work. It is not the case that information flows from the EHR system directly to the patient's cellular phone; actually what happens behind each App, there is a server somewhere and the server is provided by some other vendor, not a EHR vendor usually. The data goes throughout the EHR system to the server, then from the server to the patient's mobile device. This is important in terms of understanding the potential for a violation.

There is an App that is currently being sold on the Apple Store, I sent you an example of this, Deven, on the Apple Store it lists the organizations that it works with, one of them is Palo Alto Medical Foundation, and because it lists that, if you were a patient of Palo Alto Medical Foundation, you might assume that everything is okay for you to use that application. And you basically give it your username and password and it logs on to the system and takes the data off and puts it in the server.

I did speak to the CEO of that organization and learned that part of their revenue model is to sell that data to a pharmaceutical company who is giving them basically a referral fee to be able to get that kind of data, because I guess they can sell pharmaceutical pat…data directly to patients when they know what drugs and what problems they have. And my guess is a lot of providers may not like that. And I use that as an example of saying, there's a lot of work that needs to be done in terms of these mobile Apps in terms of how the applications work, because I think the issues go beyond the suggestions that you are talking about Deven, which is, who is supposed to learn about how that all occurs? Who is supposed to monitor that entire process? And what is a patient's assumption if they hear, oh gee, this App works with Palo Alto Medical Foundation, isn't it reasonable for patient to think, well Palo Alto Medical Foundation did some level of due diligence; they wouldn't allow it to work unless it was okay.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
For the record, I don't even know what App that is.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, so I was just sitting here thinking, you know, that if I were the Palo Alto Medical Foundation and I had not endorsed said particular App and I had a company out there who was saying that I did, I would make a phone call to this organization called the Federal Trade Commission because that's deceptive, right?

Paul Egerman – Businessman/Software Entrepreneur
Yeah, but they…because they don't say it's endorsed, they say clearly, it's not endorsed, but it works with all these organizations and then it lists hundreds of organizations that it works with.

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

Paul Egerman – Businessman/Software Entrepreneur
So it's not…they make it clear it's not an endorsement, but you still think, well if it works with it, there must be some reason why it works with it; they wouldn't allow it to work with it unless it was bad one. Because a bad one…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Well, and so for every App that has all the concerns that you described, you know, there will be another set of Apps that have sort of bent over backwards to try to deploy reasonable privacy and security safeguards who adopt privacy policies that are very obvious to patients that are written in plain English and that don't raises those issues; so hence why our recommendation is, there needs to be a lot of guidance to help patients, providers and vendors to help them really navigate the space.

In some circumstances where legitimate security issues could be raised by making a direct connection to an App that the patient is requesting a connection be made to, you know the provider ought to have the ability to say look, and certainly under HIPPA they would if those legitimate security risks arise. On the other hand, you can't use…you can't pull the security card unless you have a legitimate security risk just because the patient is engaging in wanting to download their data into an App that the healthcare provider just doesn't like for some reason.

Like there's a distinction between those two circumstances and figuring out how to navigate that is going to take guidance and we just didn't see a space for saying, absolutely under no circumstances should patients be able to…for example, be able to download to App that sells data to pharma, because ask every patient who uses PatientsLikeMe, that's pretty clear that that's the business model for the site and it's enormously popular; it's not an App, it's a social networking site. But that is something that patients…that those patients who have very serious illness find valuable because they believe that pharma can use data to help save their lives.

So for, you know, so the circumstances are too varied, the patient's levels of privacy sensitivities are too varied to have hard and fast rules here. But we can do a lot better about putting guidance out there so that people can make the choices that are right for them and for the providers to give them guidance about how to navigate this space so they're not unduly introducing security risks into their systems when they're asked to connect to Apps or devices supplied by the patient.

Paul Egerman – Businessman/Software Entrepreneur
Okay. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Lucia, did you have some…a comment?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
I just wanted to make two comments; one is for those of you on the Policy Committee who are interested, we actually had a very good deck on this at our May 1 Privacy & Security Workgroup and it was valida…put together by the team, but validated by OCR so if you want to know more about the specifics of the Access Rule under HIPAA, you can just go to that deck on the healthit.gov website, the public can, too.

The second thing I wanted to highlight is the difference; we do have a challenge or an opportunity here because guidance comes in a lot of different forms. And sometimes it's in the form of a rule, such as the CEHRT rule or the Meaningful Use Rule or rule that the Office of Civil Rights might promulgate. And sometimes it's in the form of the outcome of a litigation that the FTC undertakes and a settlement decree that people then study. And sometimes it takes the form literally and through educational websites or materials that anyone of the interested guidance authorities might promulgate and we're going to probably be playing mostly in the latter space in the immediate future because of course statutes and rules take a lot, a lot of time and a lot of work and we want to have something that's responsive and flexible to the evolving needs of the market. But I just wanted to remind all of you that guidance takes a lot of different forms.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Ah, that's very helpful and when the workgroup decided to recommend guidance, which of those flavors; clearly there's only one that can be applied fairly soon. But how did you judge, it's obviously a trade-off, how did you judge the risk for harm and the heaviness of the guidance?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I think we always err on the side of guidance that is, umm, that takes real life scenarios that people are facing and deconstructs them, you know, here are some pathways…reasonable paths forward to addressing these risks. Here's what would happen in this particular circumstance. So a combination of both the sort of general kind of guidance that is often what you will find on a website and something that can be updated more frequently through FAQs that sort of come from the experience of people trying to implement this on the ground; that's likely more easily done through, you know, so webinars, through…frankly through tweeting if the answer is short. But we didn't say, I mean, sooner rather than later, I mean, some guidance…the type of guidance that has to go through administrative clearance.

You know, our original set of recommendations came out in 2011, right? And so you have gotten bits and pieces of it from preambles to rules and…but new questions arise every day as people on the ground try to implement this and they are left scratching their…well what about this scenario, like that language addressed a similar scenario, but this has a couple of additional twists to it. So, you know, it's always more ideal where it can be much…address real factual scenarios and sometimes those can only happen through the more informal venues that Lucia just described.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
But Paul, to your point, just to add, I mean, everything that we do that we publish of that caliber is actually vetted by the Office of Civil Rights and other agencies of the necessary. It just doesn't go through the complexities of administrative procedures…rulemaking and then it has a different reliability factor in terms of how it plays out over time. But that's…we don't, you know, we don't shoot from the hip.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
And I don't think OCR does either.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Sometimes we'd like to, but we don't.

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Thank you. So I just want to underscore what Deven is saying which is this need to identify and deconstruct the pathways…this happens and to highlight that it's…it is really pressing. It doesn't have to be completely federally led in terms of the effort to identify and deconstruct the pathways, but I do think that the federal government needs to pay attention like now. And the reason I say that is because I just went to my doctor, it's taken…it's been about two and a half weeks now, and requested a copy of my health information electronically, because they're meaningful users. So a) I have that right and b) they should technically be able to produce it and it's really been an interesting experience for me.

First of all, they had no idea that they actually had to do that, so they told me no, no, no. I handed them a copy of the Federal Register saying yes, yes, yes; totally the wrong patient to pick on, I know. Anyway…and had to work my way through their chain of command through the office and this is a small practice, by the way, until finally the practice manager recognized that he could, in fact, put a CCR on a CD-ROM. And so that's what I'm going to get.

So now I'll have health information, then I'm going...I want to go to Blue Cross and see if I get my claims downloaded through Blue Button, since they participate; that's a whole other issue. What do I do it that data? I have it on a CD right now, right? So there's a real need for the guidance for consumers right now because I want to understand. And I'm not averse to people de-identifying my own health information and selling it for various purposes, but I want to know what they are.

And to the point about that the Tiger Team, the previous Tiger Team has made many a time, I don't want to be surprised by what happens to my health information. And I don't want it to be sold in an identifiable fashion either, right? So there's a lot that's happening in this space that I think is going to happen very quickly, so I just want to encourage Lucia and Karen and your team to think about what we need to do right now to protect consumers. And we're going to talk about this more when I present the consumer recommendations as well next. But just to offer my own experience and say, this isn't like we can wait for a couple of years until Stage 3 rolls around.

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

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Great. Thanks.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
And Paul, you have another comment?

Paul Egerman – Businessman/Software Entrepreneur
Yes, my comment's just in response to Christine who mentioned that she didn't have any trouble…the information is de-identified. What I was able to determine about this particular App is that information is not being de-identified. This is identifiable information that is being stored and sold. And so that…and it's also, incidentally, done for a company that claims to be HIPAA compliant on their website, which has no meaning, because they're not a covered entity. That's just my observation.

And I understand there's great potential here, but if we think about it, these Apps are going to be made available for mobile users without charge and what is going to be the model for the vendors who create those Apps that are giving it without charge? And the model probably is going to be selling data in some form or another.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
It's interesting Paul, that's a very good comment and it makes me think of some…the other discussion that we had in the Advanced Health Models Workgroup about HealthKit and other similar platforms that are trying to set their own sort of standards and policies about sort of, you know, no sale of data, no marketing uses of data, right? It will be, you know, to the extent that those are made cl…again, if those are made clear to people and people understand it and that's the…that's an important protection for them. That is…that's a very positive development, in my view.

On the other hand, it is a case that free Apps are often supported by deals made with data, right? And so if suddenly the App that was free now costs, you know, a couple of bucks a month to download because that sort of business model of data sale has…is not available to that App because they connect through a platform that doesn't allow that to take place, then it will…it's going to have an effect on how those types of Apps are rolled out.

My own personal view is that consumers should have the choice that works for them. People use discount cards in grocery stores all the time; the deal that you get for your coupons is that the data's being used by the store. But people often don't understand that, so there's a big transparent…a role for transparency to play and it's…and the fact that's not all the way clear to people means we can't make the assumption that people are always making those trade-offs knowingly. But we also can't assume they wouldn't make those trade-offs if they were presented to them. So, it's just an area that is evolving really rapidly; it's yet another reason why guidance is better than some sort of hard and fast rules about how this environment ought to operate.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So could I get a sense of the committee what's the ask from the committee members in terms of between now and what may follow that we want to vote on at our meeting?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Well I think, you know, again a lot of times this stuff gets rolled out without a mention about the supporting elements of guidance and so we're not saying that any of the…any of what's called for in the NPRM needs to change. But that this guidance, we are…we're happy to hear the commitment of agencies when we're at these meetings that this is moving forward. I think mentioning that in the next NPRM so that counsel to providers once the final rules come out say, there's something that's coming on the horizon or if it's already produced and it can be linked, given that we've got some lead time here, I think it would be really helpful. Often times we all think it's a really great idea and then it just…it's not clear what's happening behind the scenes to implement it when it doesn't somehow become part of the rulemaking, in what's called the preamble, right; the explanatory language that goes with the rule.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So I see that from the workgroup, but what about the sense of the committee members about any changes you would like to see in the recommendation from Privacy & Security Workgroup? Christine?

