

HIT Policy Committee
Transcript
October 3, 2012

Attendance

The following Committee members were in attendance at this meeting:

Farzad Mostashari

Paul Tang

Madhulika Agarwal

David Bates

Christine Bechtel

Christopher Boone

Neil Calman

Arthur Davidson

Connie White Delaney

Judith Faulkner

Thomas Greig

Gayle Harrell

Deven McGraw

Marc Probst

Joshua Sharfstein

Scott White

The following Committee members did not attend this meeting:

Richard Chapman

Patrick Conway

Paul Egerman

Charles Kennedy

David Lansky

Frank Nemeč

Latanya Sweeney

Robert Tagalicod

Presentation

Operator

Ms. Robertson all lines are bridged.

MacKenzie Robertson – Office of the National Coordinator

Thank you, good morning everyone, this is MacKenzie Robertson in the Office of the National Coordinator. This is the 41st meeting of the HIT Policy Committee. This meeting is open to the public and there are now two public comment sessions built into the agenda, one before our lunch break and one at the end of the day, and I'll just ask that you please identify yourself for the transcript when speaking. I'll now do the roll call. Farzad Mostashari?

Farzad Mostashari, MD, ScM – Health and Human Services – Office of the National Coordinator for Health Information Technology

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Farzad. Paul Tang?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Paul. Madhulika Agarwal?

Madhulika Agarwal – Veterans Administration

Here.

MacKenzie Robertson – Office of the National Coordinator

Thank you. David Bates?

David Bates – Brigham & Women's Hospital & Partners – Senior Vice President for Quality and Safety

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, David. Christine Bechtel?

Christine Bechtel – National Partnership for Women & Families

On the phone.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Christine. Christopher Boone?

Christopher Boone, FACHE, CPHIMS, PMP – Director of Outpatient Quality and Health IT – American Heart Association

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Christopher. Neil Calman?

Neil Calman – The Institute for Family Health – President and Cofounder

On the phone.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Neil. Richard Chapman? Patrick Conway? Art Davidson?

Arthur Davidson – Denver Public Health Department

On the phone.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Art. Connie Delaney?

Connie White-Delaney – University of Minnesota/School of Nursing – Dean

On the phone.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Connie. Paul Egerman? Judy Faulkner?

Judy Faulkner – EPIC Systems – Founder

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Judy. Tom Greig? Gayle Harrell?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Gayle. Charles Kennedy? David Lansky? Deven McGraw, I know she'll be joining late she had some travel issues? Frank Nemec? Marc Probst?

Marc Probst – Intermountain Healthcare

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Marc. Joshua Sharfstein?

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

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Joshua. Latanya Sweeney? Robert Tagalicod? Scott White?

Scott White – 1199 SEIU United Healthcare Workers East

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Scott. Okay, I'll turn the agenda over to you, Dr. Mostashari for some opening remarks.

Farzad Mostashari, MD, ScM – Health and Human Services – Office of the National Coordinator for Health Information Technology

Thank you so much. Often times I'll use these comments to review any things that may have been in the public consciousness or in the news in the past a little bit. Since our last meeting, a surprising amount of discussion and commentary has occurred around Health IT, and I thought that I would review a little bit of what we heard and then what some of the responses have been from within the community and other commenters.

I guess it's a play in three acts. The first act was an opinion piece in the Wall Street Journal and it really, really hurt me when they said that the ONC acts as a cheerleader and that the cost benefit, review of cost benefit analyses that was published had not demonstrated, with some exceptions I think they said, has not demonstrated either cost or health impact or benefits. And they implied that the effort was misguided from the beginning and was going to be a waste of money based on this study and also based on their assertion that the government has not set standards for interoperability and information exchange for such thing. I think they mentioned blood pressure and maybe a problem list as two examples.

So what was the response from the community, from the academic community, from the practitioners and those who have really been in the trenches on this? Well, one was to actually look at the assertions individually and in fact we pulled the 31 studies that were in that cost benefit analysis and some of them, people in this room contributed to, but 27 out of the 31 indeed found some benefit either to cost or to health care, so, 27 out of 31 not exactly what you would call with rare exception. But more to the point, a lot of those cost benefit analyses said if we invest \$489,000 on a system to do alerts we improved A1c control and one would anticipate that this would save two amputations, is it worth it?

And while that is what they looked for, these sort of narrow, I think, economic trials that say this is the cost from the ground up for this, this is the benefit, does it fit into the rubric, what we're seeing instead is Health IT as an infrastructure. Once you have that infrastructure, you can do any number of trials, any number of improvement efforts and initiatives at very low marginal cost. It would be like saying does the cost of reducing the price of milk across state lines justify setting up an interstate highway system. That's not the question. The real question is I think is...put it very well was, the real question isn't whether we are justified in moving forward with a Health IT infrastructure. The question, the real question now is how can it be implemented in a way that maximizes the benefits and maximizes the cost savings?

A great example, and again it's sometimes not newsworthy for the mainstream media, but really key for the scientific community and for policy makers to recognize, a couple of weeks ago there was an article in the American Journal of Managed Care that looked at one example of the use of such infrastructure in Minnesota to address costs, double digit inflation in the cost of high-tech diagnostic imaging, CAT scans, MRIs, PET scans and so forth.

And in Minnesota, as in many other states, they put in place a whole series of prior notification and prior authorization requirements that were really hindering and really bothering the providers that had to spend 10 minutes to get a single scan approved. And the providers in Minnesota, 45% of them who are on electronic health record systems, said what if we take that logic, whatever it is that the person on the other end of the phone has, that flow sheet that says whether this should be approved or not, what if we embed that in the EHR as a decision support, will you accept the scan and the health plans? And Minnesota said okay let's see what happens.

Well, what happened was that inappropriate scans were cut in half with inflation and high-tech diagnostic imaging was stopped and the time it took went from 10 minutes to 10 seconds. So do your cost effectiveness analysis on that when you have the infrastructure in place already to be able to do those kinds of improvement efforts, improvements in efficiency and cost, and the experience of being a provider, frankly.

The other assertion, which was untrue, was around standards. Now, this was a delicious irony in having the Wall Street Journal editorial page encouraging more government regulation on standards, but in fact we have not sat by, and as John Halamka and others have commented, in fact there are now consensus standards and I think it's taking some time for the broader community to really appreciate what a big change Stage 2 is for interoperability and exchange. Over the next 9 to 12 months, I think, as vendors begin to implement all the various standards, building blocks in Stage 2, we're going to see a real sea of change, I believe.

We have, by the way, if you Google standards hub, Steve Posnack and our staff have really created a very nice page that summarizes all of the 43 distinct standards around coding, terminology, packaging, content and transport and so forth on that page. So if anyone says where are the standards, we now have a place to point them with all the ability to drill into the details. That was act one.

Act two was a series of articles in the Washington Post, the Center for Public Integrity, ProPublica and then in the New York Times looking at billing in particular. What they found was looking back before really, before 2010 or 2011 and the decade before that, in other words before Meaningful Use. There's an association between...overall there are trends towards codes of increasing severity and there's an association between hospitals that later got paid through the Health IT Incentive Program having a sharper trend towards the higher severity diagnostic codes.

The implication there, and there were some really worrisome anecdotes around documentation occurring for care that didn't happen where a patient got their own record and said they never examined my legs why are they documenting that and why are they charging for that higher level of service. The implication there was that the government's incentive program, to encourage adoption of electronic health records, may have had the opposite effect than desired by increasing costs by increasing the distribution of severity codes.

So the response, I think, from those in the community, from providers, from hospitals, from the vendors and others, AHIMA, was first, it's not clear what here is fraud, what's appropriate payment or for greater documentation. It's not clear whether there in fact, before people were undercoding because of uncertainty around what codes could be justified based on the documentation and based on the work that they had done. There were also points made that it's not clear what the impact on total cost is. This is merely looking at one factor, the intensity of certain types of visits. It's not clear if there was more intensity of the emergency room visit whether there was a lower likelihood of the patient being admitted or whether there was a lower likelihood of high-cost imaging if there was more time spent documenting or reviewing.

And indeed, the total costs, as use of the electronic health records has dramatically increased in the past two years, total costs for Medicare are at record lows at levels of inflation for the past two years. But, perhaps more substantially, the Electronic Health Record Incentive Program, Meaningful Use, was consciously an effort to move systems away from what they have been focused on for the past decade as the data here shows around documentation and billing, and towards population health management, care coordination, patient centeredness. As Don Berwick said in the Washington Post, really this is a feature of how we pay for care. If we pay for more documentation of and more intensity of care, and more visits, well, that's what we're going to get.

And increasingly there's a shift from pure payment for volume towards payment for a whole host of other factors, whether it's accountable care. The advisory board recently released a survey that half of the health organizations they surveyed expected that by 2013 there would be an accountable care structure and it's not just Medicare, it's at least 22 different health plans have such arrangements now in place, whether it's patient centered medical homes where 76% of the organizations surveyed planned on being in such a plan, 56 plans in 41 states and the majority of State Medicaid programs now have patients that are in medical home programs.

To succeed in those payment models, information is not, and management of information, is not optional. You simply cannot manage care. You can't manage the quality of care, the total cost of care without access to better information. Others have also pointed out that electronic health records also provide tools for audit investigation and enforcement that, with a paper chart, you don't know when the notation was made, when the documentation was added, when it was appended. But with electronic health records, the immutable audit logs that are a requirement of Stage 2 certification record who did what when and those tools can be powerful in helping investigate and enforce against fraud should it occur.

And the Secretary and the Attorney General made clear that if care is being documented that simply was not delivered, that's not just bad medical care, which it undoubtedly is, it's illegal, and it doesn't matter if you do it on paper, if you do it through voice, whether you do it through transcription service or you do it through an electronic health record, that's fraud and we take that very seriously.

The other interesting point that I thought came out was the role for openness. We just heard about the results of the open notes project from RWJ where patients actually could see not just a summary of their record, but the whole record, including the notes. I think the results were something like 99% of patients wanted to continue it and 0% of providers shut it off after the trial was concluded.

But the access for patients that we're working on for consumers to be partners, to be tapped as the most underutilized resource in health care to help improve the quality as well as reducing the cost of care. I think is also important here and the ability for patients to be, again, partners in detecting out and out fraud if...and we know that there is a lot of that where patients never receive the care, they may not even be in the same state as where fraudulent billing is being done.

That having been said, I do think that it's incumbent on us with some of the information that's come to light to take another look and to have the Policy Committee take a look, take a look at medical documentation for optimal patient care. We know that there's a lot of information that's not relevant, that's not medically necessary for that visit, for that encounter. If it's copied and pasted forward or duplicated, that that's not good patient care either. So providing guidelines and best practices for what is good medical documentation, taking a look at working with our partners through the open and inclusive multi-stakeholder process we call the federal advisory committee, to look, work with vendors and providers and all who have stepped forward and said we want to help, including AHIMA, to say what would be functionality in electronic health records that's over the line?

There may be some practices that are perfectly acceptable, even good, if we want to have adherence to protocols and templates and make sure people don't forget things, but there may be some things that step over that line. Is it a prompt that says document more to get the higher billing code? That might be over the line. Is it the opportunity to bypass the audit log or to make amendments that make it not appear as if the amendment was made? Where are there lines that we can draw and provide clarity, whether through certification or through policy?

Should we take a deeper look at the audit log for specificity in terms of the information that's captured and whether more information, more metadata might be useful or more standardization of the audit log, both for security purposes as well as for billing investigation, fraud investigation and provider authentication? We've already had recommendations around stronger provider authentication for remote EHR access and the role that could play in reducing certain types of fraud. So I do think it's something that I'd like the Policy Committee to consider and to include any relevance for whether it's best practices or recommendations for Stage 3 of Meaningful Use and certification.

The third act, of course, is the change that's beginning to occur on the ground and we have our graphic for Meaningful Use that says individual organizations and we as a country really expect this to be not a one-shot journey to perfection, but a staged approach of incremental improvement, beginning with adoption and operation, meaningful operation of electronic health record within practices, collecting the structured data, beginning to practice population management. Stage 2 sharing of that information and pushing more on the advanced clinical processes and Stage 3 improved clinical outcomes. As one commenter said, let's be a little patient here. We're looking at a 1.5-year-old or a 2-year-old and we're asking them to do 6-year-old tricks. So let's be a little patient and let's look at organizations that have been at this and say, how about those organizations?

We had, I believe, yesterday in the annals of internal medicine, the largest ever study of EHRs relationship to improved impact on quality of care, largest ever study, over 100,000 patients with diabetes that found remarkable improvements in quality of care, process measures and outcome measures for patients with diabetes. Yesterday I was in New York City where the small practices that I worked with four years ago are now seeing the trends in the quality of care they deliver month over month, over month, 1% a month, 2% a month improvement. But those changes weren't visible the first year we implemented the system or the second year we implemented the system. It takes time.

So, as we think about what we're doing and how we can continue to help the providers and the hospitals, and the vendors in the field who are really doing the hard work of improvement, I think we owe it to them to do what we can to help set a level playing field through standards, through rules of the road, to help set those ambitious goals, to do some hands-on coaching maybe at times and a little bit of cheerleading is okay, too. Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, Farzad, it was great words of encouragement in response to some of the acts out there that you commented on and, as you know, we've been...we have outcomes improvement front and center for Meaningful Use from its very inception which you were a part of before your current role and we also want to thank you for putting progress notes out there in Stage 2 so that we'll accept your challenge and say how can we make those better and more helpful toward achieving the goals, which is improved patient care and improved outcomes, so we'll work on how we can do that. Thanks.

Speaking of Stage 3, this is the meeting of Stage 3 recommendations and next month we're going to be putting out a Request for Comment, so this meeting is dedicated towards vetting the kinds of questions we're going to be asking in those comments. We'll start out with some of the questions and the proposals from the Meaningful Use Workgroup, continue on to some of the questions from the IE Workgroup, the Information Exchange Workgroup, then onto the Privacy and Security and conclude with comments from the Quality Measures Workgroup, all of which are directed towards one Stage 3, but all of which are directed towards measuring and improving outcomes using this very important tool that you just talked about, Farzad. And then we'll conclude with an update from CMS and ONC. Any additions to that?

Anyone want to motion for approval of the minutes from last time which were very detailed and helpful?

W

Yes, so moved.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, second? And all approve.

M/F

Aye.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Any opposed or abstained? Good, thank you. So we'll move onto Meaningful Use Stage 3 RFC from the Meaningful Use Workgroup. Good, so George Hripcsak and I will lead this off and we're going to focus on, as you know, a couple of months ago we brought to you before some draft preliminary recommendations for Stage 3 that we're proposing for the RFC to get public comments on and now we're back having reworked some of those based on your feedback and other feedback we've received.

I want to first start out by acknowledging George Hripcsak who is the co-chair of this group and Michele Nelson who is our able ONC liaison who has worked very hard in preparing this information and guiding us through this process.