Christine Bechtel, MA – President – Bechtel Health Advisory Group
I don't have changes, but I think to articulate Deven's suggestion which is to add a recommendation in to the Privacy & Security Workgroup because the Consumer Workgroups recommendations reference yours, you know. So if we can add that in to say we are suggesting that when the final rule is published, this is what occurs. And that within some rapid timeline, and I would love to hear from folks at ONC what that might be, but within some specific timeline that we need to have this guidance and ONC, you know, might support an industry led voluntary effort around the kind of certification of Apps or exploring that issue; those things that tend to make these recommendations more concrete would be helpful. And if we could maybe draft that language between now and our next meeting as the Policy Committee, for the virtual meeting, that would be helpful.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So I hear you saying about the timeline being immediate. Paul's citation of this App that is actually using data and he says identifiable; I mean, that's a call for action now. And then maybe some, at least teasing apart the three options that Lucia said in terms of what guidance is and which we think we're comfortable with; is it only education? You're…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I am not sure, are you looking for us to do something more that's heavier handed or are you asking us to say, guidance yes, but be more clear that it should be part of the rule…noted in the rulemaking either because it's already done and we can cite to it or it's in process and its identified when it might be out, the particular topics that are likely to be covered are identified. I frankly don't see a lot of viability in an exercise that directs the government to say, you shall do this type of guidance for this type of issue because I think they, I mean, that just feels number 1, extremely directive in an environment that we don't necessarily always know what the pieces are. I'm not sure what more you're asking of us.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So the…so when we came out and said, there are three options, let's say to deal with the timing concern that people have and here are some suggestions; it's almost like that. So there are three kinds of ways you can provide guidance; you can provide a website that says here, if you seek further information come here or you can go the other extreme which is let's say a law saying what you can and can't do. But there's…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
We didn't ask for a law, I can tell you, we've already opined on that.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Understand, but you can opine on that piece, but I sense some sense of concern and a sense of urgency about whether there can be some harm from a data point of view occur in the absence of other interventions. And the kinds of interventions may be delineated and it may come to a vote in terms of which does the…do the committee members that currently constitute the committee feel is…it's not directive, it's just advice. Karen?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
So I won't have a solution, but I do just want to underscore how important this is as we're thinking about advancing doorways to the data to give people more access not only to have their own health information but to potentially direct it to efforts like the Precision Medicine cohort, as an example or other ways that they might…or to their own personal health record from a trusted third party. So it's worthy of a lot of detailed conversation.

I would just remind us all to that, as part of the FDASIA work that there was some discussion about Apps and that will be ongoing. So Jodi's stepped out, but that would be something that this team would have to…this…your team Deven would have to also incorporate, I think, with Jodi Daniel and others as the FDA and folks who are thinking about consumer protection from…just like you mentioned, the Federal Trade Commission. So there's a lot of…it's a very interesting balance that you all have raised, there's the market wanting to evolve and innovate and then there's also our responsibility to educate and protect consumers where it's relevant. So I would just encourage some more thought, but Lucia may just want to contribute some…

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
What I was going to say, there are many tributaries in motion on this topic within ONC and across the government and what I think would be appropriate is for…to work with you Paul and Karen on, when would be an appropriate time for ONC to report back on this issue to the Policy Committee and seek input? That gives us some freedom to do what we do best which is coordinating and see if we can't deliver some actual something to report to you on next in several months; give us at least the summer.

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
So and I'll say, what we came up with as…with the workgroup was a guidance-based approach and that's what we had consensus on and we never had anybody on the workgroup say, no we must be stronger and say that no Apps shall do X, right? Or there, you know, something stronger than helping people to navigate this space, you know, through checklists, through advice about how HIPPA intersects, all of the things that we talked about before.

So if someone from the committee wants to propose something stronger for the committee's consideration, we'd be ha…I'd be happy to take that specific thing back to our workgroup to opine on, but we're not going to…we gave you what we thought we needed. If you want something else, we're happy to talk about it and of course, the committee has the final word if we as a com…if the committee wants to vote on something more stringent, but I...what I'm pushing back on you is, seems like you're asking me to take another look at this whole thing. And we looked at it and this is what we think is necessary as a workgroup. If there's something more that somebody on this committee wants, say it. Because I'm not going to back and re-go over this territory, because this is what we think we need.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
You were going to add, Christine?

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Well, no, I mean I hate to follow that statement; good Lord. So…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I mean, maybe I'm wrong, but I'm like, I don't know what you people would like but just tell me.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
So I'll just…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Put it out there.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
…give you, I'll give you the context for my comments…

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

Christine Bechtel, MA – President- Bechtel Health Advisory Group
…which is, I know that we have a transmittal letter from August of 2011 that proposed a series of steps that weren't implemented…

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
…even though it was adopted.

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
So, that's number one concern.

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
But on our call preparing…the Advanced Health Models workgroup call, we talked about what guidance meant and I had asked you a question, you know, what does guidance from the FTC mean, is it just sort of best practices or whatever. And the answer that I understood was, well once FTC issues guidance, they don't have a regulatory authority, but once they issue guidance to say this is what fair trade practices are or aren't, then if there is a third-party application in the market that's doing something that is contrary to those things, then the FDA can actually do something to take some action. Is that correct or close?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, so it's the FTC.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
What did I say?

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Oh, I meant FTC, sorry.

Deven McGraw, JD, MPH, LLM – Partner- Manatt, Phelps & Phillips, LLP
Yeah, different F.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Yes.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LL
The…so what they have is, if a…what's called deceptive trade practices authority. So if a company makes a commitment to consumers and says, we don't sell your data and then it turns out in fact they do sell your data or they're very cagey about it, then they…then the FTC can use it…it's deceptive trade practices authority to crack down on that company.

The other prong of their jurisdiction is to crack down on practices that are unfair to consumers in the market place. And that's where, you know, they don't have rulemaking authority, so you get a sense of sort of how they apply unfairness through enforcement actions that have come previously. And it's one where there is a bit less certainty from a legal standpoint about how far that extends; is a patently unfair to sell consumer data? No, not necessarily. Is it patently unfair to adopt no security safeguards for consumer data? That's actually an issue that's being litigated right now. Is whether unfairness can extend to requiring…to having security expectations?

So it's, you know, it's one of those things that a HIPPA kind of regime where love HIPAA, hate HIPAA at least there are rules and its discoverable and somewhat clear, you know, this is a little bit more of like a common law jurisdiction where decisions that are made by the FTC and then upheld by the court over time through enforcement actions become the body of authority that they exercise. So, a little bit less certain, but they've been ver…much more proactive recently at putting out a lot of guidance to the marketplace about what are good practices for protecting consumers. And to saying, you know, and to inviting industry to come together through multi-stakeholder groups and establishing codes of conduct that they would then be willing to enforce across certain industries.

So that's the sort of state of play, it's not, you know, only Congress can fix the fact that we have this sort of piece of the marketplace that's…where health data's being collected and shared, but isn't protected by a comprehensive set of rules. States frankly can also act in this space, and some have. But to create this sort of nationwide protections like the ones that we have for HIPPA over health data in that sphere, would take an act of Congress. So, you know, given the environment that we have where the Federal Trade Commission does have some authority, where we're recommending that there be a lot more guidance to people to help them navigate the space, guidance that can come in an array of vehicles. We're trying to sort of deal with it…with the ecosystem we have and to try to create a better environment for all concerned.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
So I guess what I would say is the one specific proposal that I would suggest is what I did earlier which is…

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
…I feel much more comfortable with all of that information you've given us now as you did on the workgroup phone call and that component of FTC guidance is included in your recommendations from the workgroup, so that's great. And then if we can maybe say that we would recommend in our federal advisory capacity that when the rule is finalized that we receive some clear guidance that it is probably informed, as Lucia talked about, by a report back on what's going on in this space and all those things, which is to have some sense that here…there are further actions coming, these are real issues, expect stuff coming on this timeline from these people or whatever it is, but something in the final would be, I think, a helpful…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, no, absolutely because it's again, it's consistent with our guidance approach and we can be more detailed about that, absolutely.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Maybe if I could make a suggestion; so, in the process of your workgroup coming up with your firm and unanimous opinion, you must have discussed other options or other thoughts. If that's something you can include, like many…like is common, you have pros and cons for different options then at least it's something that committee can…because I'm sensing we don't…certainly don't have unanimity on this subject, it is a hard subject as all privacy and security issues are. But I think we need a little bit more leeway in terms of the committee members exercising their voice about what path to recommend.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
And that's absolutely fine, but additional suggestions did not come from our workgroup…

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
…so if there are specific things that you want us to consider, we're happy to do so; but you…I definitely need to know what they are…

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
…beyond the ones that Christine just suggested.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
And Paul probably has some. At any rate…

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So let's…I'm going to try to finish up really quick, because we take overtime here. Chris and then Donna.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
Thank you, Paul. So Deven, I actually have learned to look forward to your presentations; they're always interesting. So I just read yesterday in the Wall Street Journal an article about whales and gaming Apps, those are consumers that pay more than $100 a month on their App in game pay, and I'm wondering what the HIT App whale of the future will look like, but it's not really my question.

My question is, many industries are self-regulating, you know, no physician must be board-certified, they do it as a mark of quality and assurance to patients. And my question was, did you have any discussion about kicking off a self-regulating process within the industry and is this something that the ONC actually could help with?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, so we do, in one of our recommendations, I'm not sure where it is now; we do actually endorse a voluntary certification effort that would come from industry and that the role of the feds in that case would be to provide them with guidance and advice about, you know, both from what regulations where they apply, what they might already require and how they would interface. And areas of guidance where having industry input would be helpful.

But similarly, again with the FTC basically having the authority to advance self-regulatory codes of conduct that industry comes up with that there could be sort of the market leaders who want to really differentiate themselves could create a set of really good standards that then through endorsement almost like a boar…you feel like you need to be board-certified in order to differentiate yourself from other colleagues. So we do acknowledge that and maybe we could make that more clear since it didn't stand out from other things that we said.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP
Deven, this is Stan on the phone. That was, I think, recommendation 7 on slide 8 that we had it.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, thanks Stan.

Donna R. Cryer, JD – Founder and President – Global Liver Institute
Thank you; as a member of Privacy & Security Workgroup, to reinforce Deven, not that she needs reinforcement, but I think she has fairly articulated the consensus amongst the group. And so perhaps to answer your question, because I think Paul you tried to be very helpful in laying out sort of where the workgroup lays on a spectrum of recommendations, because the term guidance can be very weighted and loaded.

And Deven, correct me if I'm wrong, but I can foresee that the workgroup has come out with much more of a lighter end of the spectrum, both because of the timeliness, in terms of getting something out, the timeliness in terms of being able to keep something that's evolving and keeping pace with the ecosystem. And so having something…in looking at the ONC's role as a convener, convening those, umm, you know, not only other federal agencies, but other industry advocacy organizations together to come up with really a two-sided list of best practices. Sort of a one, what you should follow as a person or a vendor of App of good will in this space and then the other side, sort of what as a patient or consumer you would need to know to use Apps. And so that's the type of thing I would see as a recommendation for very sort of tangible of what we might look to see.

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

W
Just go ahead.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
I just want to say one more thing. So the other thing for you all to keep in mind is there's actually kind of a nice temporal confluence here between the recommendations of the workgroup relative to the two proposed rules and the recommendations that were supplied relative to the roadmap. Because in the roadmap we specifically asked at Office of Civil Rights with their partnership asked people to give us comments on areas in which more guidance would be helpful.

And one of the areas that came clearly to the fore relative to the roadmap was more guidance on how liabilities within the system rest between a discloser and a receiver. When the receiver does something inappropriate and, so that's already documented and that'll be reflected as we go through executing on the roadmap, and you can see how that implicates a physic…for example, to Paul Egerman's comments, a physician's worry that by working with the patient on this empowerment tool of the API, they somehow absorb something that is dangerous to them. We don't want that to happen, but we do want the patient to be empowered. So we're…there's…that's what I mean, there's a lot of streams or threads coming together here, and you're going to have to let us braid them all up.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, so I wouldn't say, I think they are light on that kind of detail. I wouldn't say they…we intended to be light recommendations, I think we really meant for the guidance to be comprehensive and good; but in terms of the level of detail, certainly. But again, I reiterate, if there are specific missing recommendations that are not at a guidance level, but are much more…much stronger, or if you want to suggest topics that we would delineate for guidance, then it would actually be helpful to hear those more directly and specifically and we'll bring them up in the next workgroup meeting.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Thank you very much, Deven.

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

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Always an adventure.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
…an active discussion, right? An finally in the morning, it's the Consumer Workgroup. Christine.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Okay, so we have some really terrific workgroup members; here they are, very diverse group of folks and very committed. So I think we had about five calls getting ready for this, maybe more, as well as off-line work and so thank you to the group members and of course to Chitra Mohla, who is our lead workgroup staff, for her hard work. So we looked at two objectives, objective 5 and 6 and I'm going to give you a glimpse as to what those are as a refresher and then go into our comments.

So first of all, objective 5 is patient access to health information; so there are two pieces here, right? One is, you offer this access and make it available to 80% of unique patients within 24 hours of the information becoming available to the EP or to the EH. And then measure 2 is around using the certified EHR to identify patient-specific education resources and providing those electronically, so no longer on paper as was the case in Stage 1 and 2, but electronically to 35% of unique patients. There's also a proposed exclusion which is the EP with no office visit or providers who are in an area with insufficient broadband.

So here are our comments. So first of all, we agree with NPRM around 80% of unique patients being able to access their health information within 24 hours. And there's a question in the NPRM, and so this is why we asked if Deven could go first, there's a question in the NPRM around, do we do view, download, transmit and an ONC certified API. Or do we just do an API, or do we do one or the other and so really what this would boil down to, is, so providers might not have to offer, for example, a patient portal which is the way that the view download function primarily happens today; so they wouldn't really have to always do a patient portal if they had been ONC certified API built into their EHR and then could recommend applications that a consumer could use to simply view and download their data through that mechanism.

So, the NPRM asks for comment on do we do both, one, the other and so our recommendation is to do both, although we do have some caveats. So the caveats are as follows; so we…well actually this is the background. So first of all, the group really understands that as a technical solution, APIs offer a lot of really important benefits, so potentially you have a lot of choice and ways that you could use your health information in the context of an application that is really suited to your unique needs and desires, what matters to you and your health and in your life.

So there's a lot of potential to break down the silos, so…address these issues or portal proliferation. I've got three portals; at my primary care, my cardiologist and my nephrologist, but really I can used an ONC certified API to bring all of that data together. So there's a lot of really good potential in APIs, but we have some concerns as well. So there…there are a couple of caveats that we wanted to hinge our recommendation on.

So the both recommendation is really contingent upon first of all as we just discussed, adoption and implementation of the API related recommendations you just heard from the Privacy & Security Workgroup. Second of all, a really concerted effort to educate small practices in particular and hospitals about APIs; as Deven said, you know, the providers are really likely to get a lot of questions directly from patients and families about how this works? What App should I use? Where else can I use it? And so the idea that we really need to help these practices understand how to answer those questions and how to be a partner in this process is going to be essential, particularly obviously for those who are offering the ONC certified API. So we don't want to leave providers sort of dangling out there, we really want to help them by giving them good resources in this area.

Third, we think that it's important to consider, and we're not suggesting that this is done, but from a technical perspective we need to know more. But we need to think about certifying additional functions of APIs other than just download transmit. And the reason is that if we are to go to a place where people could actually select the option that works best for them, offer a portal, offer an API, offer both; then we need to make sure that the APIs are going to have the same impact with respect to functionality offered to consumers to fill those gaps. So how we think about, what are the additional functions that might need to be looked at; it will be very important in this process.

And then fourth really is a clarification which is the APIs need to be publicly available. It wasn't clear to us in the rule that the APIs would be published and publicly available. The concern that we had was that if APIs are in fact proprietary and everybody develops their own API, that we would end up with instead of portal proliferation, we would have API proliferation and we would have a whole bunch of Apps, you know, that I can't…that don't really end up sharing somehow in some way. So being able to be publicly available would address that.

So we think that this approach of offering both view, download, transmit and APIs would give the marketplace time to figure this out, you know, what really works best? I also suspect that there are different options that will work better for different types of providers and specialists. So how we figure out what the impact is on consumers and on providers, unintended and intended consequences that will be really essential. So we felt like maintaining both was really important.

We also felt that maintaining both is going to continue to assure consumers that they'll have these really valuable functions like secure messaging, online medication refills, etcetera that they're using today in the marketplace, but because the APIs would potentially only be certified for view and download, we want to make sure that consumers still had access to those features and functions. And in fact, under the way that Meaningful Use for Stage 3 is being proposed, it turns out that you pretty much have to offer a portal anyway because that's how you'll get secure messaging and patient education materials and probably also patient-generated health data, So it really needs to be this way kind of de facto, but we think it's a good idea .

We also talked about the fact that we agree with the second measure as proposed, which is providing electronic access to patient-specific education resources to more than 35% of patients in the reporting period. So finally, and then I'm happy to stop and maybe take some questions before we turn to objective 6.

We also looked at the exclusion that was proposed for insufficient broadband. And what we essentially said was, similar to what I think Micky said earlier, we feel like providers should still actually be accountable for this patient engagement function of offering my health information to me, but that perhaps, since this is really a consumer focus, why don't we make it instead of it's being a complete exclusion, why don't we have it so that the provider makes the information available online, but they're not accountable for getting "X" percent of their patients to actually logon and use it because they may have broadband issues.

But really we felt like consumers are increasingly using cell phones and cellular data today, many of them will want to use libraries, churches, you know, and other outlets for broadband access to access their health information, so we want to make sure it's minimally available to them, but not hold the provider accountable for getting a certain number of patients to actually go online. So, questions about any of this or comments before I go to objective 6, which are more measures related to these functions.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Why don't we go with objective 6, because…time. Thanks.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Sure, so this is objective 6 as it was proposed. So it's three measures that are focused in both care coordination and patient engagement. The three measures, you would only have to meet two out of the three; you'd still have to report on one under the proposal, but you really only have to do two out of three.

So those measures are; first of all, getting 25% of your patients to actually go online and either through view download/portal or through an API and an App that would be able to view and download their health information. Second of all, and this is a big change from Stage 2, instead of patients sending a secure message, it's been proposed for the provider to send us a secure message to 35% of unique patients or to respond to a message that was sent by a patient. And then the third measures is that 15% of unique patients you can do either patient-generated health data or you can incorporate into the record data from what's called a nonclinical setting. That's a little bit of an unfortunate name; it's not actually non-clinical, it just means non-MU eligible provider so nutritionist, physical therapist, things like that. So it's not non-clinical, don't take offense and I didn't write it.

Okay. So essentially what we said as a workgroup are, look patient engagement and care coordination are totally essential to new models, but we need to separate them out and that the rule combines the concepts in a way that would allow a provider to potentially bypass patient and family engagement. Because what they could do is, focus on…they could pick their two out of three, right, so they could focus on sending a secure message to patients, which doesn't really require the patient to do anything or engage in any way and they could get data from a…this non-eligible meaningful use provider.

Those are awesome functions and features, no question about it; but they're really about care coordination. And so we felt like there was a missing element here and we needed to create some ways that might actually fulfill both of the objectives of care coordination and patient engagement. So we've developed three options for doing that and we have a favorite, which I'll…you can see here is highlighted in green.

So there are three options, A, B and C. Under option A, you would have…the provider would have to do all three measures; however, there are some changes. So first of all, instead of trying to get 25% of patients to go online, we're suggesting across the board that that threshold be lowered to 10%. The reason for that, and it may sound odd coming out of the Consumer Workgroup, but the reason for that is that we felt that the 5% threshold it in Stage 2 really scared a lot of people, providers in particular. And so jumping to 25% might create such a fear in the marketplace that it would lead to people really gaming the system.