So here's a list of the Meaningful Use Workgroup participants and in red are the leads for each of the categories, as you know, we have five categories in Meaningful Use rule. Here's our schedule, which is starting with today which is to review the updates we've made since our last talk with you a couple of months ago in preparation for releasing our Request for Comment to the public that will be due before the Christmas holidays and December 21st. ONC will synthesize all the feedback we get then it will be reviewed with the various appropriate Workgroups and we'll come back here in March of 2013 to present the revised Stage 3 recommendations having received the input from the public moving towards a May 2013 transmission of the final recommendations from this body on to ONC and CMS.

Remind you of the guiding principles which is this is a dynamic process and we're not shooting for the past, we're shooting towards the new way the world is going to operate, that is one that Farzad described as moving towards team-based care, outcomes oriented care and managing populations not just individuals and transactions one by one. It also addresses squarely the national health priorities as described by the Secretary. This is intended to have broad applicability both across this country and across the specialties the providers practice in, and to not stall, that is keep moving forward. If we've finished, if we've topped out on something, for example, we've already reached the 80% threshold, then let's move on to other things that are critical to improving care and health.

That these objectives are achievable, so in order to stop the flow of the creation of more silos, we look for mature standards so that we can interconnect this information which is so important to care coordination, for example, and that it would be reasonable and feasible both from a product point-of-view but also from an implementation point-of-view. So, those are things we've used to try to guide some our recommendations.

Here's a key, a legend for the matrix that you see. Red items are changes from Stage 1 to 2. Blue is from 2 to 3 recommendations and green is what we've talked about since what we've created or revised since we last talked to you in August. So, during this conversation we're going to be focusing in on the green items, the changes, and also on Stage 3 recommendations versus Stage 4 or further, future stages.

So, we'll begin with Subgroup 1 which is the Improve Quality, Safety, Efficiency and Reducing Health Disparities. It's not going to be easy to read on the screen, but you all have it in front of you, again, I'm going to highlight the green. So, as you know, CPOE is one of the most important recommendations or objectives for the EHR Incentive Program. A lot of it has to do with the way the system helps shape or provide support for decisions rendered at that time of ordering. One of the challenges we've had is that medication errors is one of the classes of errors that has caused us the most harm, so we wanted to concentrate on that and drug/drug interaction is one of those potential, you know, has potential to cause harm.

One of the things that's been challenging is that using the existing drug databases there's a high degree of false positives and that causes problems both for the clinician to say, well, which one of these are really impactful and which of these alerts are false positives and it also has ancillary effects in terms of decreasing the perceived values other clinical decision support interventions. So, that's why it's so important to us to get a better predicted value out of these drug/drug interactions.

So, one of the things we're recommending from a certification point-of-view is that EHRs be able to take in or to consume externally maintained embedded lists of drug/drug interactions, some that are important and maybe there's even lists of things that should not be causing alerts. So, the first list we're talking about is what we call the never list. So, there are many extenuating circumstances where you may use these two drugs or drug classes in a particular patient, but in some cases, there are never lists, in other words, you should never, almost virtually never use this combination and there have been, since Stage 2 was prepared there has been a study that points out a list of these never interactions and David Bates is one of the authors of that study.

So its lists like those that are vetted through rigorous research and published in the public domain under peer review where you'd like to have the EHR take that into account as part of its clinical decision support intervention and in this case involving drug/drug interaction. So, that's one of the things that in green show that we would, one, want the EHR to have that kind of capability and, two, have an objective of the EHR system from a CPOE point-of-view be able to check for never drug/drug interaction lists.

The other part which is in the lower half of the Stage 3 recommendation deals with lab tests. As you know, one of the denominators are test orders and lab orders is one of those things that is measured in the EHR Meaningful Use Incentive Program. The addition here is for the EHR to also have the capability of not only transmitting lab test orders using standards, but also to track those results and the purpose there is to be able to know when results come back in for something you've ordered so that you can watch out for things falling through the cracks. By the way, what I'll do is go through each category and then we'll pause for committee comment.

The next one has to do with referrals and transition. As you know, care coordination is a big emphasis in Stage 2 and so one of the things we want to do is to have the denominator when a referral is going to happen or a transition is going to happen we want the system to be able to track that. So this requirement creates the tracking, both the capability to detect an order that's a referral or transition and to measure the turnaround time, for example.

The next one on slide number 9 we're talking about formulary checking, this is not in...the change here is to look towards Stage 4 or beyond Stage 3 and the idea is to be able to prompt clinicians, Farzad, in his earlier comments talked about this prior authorization problem, prior authorization. If you're going to have a medication that is not on that patient's health plan's formulary then this will help the efficiency with which you get prior authorization for that medication if so indicated for this specific patient. So, that's not something for which there are widely adopted standards now, which is why we're not making the Stage 3 recommendation, but we're putting it in as a signal for future stages.

Next one, ID #104 has to do with demographics. Here's an example where we went from 50% in Stage 1 to 80% in Stage 2 and so we're recommending, since 80 has been sort of our nominal topping out threshold, we're recommending to remove this as an objective for Stage 3, it doesn't mean the use of this goes away, but we no longer are advancing that in terms of raising the threshold. In addition, we're asking that certification criteria be put into place so that EHRs have the capability, that is they have the feel and the functionality so that users can store occupational and industry codes and sexual orientation gender identity, as well as disability status.

The next three have to do with problems, medications and medication allergies. As we had signaled before, these are really high value information about a patient and we want to make sure they are both accurate; they are all accurate and complete. So one is to...in the past we've made them objectives that you have these things and you use them. Now we're trying to move toward system supported ways of maintaining the accuracy and completeness of this. So you can imagine, for example, in a problem list, you can use lab test results or medications or even vital signs, you know, such as blood pressure or BMI to support diagnoses made that appear in the problem list. So, we are suggesting that EHR vendors develop functionality to help the user maintain the accuracy and completeness of those lists. We weren't prescriptive because we wanted to allow innovation to take place, but that's the purpose of having these recommendations for Stage 3.

Next page, on page 12, has to do with vital signs and smoking status. Again, these are both at the 80% level in Stage 2, so we're recommending that they be retired as objectives, but they can appear, of course, in clinical quality measures. So, this is an example of we now have the functionality and the use by Stage 2 of these important data fields now let's apply it towards outcome measures. Are we decreasing the amount of smoking that occurs in the population? Are we improving the BMI of our population? So it's much more directed into the outcomes side, which is CQM.

The next one is ID #112. This has to do with advance directives. We're proposing that its menu in Stage 2 for hospitals and we're proposing that it go to core in Stage 3 for hospitals and menu for EPs. In the final rule, there's...in the preamble it talks about how there's still a lot of unresolved issues and so our plan is to have a listening session so that in the future we can better uncover those and address those.

In ID #113, page 14, we're talking about the important topic of clinical decision support interventions and here we've taken an approach, after listening to the feedback last time, of going towards maintaining the 15 clinical decision support interventions, but instead of saying pair them up with five, you know, just any five clinical quality measures, moving towards a...making sure that it addresses some of the national quality strategy domains, such as preventive care, chronic disease management, appropriateness of lab and radiology orders and advanced medication related decision support. So we're saying that of the 15 they must...you must have at least one in each of those four categories.

The other thing we're looking towards in future stages is a better way of maintaining, it's often called knowledge management, maintaining knowledge through a public process and being able to deploy that knowledge throughout individual EHRs. So that's what you see in Stage 4 place holder.

On page 15 in ID #115, we're talking about patient lists and here we're clarifying in response to questions raised in the committee in August what we mean by dashboards is the traditional way of quality reporting is to take essentially a retrospective view back about a population and that is not providing a contemporaneous view for the individual provider at the time of care and so this dashboard is really a much more contemporaneous way of presenting information that can affect the care of individuals that appear before the provider during that day. So that's what we meant by that. We didn't mean it to be calculating in real time because one of the concerns raised was that it would be using too much CPU horsepower, but it's really to get more contemporaneous population management tools in the hands of providers.

On page 16, ID 117 this has to do with missed batches in terms of the eMAR and this is clarifying the question about "well what are you going to do with those reports" and we're just clarifying that this is not for public reporting this is for internal use and quality improvement.

Page 17 doesn't...the only addition here is in the imaging objective to include ECGs as an important...it's an important waveform, but in the terms of this requirement could appear as an image. Skipping ahead beyond page 18 and 19, that finishes up the category 1 in terms of Improving Quality, Safety and Efficiency and Reducing Healthcare Disparities and that's a discussion of the items that we've changed since our last meeting. So, let me open it up now for comments on our revisions. Judy?

Judy Faulkner – EPIC Systems – Founder

I have a few, Paul. Let me see where do I start, hold on, okay. The first one is your slide 6, transitions with orders. What about transitions that don't have orders? Do all transitions have orders and how do you deal with ones that don't have orders?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's one of the unanswered questions in terms of how do you get the denominator and so...

Judy Faulkner – EPIC Systems – Founder

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And so this is a preparation for saying that most transitions...we're encouraging people to have transition orders and referral orders. You can't, I mean, if someone self refers then we won't be able to capture those.

Judy Faulkner – EPIC Systems – Founder

Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

But I think in terms of how the measures are being constructed in the final rule, for example, it's really based on orders.

Judy Faulkner – EPIC Systems – Founder

So we just have a different denominator then?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And we have a different denominator, correct.

Judy Faulkner – EPIC Systems – Founder

Okay. Next is slide 11, these are hard to read. Can I make a proposal that when we have tiny print like that, either have a bunch of 20-year-olds here instead of us or put them one per page.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, we can do that, right?

Judy Faulkner – EPIC Systems – Founder

Yeah, question on that one where it says...I'm not understanding when it says, the middle one, on slide 11, it says use of problems and lab test results to support maintenance of the medication list, could you explain that a little bit more?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Sure and just for the audience or all those over the age of 20, this has to do with maintaining the accuracy and completeness of the problems, medications and allergies and in particular Judy was asking about the medication list and what is described here is to use problems, medications or problems and lab test results to help clinicians maintain an accurate and up-to-date medication list. So, for example, if you have something on the problem list such as diabetes and there are no medications treating diabetes, that might be one thing the system could point out to the user, are you missing something from the medication list.

Judy Faulkner – EPIC Systems – Founder

Okay. So, what you're saying is use those other areas there to query the physician as to whether something is missing?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Correct or something is done. So, let's say you've got something that...an antibiotic and there's nothing on the problem list that would indicate something for which a chronic medicine would be.

Judy Faulkner – EPIC Systems – Founder

Okay. So, basically you're looking for discrepancies between the two.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

We're looking for discrepancies and there's still just spotting mechanisms for the clinician users, they do not change things automatically, that was another question that came up last time and David Bates...

David Bates – Brigham & Women's Hospital & Partners – Senior Vice President for Quality and Safety

...there's publicly available stuff that we put out, for example, that shows that shows that it makes a big difference and the providers like it.

Judy Faulkner – EPIC Systems – Founder

Yeah, I'm not against it, I'm just trying to understand what they're meaning when they write this.

David Bates – Brigham & Women's Hospital & Partners – Senior Vice President for Quality and Safety

Yeah.

Judy Faulkner – EPIC Systems – Founder

Thank you. The next one is slide 14. I wonder whether we should use the word interventions, 15 clinical decisions support interventions. To me an intervention means someone does something, then there's a message saying you didn't do it right and I'm wondering whether this is going to be time limited and that the growth of EHRs are going to help them do it right rather than intervene when they're not doing it right and I wonder whether the terminology should change there.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

It's a fair question and I think we picked this up from the NPRM language. In other words, I think the idea was to avoid the word rule, so oftentimes people will refer to clinical decision support rule and the expansion to intervention was to say it could be just applying different colors, it could be a graph, there's all kinds of things that would support or intervene from the clinician's point-of-view, so it was not the action that the clinician did, it's an intervention of the system to support the human user.

Judy Faulkner – EPIC Systems – Founder

I still think a different word may be better.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Right, we're open to those suggestions but that's the intent.

Judy Faulkner – EPIC Systems – Founder

Yeah, maybe it should be interventions or guidance, something like that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's a good word. Are you done? Okay, Gayle.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you. I want to go to slide, again, I think I need a new pair of glasses or certainly bigger print. I think its slide 9, yeah. Okay, talking about as kind of a precursor for Stage 4, as a place holder, I think there are some things there that you can incorporate in Stage 3. Every state or most states now have stood up a PDMP. This is...drug abuse is...prescription drug abuse is a huge problem. I think there is a way now in Stage 3 and certainly by 2016, 2015 that this should be incorporated, that they should be able to see that PDMP.

Also, every state has a Medicaid formulary list and the amount of money that can be saved through those formulary lists for Medicaid should be incorporated into Stage 3. You should...that should be a certification requirement that you go out and pick up that formulary list from Medicaid for each state. If you're in Florida you should be able to get that. We started a program back in 2003 in Florida with hand held PDAs and we were able to do this in 2003-2004 and we saved \$6 million a month on our drugs spent, you know, Farzad, you know, the criticism that we are getting out there in the media that this is not really cost effective is totally negated by the figures that we can prove in Florida.

So let's incorporate Medicaid lists, formularies that are available and embed them or, you know, have the ability to go out and get them so that we can at least in our states start seeing some reductions in drug spent.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's a fair comment and I'll let Jodi respond. We were concentrating on the broad sector, so in the private sector, at least HIT Standards Committee was saying that we don't have this information yet in the complete form, either knowing exactly which plan a patient's on or all the information about all the various plans from the insurance companies to know what formulary applies, that was one of our challenges.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Well, anyone who is on Medicaid has a Medicaid number, so you have that ability; you're capturing that anyway within your record. And if you have that embedded then automatically you should, within your record, be able to bounce off the formulary list.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So I think that's something we didn't capture completely. So we can certainly go back and ask about particularly the Medicaid because you're saying...

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Medicaid.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Because, you're saying that it exists in states. Jodi, do you...?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

And that could be a precursor to really start developing the technology so that when you get, when Blue Cross/Blue Shield or United, or whatever has the ability, you have the ability to get their formulary lists, which are out there, you know, those are there, this is a real way of at least directing, you know, I'm sure there are options that physicians can override and whatever to use another medication depending on that individual patient, but if you really want to look at the value here from a fiscal point-of-view that's where it is.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

No, that's a very good point. Jodi?

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

So, I just wanted to comment on the PDMP portion of your comment. So, we have been working to try to do some pilots of making PDMP data available electronically in real time to prescribers and dispensers in order to take that wealth of information and try to make it available as the doctor is writing a prescription or as a pharmacy is prescribing so that they can...to see what...get access to that information because one of the criticisms is that there's all this information there in the PDMPs, but doctors either don't have access to it readily or they get it but after the patient has left. So, they can't actually use it to make decisions.