I have had colleagues who, for example, have already been locked in the exam room until they logged onto the portal in the office, you know, they're not really meeting the spirit of this objective, but they're really concerned about it, so they are doing all kinds of interesting things to game it. We want to prevent that so we felt like going from 5% to 10% is still a signal that patient and family engagement is essential, it's essential in new models of care, you can't get there without it; but wanted to be more reasonable about that, so that's across the board for all three options.

So again, in option A, you would have 10% of your patients going online through either/or. You would also have 35%...the secure messaging as I described it would remain the same, which is providers send and then finally for patient-generated health data, keep it the same as it is, which is really an option, either it's actually patient-generated or you're getting it from another non-MU setting. But really an important clarification that again applies across the board, patient-generated health data does need to be provider requested.

If you guys remember, that was the original recommendation that we made I think it was last year, early last year with respect to Stage 3 because when you have patient-generated health data that is provider requested, it answers a lot of the questions and concerns stated in the NPRM like, do you plan for this? Well of course you have to, right? And do you just turn it on and not let anybody know; is it automated, in other words? Do you have to verify it from an independent, you know, in some sort of independent fashion? If its provider requested that answers two-thirds of those questions and will mean that hopefully providers are working with patients to choose the type of data that they're requesting, figure out the mechanism that will work for getting the patient-generated data into the record, all of those things. So that's option one, which is basically a small change in number one, but do all three.

Option B, which is our favorite here as a workgroup is require all three measures, again change the threshold to 10% for measure 1. Keep measure 2 the way it's been proposed, which is the provider sending and then measure 3, which is separating out the patient-generated health data from the non-MU eligible provider data and moving that data down to the HIE objective. So what we felt like, one of the things that I know Micky talked about in his presentation to the workgroup is that the more trading partners you have the more you're going to be able to trade.

So this would essentially change the HIE objective to say, you can send or receive a summary of care or the receive can also be receiving data from a non-clinical setting. But this provision would then be tightly focused on patient-generated health data in the true sense and that the threshold, because the threshold…now it's focused on this data type, the threshold would be lowered to 10%.

All right then option C would be meet two out of the three, instead of all three; so again, lower the measure 1 threshold to 10%. In measure 2 the big change here would be moving secure messaging, since it's a provide send, and making it be an option under health information exchange, which is the objective 7 that Micky reviewed earlier and converting this back to the 5% of patients actually send the secure message that we have right now in Stage 2. So that way it is directly patient engagement and then finally changing the patient-generated health data, you know, as I just described which is, you know, you're kind of moving that, the nonclinical to HIE, you're moving the secure messaging there and really focusing in on true patient-generated health data.

So, this is, just so you guys have it, is a little bit more expanded view, it's in your slide deck, but this is option B that I just described. And just an overall comment that we agree with the proposal in the rule to not count administrative or financial data as…toward the secure message threshold.

So given time, I'm not sure it makes sense for me to go through this; if you guys want I can; this is how option C, if the committee were to select that, this is how option C would change and we had asked Micky; we know they didn't have more workgroup meetings scheduled, but we'd ask Mickey to maybe take a look at this. So we could have that discussion, if folks are interested, but this is how option C, if selected, would change the health information exchange objective 7. Okay. So…

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Good, thank you, Christine. Questions, comments or lunch, I guess.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
I love going right before lunch.

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

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

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

Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System
In your option B, in your measure 3 it makes a total…a whole lot of sense for a provider environment as a physician...you articulate how you see that really playing and creating value in the hospital environment?

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Sure. So the term patient-generated health data is not strictly defined in any sense, so conceivably a hospital could use this in the ways that were most useful to them; so this is really about, for example, you know, preplanning, you know, getting surgical information or prep information for surgery that's going to happen at the hospital. This could also…and so you can have…in preparation for an admission or something like that, this is where I think it will be most helpful.

I think for hospital folks, I would ask them to weigh in on that because I'm not clinical, but some of the hospital repre…or the folks with hospital experience on the workgroup felt like the 10% was very, very achievable in the hospital environment. It also does not have to be before the encounter, it could be after the encounter; so we talked about…or after the admission, for example. So we talked about, you know, post-admission patient reported outcomes or what's going on with the discharge plan that we recommended for you? How are you doing, progress against goals? So there's a huge amount of flexibility for the providers in how they might use this criterion and that's the goal. So it could be a survey, it could be…you could use secure messaging; whatever it is, it just needs to be health data not administrative data. So, there should be some great value for providers here.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Anything else? Good, thank you, Christine. So let me try to summarize where we are in terms of the four groups that you've heard present and like to see if we can't get some agreement on at least part of them. So the first group talked about the overall approach and three of the objective…wait, like four, five of the objectives. The second group talked about interoperability. The third group talked about privacy and security and the fourth was consumer.

So, do people feel comfortable with the recommendations that came forward in the first group, which talked about CDS, electronic prescribing, public and population health, umm, there's one…CPOE and the overall approach. Did that seem to fit well with folks?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
I have a procedural question?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
That's being investigated.

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
We do have both old members and new members here…

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
…so we can't have all members…

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Right, we can't double vote.

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

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
The old members vote as they've been a part of the discussions and especially David and Christine have presented some of the recommendations. So, the new members should abstain themselves from the vote.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Right. Thank you. And that would apply for the virtual call as well.

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
But thank you for…that's right. Okay, so how do people feel about the fir…the recommendations coming forth in the first group presentation? I didn't hear any major objections…

Christine Bechtel, MA – President – Bechtel Health Advisory Group
…the quality measures piece in that one, right?

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
So I think David had some additional framing that he wanted to add, didn't he?

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Yeah.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Yeah, we accepted that in terms of…

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Great.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
…we're going to forward with it, yeah. So I think that…what I am trying to do is, we only have an hour and a half together on the phone, we're going to have to cover both…anything that we have left over from this presentations and the one in the afternoon. So I'm saying that that the first presentation won't be repeated, we'll make some changes in response to the comments, like we normally do.

The second one had to do, this is where the selfies came up and probably three or four topics that could either use some language, or in the case of selfie, I think we had difference of opinion; we need to figure out which opinion to go forward with as a recommendation. Or it's possible that it's actually clarifying, as I mentioned, it's sort of there's the coordination of care and there's the exchange of information and maybe there's a way to clarify that. So it sounds like that group would come back and concentrate on the three areas where we had some discussion here.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
…another presentation, right?

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

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
The impact of the last presentation…

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
And that's a really good point. Is that okay Micky? Okay. The third group was privacy and security and I think the discussion point there is around the level and types of "intervention," and I'm including guidance…even like guidance to be intervention, in terms of trying to weigh the balance between the obviously potential benefit and the risk for harm in terms…from a privacy point of view. So we'll work with Deven on what kinds of options to work out or flesh out so that the group can vote on one or the other. Okay?

The Consumer Workgroup, I didn't hear anything. Her final matrix in terms of the changes in the threshold and the moving over into HIE. Any disagreements with that or do you want to…is there anything you want to bring back from that discussion?

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Option B.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Ah, we're assuming option B, I guess.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
That's what I'm trying to clarify.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Right. Okay, hearing none, so we're going to not revisit the group 1 presentation. We're not going to revisit the Consumer. We will visit topics from the interoperability and privacy and security. Good. And then anything else we have left over from the afternoon's discussion. Okay, thank you. Why don't we open for public comment, please?

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
If there's anyone in the room who would like to make a public comment, please come up to the table. Please state your name and the organization that you're representing. As a reminder, public comment is limited 3 minutes. And while we wait for those to get settled at the table, Alan if you could please open the lines.

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

Thomas R. Bizzaro – Vice President Health Policy & Industry Relations – First Databank, Inc.
My name is Tom Bizzaro; I'm a pharmacist and vice president of health policy and industry relations for FDB, First Databank. I would like to comment on the issue raised by Dr. Tang on defining the enabling of drug-drug interactions. I would recommend that enabling DDI include allowing customization DDI by providers. This would include allowing providers to determine the level of severity actually used as well as customization of individual alerts to make those alerts more pertinent to the practice setting, the knowledge and experience of the healthcare professional and the type of institution.

As a data knowledge provider, FDB recognizes that in some instances alerting at certain severity levels and the customization of individual or class of alerts is appropriate and increases usability. I would also like to say personally that I'm pleased to hear that Dr. DeSavio will be continuing in her role as National Coordinator, along with this role as Assistant Secretary of HHS, and I'm also glad that I will not be managing her schedule. Thanks for the opportunity to comment.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you. We're going to go to the phone, Adrian Gropper.

Adrian Gropper, MD – Chief Technology Officer - Patient Privacy Rights
Hello, Adrian Gropper with Patient Privacy Rights. My comment relates specifically to interoperability for patient-centered care. The fragmentation of transports and ad hoc governance mechanisms in the Meaningful Use introduce numerous compromises when viewed from the patient perspective. These compromises are most evident in a lack of transparency, inadequate accounting for disclosures, over-reliance on consent instead of authorization, inability to segment information, interoperability with non-HIPAA services and loss of provenance in patient-mediated exchange.

We urge Stage 3 take the spirit of the JASON Task Force to heart and define the public API in terms of the HIPPA patient right of access. The public API must require the ability of the patient is known to the practice, to completely specify the endpoints that would be allowed bi-directional access using policy neutral FHIR OAuth 2 standards. The public API must make available all of that patient's information accessible in digital form to anyone else via any other transport under other HIPPA clauses, including treatment, payment or operations. The public API must not impose any restriction on the nature, security, location, trustworthiness or other policy-based delays or constraints by the institution holding the patient's data, unless the institution has disclosed such restrictions prior to patient registration.

In summary, Meaningful Use Stage 3 must define the public API and the patient right of access and delegation to the public API so as to resolve the fragmentation and governance issues that we have today. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you, Adrian. Please go ahead.

Kelly Cochran, BSN, RN, MS – Policy Advisor – American Nurses Association
Hello, my name is Kelly Cochran and I'm a Policy Advisor with the American Nurses Association and my comments today are really dovetailing on the previous conversation regarding care plans. As part of the process that ANA uses to inform our comments for the proposed ruling, we receive feedback from experts, and we had particular comments from an expert ANA member that I'd like to read briefly from in regards to care plans.

The expert is Dr. Laura Heermann Langford; she's from Intermountain Healthcare and her comments are in alignment with the care plan workgroup at HL7, the international standards group. Dr. Heermann Langford is also concerned that the care plan is being…how the care plan is being represented in the MU3 document and asking for a care plan field is thought to be inadequate. This downplays the needs of…and importance of the care plan. It's analogous to the concept of a care plan section in a physician's note. The work that Dr. Heermann Langford has been involved in recognizes this is the main difference between physicians and other care disciplines in approaching care planning.

To physicians the care plan is a section and they're primarily a retrospective note that usually only includes orders and follow-up instructions. Other disciplines usually approach the care plan as a unique and distinct perspective document that includes not just the upcoming orders and follow up plan, but also contextual data surrounding the overall patient's care for such preferences as…care such as preferences and care barriers. While it is recognize and commended that the Meaningful Use 3 document is calling for the inclusion of goals and instructions usually seen in care plan documents, not plan sections, it is concerning that these will not be sufficient in adequately coordinating and ministering care.

The testing requirements for MU2 have called for creation of a small number of specific goals, such as weight loss and smoking cessation. It is concerning that these will…I apologize…and patient instructions provided. They did not call for progress towards goal or other related goal-tracking and care plan data as test data. Approach…this result in these few items being sufficient for all care plans and care planning.

She's concerned that the approach purported in the MU3 document will lead to a check box approach of including a goal or two along with a few instructions, but will entirely miss the intent of the true interdisciplinary, coordinated, patient-directed care and perhaps the document could be improved in this area by simply removing the word "field" and call for "care plan including goals and instructions."

She provides further comments that I'd be willing to share and will include in our comment. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you. We have one final comment, Madeline?

Madeline Jay, CIPP/US – Senior Software Engineer – Johns Hopkins Hospital
Hello, my name is Madeline Jay and I'm with the Johns Hopkins Hospital and my comment is regarding interoperability and HIE. Some EMRs define security by view, and if you remember back, I can't remember what month it was, when a patient with Ebola went into the hospital in Texas and the nurse didn't…had the view and one of the doctors didn't have the view saying the patient had been out of the country. And I am concerned because if a doctor's view doesn't contain information or a care provider or prescriber's view doesn't contain the information and we don't allow selfies to integrated networks that we could miss patient information, necessary patient information. That's all I have to say. Thank you.

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Thanks very much. We are a bit behind schedule. We're scheduled to take, right, at this point a 40 minute lunch and reconvene at 1:30, is that okay with people? We're trying…okay, so we'll get back together at 1:30. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Okay, I think we are ready to be started, if everyone could take their seats. The lines are open.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay. Welcome back after lunch and we're going to start off…so the second part is going to be on the Certification…the 2015 Certification NPRM and there are two sections we have. We once again are visited by Deven McGraw, who is going to talk about the privacy and security implications of the Certification NPRM and then followed by David Bates and Larry Wolf on the Implementation, Usability and Safety aspects. So Deven.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, thank you Paul. Once again, here we are. So there were a couple of parts to the Certification Rule that fell into our sphere of influence and activity, in part because they were issues that we took on previously; and that's the issue of Data Segmentation for Privacy. And within the Certification NPRM, are the proposed adoption of two new certification criteria that would focus on the capability to separately track and segment documents that contained sensitive health information and there's a criteria for DS4P send and DS4P receive.

What's been proposed is an HL7 vetted, fully balloted standard. It would not be part of the base EHR; so that means that providers could purchase software that included these standards and it would be…and if they intended to use it to meet Meaningful Use, for example, exchanging data that are subject to more sensitive privacy laws, such as the federal rule governing substance abuse treatment information from covered substance abuse treatment providers. And that's the rule that again, has protections that follow the data, regardless of who has it, or maybe potentially other state laws that grant additional privacy protections to certain types of information. And so if a provider wanted to be able to actively exchange that and potentially boost his or her compliance with the law, they could purchase the module and it would be certified to that standard and therefore they could use it to count certain transactions in their meaningful use; but it's not part of the base EHR.

So here's a little bit more details on the proposal for send; the technology has to enable a user to create a summary record that's formatted in accordance with the C-CDA standards, but then is able to be tagged and restricted and subject to restrictions on redisclosure in accordance with the DS4P send standard from HL7. And then on the receive side, the technology has to enable the user to be able to receive the summary record that's been tagged as restricted and subject to restrictions on re-disclosure, again according to that HL7 standard.

What is tested in certification is the ability to segment at the entire document level. And so while there is some technical capability out there to be able to do this more granularly, so not at the entire C-CDA, but with respect to data within it; but that's not what has been pilot…previously piloted and that's not what has been proposed for certification.

In general, we agree as a workgroup that the proposed criteria are a good initial step toward the ability of an interoperable healthcare system to be able to compute and persist these…any applicable sort of set of privacy standards that might apply to data. And we also think that this type of technology should certainly be available to those who seek to implement it.

But we are not sure that the criteria are necessarily ready for certification. And so ultimately the decision about standards maturity is one that is typically taken on by the Standards Committee, and one that we continue to think is within their purview to decide. So our message is, there's value to this and there's value to getting more and more experience with these types of technologies, but whether it's ready for certification or not we think is something that the Standards Committee really ought to opine on and in accordance with the criteria that they use to decide, is this mature enough for certification versus being a standard that might be worth using in the marketplace.

We had a lot of concerns and frankly, we had looked at this issue as a Tiger Team and brought it to the Health IT Policy Committee previously, in terms of Data Segmentation for Privacy as it had been piloted by the Standards & Interoperability Framework using the model of Part 2, which is the federal regulations that govern substance abuse treatment providers and the data that they create and then share.

And then once they've shared it, frankly those protections and obligations about getting the patient's specific authorization for any redisclosure attached to that data. And as it goes down the chain of being shared, the protections have to be persisted each and every time. The sender has to persist them, the recipient has to acknowledge them and then also persist them with any subsequent sharing that may occur. And we had recognized, even at the time when we first looked at this technology after it was piloted; there's a lot that gets put on the recipient provider for which the technology is a good step forward, but it doesn't sort of get you necessarily completely over the goal line.

First of all it applies to the entire document as opposed to necessarily just the data that would trigger the protections. And in the case of Part 2, it's data that has the potential to identify someone as a person receiving substance abuse treatment or a person who is experiencing issues with substance abuse as opposed to every piece of data or data that is clear it comes from a substance abuse treatment provider and so therefore that implication is there, but that may not necessarily be the entire document.

When you have document level sequestration, all you can do is read the document; it can't be parsed and interdigitated into your EHR, so that makes it harder to use clinical decision support on that data. There's a lot of policy uncertainties about, well, is the data still protected if I get it from the patient voluntarily as part of a patient encounter versus having it come from a Part 2 provider. That's a piece of policy clarification that we're hoping that the Substance Abuse and Mental Health Services Administration or SAMHSA will provide, but that hasn't necessarily been provided yet.

And that yet the recipient of, you know, the sender's piece frankly is a little bit easier. I've gotten the patient's authorization to send it. I've sent it with the right tag on it that says the information is restricted, but that that then triggers a lot of uncertainties on the recipient side and whether you have that receive technology or you don't, you get one of these documents, the obligation still attaches. And so, you know, and then of course as we discussed in…when we first talked about this criteria, it's not clear that it fits that well with other types of sensitive data laws that may not have those same redisclosure prohibitions attached to it, so it might be an over-fit for that environment whereas it's not clear that it gets you all the way there, even in the Part 2 environment.

And then, of course, the whole idea that data would be withheld from a healthcare provider that might be relevant to a patient's care is very unsettling to a lot of healthcare providers. Even though the law is already on the books and the issues of sort of weighing, you know the need to provide patients with additional guarantees of confidentiality versus the potential impact on treatment were weighed when those laws…presumably when those laws were passed and continue to be weighed and vetted. But it comes up each and every time this issue lands on our plate and so it's worth mentioning again that this is something that makes a lot of people very nervous, even though there are a lot of patients who think it's, and patient advocates who think it's very critical to have this. And of course the laws are on the books.

Again, even at a voluntary level and frankly, this is what the Tiger Team had recommended be potentially pursued in an era where we had voluntary certification criteria as opposed to the approach that's taken now which is that there isn't really necessarily such a thing as voluntary certification criteria, but there is a distinction between what's required for the base EHR versus what a meaningful using provider might decide that they just don't necessarily need to purchase in order to meet their obligations under Meaningful Use.

You might have to verify offline if you're a sending provider that in fact the receiving provider knows this document is coming and is covered with this technology and ideally to know that the receiving provider has some capability for being able to honor the redisclosure prohibitions, whether they have DS4P receive or not. So there is a bit of out of band communication that might be required because we don't have a capability today of sort of flagging yes, I can; yes, I'm willing in terms of receiving documents that have been sequestered or segmented in this way.

And of course, as was pointed out in the interoperability roadmap and as we discussed in our comments there, when you go out of the sort of federal Part 2 regime and you get into the space where you have a lot of different state laws that provide more granular privacy protections, they may be aimed at a lot of similar types of data, but the laws themselves are not harmonized in terms of when consent is required, what are the elements that are required to be collected in order to have the patient consent to sharing of that data. And so without that, it's very hard to say, from a technology standpoint, to develop the tools that can then be useful to providers across a multitude of settings involving sensitive data.

So we recommended the Standards Committee address this issue in terms of standards maturity. But nevertheless, we're ha…we do think that there is value, not only to having the availability of the technology; we're happy to see that there is an HL7 standard that has been balloted and vetted out there. While it might not be mature enough for certification at this stage, depending on what the Standards Committee thinks, it is important to have it available out there to enable this data sharing.

And because we think that the more granular type of segmentation, as opposed to the whole document approach, is going to be really critical and we don't have enough on the ground experience with how well DS4P would work for that more granular segmentation, whereas we do at the document level. And without some experience in the field with how that works, whether through planned pilots or through some subsequent study of in the field experience, sort of like a pragmatic clinical trial, we…we're never going to learn and be able to progress the technology without that.

So, we just decided that it wasn't our role to say whether or not it was mature for certification, but we definitely see the value in having these technologies available and begun to be used by those providers whose patients…who have patients that are going to be referrals from substance abuse treatment providers, that live in states that have additional granular laws that are going to attach and the ability to be able to utilize technology…begin to utilize technology, even if it's imperfect, to be able to try to help them comply with those recommendations, is essentially where we landed.