So we have just started piloting, we had 7 very small pilots, but we've had some great success with it trying to both make the information available and get doctors to use it. We have some anecdotal evidence at this point where it actually has changed some prescribing practices. Again, they're very small pilots, so we are trying to get some analytics from it and we've just extended the timeframe of this for another 6 months so we'll get some more and better data.

We're also coming up with a toolkit to help other states and programs to try to implement this as well. So right now my understanding is that there isn't capability everywhere to be able to get real time access to PDMP data through...electronically through EHRs. We're trying to change that trend and make it easier for folks to do that and actually the question came up of whether or not there could be a requirement as part of Meaningful Use, at least where it is available, to, you know, either a requirement that the EHR be able to incorporate that information or that the doctor check it. It was something that was just raised recently, but is actually a fairly intriguing concept at least from my perspective in trying to advance the use of that information in helping to address the prescription drug abuse problem and to help providers in making treatment decisions and prescribing decisions.

If there's anything...we just extended this contract for another six months, so if there's anything we can do to help make that more of a reality so that we could incorporate into Meaningful Use or it could be considered to be incorporated into Meaningful Use, I would be happy to take any suggestions because we're just working with the contractor now to think about how we can advance this.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

I would suggest that it be a certification requirement that the EHR have the capability to do that.

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

And some of the problems that we have is that some of it is...there's some state law issues in some states. There are...you know, and then there's also the PDMPs themselves may not have the capability of incorporating it into an EHR. There's a lot of pieces that have to come together to make it work. That said, there is at least, I think, one of the pilots where they just made a link to the PDMP's website available through the EHR so that it was at least easy for the doctor to find it even if it wasn't, you know, actually, you know, consumed by the EHR. So there may be lots of different...there may be some flavors on the scene and maybe we could ask our contractor to make some recommendations on whether or not there could be some criteria for EHR certification.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So we should at least incorporate this in our RFC.

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

That would be great.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

To learn more about it. Yes, thank you. Thanks, Gayle. Marc?

Marc Probst – Intermountain Healthcare

I think...oh, sorry.

Madhulika Agarwal – Veterans Administration

Oh, that's okay. This is Madhulika Agarwal, on slide 10.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Slide 10?

Madhulika Agarwal – Veterans Administration

So, in the demographics I think it would be good to add the disability status so that we are consistent with the final data collection standards.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So it is there, right? Occupation, sexual orientation, gender identity and disability status.

Madhulika Agarwal – Veterans Administration

I did not see that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

It's the third bullet.

Madhulika Agarwal – Veterans Administration

Oh, is it...?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Right there.

Madhulika Agarwal – Veterans Administration

Ah, thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. And the question raised there and we can query in the RFC is the difference between the patient reported and the medically determined as part of, you know, regulations and policy, but incorporating disability status as one of the demographic pieces of information is what we're asking for EHR vendors to supply.

Madhulika Agarwal – Veterans Administration

Okay, thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Marc?

Marc Probst – Intermountain Healthcare

Thanks. I'm incredibly...

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

We have 3 things to do?

Marc Probst – Intermountain Healthcare

No, no, no it was 5.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, five.

Marc Probst – Intermountain Healthcare

We'll get into that another time. I'm incredibly impressed by the work that the Workgroup has done and the detail that's there and I think you're living up to the tone that you set in those early slides. So I don't have a specific on this particular category, just as you've gone through it, overall, have you tried to categorize what these changes mean? I mean some of them are absolute software, we've got to go in and create things, you know, and ways to load certain pieces of information. Some of them are simply operational change, you know, we're going to use it more and then some of them are really certification change which may, and probably implies more of the technology changes. Is anyone categorizing that?

I mean, there is a general sense of exhaustion, you know, of all the things that are coming through Meaningful Use and again, I'm very supportive of what you put down. I mean, I think you've really thought through it. I just want to have a little more maybe empathy toward what are we asking the Healthcare IT environment to do and do we fully understand that so that when we communicate it or support it, we know what's happening there? Has someone done that analysis or could someone do that analysis if they haven't?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think that's a reasonable suggestion. We do talk about it in the Meaningful Use Workgroup as ideas get put forward and it comes in the category of reasonableness and feasibility, but I...we could potentially, you know, create a matrix to help quantify it better, at least give our thoughts about it, that's useful feedback.

Marc Probst – Intermountain Healthcare

That would be great, but, again, I mean really good thought by the Workgroup.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you. Any more comments on this category? Okay, let's move on to Subgroup 2, which is the Engage Patients and Families. Okay, so the first one, this is page 21, under the view download and transmit, the addition here is to try to incorporate the results of the pilot that's being done for so-called automated Blue Button. So, Blue Button is the capability of an individual to download information about their health and automated is to essentially be able to subscribe to this information and designate its transmission to certain places, let's say a specialist. Apparently, there is an ONC, I believe, sponsored pilot that's going on and that pilot should be completed before our recommendations come out, so this is a place holder to take advantage of the results of that pilot to see if that subscription, if that automated Blue Button function works well then we would encourage putting that into Stage 3. So, this is somewhat of a contingent recommendation for Stage 3.

In the future, we are already talking about how do we incorporate more and this appears in the Stage 4 column, how do we incorporate more and more of patient-generated data, and we recognize that we have to find a way for the system and a workflow for the providers so that they can view this information and then incorporate it into their record or not or at least designate it as patient entered. But the staging process of when information is coming from the patients, how do we stage that into the electronic health record. So that work...there's more work to be done and that's why we've indicated that as Stage 4 or future.

On the next page, page 22, having to do with more on the topic of patient-generated data, you might recall that we had somewhat of a complex, you know, proposal before you last time, so we've sort of simplified it and we're saying there's a lot of information that comes from the patient such as patient reported outcomes, it could be previsit information, it could be shared health goals, anyway, there's a lot of information that can usefully come from the patient and with HIT and patient portals, this can be facilitated and a generic way of doing that is through semi-structured questionnaires. Semi-structured means some of it would be coded in standards and some of it would literally be just free text.

So, whereas this does not have a rich amount of standards backing it, we're proposing this as a menu item, but as a generic function, semi-structured questionnaires for gleaning information that comes directly from the patients. So that's what this is all about and we're asking about the functionality that can be incorporated into EHRs in order to do this and as well as what are the other issues related to this. One of the things we've considered and there's a commission paper from ONC about the legal implications of having this information from patients appear in the record. So we're going to receive a report from that, I believe, at our next call.

Next page, 23, is no new changes. The only thing for clarification, you see the long list of things that may be in a summary of care or clinical summary, these things are voluntary. In other words, if there isn't any appropriate information in that field, then it doesn't have to be reported.

On page 24, in patient specific educational resources, we also had a rather complicated description last time about Non-English language support and we are trying to clarify it here. In other words, for the top five Non-English languages spoken in the United States the request would be that the local organization supplies those based on their local population. So we're limiting the scope to the top five Non-English languages in the United States and then tailoring it to the individual organization and their attachment area.

Page 25, there's no change and similarly with page 26. So let me open it up for comments on this category, Engaging Patients and Families. I think people are trying to read the fine print, but is there any comment on the phone? Okay, Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you so much, Paul. On engaging the patients and dealing with the information when it is downloaded, I know we've had some conversations on privacy and security about that in particular and when it goes into a personal health record. Is the idea that...is the goal here to be able to download and then be able to have the capability to export it into a personal health record and at what point does the liability for that end for the physician?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So one transport, yes, so its view, download and transmit?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So the transmit function...

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

The transmit aspect of this.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Is intended to go to wherever the patient designates it.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

To wherever the patient designates it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Right.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

And what happens and is the assumption that they would have also the ability to transmit it then to either another physician's record, to an HIE, or to a personal health record?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think that's the intent and from a liability point-of-view once the patient has...if it's going provider to provider then it would be covered under HIPAA in a sense, if it is going essentially through a patient to another patient, let's say a portal.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Correct.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

My assumption is that would be the patient's responsibility in terms of what happens to it. I'm looking over to my ONC colleagues to see if that's a correct interpretation. And Joy is stepping up.

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

So, this is Joy Pritts, so once the information is transmitted to a patient, it is the patient's responsibility for how the information is handled just like in the paper world if a doctor gives a patient a copy, a paper copy of a record, the patient is then responsible for how that information is handled.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And is that transit, Joy, so if the patient says I want you to send it to my specialist, I can see it's a provider to provider and that's a standard HIPAA transaction.

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

That's correct.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

If the patient says I want you to send it, you the provider to send it to somebody's health vault, then even though the patient didn't physically have it, does that logic apply?

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

Yes. It's the same as if you said I'd like you to send it to my mother, for example, for safe keeping.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay.

Marc Probst – Intermountain Healthcare

Does that take place once or every time?

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

I'm not sure exactly what you mean by your question, Marc?

Marc Probst – Intermountain Healthcare

Well, in each visit if they wanted to change who they're sending it to, you want to send it to your mother or I want to send it to Dr. Jones, do they make that election? I'm just trying to think of how I build it into a system. Do they make that election once and then I know where to send it or are we saying they can make that election every time or to three or four people?

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

You mean under view, download and...under this standard?

Marc Probst – Intermountain Healthcare

Yes.

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

I think that's still under discussion.

Marc Probst – Intermountain Healthcare

I think we have to define it if you want us to build it.

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

We understand that that's an issue and there are some...there are some policy issues behind that because these are issues that have not really been raised in the paper context.

Marc Probst – Intermountain Healthcare

Right.

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

And so it's a different paradigm than under the way information has been provided to individuals before.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So, hopefully that will be covered under the auto Blue Button because that's how this...

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

That's exactly where we're looking at some of these issues and we have started looking at them and we'll be coordinating with some other offices within HHS and others to try to get some answers as to...policy answers as to how this may work.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

And is that covered under HIPAA? If I give you transmit...if I give you...it has to be documented in the record that I want this transmitted, I am giving permission to transmit this information for someone else to have it that's not...whether it is my mother, a health vault or someone else, what happens in those situations and that is not a HIPAA transaction, I would presume, and where is the liability?

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

I don't know how your question is really different from where we just answered where the liability was, but let me...let's work on this a little bit. So, for one thing we're in a little bit of a difficult transition time because we have the HIPAA privacy rule which gives patient the right of access with certain rules in place. You also have HITECH which gave...clarified how individuals may access their information electronically. We have a Notice of Proposed Rule Making that's out on that, but that has not been issued in final form.

So the answer that I'm going to give you is premised on the existing rules not what would happen under HITECH as it's been amended, okay? So I just need to set that base first. Currently, when an individual...an individual has the right to request a copy of their own health information in any format that the provider...that's readily available from the provider. There is no requirement under the privacy rule as to what format that request must take. Does that help answer that first question?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Yes.

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

Okay, so we looked at this issue in great detail about what the state laws...because there's state laws here as well.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

I know.

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

And there are some states that do have requirements for what that request form or the format of the request, what information that would have to contain. So, HIPAA does not require anything, some state laws do and in practice many providers do have, currently in the paper world have forms that they like the patients to fill out because it's a standard way of collecting their information. They're allowed, under the rule, expressly allowed under the rule to say you must provide me, you must request your information, access to your own information in writing as long as they tell the patient in advance about it. So, you can't just select certain patients that you're going to put that requirement on it has to be a general policy. Okay, so, I think that answered part of your question. Now, let's get to the next part.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

The transmitting, let's get to the transmitting of that information and obviously you have to have the documentation, it's got to be, you know, certification standards to require the documentation of the permission, then the documentation of the transmission to who and that has got to be built into the electronic health record in order to be able to do it. Once that happens and it is transmitted, the permission is granted, if it's a Non-HIPAA entity such as a parent or a mother or somebody or an electronic health vault or, you know, personal health record, the liability ends with that signature to transmit, the permission of the patient to transmit, am I correct? So, once the physician, the hospital is no longer liable.

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

I think you're asking a very interesting question and I don't know if the answer off hand...we need to look into that is, is it the decision to transmit or is it the receipt?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So, I think what we'll do since we're probably not going to get a final on this, we'll record this and actually query this, you know, address this topic in the RFC because this is an important and obviously still unclear area.

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

Right, because...

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And a new trail to blaze.

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

I'm just going to give a hypothetical here. If...never mind I won't give a hypothetical. There are circumstances where you can see where depending on how information is sent that the responsibility for sending that information may not end until it is actually received by another party.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

And if you go through an HIE, what happens under that scenario?

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

There are so many different HIE paradigms that it is almost difficult to answer that question without having more facts.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

I think this is a very problematic area that has got to be really looked at and the liability issues and breach issues, and fears out there are very concerning. People are very concerned about this. And when you transmit that record it becomes problematic at the patient's permission, certainly, where is the liability, where do things happen at that point.

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

I would posit that it is...I have understood, I have heard a lot of these concerns about liability. I think that any time we introduce new ways of sharing information, those concerns surface. So we've also heard those concerns with respect to sharing health information with other healthcare providers. You hear those same concerns with sharing information with a health information exchange organization. So, I'm not surprised to hear them. I think we do need to put them in that context, though that anytime we introduce something new these concerns do arise and legitimately so, people do want a little bit of certainty in how they need to operate their business.

Christine Bechtel – National Partnership for Women & Families

Paul, it's Christine Bechtel, can I get in the queue on this?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Sure, is it directly to this question?

Christine Bechtel – National Partnership for Women & Families

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Why don't you go ahead, then?

Christine Bechtel – National Partnership for Women & Families

Thanks. I would...I think in a related topic, I would say that one of the recommendations that the Tiger Team on Privacy and Security made was around warning patients before they download. This is a little different than transmit, but obviously related and I think it was the Markle Foundation that crafted some model language around what would pop up on the screen to alert patients when they are about to download and I would imagine similarly, you know, transmit their health information that tells them essentially that you're now responsible for this and you need to protect this information and don't put it on a public computer, etcetera, and then give them an opportunity to confirm whether or not they still want to download based on where they're at.

I don't know how that recommendation is reflected or not in Stage 2 because obviously view, download, transmit is part of the Stage 2 rule it's not just in Stage 3, but I think it would be very helpful to understand from ONC and also from the VA and Medicare who are, you know, already doing at least view and download, how they're approaching this, whether this is something that could be or should be part of certification or whether it's a best practice that needs to be disseminated to the vendor community and potentially through the RECs, but I'd love to get some feedback on that.

And then the second piece that I would just add, I think, coming back to Marc's question is, and, Paul, you alluded to this, that there are, and Jodi did as well, some pilots that are happening, I think this fall around the auto kind of set and forget and how you would technically build the ability for the patient to say, okay,

every time I go to my cardiologist I'd like you to transfer a care summary back to my primary care physician and to set that up in an automated way or to allow me to go in and one time say, okay, there was enough that changed in my care at this visit that I'd like you to send a care summary to this other provider. Those pilots are happening now and so the first slide in this section was really about monitoring what happens there and making sure that we learn from them and potentially build it in if they're successful.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, Christine. And so I think what we'll do in the RFC is to lay out in a preamble what we do know and then try to enumerate in questions what we need feedback on because it's uncovered ground.