It is admittedly in a bit of a different place than where we were as a Tiger Team. We have some new members on the group and I think the other thing that was persuasive to this particular workgroup is that even when we said, back not even that long ago maybe just over a year ago, that we thought DS4P, the pilots were…took an initial set of first steps and it should be considered for certification, we had a laundry list of concerns attached to that. And we said the Standards Committee needed to weigh in on the maturity issue.

And so here we are with a proposal for certification without the weighing in from standards and without all of the sort of angst and concern that had been a part of our original set of recommendations, but somehow didn't necessarily made it into the proposal…to the proposed rule.

And so with respect to pharmacogenomics data, there is not a criteria or criterion necessarily specified around the privacy and security of this data, because it may, in fact, be covered by more sensitive data laws. There was a set of questions in the NPRM for which we tried to address a few of them. And one of the questions was whether DS4P could be leveraged as a technology that would enable providers to collect pharmacogenomics data and yet still be able to protect it in those circumstances where additional, in this case it would be state law, would apply and would…may require more stringent consent than HIPAA does for the sharing of that data, because it involves genetic data.

We essentially believe that it's premature to think about introducing certification for pharmacogenomics data generally, in part because while there may be a few use cases for which the science has clearly established that there might be some value to having it for prescribing purposes, it isn't so widespread as to suggest that it's…that a standard for that…for the data, particularly around the privacy and security aspects of it necessarily make sense at this time.

And I think probably more persuasive to us was the idea that the for DS4P technology, with its entire document level approach, for the element of pharmacogenomics data that might be in it, may not be the right approach. Number 1, the state laws may not have the redisclosure prohibitions for which DS4P was designed and so it…that would create a potential technology over-fit. Because if you don't have the recipient with an obligation to then further protect it against disclosure, they don't need the redisclosure pieces to attach to it, which means that they could use it in clinical decision support…could allow it, you know, the danger with having it used in clinical decision support as you may remember is, it might be inadvertently disclosed without the flag that indicates that it's sensitive.

And since the real value in having pharmacogenomics data is to enable clinical decision support, so that you're prescribing the right medication for the person with the particular genetic profile for which it's clear that it would be helpful to have that data, the inability to use CDS, clinical decision support on pharmacogenomics data that's been protected by DS4P, makes it a lot less valuable in that particular context.

So our sense was that this was an area to keep your eye on, from ONCs perspective to keep seeing where it's evolving both in terms of the science, because clearly there were members of the workgroup who definitely saw a lot of promise in the use of this data for prescribing appropriate precision medicine prescribing purposes. But others on the workgroup said, well, you know, there might be one use case or maybe two, but it's so nascent that it just feels premature to be loading all of this technology into systems to accommodate it when even the technology that we do have, at least with respect to the privacy and security issues, doesn't really…it's not necessarily the right fit for this particular type of data because of the consequences of the use of the technology and its potential impact on the use of clinical decision support.

So again, we're not the workgroup or not even the committee that says whether things are mature enough for certification. But we have opined on this issue of DS4P in the past, so given that it was in the NPRM, and I think, I suspect that ONC thought that they were doing what we asked it to do, but certainly the opinion of this workgroup is that Standards Committee should decide if it's really ready for certification. Because we certainly as a workgroup consensus would not have come to the consensus that we thought that it was, this particular workgroup. And…but we still wanted to make sure we communicated that there's value to continuing to go down this road, because these laws do exist and the need is very great to be able to share that data.

Only earlier today we talked about having behavioral health as a priority. If we're making exchange and collection of behavioral health information and focusing on it for quality measurement purpose is a priority, we've really got to figure out how we're going to be able to do that and accommodate the laws that provide additional protections for this data which, as much as some people wish they would go away, whether they do or not, or whether they should or not, is not really not a question on the table for us to exist. And we have to help providers accommodate them.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Thank you, Deven. Any questions or comments for Deven about this…these two points? And Paul Egerman is on the phone.

Paul Egerman – Businessman/Software Entrepreneur
Yes, thank you Deven. My comment is, even if the Standards Committee decides that the HL7 standard is mature enough for certification, I think it is a mistake to certify this data segmentation approach. Because the certification process in effect is a process which ONC and the government votes and says, this is the best technology approach to doing data segmentation and causes vendors to go to that approach. And, you know, Deven as you said, there are alternatives that are more granular and this is an opportunity where we need some innovation. I mean, there's a clear need for this concept of additional privacy and it to me, would just be a mistake to choose one approach and say this is the one that's going to be certified, because I think that that's going to thwart the possibility of innovation of other approaches.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, Paul that's a great point and I remember that you raised it before; I think where…what we were struggling with before and what I think we're continuing to struggle with now is, does certification help lay the groundwork for adoption of this and further refinement of the technology? Or does it squelch it because it hardwires in a certain approach? And clearly you believe it's the latter. I think initially the Tiger Team felt it was the former and we've evolved as our membership has changed to be more a majority of folks feeling like it's…worried about the latter.

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

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So my question is really to ask you about a particular consideration because we spent time this morning talking about the importance of medication reconciliation and we also talked about the importance of being able to have a reliable problem list and one that accurately reflected a patients conditions. And so as I think about medication reconciliation, has there been discussion maybe in this group or others, some medications are known to be specific for those with substance abuse disorders.

So I'm thinking about prescribing Naloxone so that a patient has it available or their family could administer it to them, buprenorphine is another one. Methadone of course has more uses than just for substance abuse. HIV related drugs are fairly specific and not used for other conditions. And so what was the perspective of how there would be a reconciliation of these important but competing goals?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Right. So the technology, if the segmentation is applied at the document level, which is what the certification criteria would direct, because that's what DS4P focused on. If that data were…on those drugs were in that document then it would be a read only document. So the physician…the EHR would not sort of automatically act on it, populate decision support and be able to tell the healthcare provider, for example, there's a contraindication, potential drug-drug interaction with the drugs you're taking. They would have to mentally be able to sort of do that.

And for Part 2 data, so this is data that comes from a covered substance abuse treatment provider that is sent to the physical care provider with the restriction on the data, it's kind of not clear from a legal standpoint whether the provider can then subsequently get that information from the patient. Because what's interesting about Part 2 is that it covers the data when it comes from a substance abuse treatment provider, but it doesn't cover the data when the patient voluntarily tells you what it is. So that leaves open a question, well what if there's…is there an intervening act, right?

If the data comes in from the substance abuse treatment provider, can the provider look at it and say, well I wonder if I could subsequently source this data from the patient and then it wouldn't be covered and then I could hand-enter it in, or, you know, however it gets entered into the EHR through click the box and it wouldn't be covered by Part 2 and then I could put it in my decision support tool. And then, you know, so in some respects we have one of those problems where not only do we not have the technology in exactly the right place, we also have a set of policies that are not necessarily as clear as we would want. And that's just talking about Part 2, which at least it's one federal law.

For HIV test results and HIV drugs, depends on the state; may not be protected at all in one state, may be protected in another, you know, it may be maximally protected in another state in terms of the consent. And that's the harmonization issue that was raised in the interoperability roadmap. So, it's a bit of an uncertain playing field and remains one today and it's one of the reasons why there's difficulty in getting behavioral health providers into the exchange…into health…formal health information exchange that has been setup because there are concerns, well we won't be able to…people can't handle this data and we're just going to have to keep sharing it by FAX.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
So, it's messy. And unfortunately while DS4P is again an important step forward, by itself it probably could never fix the mess because there are policy implementations to be fixed, too. But even so, in terms of it being sort of ready for certification, we're sending it to standards. Paul says, not ready. There were a number of folks on our workgroup who said, not ready.

What we were able to get consensus on what that we should let standards decide whether it's ready because I think there were some members of our workgroup who were more hopeful that we could…who were of the view that certification lays the groundwork for more innovation versus Paul's I think very well-articulated view that certification is a stop to innovation because it's hardwires something in. Which view is the right one? We punted. Help us Standards Committee.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay, any other comments? Okay, thank you, Deven. So David Bates and Larry Wolf are going to walk us through the Implementation, Usability and Safety Workgroup recommendations.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
Great. We had a lot of spirited discussion and we'll try and go fast. This was our workgroup. We had an awful lot of things to address and we divided into three groups to address all these. Group 1 was led by Steven Stack, group 2 was co-led by Janey Barnes and Bennett Lauber and Group 3 was led by Michelle Dougherty. And I'm going to give you some overarching thoughts at the beginning and then we're going to go into some specific thoughts. And we provided a very long appendix, which includes narrative, of all our recommendations in detail.

So we recognized that redesigning the program into a modular approach adds some flexibility, but we felt that it also makes the program substantially more complex, especially for stakeholders who have to address multiple modules and certification requirements and various agencies and regulators and payers. And because of this change, ONC's role as a coordinator is going to be even more important than it already has been.

We thought that this step would bring forward several specific challenges; one, that because the program becomes more complex, it could drive up costs for certification, particularly for those who have to certify and test for multiple modules. Second, we thought that it might be hard to keep the modules and their requirements at the foundational or building block level and not expand their scope unnecessarily. And then third, other parties that identify certification paths and/or require compliance with a certification module could erode the foundation building blocks if they required a module that required modifications and add-ons.

In terms of the utility of CHPL; we appreciated the recognition in the NPRM that CHPL is hard to use, although there's been some recent developmental work on it and it's actually now substantially better than it was, even just very recently. The NPRM says that ONC is going to rewrite CHPL in 12-18 months. We thought that was a long time. It would be nice to at least have some iterations more quickly than that. And it will be really helpful if the data can be made more usable as is proposed.

Another point that came up was that some software comes from sources that are not provided by vendors and providers use self-developed software and open source software and there are vendors who have a hybrid of software from multiple source types so that really creates some issues in some situations.

There was a major overarching concern that certification was being used for a lot of different purposes now, including HIT Safety, Vendor Business Practices, helping individuals with disabilities and while the group felt that all those areas where important to address, there were members of the workgroup who very strongly felt that certification was not the best way to address some of these issues.

Another issue was the shift from functional requirements to interoperability and privacy and security and we noted that there was a shift away from functional requirements with respect to these areas. There were workgroup members who felt that in this version the criteria were focusing solely on interoperability and privacy and security and that functional capabilities should not be included.

With respect to the timeline, there was concern that the timeline in the NPRM might not allow sufficient time for eligible providers to being their reporting period. And while even though the start date is optional, health IT suppliers would have to deliver full operational software to providers well in advance of that date if the providers are actually going to be able to implement.