Christine Bechtel – National Partnership for Women & Families

Agree.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Judy?

Christine Bechtel – National Partnership for Women & Families

But I'd like to also get feedback from ONC on how the language that, you know, that the Tiger Team recommended is or is not already being part of Stage 2.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Right, I think that's part of what we do know or should know. Judy?

Judy Faulkner – EPIC Systems – Founder

Sure. I think the whole thing about how do you determine that the patient has agreed to this, whether it's for interoperability or whether it's for I want to send this to my parents, is a really tricky thing and I find that the healthcare organizations we talk to it's a big problem. They don't want storage of paper, what do they do with all this paper and how do they educate? They can educate the ED pretty well, but it's all the individual doctors and all the offices where such a discussion may occur that is a challenge to educate and having signature pads everywhere is a problem as well.

And I wanted to give a personal example on this because I think we have to look at liability versus health care. I went to the eye doctors the other day and I went to a different place than I usually go and I said "why don't you bring my record over" because I wanted him to see the prescription I had from the other eye doctor. Well, it said patient authorization needed and he just froze, he had no idea how to do it. There was no printer in the room. There was no way that he could then get it from me and what happened, he didn't get it.

And I do think that for good health care we need to make sure that we don't have so many barriers up for liability and patient authorization that we can meet the needs of the patients who say get my data over, but there's not so many barriers that it becomes too hard either in terms of how you store it or how you get that authorization.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

It's a fair point. I think this is going to come up under the IE Workgroup recommendations here this whole consent management.

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

Well, I would also like to note that we have been...my office in particular has funded a pilot on how to obtain e-consent that is launching this month in the Western District of New York, it's under slightly different circumstances, but it is exploring ways of providing the individual information in kind of novel ways using, in this case, tablets for videos that can answer a lot of questions and that would record the consent electronically. So, we are aware of these issues and we are exploring ways to help facilitate the education of the individuals and to facilitate obtaining their permission in order to exchange.

Judy Faulkner – EPIC Systems – Founder

I can see doing that at key stations, but there I am in the doctor's office he wants it at that moment and I don't know that we would have tablets everywhere just for that any more than he would have had a printer there to print out and I'm wondering whether we can do something. Maybe we have a patient code that the patient can enter into the computer and then it's stored and then there doesn't have to be paper and there doesn't have to be a third-party device that has to be hooked up, supported, paid for, etcetera. Something, though, that makes it easy enough to do and that doesn't require that extra stuff.

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

Well, it's a challenging area, as you know, you know, a lot of this should have been...is supposed to be being done under paper and some of it isn't and so the first hurdle here is really getting a lot of people used to the idea that patients even have these rights even though they've been in existence for a long time and then the second step, of course, is being able to implement those rights electronically and we are contemplating a couple of different ideas here, one is an authorization that you give...that a patient gives to have their information shared with another healthcare provider or for some other purposes or usually...excuse me, an authorization they give to have their information shared for purposes other than health care or either for treatment. Then there's consent which is for treatment and then you have patient access to their own records. So, there's actually three concepts that you were discussing at the same time and unfortunately the rules for each of those is just a little bit different.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So I think we'll try to explore this in depth in the RFC.

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

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

As well as, as I said flush out what we do know based on Stage 2 final rule, because there's the transmit in there. Any other questions, comments on other topics in this category? Okay, we'll move on to category 3.

George Hripcsak – Columbia University NYC

Thank you, Paul. Good morning. This is George Hripcsak, thank you for the opportunity to present.

I'll go forward to slide 28. This is medication reconciliation; recall we edit allergies and problems. The green addition is simply that we queried the Standards Committee; they said we could get the standards in time, but we needed to start working now. This is simply a reminder that, yes, we should start working now on those standards, specifically for the nature of the allergic reaction.

Next slide on summary of care record, we've left it the same except that we want to align what we're doing with the S&I Longitudinal Coordination of Care Workgroup. So, this is a certification criterion, this is not asking eligible professionals to do any more, it's just saying that the electronic health record should incorporate the data sets that are intended. So this Workgroup created three related documents and two of them are relevant to this objective, specifically the consultation request and the transfer of care document. So, those two documents have a set of fields that might be relevant and the idea was to include those documents as potential things that could be filled if desired by the eligible professional.

Moving to slide 30 is actually pushed forward to Stage 4; the green part is just requesting starting work on standards so we'll be ready by Stage 4. Going to slide 31, on beginning to close the loop on referrals. This is related to my previous comment, again, the S&I Longitudinal Coordination of Care Workgroup, this is that third document I mentioned, the shared care encounter summary, once again including fields but not mandating that they get filled by the eligible professionals.

Moving to slide 32, and this is the final slide in this group. This is a recommendation...this is an objective developed by the Information Exchange Workgroup transferred to the Meaningful Use Workgroup because it's really a Meaningful Use objective. The information Exchange Workgroup will be presenting in a little while on specific IE issues, so this is really a Meaningful Use objective. So, let me put this one forward. So, you have not seen this one before. This is that EH will send electronic notification of a significant healthcare event in a timely manner to key members of the patient's care team such as the primary care provider, referring provider or care coordinator. Now it states with the patient's consent if required and I'll explain that in a moment.

And then the measures that 10% of patients with a significant event, so a typical significant event would be discharge from the hospital or admission to a hospital, in fact, would send notification. So this is first of all a very good idea. I know one of the main complaints we get from primary care providers is they don't know what's happening with their patients, they get admitted and discharged and they never hear about it and the patient gets lost to follow up. So, it is an important of thing. A couple of things come into here.

One, is it says with patient consent if required. The idea here is for other objectives, the patient's there in the room and they say I want this transfer to happen. In this case the patient's not there in the room so they'd have to have given consent ahead of time to have this event that is, say an admission to the hospital sent to their primary care provider. This was a recent addition, so I think it needs more work, but I think because this is just an RFC at this point, I think it's reasonable to put this forward in Stage 3 and I think that some of the work we just talked about with Paul a moment ago in the RFC, this should be dovetailed onto that. And the other part that's going to be important is provider directories, but we know that and we're working on that. And that is the last of the slides for this section. So let me open it up to questions.

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

Thanks. I have two questions. One is...and maybe this is for this section, but maybe a little bit for the other one and a lot of this is around looking at an individual patient record, what can the system do and I guess my question is around care coordination maybe more so, but even on some of the other ones, is there an issue of what the EHR overall can do for the practice to help them recognize the challenges in their patient population? So, for example, not just have it within the individual patient file, but you turn on the EHR and it says you've got, you know, four priorities or we're estimating for you, in other words, some capacity of the system not just at the individual patient level and is that even a fair question to be asking at this point?

George Hripcsak – Columbia University NYC

So, I think the first objective that comes to mind is patient lists and being able to survey across your practice, divided up by different...so look at this, how am I doing on...how is my practice doing on diabetes and popping at the top of the list should be the ones say most out of control. You know that can be hard to do, but I can bring up my patients with diabetes and see whether they've gotten hemoglobin A1c for example.

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

Right, but in this area it would be like, you know, three people were admitted last night or we're looking and, I mean, again, I would imagine a fair amount of flexibility, but it might be that like there's a pattern of admissions that certain patients are having that, you know, are ringing alarm bells and you may want to pay extra attention to these patients. I mean, something that is a tool for the practice, just like it would be where you could click into the diabetes measurement and say, I really want to increase my diabetes, you know, numbers and what do I have to do, who do I have to help for that, but this is more like, you know, how do you...it has more of an analytic component.

George Hripcsak – Columbia University NYC

That's what I was going to say. So, this is more, exactly, more advanced analytics, it's exactly what everyone is, you know, trying to work on and so I have to think about how that first objective on diabetes would expand to be more general and actually cover the areas that you're talking about, so maybe that's where we need to head in Stage 4. David?

David Bates – Brigham & Women's Hospital & Partners – Senior Vice President for Quality and Safety

We just did a national survey for NQF on this and called a number of the leading organizations around the country and they're actually remarkably primitive in terms of what their records, you know, do right now. So, it's been hard for me to think about, you know, what we should ask for in terms of Meaningful Use. I mean, I want our record to be doing the kinds of things that you're describing, but the tools to do that are kind of not yet available. But I think it's something that we need to sort of stay focused because we recognize that that's where we'll need to want to...where we want to go.

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

I mean in terms of a point of getting public comment, it may be something that's worth doing and even if you just started by saying, you know, something. I mean, you probably, you know, could do something.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, part of the opening for that is where I used the term dashboards, so that was the sort of the more ad hoc population view with drill down capabilities. So, we didn't prescribe exactly what's to be done, but that's one of the ways to fulfill that.

George Hripcsak – Columbia University NYC

Okay, other questions? Questions on the phone? Okay, then I'll move on to category 4. Starting on slide 34, this one on using the immunization history that we collected in Stage 2 and 1 had no changes from our previous presentation. Slide 35, on capability to receive recommendations, that is not just to have the raw data about what immunizations occurred, but actually to get some help on what comes next, we lowered the threshold to 10% and the reason for that...from when we had last presented. We had presented 20%, we wanted to be consistent. In other areas when we were introducing something new we thought that getting it into the EHR through certification and then having people start use it was a good first step and so rather than arbitrarily making some of them 20% and some 10% we went for consistency and tried to change them all to 10% and that's the reason for that change there in green.

The next objective is actually unchanged from Stage 2, never mind our previous presentation. Next slide, 37 is Stage 4, stage undetermined and actually no changes. Slide 38 is no change from Stage 2. Slide 39 on reporting to a registry, no change from what we previously reported except, again, we made the change from 20 to 10%, again, to be consistent.

Next slide, on reporting to a second registry, we have the same change from 20 to 10%. In addition, although the whole thing is in green, this was previously a later stage and we moved it into Stage 3 because Stage 2 had two registries, so it made no sense to take it out of 3 and put it into 4. So we just were consistent with the Stage 2 final rule.

Let's see slide 481 has no green, but I'm pretty sure that the 20% written there is a typo and we intended to change it to 10% and Art who is on the phone can comment if I'm not right about that. I checked with Michele and I think that we should have changed that to 10%. Slide 42 is stage undetermined about adverse event reports and I believe that completes the slides. So let me open it up to questions, thanks.

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

One question, I wonder whether this has come up at all, just the ability to receive a general urgent public health message, you know. We've done a pilot for a program in Maryland with Medscape where Medscape sends out an urgent public health message from, you know, the Deputy Secretary for Public Health or from me and they initially were a little wary about doing it for us, we kind of begged them to do it as a pilot and it was enormously successful, their click through rates were way higher than a lot of the other things that they've done and they are now marketing it around the country.

And, I wonder whether just a simple idea like if we had an emergency, if there was a measles outbreak, if there was, you know, something that just can't be defined, that just the ability for an EHR to hook up to a public health, you know, we use this very judiciously and you could always disengage, but the ability to be able to get those things, just, you know, a general public health message might, you know, right where the clinicians are rather than having to rely on, like, 25 sort of mediocre ways that we have to communicate with people might be helpful.

George Hripcsak – Columbia University NYC

Yeah, that's a very interesting comment. I think what we've done, and I'm not saying this is right, we looked specifically for ways in which it was patient specific within the EHR that is not using the EHR as a broadcast medium, but for patient specific, so we do have that in Stage 4 or stage undetermined for the public health agency to tell us you should look for measles and here's the patient you should be looking at, so that's actually in here.

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

Right.

George Hripcsak – Columbia University NYC

But, as far as using it in a more general form where I log onto the EHR and before I get to any patients it tells me just be on the lookout for this. We hadn't addressed that. I don't know, Art, do you have comments about that? Art, are you still on the phone?

Arthur Davidson – Denver Public Health Department

Yes, George. I don't believe we've specifically spoke to what Josh is suggesting. We have that idea embedded, as you say, in I think its 02B, the 402B, that's slide 37. The local or state health departments could provide a message and criteria for looking for items and even telling the EHR when to report an item. The CDC currently uses the health alert network as a method to spread information, Josh, as you're saying. I agree, it could happen at the point of care, it has not been something we considered in this as it's not really got a standard yet.

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

I mean, yeah, the health alert network is great, but it's, you know, very long messages and it's, you know, generally national things, but there are a lot of things that, you know, happen, we had a bat at a Ravens game, you know, I mean there's just different things that we would do a communication about and the response has been very, very positive from the medical community. So, I mean just in terms of something to think about where you might want to get...it would be very technically easy compared to figuring out which patients might have measles, you know, to be able to do that could be helpful and perhaps, you know, would be something that, you know, wouldn't be averse to doctors.

Arthur Davidson – Denver Public Health Department

I agree with you, Josh, that that's something of value. I think the system to make that happen may evolve. We could also use a provider directory as a method to send out a message via direct to providers. So the idea is there. I don't know how it would happen and it really hasn't been played out enough in a standards world for us to recommend it at this point. I think everybody's in favor of that concept, though.

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

It maybe something to get comment on at some place along the way.

George Hripcsak – Columbia University NYC

Other questions? Okay, thank you. I'll turn it back to Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, thank you. So, with these helpful additions we'll revise the RFC and we'll be including this in our RFC for November along with the other presentations you're about to hear. Thanks very much and the next one is going to be a report from the IE Workgroup on some of the things that were not in Meaningful Use, we covered some of them here, but Larry Garber is going to be talking about some other recommendations. And Larry is on the phone.

Lawrence Garber – Reliant Medical Group

Yes, thank you. I'll take the next slide, please. So, our Workgroup on the IE Workgroup was quite extensive and many of you are actually on it and I appreciate the work that you put into this and the great thought. Next slide, please. So, we have three things that we're going to talk about today. One is querying for patient information, one is querying a provider directory and one is addressing data portability.

So, on the first issue, the querying for patient information, Meaningful Use Stage 2 clearly supported communication through...during transitions of care, during planned transitions of care, but it turns out some very important clinical events take place when there actually is no plan to transition. So, for instance, when a patient shows up in the emergency room they're very vulnerable, high risk for adverse events, yet no one knew to push information to the emergency room to let them know about this patient. There are other similar situations, you know, when you send a referral to a consultant, you know, at the time of the initial referral there may be some information pushed to that patient, but when the cardiologist sees the patient for follow-up at one month and three months there's no additional referral necessary so there's no information being pushed to them letting them know what's been happening with the patient in the interim.

So, we wanted to come up with a mechanism to support communication when there are unplanned transitions of care. Now, in these cases the actual record holder, the holder of the most recent information, you know, doesn't know that the transition took place or if they do know that it took place they don't have the patient physically with them to obtain the necessary consent. The patient is at the consultant or the emergency department. So, we wanted to have a mechanism that supports gathering the information, pulling it to the place where the patient is at that moment in time.