And complexity; this has come up multiple times today, but some workgroup members felt that this version of certification was not responsive to feedback, that previous iterations were too complex and that this makes things even more complex.

In terms of maturity of standards; some workgroup members had concerns that some proposed standards haven't matured enough to be promulgated through regulations and they suggested that ONC and CMS consider using other mechanisms supportive of pilots and limited deployments in production environments.

In terms of variations among providers certification; there was a feeling that certification requirements that impact one segment of the market should also apply to the partner whose being certified. An example would be, if your…if a vendor is sending data to a health department, the…there was a suggestion that health departments also should go through some certification approach. The notion was that this is going to add significant cost and complexity if providers and EHR developers are required to develop and implement multiple interfaces rather than say a standard interface.

We had a lot of discussion around user centered design. And the feeling amongst our usability experts in particular was that the NPRM requirements, if adopted, contain some instances in which the basic definition of a user centered design process would be violated. For example, if you replace summative testing requirements with…by just focusing on formative activities. What they felt was that that suggested a user centered design process is not required. And then there was also a feeling amongst that group in particular that the safety-enhanced design requirements don't require a process that includes all the things that are listed there under…as bulleted, which they should. So those are the overarching thoughts.

Again, group 1 went through this set of things, and I'll just go through these, particularly focused on principles of proper conduct for ONC and the ACBs and then decertification. In terms of proper conduct, we felt that there were a number of areas where clarification was needed and we provided a list of those. I won't go through them all now. With respect to transparency, some members supported the notion of transparency as put forward, other members were skeptical about whether or not the…having vendors expose more data around what they were charging would actually be helpful.

With respect to compliance, there was a strong feeling that it would be helpful if ONC could develop a more rigorous and protocol-driven complaint process so that complaints come in and they could be managed. With respect to open data, we were generally supportive. We suggested adding a few specific data elements. With respect to adaptations, there was again some division within the group; one substantial group, within the subgroup, felt that these recommendations were already in place and that this would be redundant or duplicative and another group felt that the recommendations could be helpful.

We had a lot of discussion about decertification. This would be related to blocking interoperability, typically. Our feeling here was that if this were to be implemented, it would require further consideration and study. We noted that providers could be blocking, as well as vendors and blocking by either providers or vendors could be appropriate, depending on the clinical circumstances.

And finally, this is a big stick in that if decertification were implemented, there would be major burden to both providers who were using a previously certified product and there would also be burden to patients.

So overall I think the feeling of the group was, well it was reasonable to hold this card, it's not one that you would really want to play. And I will stop there and hand things over to Larry.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So picking up, David laid out the structure; we had three groups that looked at various sections. And so let's continue the discussion here with some of the safety-enhanced design questions. So, there were a variety of hot topics, and this was certainly one of them that got a lot of attention. I think some of this actually revolves around various levels of education and familiarity with what is safety-enhanced design? What is user centered design? How do these things really work?

The workgroup has had many presentations actually over the months about what leads to better design and so there was some of that informing our discussion as a group. And there was discussion in specific about whether this was something that would benefit more from continued guidance and best practice being promulgated or whether this should be baked into certification.

So having said that, the current certification criteria has led to some variability among the ATCBs in how they interpret it and act on it; some of that's been cleaned up, I'm told, with subsequent FAQs and advice from ONC. The current NPRM has 7 criteria that were felt in general to be helpful towards providing more consistency across how the ATCBs interpret what they're supposed to be doing with this.

There was some thoughts about getting further guidance from NIST in terms of providing some standard scenarios around usability so that there could be some comparisons among providers of is this a better or worse level of usability? And there were a bunch of specifics that had additional questions for clarification that are in our appendix.

And there also was a fair amount of debate about what's a sufficient number of test participants? The people who are deeply experienced with the usability were arguing that if you had less than 15 that you really didn't have a big enough sample to understand usability. And we had others who felt that given certain circumstances around the size of the development team or the target audience, that if this was self-developed software for a single practitioner to use, bringing in 15 test participants to assess usability when there's only going to be one end-user might be overkill. So this generated a fair amount of heat and we'll let that continue.

So continuing what David talked about about formative and summative testing. It was felt to be that we needed really both of these in place to provide a good balance. That retesting seems to already be addressed and so we were suggesting no real change in that.

QMS is another thing that spun up a lot of discussion because the word quality often gets interpreted to mean clinical quality. And so while this is looking at how systems are developed and the quality of the development process, if nothing else there is some confusion out there when people first read this section of the rule. Having said that, it was felt that this is really a good segue into risk management in general and that there might be a lot to learn from some of the existing risk management processes that are out there, including some potential standards that could be built on. And then again, this was another place where some members of the workgroup felt that we were increasing the complexity of certification.

Similarly with accessibility technology, that while this was generally supported by the workgroup again, some folks felt this was over-burdensome. And it think again the comments that we were hearing were consistent with things earlier today about the certification process, does that enable innovation by creating a floor or does that lock out further innovation because it defines what's going to be done and people implement to the certification criteria and that's as far as it goes. So that's a continuing, I think, debate about whether this helps or hinders further innovation.

So moving on to the workgroup 3, a variety of things here. So pharmacogenetics seems to be getting a lot of attention here. In general we felt like this was a good example of a priority area that in many ways is emerging. And so again we were deferring to standards around…the Standards Committee around whether the standards were sufficiently mature. But we were looking to move forward with this ability of ONC and others to start to identify, these are priority areas that ought to be addressed. And again that certification is probably not the place to initially develop standards, but ONC certainly in its role as coordinator could be advancing standards development.

Then there were some technical shifts in naming. So we generally agreed that spelling out the "H" in health IT was a good thing to do. That the modifications to the certification program that was really moving forward modular certification and removing the sense of complete EHRs; while that probably was inevitable and we had to go there; that it creates complexity. Because providers are now requiring modules and they're focusing on modules and it really isn't practical to look to test for interoperability among modules and that we have examples even from single vendors of modules that don't work very well together. So it's a tough thing to assess how well modules will work.

And finally, in general we supported separating the Meaningful Use Program from the Certification Program, but that there are still areas of overlap. And I think it was brought out earlier that this could create additional complexity because now a provider that's needing to participate in a program, can't just look at, okay, I have my certified software; check I'm done. But there may be additional things in the regulations of the program that they're participating in that require that they do more than just acquire the certified software.

Again, we're supportive of certification being expanded to other settings and some of the ones were called out in the NPRM. Base EHR certification, I actually was hoping that Deven's group would have commented on this. The way in which privacy and security is handled in this NPRM is different.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I can tell you the Standards Committee is all over this.

Larry Wolf – Health IT Strategist – Kindred Healthcare
Okay, good.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
The privacy, Dixie and Lisa Gallagher's workgroup; so that's…we didn't take it on and that's why.

Larry Wolf – Health IT Strategist – Kindred Healthcare
Great because we looked at this and we were scratching our heads; what exactly does this mean?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, as did I.

Larry Wolf – Health IT Strategist – Kindred Healthcare
Okay, very good.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
There's another punt.

Larry Wolf – Health IT Strategist – Kindred Healthcare
Thank you. Okay. And we've talked about the trade-offs between what flexibility might enable versus the complexity it might bring with it and the cost associated with that. So I think that's it for our highlights.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Good; thank you. Comments and questions? Give specific asks of the committee in terms of trying to decide between one and another? Are we…no. Okay, are people comfortable with this set of recommendations?

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

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

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
…come forward with this…will the recom…would the recommendations come forward in that qualitative way that you have that most and some or some comments came forward in certain ways, as is in the text and the slides?

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
I think that's probably the…there was really some substantial division within our group and we could not reach consensus about some of those points.

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

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

Donna R. Cryer, JD – Founder and President – Global Liver Institute
I have a question just clarifying examples from the group 1 discussions, examples of when your workgroup thought it would be appropriate for blocking by providers or vendors.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
So an example would be if a provider had some data and they thought someone were trying to access it inappropriately.

Donna R. Cryer, JD – Founder and President – Global Liver Institute
Thank you.

Larry Wolf – Health IT Strategist – Kindred Healthcare
Also to comment, there was some additional concerns that there might be security and performance related issues. So there might be an agent of some kind that was making very heavy demands against a provider's information systems, something like a denial of service attack and that it would be appropriate to shut down those requests as a way to protect their infrastructure.

Donna R. Cryer, JD – Founder and President – Global Liver Institute
Thank you.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
Yeah, in some of our own services, hit our main database 5000 times a day; so the issue of managing things like that I think is real.

Christine Bechtel, MA – President – Bechtel Health Advisory Group
I just have a question about an earlier slide. You guys seemed to say, and I couldn't tell if it was a workgroup comment or just one person on the workgroup, you were talking about certification not being appropriate for things like HIT safety or helping individuals with disabilities. Could you say more about what you meant, or what that means?

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
So there were some individuals within the workgroup who felt that. We weren't trying to say that certification's not helpful for improving HIT. Disabilities is more complex and the…for example, there were some members of the workgroup who felt that it should be up to vendors to decide to what extent they wanted to enable their product for people with disabilities and that that could be a competitive advantage for them. So that's one example around that. I can't remember what the third issue…the third was; there was a third thing on the list there, too. Do you remember?

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Yeah, vendor business practices and HIT safety and I guess…let me clarify my question.

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

Christine Bechtel, MA – President – Bechtel Health Advisory Group
I'm a little bit worried because it seems to be…this is a such as statement; so the statement to me actually says is, expanding the use of certification to address several policy concerns in general, your such as happens to be HIT safety, but I would assume you could sub in whatever else, isn't really appropriate. And I don't agree with that and I guess I would be…I'm concerned that this state…if this statement were to go forward as part of…as representing the workgroup at all. I would just want to understand a lot more about it. Because I think you can pick off almost any area and debate the merits of whether that area is something that should be included in certification, but certification is an overarching strategy for enabling common functionalities among systems and functionalities that are based on standards so that systems can talk to each other. I mean, that's kind of like the core of certification, so I want…that's why I'm really trying to understand, what do you mean here?

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
Sure. So certification is a floor…

Christine Bechtel, MA – President – Bechtel Health Advisory Group
Right.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
…right? Because basically applications have to be certified if they're going to get a meaningful level of use in the market and I think there was a feeling of probably most of the people in the workgroup is that it should not be used to solve all problems...