The second feature that we wanted to make sure was in place was that we could do this without a master patient index. There are a lot of models, whether it's record locator services or central repositories where a master patient index is required and we thought that for Stage 3 that that might be excessively complex and we knew that there were models where you could do queries without requiring a master patient index and so we actually modeled this after something that we know that Epic has been doing for many years with many customers, a model of querying that doesn't require a master patient index but does ensure that patient consent is obtained.

One of the other features of our design and that design that Epic uses is that the consent is defined by the record holder and that's particularly important as you move across state lines where it's the record holder's state's laws that often supersede HIPAA and need to be followed. So next slide, please.

So, we're proposing just certification criteria, not a Meaningful Use objective and that in this criteria that there are several steps to the way this works. So initially what happens is that one EHR, let's say the emergency department, queries another entity such as a primary care physician, but it in theory could be a portal or a community database, and queries sends information about who they're looking for and who's requesting it and why it's being requested. The response from that record holder is that either, you know, here's a list of patients that potentially could be matches, here is a...if there is an exact match, here is a list of documents, but it also checks to see if they're authorized to release this information to this person for this purpose.

If an authorization is not already in place that instead of sending a document list, it actually replies with the need for obtaining an authorization and where the authorization language can be obtained. It may very well be that the record holder's EHR has that language and can send that or it may be that there is some other library of authorization documents that can be referred to.

When the requesting EHR, that would be the example of the emergency department, has obtained the authorization from the patient they send back...a message is sent back from that EHR saying that they...asserting that they have obtained the information or the actual copy of the signed authorization is sent back depending on what the record holder requires and then at that point the document list is sent and then specific documents can be selected. So it's something that doesn't require a central master patient index. It does accommodate the need for the correct authorizations to be obtained before anything is released.

It does...the way we have this set up is that the record holder institution is in charge and they can decide how automated this process is or how manual this process can be so that no laws are broken in the process of releasing these authorizations. Paul, do you want me to stop for questions at this point or go through all three?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Why don't you go through all three, please?

Lawrence Garber – Reliant Medical Group

Okay. Next slide, please. In this EHR certification criteria we've been recognizing that through Stage 1, 2 and 3 the provider directory is so crucial for the direct exchange of information through transitions of care even through queries that without a provider directory that can be used efficiently that many of these processes and the benefits that we're expecting in terms of improved care coordination and reducing readmissions and patient safety, that those will not be realized unless there's a convenient and efficient way to know where to send the messages and to obtain the appropriate certificates and send them securely.

So we're proposing for the next phase of EHR certification that EHRs be able to query a provider directory that's external to their EHR. So we're not specifying exactly where that provider directory is, but that they're able to obtain information and at least obtain entity level addressing information as opposed to, say, specific to an individual provider, at least if a message can get sent to the entity where that provider works then we will have accomplished a great deal.

One of the key things that's happening right now is that every state is solving this problem on their own and we feel that this is a market that's broken and needs some federal guidance to organize this. We did want to ask that a question be put out in the Request for Comment to get feedback on how mature the current standards are to support this criteria and what experience people have had. We know that, like other standards, there are so many to choose from and we want to be sure that there are successful ones out there. Next slide, please.

Now, data portability, so Meaningful Use Stage 2 has a fair amount of support for the ability for a physician's practice or a hospital practice to move from one electronic health record to another and specify that there needs to be able to dump out a summary document for all patients in the electronic health record and we believe that that was a great start.

We weren't confident that we could necessarily move further beyond that for the next phase of EHR certification, so we wanted to pose the question as part of the Request for Comment as to what we could do to move this further, to further improve the ability to switch from one EHR vendor to another and we left it as an open-ended question, you know, we suspect that there are a lot of nuances, that it's different for hospitals versus ambulatory practices. We suspect that, you know, some data, whether its images, may be more important or less important, depending on what they are and so we're hoping to get responses on some of those nuances to see if we can push the ball a little bit further forward. So that concludes my piece of the presentation.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, Larry. Comments, questions? Deven?

Deven McGraw – Center for Democracy & Technology – Director

This is Deven McGraw. So, I worked with Larry and the other members of the Information Exchange Workgroup to try to frame the query capability to make...to, again, specify the circumstances under which we're sort of looking at allowing for query and, again, to make sure that, you know, it really is the record holder institution that directs what their EHR does. But I do think we probably need for the Tiger Team to sort of take a look at this particular use case or set of use cases in light of what we've previously said as a committee about consent, fair information practices and think about how it applies to the specific circumstance. So, not able to do that in time for this RFC, but certainly if this is included in the RFC, which I would support, we could begin working on that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's very helpful and of course that bears on the previous discussion about transmit.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

It's all getting information to flow, who has to be involved and what's the liability and it's a big deal.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So, on your agenda, thank you. Josh, is that your card or is that left over?

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

Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

No problem. Anybody else? Okay, thanks a lot, Larry.

Lawrence Garber – Reliant Medical Group

Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And thanks to the team. All right, Deven, you're up, and welcome from Pittsburgh, yeah, Deven got diverted on her way here last night due to the fog, so she...

Deven McGraw – Center for Democracy & Technology – Director

Yeah, they apparently had less than a quarter mile of visibility in the Baltimore Airport last night and very early this morning. So, thank you to the folks at the Pittsburgh Airport for making it as comfortable as it could possibly be, but I'm actually really glad to be here. So, we as a Tiger Team did some thinking about some RFC questions for category 5. Category 5 is of course protecting the privacy and security of healthcare information and traditionally there have been Meaningful Use objectives and certification criteria that are intended to promote or support that category.

We have...I'll say it's sort of three buckets of questions and as usual we never present anything to you that doesn't have like a gazillion words on it, but, I'll try to summarize it as much as I can. So, this first set of questions really goes to the issue that we just covered as a policy matter before the Health IT Policy Committee which is, you know, the issue of authentication of user, provider users of EHRs and at what level of assurance, and in what circumstances should we require more than just user name and password, which is typically customary, but doesn't always provide the most robust security.

And so we're...the questions that we're really asking here are aimed more at sort of whether there ought to be certification criteria to support that. And we think it's an important set of issues to get feedback on because it's not...I don't think it's necessarily a slam dunk yes answer because there is a lot of flexibility for example in the NIST framework in terms much how you meet level of assurance 3, so if you're going to have a certification criterion what does it look like?

And we also got a fair amount of feedback during our deliberations on the policy issue that the NIST document, which is initially designed to be used by individuals who want to do remote business with the government, but it's quite often used in the private sector by reference, whether it's got the right set of...whether it works well in the healthcare industry in terms of what factors will count as your sort of second factor for multifactor authentication, again, beyond user name and password, which is just one factor, you need a second factor. So, this set of questions is designed to sort of scope out public comment on that issue around EHR certification.

And here, again, this is probably more for the public and for those who are not sort of privy to our previous discussion, but we...in our policy recommendation we said for provider users, you know, certainly by Stage 3 of Meaningful Use for remote access they ought to be authenticating it beyond user name and password and we actually defined...set some parameters around what would be considered to be remote access and we have just repeated those here on the slides and then there's a link to the latest NIST guidance for anybody who wants some really good bedtime reading. It's heavy duty stuff, for security professionals it's like a Bible, but it's a little bit hard to read.

So, the next set of questions really target the fact that CMS in thinking about Meaningful Use objectives in this category has been quite amenable to looking at the existing security rule obligations and thinking about spotlighting one or two of them for criteria for Meaningful Use objectives. So we saw in Stage 1, for example, the focus on performing a security risk assessment and correcting deficiencies. Already a requirement in the security rule, Meaningful Use essentially shines a spotlight on it.

In Stage 2 at the recommendation of the Policy Committee we shined a second spotlight on the issue of addressing the implementation of encryption of data at REST, no change to what the HIPAA security rule already requires, but just shining a spotlight on it as part of attestation. So, this set of questions really says "hmm, this is a strategy for Stage 1 and 2, should we be continuing this strategy for Stage 3 and, if so, what other provisions of the HIPAA security rule should we be focusing on?" So, it asks the general question and then also tees up something specific that was of interest to the Policy Committee in terms of our own consideration of what would be a candidate for a spotlight in Stage 3 and we would want to get some specific feedback from the public on that as well and that is the issue of doing outreach and training to staff and sending them security reminders.

Lack of training is one of the top five complaints received by the Office for Civil Rights in terms of the HIPAA violation and it's also been spotlighted in a number of the enforcement actions that have taken place over the last year, year and a half or two. So, we're interested in getting some feedback on that specific issue.

And then our last set of questions has to do with the use of the audit trail for functionality that may not necessarily be possible with the current audit trail standard. The audit trail standard that's currently in the...so this is another one that's really more for...that is just for certification. So, the audit trail standard that's currently in the 2014 criteria is a standard that was recommended by the Health IT Standards Committee and that came out of its Privacy and Security Working Group.

We have four members of the Standards Committee, many of whom are also on the Privacy and Security Working Group, including its Chair on the Tiger Team, and so they are supportive of going out to the public and asking questions about whether this current audit trail standard is actually good enough to be able to sort of do some robust analytics in terms of investigations of record access across the enterprise and also potentially with respect to looking at audit trail functionality as maybe a possible solution to this issue of a standard for accounting of disclosure that we can't seem to really crack very well with the current standard we have continuing to be optional and us not making very good progress on resolving the connection between the policy and technology that's going to be really critical to being able to implement the changes that congress mandated in HITECH.

So, again, this is an RFC. We could get a lot of comments back that say audit trail does not equal accounting of disclosure and here's why, but that's not the only purpose for which an audit trail might be more useful if it had a greater level of functionality and it's essentially a set of questions that our standards folks helped us design to try to get some public feedback and that's it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, thanks, Deven. Questions, comments?

Deven McGraw – Center for Democracy & Technology – Director

Wow.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

This might be the shortest ever.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, compared with the last one, too. So, while we have a few minutes I want to do a public service announcement. The Tiger Team and the Privacy and Security Standards Working Group, and I think the Consumer Empowerment Working Group, I may not have the name right, of standards, are collectively having a virtual web hearing on the 29th of October from 12:00 to 4:00 to look at the issue of patient identity proofing and authentication, which we said we would do after we finished with provider users and we're doing that. We're going to do it on the web. It will be interesting to see how well that works since we...you know, I know Meaningful Use has had...some of the subgroups have had web hearings, but this is going to involve about 12 different people testifying in addition to multiple people involved in potentially asking questions and it will be interesting to see how well it works, but we think it's a format that will enable more people to be able to participate given travel constraints and we'll see how it works.

And, so, you know, certainly if others of you would like to participate who are not on any of those Working Groups we would welcome your participation. I think it would be helpful to know if you do want to participate and you want to be able to have a live line for asking questions so that logistically we can make sure that that happens, and we can let you know about the logistical process for...because I think we're going to use, you know, the hand ask question thing because we won't be able to see people. So, we need to know you're out there.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good and that also of course bears on this morning's conversation.

Deven McGraw – Center for Democracy & Technology – Director

Exactly, which I missed, but I'm going to read the transcript.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, any other final comments? If not then we're trying a new method of making sure that we have timely comments from the public even during a meeting. So, we have some time scheduled now and then at the end of the afternoon for public comment. And just to tee up, does anybody know whether Jim Walker is available earlier than 1:00 p.m.

MacKenzie Robertson – Office of the National Coordinator

I'll follow up with him on e-mail.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Oh, okay, great. Okay, so now it's open for public comment.

MacKenzie Robertson – Office of the National Coordinator

Operator, can you please open the lines for public comment and while we are waiting for that to happen, if there is anyone in the room that would like to make a public comment if you could please come up to the table.

Alan Merritt - Altarum Institute

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

MacKenzie Robertson – Office of the National Coordinator

And, I do just want to make a note that public comments will be limited to 3 minutes.

Kelli Emerick – Executive Director – Secure ID Coalition

Hi, my name is Kelli Emerick; I'm the Executive Director of the Secure ID Coalition. Our coalition is really focused on user privacy. And I want to just first of all congratulate Deven and the work that her group has done in looking at provider authentication. This is a really critical area and the ability to make sure that providers are who they say they are when they're accessing records is certainly something we are really concerned about. I would just add that I know they came back and looked at level three authentication functionality as defined by NIST, we certainly support that, in fact we would support not only that being a floor but providing some flexibility for providers to go higher. So, we would suggest a change to say level three or higher going forward.

I want to comment on the discussion this morning regarding engaging patients and families and again that authentication question of providers. Who is allowed to have access to information? Where is the liability? How do we know that somebody is who they say they are, not only on the provider side but on the patient side and the designated person potentially on behalf of that patient? So, again when that information is being sent or that record is being sent how do we know that it is being sent to the right person?

User names and passwords are pretty common across all of technology today, certainly, that has not been too effective if any of you have children, you may know that their Facebook accounts get hacked by their friends all the time, their user names and passwords and again knowing that we're getting that information to the correct person and how does an authentication function occur, so again we can verify somebody is who they claim to be.

So, I would really, really encourage the committee to take a strong hard look at this going forward in Meaningful Use 3 and really spend a lot of time thinking about how do we assure that transfer of information is going to the correct user.

Joanne Lynn, MD – Director Center for Elder Care & Advanced Illness - Altarum Institute

Hi, I'm Dr. Joanne Lynn I work on serious illness and elder care, I'm the Director of the Center for Elder Care and Advanced Illness at Altarum Institute, and I'm quite perplexed as to why you've moved the care plan from Meaningful Use 3 into the hoped for Meaningful Use 4? It was not terribly controversial and it just sort of shifted. In the presentation today, Paul and George didn't really give any explanation for it. This is the most important piece of mobilizing services for the seriously ill. We are going to almost double the number of people who have serious chronic illness over the next decade. Everything else we are doing in records is effectively backwards looking or looking only for right for today or today you take these medicines.

The only place where we start talking about people's futures is in this little piece on care plan, it's slide 30, and what was there, as of, I thought a relatively uncontroversial care plan element in the electronic records in the last round has just slid into, you know, as I say the maybe we will eventually get there Stage 4. You know, it would be nice to have more of it be digitized rather than narrative, it would be nice to specify some more of it, but these are really, you know, seven or eight relatively uncontroversial elements and what's the person's future or what's their current care plan, you know, how much do they know about it, who's on the care team. You know, let's get a place in the record to start putting these things in.

There's a similar issue with the advanced care plan which is back on Slide 13. I understand there will be a listening session before you come to terms with this, but surely we are far enough along to start carrying a PDF of people's care plans and maybe the designation of the surrogate. There's nothing more important when a person shows up, you know, very sick in an emergency room than knowing these quickly-needed elements about what their goals are and what they have already decided and to say "yes" or "no" that they have an advanced care plan is really so trifling as to be kind of irrelevant and maybe even kind of increasing liability if it doesn't carry the advanced care plan with it why have it?

You know, the VA has had advanced care plans as PDF for a decade or more, this is not hard to do. So, it seems that both of these really need some re-attention. I know they're not part of the standard hospital perspective, but that is in fact the problem is that patients need these care plans into the future as they move around in the system, it belongs to the patient. There is nothing more central to patient centered care than the plan of care, it spells out the services, what the caregiver can do, who's on the care team, all those sorts of those things. Why have we let them slide? Do you want to explain, Paul, or do you just sort of stand there?

MacKenzie Robertson – Office of the National Coordinator

Thank you for your comment. We'll just go to the next one.

Joanne Lynn, MD – Director Center for Elder Care & Advanced Illness - Altarum Institute

Thank you.

Mari

Good morning, thanks for the opportunity to comment. I appreciate you guys opening up the comment timeframe twice, that's really helpful. I know we asked for that. I'm going to just start with a question on page 11. I'm going to put on a consumer patient hat first and then I'll go to my professional roll.

MacKenzie Robertson – Office of the National Coordinator

Could you just justify yourself first, please?

Mari

Yeah, so as a consumer, my name is Mari, patient, on page 11, not slide 11, but page 11 there is under engage patients and families, there is an item that is SGRP 2, new for Stage 3, offer or objective offer 10% of patients the ability to amend their information. So, as a consumer I have a question about that. I have a pediatrician for my children and we have an EHR and I'm not sure if the doctor gave me, and I do see the copies, they give me stuff, I'm actually not sure I'd notice if there was a problem or an error. So, just as a comment as a consumer I'm not sure that I would know that. I see like the little charts they give me. I see like the ICD-10 code which, just from being a savvy and health policy I know what ICD-9 code is, and I know that I could Google plagiocephaly, which I never would have known what was, but just looking at the record as it spits out I'm going to tell you right now I'd have no idea if there was an error.

Okay, putting on the AMA hat. Here with the AMA. I'm going to stay now on the same exact measure, I'm just wondering, again, like how this would actually happen from the physician perspective and how the patients would be like perceiving this, you know, I'm not sure that I would...I think it might be a little strange if the doctor said, hey, do you want to see if I've made an error in your record, that's a little odd to me. I mean, because on the surface it suggests that I have made an error, so do you want to make sure I didn't make an error. So, I think, you know, there may be some more consideration we need to give to that, because you're basically saying like you might need to change your information here. The second comment would be is that HIPAA already allows for a process to do this if you think you have a problem.

Okay, so my second comment is respect to certification process and it goes back to Dr. Farzad's comments or Mostashari's comments at the beginning, I think there's a lot of things that we would agree with, I don't think the AMA thinks that EHRs are perpetuating fraud or up coding, but given the fact that there is going to be this proliferation in use of EHRs, we think it would be prudent for the certification process to take into better account some kind of protections and mechanisms to insure that there isn't some inadvertent misuse of the product not in fraud but just, you know, leading them down a path that they shouldn't be led and we have comments on this, we have commented 2 times in both Stage 1 and Stage 2 on the certification rule. So, we would support that and we encourage you to work with us on that.

Then my last comment I would say is with respect to Stage 3, you know, we're still sort of in the process of digesting Stage 1 and Stage 2. We don't have a firm understanding of where things are going to land and, you know, we've advocated to CMS that we think an evaluation process is needed at a very minimum, I know that takes doing an evaluation, a full blown survey has to go through OMB approval it's a lengthy process.

However, in the meantime while you can consider that as an argument for the need for that, you could do something while their...like during the attestation process at the very end maybe build in a series of like 5 questions that said, you know, what was the...and this would just get to the guys who are actually even trying to meet Meaningful Use, what was the hardest measure to meet, what was the easiest measure to meet, you know, on a scale of 1 to 5 how hard was it for you to achieve this? I think those are really basic and I think that's a fair request. So, in the interim while you're waiting for a full blown evaluation and we don't believe that that's happening, that would be an interim step that I think that CMS systems could accommodate.

And then, lastly I'll conclude with an argument that we would like to make that just, if you miss even one single measure, whether it's in Stage 1 or Stage 2 by 1 percentage point you have failed and I think that that's a really high threshold to have to meet. I don't think that there's anyone out there who gets an A+ on everything. So, I think what we're asking you for is some dialing it back a little bit and saying, you know, if you meet $\frac{3}{4}$ of the measures, $\frac{3}{4}$, you know, you try to meet all of them but you only meet $\frac{3}{4}$ that's 75% that you have in fact gone from like doing nothing electronically to doing a lot electronically and that is...we think that that's a fair request and we hope that you'll consider that and perhaps suggest that in the RFP. Thank you.

Diane Jones – American Hospital Association

Good morning, I'm Diane Jones with the American Hospital Association, thank you for this opportunity to comment. Thank you also for having multiple opportunities today for public comment. As the FACA Committee noted at the outset relative to the timing of Stage 3, I'm going to focus my comments specifically on that issue, and so first I have a recommendation that the committee recommend and consider seriously, and undertake a delay in the release of the Request for Comment for Stage 3.

We heard earlier that there would be a timeframe of a November release and then subsequently comments due in December and aside from any issues relative to end of year activities that many people engage in, the reality is at that there are providers who will be in that same timeframe very much focused on attesting in Stage 1. In addition, there will be others who are very focused on understanding what is in Stage 2 and so I think the timeframe is going to be a bit challenging to also ask individuals to provide a response relative to stage 3.

Second, I would urge the committee to include in your recommendation for the Request for Comments; whenever it's released that you have in fact a 60 day period to receive those comments back. Certainly, we understand that there are pressures to move swiftly being cognizant of the availability of or time rather for people to prepare for the actual start of Stage 3, but the reality is that a 60 day comment period really would provide time for the multiple and diverse stakeholders who are participating in this process to provide a response that is thoughtful, that's informed, perhaps based on some of the experience and that along with some of the comments that were shared today relative to projects and pilots that is underway, might be...all collectively might be beneficial for folks to consider and incorporate in their Stage 3 comments. So, again, I would urge you to have a 60 day comment period for stage 3. Thank you.

MacKenzie Robertson – Office of the National Coordinator

Are there any comments on the phone?

Alan Merritt - Altarum Institute

We have no comments at this time.

MacKenzie Robertson – Office of the National Coordinator

Are there any more public comments in the room? Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

MacKenzie, as a member of the public...offer a public comment?

Judy Faulkner – EPIC Systems – Founder

I just wanted to request a few things that aren't specific to the reports like could we ever have a general discussion among ourselves, so we have a public comment, but the problem is that the public comments can talk in general, but we have to respond to just the discussion up there and I think there's some topics like the...sorry, the fact that we...that I'd like to bring up like we get the write ups yesterday, how do we do a good job if we get them yesterday and don't have enough time to read them, get feedback?

I'm getting e-mails from technical folks, but it is too late. I'm writing back to them and saying too late. Is there a way that we could get these things earlier? Could there be some schedule that folks have to say this is a date they have to be gotten to you folks so that they can get to us in time to do a higher quality job for the country?

So one is can we have occasional discussions that are outside of just answering a question with respect to the slides or the discussion that the speakers have? Two, can we get stuff earlier? Three, a question about Stage 4, which is if this is a difficult time for health care financially, is Stage 4 funded? Will there be money for Stage 4? How will that work?

And the last thing I wanted to just say was it would be great if we could have a single national standard for immunizations. Right now the states have separate standards, it makes it very difficult and that's a really important area that if we could have a single standard then I think that would help children everywhere.

MacKenzie Robertson – Office of the National Coordinator

So to address some of those, we are instituting administrative meetings where the committee can discuss things internally in terms of process and materials, so that is something that we could bring out during our administrative meetings.

And then in terms of...for the agenda, I've e-mailed James Walker to see if he can push up his time, but I haven't heard a response back yet. So if we want to break for lunch now, maybe we can do 45 minutes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And we'll do Elizabeth Holland or Jodi could probably give the ONC update earlier; right? That's one way to advance this conversation. Okay, so we can still maintain about a 45, if we got back at 12:30 that puts us well a half an hour versus do you want to have a longer lunch break?

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Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. I think people are looking for...so 12:30 especially since some orders have been done ahead of time for lunch. Gayle, did you have something you wanted to...?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Yeah, in the way of kind of comment among the committee since we do have a few minutes I would like to make a few comments if general and I know we're doing...we have a lot of ongoing pilots and I was delighted to hear about some of them today. I think one of the things we might, as a committee, would like to be informed about are a variety of these pilots that are going on and the outcomes or at least some preliminary indications and what's going on within them. What is being learned? I think that would facilitate us in decision making and also open up a whole lot more questions as to where we can go. So pilots are important. Pilots give...tend to see positives and negatives, what's going on, what are we learning and what are some pitfalls that perhaps we might avoid and what are some good things that we might want to implement.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, Gayle, and that's one of the purposes of having ONC updates is to try to get some of those, but anything that you hear about we can certainly queue that up.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

If we could have a list of the pilots, if we could have kind of a general, you know, what is going on out there, what's the purpose of that pilot. What issue are they addressing? And kind of circulate that so we even know that these pilots are going on.

Neil Calman – The Institute for Family Health – President and Cofounder

Paul, this is Neil, can I just ask as a follow up to that one question?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes, Neil.

Neil Calman – The Institute for Family Health – President and Cofounder

Is there some transparency in relationship to how the pilot sites are selected? I think I'd like to hear about that as well. How does ONC determine what pilots it's looking for and how do organizations have an opportunity to apply to be pilots in various programs? Because we seem to always hear about them as it happens but I don't really understand the process by which these things are determined.

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Paul, this is Jodi, often times when we're doing these pilots it's through a contract. So, often it's the contractor's process for selecting pilots and we work with them on setting criteria and all of that and approving whatever they're coming up with. But often times the pilots are... will contract for pilots to be administered through a contract. And so often times it is their process for selecting pilot sites based on some criteria that they've approved through us. That said, if there is a way that we can maybe do a better job of letting folks know in advance so, you know, they can encourage folks to participate or apply to participate or that sort of thing perhaps there's some opportunity there and I can bring that back.

Neil Calman – The Institute for Family Health – President and Cofounder

Yeah, I think that's very helpful.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I'm hearing there a lot of interest in all of the work that is going on at ONC. We know how much work there is going and how fast paced it is. We'd just like to be able to incorporate some of the results particularly in some of the deliberations. So, that's good feedback.

MacKenzie Robertson – Office of the National Coordinator

And, Paul, before we break I want to take a moment to recognize that we have a new HIT Policy Committee member with us today, Christopher Boone, he's from the American Heart Association. If you just want to give a brief introduction of your background to the committee members I think that would be great.

Christopher Boone, FACHE, CPHIMS, PMP – Director of Outpatient Quality and Health IT – American Heart Association

I think you just did it. Well, you know, as MacKenzie just stated my name is Chris Boone and I'm the Director of Outpatient Quality and Health IT at the American Heart Association where I lead...well, we're doing a number of different things, but I lead a lot of e-Health initiatives that we have at the association as well as an outpatient quality improvement program called the guideline advantage which is a tri-agency partnership with the Cancer Society and the Diabetes Association. We're also doing a lot of things on the consumer health front that...so, I'm hearing a lot of this dialogue is very interesting and I hope to chime in and add that value as soon as I get up to speed on exactly everything that's happening. All right, so that's it, thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, welcome, Chris and thanks, MacKenzie. So, not to deny us the full lunch break why don't we go until 12:40 to give us the full 45 minutes, thank you.

MacKenzie Robertson – Office of the National Coordinator

So, its 12:40 if everyone can start heading back to their seats we'll go ahead and try to keep onto the agenda.

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

Hello?

MacKenzie Robertson – Office of the National Coordinator

Operator, can you please open the lines back up?

Operator

Lines are open.

MacKenzie Robertson – Office of the National Coordinator

Thank you. Jim, are you on the line?

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

Yeah, how are you?

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jim. We'll be getting started just in a second.

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

Great.

MacKenzie Robertson – Office of the National Coordinator

So, Paul, I'll turn the agenda back over to you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, thank you. And Jim, are you on the line?

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you. So, thanks, Jim for being here earlier. So, we ran ahead of schedule and so we're just trying to move the agenda along so that we can get out early as a treat.

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I like that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yeah, there is a lot of support here for that. So, Jim, thanks for pinch hitting for David Lansky on this Quality Measures Workgroup report. Jim is going to talk about some of the concepts and Request for Comments coming out of the Workgroup. Okay, Jim?

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

Thanks, Paul. So I take it you can see the slides.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes, we can.

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

Great. So, what the Workgroup has been working on is a way to rethink the development of quality measures to make them more useful in the various environments in which they need to function. I think that's enough to say on...and so the business end of that is a Request for Comment that we're going to discuss the outlines of today and then following that a transmittal letter. I think I'm ready for the next slide.

So, in terms of conceptual framework the purpose of all of this is to use Health Information technologies to help us to capture data, act on it and then exchange it among the various members of the patient's care team to improve quality and critical to this is the concept of using input from the patient's entire care team obviously including the patient lay caregivers, and then also sorts of clinicians that is are involved in the patient's care. To use measures to achieve that, the second column there, we are thinking in terms of packages of process outcome suites, clearly outcomes are the critical measure, but from any care delivery process view it's important to have some help particularly for small organizations knowing what the processes are that have been shown to correlate causally with better outcomes so that they have guidance on how to design processes and also how to measure how they're doing.

The second element that is developing de novo instead of legacy measures, we're going to come back to that but just a language note, de novo here doesn't, I believe, mean ex nihilo, but more taking the content of an existing measure to the extent that it's evidence-based and important to the population, and then starting from that point and developing all of the rest of the measure de novo and it turns out that trying to retool existing measures often involves so much rework that it would be simpler and more effective to just start all of that work from the beginning from the content. Then the last part of that is to align the measures with the functional objectives with the outcomes that we want to achieve in the population.

The third column then is the quality improvement platform and here the core concept is that for sub-bullet creating supporting flexible standardization so that there is enough standardization that the environment is consistent and coherent, and that it's possible to develop processes and measures that can be reused widely, but still to preserve the flexibility that's needed to apply the standards to specific localities and also obviously to specific patients and it turns out that that flexible standardization is one of the most important and trickiest parts of process engineering or system engineering.

And then the last bullet there is to encourage the development of population management tools so that individual eligible providers but especially clinics and hospitals and other organizations have the tools to be able to monitor their performance in supporting a whole population's care and identifying where the gaps are and addressing those expeditiously and efficiently both.

And then the fourth column is the measure pipeline. There are a number of questions about how we choose the right measures, one of course is the six prioritized domains that you all know, and then another is to identify exemplars, measures that do a particularly good job of reflecting the best evidence of matching the needs of a population, of being truly manipulatable electronically and for the most part automatically so that they provide kinds of beacons or models for developing other related measures.