Larry Wolf – Health IT Strategist – Kindred Healthcare
Yeah, so I think that again, this is an area where there was a fair amount of diversity of opinion on the workgroup, so I don't want it to sound like what we've presented here is sort of the controversy is the take away. So I think the take away was, as you were suggesting Christine that certification is a very powerful tool and that it should be used advisedly and that it should be used in places where there are clear standards and therefore there is actually something to build on. And that if nothing else, people are looking at Direct as an example of maybe premature pushing a standard that turned out to need a lot of operational things that weren't really in place and how much is it moving forward?

And, you know, in some ways, we don't know yet, right? It's still pretty early in the use of Direct to know, was this a good thing or not to have pushed forward. So I think that's sort of the push-pull tension. And also, I think, a concern of, that we've seen again and again where setting something in certification or setting something in Meaningful Use gets seen as the ceiling, when it really was intended as the floor; and so that that's some of the push-pull here. So I think in general, there's a lot of support for certification as a base to build on and some concerns about, does it get...

Christine Bechtel, MA – President – Bechtel Health Advisory Group
So I'd like to just maybe suggest that you guys could clarify that a little bit? I mean, we don't usually get slides that say, overarching comments which one would assume is the workgroup. And then it's like, well one member said, you know. So I don't…I'm worried that people will misinterpret this as reflective of the group; you're saying it's not. And…but Larry, I think the articulation that you just made, which is, there are certain circumstances where certification is a powerful tool, such as X. Y and Z, you know, clear standards. That would actually be helpful and probably more reflective of the conversation than the content that's on that particular slide.

Larry Wolf – Health IT Strategist – Kindred Healthcare
Good. Thank you.

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

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
I had something similar that I was going to ask of you guys which is, because there are some areas where it does seem there's some tension. I'll give you an example which is that the complexity of certifying outside of the MU providers and into other areas of the care continuum can be burdensome. On the other hand, it's really important because you want to make sure that the care continuum is receptive and public health and other parts of the health ecosystem are certified to receive data, etcetera, so you mentioned public health.

So if there's anything in what you've already done or as you go forward that you could help to tease apart some strategies that would guide us in how to solve both of those simultaneous. Because it's probably true that we need to, maybe there's some item ordering, maybe there are some recommendations that came out of you conversation, so it would be helpful to hear that. And I think also, to this point about some places where you had consensus and some strategy that you could recommend to lift to the top.

And I may just ask the group, I don't know if it's in the context of the Certification Rule or beyond, but you mentioned two areas that we have been asked to look at by many parties, Congress included which is information blocking and, I hope everyone here is aware, we put out a report in April on health information blocking and proposed what we have in hand to do and where we think there are some gaps. If there are some suggestions your group has around the certification program that would be welcome not only in this space, but just generally. And then I think also for usability, the angst of providers on the frontline is that the systems feel clunky and are there things that we should be thoughtful about with certification, the Certification Program; that would be helpful.

So…and again, perhaps maybe that's the that is the next chapter of the work of the committee is thinking about user centered design, usability and the role of ONC and others in advancing or supporting that.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
Yeah, thanks. That's helpful; we will be addressing some of that, in particular making some recommendations about what could be done with respect to usability going forward.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
And so I guess to follow up on what Karen said, you're summary about the decertification related to information blocking, there are some hints of something that could be…could or should…shouldn't be done, maybe just explicating on that a little bit would be helpful. If…

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
I'm going to…I thought we were fairly clear about what we suggested there, but we'd be happy to supply some additional detail. I mean, we felt like it was something that would require…

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

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partner
…some objective consideration from a multidisciplinary group before you actually implemented it.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay, thanks. Umm, Paul Egerman on the phone?

Paul Egerman – Businessman/Software Entrepreneur
Yes, can you hear me okay?

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

Paul Egerman – Businessman/Software Entrepreneur
Hello? On this issue about certification, I think it was Christine was raising; the reason, I was one of the people who raised the issue in the workgroup. And the way I look at it is certification should be about software testing and when I see a lot of what's in the NPRM where certification is being used to address issues related to vendor pricing or contracts. On yesterday's call, people want to talk about nondisclosure agreements. To me that's expanding the certification effort and expanding ONCs role into a situation where it's trying to regulate the industry, as opposed to simply certifying software.

And that is where the fundamental challenge is. And I understand that there are a lot of interesting concerns about some of these issues, but, you know this morning we talked about the Federal Trade Commission as it relates to App vendors. But it seems like ONC is taking a very different role in terms of vendor pricing and contracting kinds of issues and certification's simply not the right place for that.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
I guess that's a statement but you didn't say that it wasn't.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners
I think Paul just gave some very good examples of things that a number of people felt.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Yeah. Any other comments? Okay, so I think one of the asks that Karen had is a little bit more detail and concrete suggestions that perhaps the committee can react to, and it think it obviously would be helpful to the Office. So that would be follow up for the call.

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Seem reasonable? Okay. All right, thank you very much, David and Larry. Anything else to add to that ask back for the call? Any other comments about what we've gone through so far? So we're basically getting some further follow-up from Privacy and Security, Interoperability, Usability and Consumer, yes, on our call on, when is that call? May...

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
May 22.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
May 22, hour and a half call; so we'll finish this up and then take a vote and then that'll become part of the transmittal letter. Okay, any other further business for today, before we get to public comment? All right, why don't we open it up then, please.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
All right, if there's anybody in the room that would like to make a public comment, please come up to the table. As a reminder, you have 3 minutes for public comment. And I'll turn it to Alan to open the lines.

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
So while we wait for public comment, as Paul mentioned, there's a 90 minute virtual meaning on May 22 where we'll do the follow up from today's meeting. And then following that, we have a hearing on June 2, Paul's workgroup, the Advanced Health Models group is sponsoring. So, lots of activity still happening, but hopefully after all of your hard work on both the Interoperability Roadmap and NPRMs, you'll get a little bit of a reprieve, hopefully, over the summer months. And it looks like we do have a public comment. Tim, please go ahead.

Tim Schmoyer, MS – Chief Technology Officer - Jericho Systems
Hi, this is Tim Schmoyer from Jericho Systems and I know that the public comments that I submitted over at the chat will be included. But I did want to add about

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

Tim Schmoyer, MS – Chief Technology Officer - Jericho Systems
Oop, can you hear me?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Let me remind people what Michelle said at the beginning which is, for the FACA groups, it's helpful to have our disclo…our conflicts or potential conflicts rather, disclosed. So what we're going to do is between now and the June meeting, we'll provide you with some guidance in terms of what you should look for in terms of potential conflicts and then we'll be disclosing that at the beginning of each meeting to help us all interpret our comments.

Well thank you so much for getting through this day and we will see…we will hear from you on May 22 on the call. And Christine?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

I just wanted to say something at my last meeting, just to say to everybody thank you very much for all of your hard work and collaboration. It's been 6 years and a lot of really good stuff has transpired and so I'm very grateful for the opportunity and for the opportunity to collaborate. And I'm excited to see where everybody goes in the future. But I just want to say thank you and including Joe, who always gives me a voice, thank you Joe. But thank you all very much.

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

Thank you Christine; and we will be hearing from you in the later call. Thanks all and have a safe drive or fly back.

Public Comment Received During the Meeting

1. This is tragic. Are these people out of their minds? They expect EPs to be doing all this craziness? Never happen.
2. When is the Data Update from CMS going to be provided? I noticed that it was on the draft agenda I printed from the FACA website, but it is not on the agenda today. Last month, CMS had promised the EP attestation numbers at the last meeting. We really need to know what happened in the 2014 reporting year. Thank you.
3. Michelle, This question does not relate to the morning's presentations and discussion. So, only share during Public Comment per your discretion, or just provide my question to the committee later. Thanks.
4. Other transport under other HIPAA clauses including Treatment, Payment, or Operations. The Public API must not impose any restriction on the nature, security, location, trustworthiness, or other policy-based delays or constraints by the institution holding the patient's data unless the institution has disclosed such restrictions prior to patient registration. In summary, Meaningful Use Stage 3 must define the Public API, and the patient right of access and delegation to the Public API so as to resolve the fragmentation and governance issues that we have today.
5. Jericho Systems is implementing DS4P and extending data labeling and segmentation to fusion centers. The demand is growing.
6. Info Blocking is a symptom of no certification or poor certification
7. Here's the text: My comment relates specifically to interoperability for patient-centered care. The fragmentation of transports and ad-hoc governance mechanisms in Meaningful Use introduce numerous compromises when viewed from the patient perspective. These compromises are most evident in a lack of transparency, inadequate accounting for disclosures, over-reliance on consent instead of authorization, inability to segment information, interoperability with non-HIPAA services, and loss of provenance in patient-mediated exchange. We urge Stage 3 takes the spirit of the JASON Task Force to heart and define the Public API in terms of the HIPAA "patient right of access". The Public API must require the ability of the patient as known to the practice to completely specify the endpoints that will be allowed bi-directional access, using policy-neutral FHIR / OAuth2 standards. The Public API must make available all of that

Meeting Attendance								
Name	05/12/15	04/07/15	03/10/15	02/10/15	02/10/15	01/13/15	12/09/14	11/04/14
Alicia Staley			X				X	
Anjum Khurshid	X	X	X	X	X	X	X	X
Aury Nagy							X	
Brent Snyder	X							
Chesley Richards		X	X			X		
Christoph U. Lehmann	X	X	X			X		X
David Kotz		X	X	X	X	X		X
David Lansky	X	X	X	X	X	X	X	X
Deven McGraw	X	X	X	X	X	X	X	X
Devin Mann			X	X	X	X	X	
Donna Cryer	X							
Gayle B. Harrell	X	X	X	X	X	X	X	X
Karen Desalvo	X	X	X	X	X	X	X	X
Kathleen Blake	X							
Kim Schofield		X		X	X	X	X	X
Madhulika Agarwal		X						X
Neal Patterson	X	X		X	X		X	
Patrick Conway								
Paul Egerman	X	X	X	X	X	X		X
Paul Tang	X	X	X	X	X	X	X	X
Scott Gottlieb		X		X	X			X
Thomas W. Greig		X	X			X		
Troy Seagondollar	X	X	X	X	X	X	X	X

Total Attendees	**16**	**19**	**17**	**17**	**17**	**17**	**14**	**13**