And then finally to really support innovation, are there ways that the community, the wider healthcare community could be engaged in identifying measures that perhaps in the first instance would apply only to them but then through a process of review and standardization, and optimization might be broadened to become valuable measures for larger populations.

So then the next slide is...the next several slides are sort of statements of program purpose. This is overall the next ones sort of follow up on that, but here the message is that the measures and the measure sets are needed or one of their core purposes is to make EHRs useful tools for the capture, manipulation and reporting of quality in a way that's maximally efficient, in a way that repurposes the data that is needed to do quality care and turns that into reporting almost automatically and with minimal extra effort and obviously all of this with the intention of improving care and particularly the part of care that is the experience of patients and also providers remembering that, particularly for patients, the experience of care is one of the dominant measures of quality.

So, then sort of the sub-points under that, as I said, the measures should be designed to capture data that is already being captured for quality care without the addition of, you know, without additional care documentation or data inputs. The second point is that the calculations for the measures and their general implementation in EHRs need to be flexible enough, need to be based on flexible and adaptable platforms, software platforms so that as additional measures are created or as measures are updated it becomes efficient particularly from the care delivery organization stand-point but obviously also then from the vendor stand-point to make those changes.

The next bullet is that providers may need to be able to configure measure calculations to manage...to reflect local workflows and there may be technologies or specialties that aren't available in a particular setting for instance and those kinds of irreducible differences need to be able to be represented.

And then the last bullet there the idea is that rather than quality measurement being something done after the fact and sometimes a long time after the fact, quality measurement becomes really an aspect of business process management or workflow management where quality is being measured and fed back into the system producing improvements in the system in a near real-time way so that both the processes improved, patients and clinicians experience are improved and the reporting that comes out of it represents the reality of the care and it's quality as well as can be.

The next slide, so the Measure Workgroup is talking here about the idea of retooling legacy measures, but noting the difficulty of doing that either with high fidelity or with anything like efficiency, it becomes a question of whether it's cheaper and easier to build a high quality house on a new piece of land or to customize an older house, as you know, the older house can end up being more expensive and less adequate product at the end. So, the question here that we want to get comment on is this shifting away from retooling legacy measures reasonable and desirable. What would be the benefits of doing it and what are the potential adverse effects that may not have been anticipated at this point that would, you know, that would either counsel caution or maybe make it not a good idea.

And the next slide, so here is the interest in population management. Enabling any care team, clinic, hospital or single eligible provider to monitor the effectiveness of their work and so, you know, the first question is what kinds of evidence are available for the effectiveness of this kind of population management and then as a subset of that, what is the evidence for business, what's the value proposition? Is this something that costs a great deal of money but it's hard to identify, commensurate pay back and particularly measured both as clinical quality and financial or is this something that there is a clear business case for doing.

And then the second would be what are the technological challenges and here the issue is that this field is new and dynamic, and one of the things that concerns the Workgroup is how much we can provide guidance without being so prescriptive that what we inadvertently end up doing is delaying or even making impossible valuable innovations. I think the Workgroup probably has the sense that in five years this particularly will look vastly different than it looks today in all but maybe a few places.

The next slide is about, you know, a pipeline, how we create a system that produces a consistent set of quality measures assuming particularly that care delivery organizations to really deliver quality across a whole set of patient problems, venues and so forth. We'll need a substantial number of high quality measures and that many organizations will not have the means to develop themselves. So, there are two approaches to this idea of having, of reaching out to the sector as a whole and asking them to identify quality measures.

So, as you see down below there one approach, and perhaps might be called conservative, would be to identify certified development organizations and perhaps those would be learned societies, but other organizations with demonstrated capabilities and commitments would be identified who would develop and release, and report measures for Meaningful Use and then the other would be, and I don't believe the Workgroup thinks these have to be mutually exclusive by the way.

The other approach would be then to allow any eligible provider to contribute measures but then, you know, would there...what kinds of constraints would there need be in terms of the numbers of these that an eligible provider might use in terms of how such measures might feed into a review process that would identify particularly valuable ones for further development and perhaps widespread use. So the question there is what kinds of constraints would be needed to make this sort of approach something that was optimally effective and non-chaotic I guess. The next slide then is our thank you to all of you and opening the discussion.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Jim, this is a really important topic just as we all know that HITECH was poised to help enable us to both measure and deliver better care I think the quality measures themselves is a big ticket on the way to that goal and it reemphasizes what Farzad said this morning about the program and how we're building an enabling tool.

If you go back to Slide 3, I don't know who is controlling the slides, but it's really useful to highlight, we have a set of measures that were constraint...that were developed in a constrained world where the only electronic data were claims and administrative data. As we build this new world with clinically rich data from the EHR I think that many, many more things are possible and I think that's what we're trying to do.

If you back it up to one more there are four columns. So, the e-Measure, that's this concept, that one, please, thanks, the concept that we now have, we're still tackling the same concepts in terms of why we're trying to improve health and quality of care, but we have far better tools, we have the potential for having far better tools. So, that's why shifting from retooled, what we...by time limitation, the only thing we do for Stage 1 and mostly Stage 2, to something where you consider the source, that's the de novo part of it is really important.

We've talked here in the QI platform before on how we want to make sure that these measures almost come as a by-product and not as an extra burden on the providers in terms of calculating them and then what Jim also mentioned is the population management tools, what Josh Sharfstein talked about this morning, not just a retrospective scope on what we have done, but what are we doing day-to-day and on a daily basis how can we improve the health of the population we serve?

And then finally, the pipeline at the end is a way of saying take advantage of this same process in EHR incentives and can't we stimulate and create a pathway for measures that are already in good use in different organizations who already have an EHR, can't they be surfaced as an alternative way of bringing forth innovative measures that can go through the same process afterwards but can't we start even hearing about them as part of this program?

So, I mean these are really potentially game changers and it comes at the end of this process because we have to have the tool in place, we have to collect the data, but in Stage 3 and beyond I think there's going to be a real emphasis on this side which is why we're addressing this in this RFC sort of giving us a lead time in developing these measures and vetting them. But, let me open it up. Gayle has the first question or comment.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you. And I share your enthusiasm for this really being the area where there can be major changes in where healthcare is going in this country. I think we really want to see the innovation that can come about in improving the quality of care this is where the rubber meets the road truly in quality of care improvement. But, I do have a few questions and a little bit of concern because as we move into this arena we have to really do two things.

First of all, make those measures appropriate for the provider who is using the tool. So, without a real conversation about specialties and without addressing and really making it meaningful for the individual, the provider using that tool, we're not going to accomplish the goal we want to accomplish and I have had great concern as we have move forward we have not really addressed specific specialty areas and developed measures. And there's a measurement community out there that does have measures that really can be utilized and we need to democratize down to the very specialty level.

Then you get the question of well, as we develop new measures who's going to vet them? Who's the ultimate decision maker? You know, I think those kinds of things really take a very large discussion outside of the purview of ONC and there are measurement communities out there. There are groups that do this and do they have the expertise in electronic health records to do it appropriately? So, I think this is going to take a lot of collaboration and quite a bit of time to...and vetting and validating to know what is appropriate.

So, I really think this is going to be an ongoing project and I have a lot of questions about it and I just, you know, the comments will be very telling I think, but I think they will raise even more questions and then the ultimate, where we go in Stage 3 of Meaningful Use is going to be very difficult. So, I'm looking forward to these comments and I'm sure other people will join me in that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Jim, do you have a comment or response?

Jesse James – Office of the National Coordinator

This is Jesse from ONC; I can make a quick comment on Gayle's response which gets right to the heart of the idea of the innovation track. So, there were sort of two motivators for the Workgroup and for ONC, our thinking on the innovation track was, one, inside of ONC we found measures and good measures in different parts of the federal system that were EHR-based but often did not go through NQF endorsement, the typical pathway for national measure endorsement, some from VA, some from DoD and that made us...that reminded us that there are great measures out there that we just haven't necessarily had our hands on.

And also, as we read comments from the Stage 2 proposed rule where many specialty societies and even vendors said that they're pushing us to open up Meaningful Use, the quality measure set to that exact end of making the measures individually meaningful as possible for the specialists sub-specialists and sub-sub-micro specialists, as Kevin Larsen puts it, the left eye surgeons who only do retinal detachment on left eyes, they have their own measures and they understand the clinical science often to an extent that's beyond that of the typical measure developer.

So, we see an opportunity to make Meaningful Use and the Meaningful Use of the CQMs more meaningful at the provider level by...absolutely by democratizing the process. We haven't entirely figured out what the vetting might look like, but we've had some early conversations inside the Workgroup and inside of HHS on what this might look like, but what we would really like to get...it's almost throwing the question back to the public to say is this something of value and how might we build structure around it?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, Jesse.

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Go ahead.

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

This is Jim; I think to Gayle's point, excellent points. I think we're going to need to figure out how to create a two-track process where we cast the net as widely as possible but then there is a transparent and principled method of vetting. So, for instance, you know, in view of the evidence that for many surgeries the patient should get a dose of antibiotics within an hour before the surgery and you can think of...Peter Pronovost's checklist for surgery, there are some things that really are cross cutting and have very large population impacts, and very strong evidence bases and so I think we want to sort of balance the two which will be the trick of course.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And, I can also maybe respond, Gayle. So, I think part of these recommendations are to address some of the very problems you've raised let's say in terms of specialists, one of the big beneficiaries could be like orthopedic surgeons who may go through a whole career and not even actually know how many of their patients walk again without pain, but you could never do that on paper. Now that we're making HIT in the form of patient portal or PHRs available maybe we could get that kind of information and it seems like that would be extremely useful to surgeons as an example.

Your question about vetting, we certainly do have in place NQF, which as you know has joint committees made up of domain experts that view from each specialty perspective the validity, the scientific rigor, etcetera for these measures and this is basically to stimulate more of the supply side into that same process, it wouldn't circumvent it, what was described as a mini-submission form is actually a mini-NQF submission form, so not the same amount of detail and work, and testing going into an NQF submission form but still whoever is submitting has to say there was some scientific basis for that, this is useable, this is feasible, so on and so forth. It was just to stimulate the pipeline really. Other comments and questions?

Well, we're doing pretty well today, I don't know, in getting through the agenda, but, no I think, this is extremely good work that has gone on by the Workgroup and thanks to Jim for presenting and David Lansky for leading the group, but it's really important and we're trying to put this in front of the public because this would be potentially a game changer and a change, you know, at least a modification of the current pipeline that we use for quality measures and it's really to try to take advantage of and leverage what's going on in the EHR Incentive Plan. Kevin?

Kevin Larsen – Office of the National Coordinator

This is Kevin Larsen, sorry I'm late. I think another question that we have around this is, what would the certification implications be for this wide new variability and type of measures that come through so for example we're now certifying the measurements for MU2 and we're certifying certain data elements and certain components. There is a question about what the constraints are like on this innovation process and a question about what the certification should look like.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good point and actually that goes to the QI platform. So, no longer will...I mean it would be a change from the current certify how a product calculates a measure to how do products enable new measures to be developed over time and quote plugged into a platform that calculates them. So, there's a lot of change here but I think it's a lot of change for the better. We do know from public comments and testimony that working on the quality measure has been one of the biggest time consuming jobs of qualifying for Meaningful Use. Any other questions? Deven?

Deven McGraw – Center for Democracy & Technology – Director

It's not a question, this is Deven, I just note that the Agency for Healthcare Research and Quality about a month ago issued a big Request for Comment on like 20 different questions related to quality measurement coming out of electronic health records and I don't know sort of what their timetable is for acting on them but it seems as though we're sort of seeking some similar information which might make it easier for commenters because they can just send us what they sent to AHRQ, but we might also, if those comments are available publicly it might be helpful to see what folks have submitted as part of that process as well.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's a really good point. Kevin, do you know?

Kevin Larsen – Office of the National Coordinator

Yeah, we worked with them on that request and Jon White who is often here was really the lead on that. So, we will be sure to integrate that work, but thank you again for reminding us.

Jesse James – Office of the National Coordinator

Right, Jon White has said the timetable will be closer to January for them to start to synthesize the comments back from their RFC.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's probably about the time we would synthesize ours, so hopefully....

Deven McGraw – Center for Democracy & Technology – Director

We'll have a synthesizing party.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yeah, right. Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

That's a great point if AHRQ is looking at that as well I think there needs to be some coordination and perhaps when their comments come in we could...someone on staff could vet them and bring to us comments from them that are particular to the kinds of discussions that we're having in this committee.

The other point I do want to make is that as payment models change, quality measures become even more important and that's why the ability to really make them specific to specialties is very important and needs to be...there needs to be the capability within a record, an electronic health system record to be specific to the individual provider. There needs to be that flexibility built within the record and whether that is certification requirements to be able to accept modules coming in that deal with quality measures specific to different specialties would be extremely helpful.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, thank you, any final comments on this? Jim, anything final from you?

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

No, thanks, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, Jim. All right, we'll move onto our next item which is an update from CMS and our continuing updates about the program.

MacKenzie Robertson – Office of the National Coordinator

So, unfortunately I haven't been able to get a word back from Elizabeth to move up on the agenda.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay.

MacKenzie Robertson – Office of the National Coordinator

Ah, hey, what great timing.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yeah, is it okay?

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

That's okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

I thought I had time for lunch, but I guess not.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

You still do, just after speaking.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

Okay, so I do have slides, but the problem with having this meeting so close to the beginning of the month is we don't have all the data in. So, I'm sort of winging it here today, so it's not going to be your usual Rob Anthony all polished and pretty, it's going to be much more rough so just bear with me. So can I have the next slide? Oh, this is my clicker, okay. No. Okay, oh and I cannot read this at all.

So, these are the registration numbers. Okay, great, thank you. The registration numbers are up and it's interesting because 20,000 in one month is actually the highest we've ever had so we were very pleased to see that. We believe that part of that is we did some messaging around the October 3rd deadline, so October 3rd is actually the deadline for people to begin, for eligible professionals who want to get a 2012 payment October 3rd is the last day they can begin their 90 day reporting period and so that matters because if you start in 2011-2012 you could still reach the maximum of 44,000 over the length of the program. So, people want to get in, they can start their reporting period and they would be attesting in January and February. So, those are our registration numbers.

When I did this last night I did not have the Medicaid numbers so I wanted to put something in here for Medicaid but then of course today I got the Medicaid numbers, so now I have more information. So, essentially for Medicaid, this is good news, we have 49 of the 50 states launched at this point for the Medicaid Program. The state that we are missing, the last state that came on was New Hampshire and the state we are missing is Hawaii. Puerto Rico was the first territory that came on and they just came on, and we are hoping that some of the other territories and the District of Columbia come on soon. So, that's all good news because we were hoping that we would have everybody on board in 2012.

This is where you see the trending of the registrations and that's where it's exciting because we see September, you know, the numbers just keep going up and so we're sort of running a two-part program now where we're trying to go out and educate people on Stage 2, but we are also very cognizant that there are people out there who are trying to get on the bus, trying to meet Meaningful Use in Stage 1. So, because of that we did a whole lot of outreach for Stage 1, but we feel like we need to tweak that and so we're looking for suggestions on ways we can meet more people because really the goal for me is to have nobody get hit with a payment adjustment, to have everybody be Meaningful Users and so I can't just concentrate on education on Stage 2 stage because I have people needing to learn about Stage 1 and don't even get me started when you talk about Stage 3, because I can't get there yet. Rulemaking is a lot of work and I just can't break it to my staff that we might be starting it again soon. So, I know you're discussing it, but it's a good thing I'm not listening to those deliberations.

Okay, so here are our Medicare numbers. So, the hospitals, we have some good news, it's not here because this is through September and again, because this is so early in the month these are just estimates and we will be publishing the final reports when they're ready. But the numbers are up and for Medicare we paid over \$4 billion dollars. This is October 3rd; October 1st was the first day for hospitals to come in and attest for Stage 1 for their second year because they needed a full year reporting period and so that was the end of the fiscal year.

So, we had 12 hospitals come in the first day. So, I was worried that maybe the system wouldn't work, but it was fine and it was not John Halamka, he was first last time, he was not first this time, so, just saying. We thought he was going to be there, but we're hoping, I mean, he may have attested by now, but that was just, I needed to know that the system was actually working letting people come in for their second year, so it is. We're on guard now and in January again we will be on guard because we will have a lot of EPs coming in because just from the day we sent out the LISTSERV reminding people of the October 3rd deadline our call volume and our call center spiked and we were having so many hits against the ONC certified CHPL to get the certification number that multiple times we almost crashed the system. So, we have now bought additional capacity and so we believe we're going to be good for January and February when a lot of people come in again.

And, so now just to discuss Medicaid, I know I don't have the number, but we did pay 4,380 providers, eligible professionals in September and 138 hospitals. So now we have actually paid 62,777 Medicaid providers for a total of \$3.5 billion. So when you add that together it is \$7.7 billion we have paid out so far. And I believe in the next month or two the numbers will be really high because we will be paying all of the hospitals we paid in 2011, we hope, that's one of the things we're monitoring, checking to see whether all of the hospitals who came in last year actually come in, and we're actually, as the time wanes down we're going to make some phone calls to make sure that everybody understands this is the period of time they need to come in because if they were able to meet Meaningful Use last year we believe they should be able to meet it this year and so if there are issues we want to know what they are so that we can figure it out, but we only have three days of data now. So, we're not quite to that point, but I'm sure when Robert Anthony comes back next month he will have more information on that. He's in Europe and he has been in Europe three weeks, three long weeks.

Okay, so the attestation data is the attestation data we keep coming back and reporting, but I was looking, comparing what he presented last month and there isn't a lot of like "oh, my gosh what happened" things moved up slightly but nothing really significant and so these are just the reminders of what the data means. So when we look at this, this is just about the same chart we saw last month, except for medication allergy, it went from 96 to 97. So, people continue to blow away the percentages.

The big change here was CPOE exclusion went down to...dropped from 18% to 17%. None of these I think are significant. For patient here...let's see, electronic access dropped from 2% to 1%. Here, summary of care went from 89 to 90 and everything else is just staying the same. Immunizations went from 37 to 36. For hospitals, medication lists went from 97 to 98 and CPOE stayed the same. The only change here, I think, is drug formulary went from 14 to 15 and incorporate lab results went from 16 to 18, yeah, so those are the only changes. Here patient education went from 71 to 70 and deferring went from 62 to 60. Summary of care from 93 to 92. So you see all of this is very consistent really. Everybody continues to just blow away the percentages.

Okay, so just as a reminder, because I like to remind people of things, everyone starts in Stage 2, can't lose sight of stage...everybody starts in Stage 1, can't lose sight of that although Medicaid does start in AIU, hospitals only have until the end of November to attest and receive a payment, so that's if they're in their first year or their second year and all of the second year people need to come back. EPs have until...they have until January 1st to start attesting through, this is not a leap year, it's not going to be a leap year so they only have through February 28th, they have a whole day less than last year and we already talked about starting the reporting period.

We are busy working, Travis Broome and Robert Anthony have been doing numerous webinars, I've done a few, but they've done the lion's share of them. We are planning to do, probably not for a month or two another series of webinars to get into a deeper dive for Stage 2 in addition do more Stage 1 outreach; although I will tell you our ability to travel is just unbelievably compromised because we have no travel budget pretty much.

We are in the process of doing specification sheets, I believe they will all get posted in the month of October, so this is exactly what we did last time where we go into a particular objective and measure in detail, pulling all the information that's in the federal register on all of the many hundreds of pages into one page for each, one or two pages for each measure and we add the FAQs that are associated with that in one place, so that if you have questions about a particular measure you can go there.

In addition we are working with ONC to try to develop technical specification sheets for vendors. Through our experience with Stage 1 one things we realized was vendors were interpreting our words in 100 different ways and so if we put out these technical specification sheets we hope we can try to have everybody understanding things the same way we understand things and we're trying to have a better dialog with the vendors because I know a lot of providers were very distressed when they learned that the EHRs weren't calculating things correctly and a lot of patches that went out and so we're hoping that we can try to fix that before they get into heavy coding for Stage 2.

We are working on additional frequently asked questions and we do owe people guidance on exactly how they will apply for the payment adjustment hardship exceptions. So that's the spiel for this one.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

One of the things I remember in the earlier days that Rob used to present and maybe this is feedback back for him, he used to have this graph and you could see the rapidly accelerating...I see that in the numbers but maybe that's just additional ways we can show how successful the program is.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

Yeah, I wonder how...does anybody know when the next month's meeting is, it's not like the 1st week?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think its...

MacKenzie Robertson – Office of the National Coordinator

It's November 7th.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

Okay, so that gives you a little bit more time. So, I'll him to do the graph and we like the pie charts too where you see out of the whole how many.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yeah, those are helpful.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

Yeah.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

No congratulations.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

It's hard when I didn't have Medicaid data to do those last night, but...

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Yes, I've asked in the past and we still don't have it yet, is the percentages of the whole pie, how many eligible professionals are out there who are Medicare providers who would be attesting, so if we are...how many...do we have 20% of providers actually being Meaningful Users, do we have 25%? How many hospitals there are? I'm interested in percentages, I want to know...

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

Yes, I thought he had been presenting that as the pie chart.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

I'd really like to see percentages.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

Right, so I only have the July numbers and at that point we were at 23%.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Twenty-three percent? Okay.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

In July, yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

In the past Rob has talked about 23% and something like 55% of the hospitals.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

Right, that's the July number, so it's more now and so it will be very interesting.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

So, we can make sure we get those.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

Yes, next month we'll definitely have those updated.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Other comments or questions? Great, thank you, Elizabeth, just in time.

Elizabeth S. Holland – Director, HIT Initiatives Group, OESS - Centers for Medicare & Medicaid Services

Now, I'm back to the Hill.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

All right, now we're ready for the ONC update. Jodi?

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Okay, great. I have been on deck since after lunch, MacKenzie said "you're on if so and so doesn't show up, you're on if so and so doesn't show up" so Liz, I'm on. Okay, great, which was good because I got a little bit of information that I can share, particularly on the PDMP Project, so I got a little bit more data so I can share that with you since I know there was some interest in that and I'm happy to come back with more.

So, first I wanted to talk to some of the basic housekeeping stuff that folks might be interested in. We are still working on selections for the Policy Committee and Standards Committee based on our nomination process. We are aiming for this fall, probably a little bit later in the fall since fall already started. But to let folks know about the slots that ONC or that HHS has authority to select. So there's only one slot on the Policy Committee, there are a number on the Standards Committee, so the Standards Committee has a little bit more at stake, but we will get back to you all as soon as we have something to report.

I don't remember if I mentioned this last time, but we are working on an online database to get names, nominations for folk who is are interested in participating in Workgroups or providing expertise with respect to hearings and the like. We will have that open on our website, we're hoping it will be live next week and we will be using that to solicit nominations for what we will start up as our newest Workgroup on Consumer Engagement for the Policy Committee as well as the Consumer Engagement Workgroup for the Standards Committee, and we will be actively soliciting nominations through our website through that new process.

So, I want to let folks know we'll make sure that you know as soon as that's open so that you can let others know if folks have either come to you for interest or you know of others who might be good folks to participate, that is just one way that we can get input for nominations. We're hoping that it will give us a much more diverse group of folks to select from and that we might learn of some folks who have excellent expertise that we may not be personally aware of or that folks on the committee may not be aware of. So, please encourage folks to nominate themselves or others and this is the public call for folks as we do make that available to let us know about your expertise and interest in participating in our process.

On our strategic planning I wanted to just give a little update, so we had put out our Health IT Strategic Plan last year. We did say that we wanted to keep that fresh and we are starting to do that in pieces where we feel like there are areas that need some updating or would really kind modified our strategy somewhat since that came out. There are three areas that we are looking at, one is on our Consumer e-Health strategy, we actually came up with our Consumer e-Health strategy in our strategic plan before we had a Consumer e-Health Program, so a lot has changed in the last year and a half, and so we will be refreshing that actually hoping that we will have an innovative way for getting some input into our Consumer e-Health strategies, so stay tuned.

The second is on security and Joy Pritts is working on that sort of flushing out a more robust strategic plan on security. And the third is on safety which is aligned with our efforts and our commissioning of the IOM report on safety and our intent to build on what we learned from the Institute of Medicine report in developing a strategy for safety with respect to Health IT.

So, with respect to safety, they'll use that as a bridge to note two things that I think maybe of interest to folks. First, I wanted to say that there was some legislation, FDA legislation, the FDA Safety & Innovation Act that tasked the FDA to work with ONC and FCC to create a report for proposing strategy and recommendations on a risk-based regulatory framework for Health IT. So, the goal was a coordinated approach on oversight of Health IT that promotes innovation but protects patient safety as well and avoids regulatory duplication.

So, the FDA was given a lead on that. I wanted to let folks know we are working collaboratively with the FDA on this and they will be holding a series of public meetings for input on this. Again, ONC is working collaboratively with the FDA in setting those up. I wanted to let folks know about those, pay attention they will be posted in the Federal Register and we will also try to post it up on our website, FDA will have it on their website to try to get broad participation. There will be one this fall in DC so hopefully the announcement will come out soon.

Also, we just asked and we will be having next week, for folks who are not DC-based at the Health 20 Conference for anybody who is participating in that, me and hopefully somebody from FDA, Bakul Patel, at least by phone or by video, we're not sure if it's going to work or how it's going to work yet, we'll just have a very brief session to get some early input.

We have just a short window there but anybody who is at Health 20 I encourage you to come and give us your feedback, but like I said, there will be multiple opportunities and we will try to make them in multiple locations so they're not all in DC. The first one of course though will be in DC. So, more to come, stayed tuned on that.

But, the goal for that, like I said, is Congress asked for a report, I think it was an 18 month timeframe that they suggested for the report to come out on that and we hope that our safety plan will be sort of a first step in getting some input and thinking on that request from Congress.

I also wanted to mention with respect to safety that we did just award a contract called Promoting Patient Safety through Effective Health IT Risk Management with the purpose of identifying, implementing and evaluating risk management interventions and processes designed to avoid and mitigate Health IT related errors and risks both in large health organizations and small ambulatory practices. They will be looking at...sort of testing out some mitigation strategies and then doing some evaluation about the effectiveness, sustainability and success of those intervention strategies and tools.

And they will also be building on some of the work we did...we are doing through our unintended consequences contract to build what we are calling the Safer Assessment Guides or Safer Checklist as one tool to consider in trying to help mitigate risk. So, this was a contract awarded to RAND, we just awarded it, so there is nothing more to report on the status of it, but we're really excited at thinking about how to mitigate risk and help improve safety from that perspective. So, stayed tuned, this is a year-long contract with the potential for an additional option period. So, again we will be working...we're still working on our safety plan and still hope to get that out within the 12 month requested timetable that the IOM suggested.

On CQMs we know people are anxious to see the CQM specifications released, we're working on it, stayed tuned. And, unless anybody else has anything else to say that's as much as I can say on that topic.

Kevin Larsen – Office of the National Coordinator

The language that I understand, and correct me if I'm wrong, is that it's on or about the same time as the rule is released and so there is a kind of a time window that we're working in for that posting and they're soon ready.

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Okay and then the last thing I wanted to talk about, because there was some interest in this, is our PDMP work, Prescription Drug Monitoring Program work for folks who don't know the acronym, so there has been increased interest in the department on the issue of prescription drug abuse as a problem of epidemic proportions in our country and we took it upon ourselves to figure out how...what piece Health IT can serve in helping to address the problem.

So, there are lots of different components in this problem, we're not going to solve all of them through Health IT, but we wanted to see where there was an opportunity for using Health IT to address this problem and what we identified was that there was this great resource of information through the PDMP Programs at the state level and we learned also that a lot of providers either don't have access to that easily or don't have access in real-time or just don't know about it, or don't...whatever, there are a lot of different issues but providers were not routinely checking for PDMP information or able to get access to it in a timely manner to actually make prescribing decisions, and pharmacies were not necessarily having access to it to make dispensing decisions.

So, what we did was, we have a contract right now where we were focused on looking at standards and policies that were necessary to connect existing health information technologies to increase the timely use of the PDMP data by providers, emergency departments and pharmacist. We started with a series of Workgroups to address specific problems that were identified in trying to connect this information, some of them were policy issues, state law issues, standards issues, technical issues they ran the gamut and we did get a series of recommendations from these Workgroups on how to make this work easier and then we started on the path of doing some pilots to try to incorporate some of those recommendations and try to connect the data and make it more easily accessible to providers in real-time.

So, the first phase of this contract just ended and we just extended for it another 6 months. The initial pilots that we had, we had for folks who care about the locations of them, we had two in Indiana, one in Michigan, one in North Dakota, one in Ohio and one in Washington.

The way these were selected we actually did a series of calls with PDMP Programs with the State Health IT Coordinators. We tried to let as many folks know as possible about the opportunity to participate in these pilots and our goal was basically to get as many and the best pilots we could to try to test this out in as many different environments and different mechanisms as possible. So, we were trying to get some for pharmacies and some for EDs, and some for physicians, and different ways of connecting the information. So, we tried to get a diverse set of pilots.

What tended to be the limiting factor was we were trying to do these quickly so there were some folks who either didn't have, either they had some state law impediments or they were working with vendors that were involved in connecting, you know, vendors for the PDMPs or at the state level that weren't able to do the work necessary to make the connections in a timely manner given our tight time constraints. We have now extended some of the initial pilots to get some more data. We've also opened it up to implementing new pilots and have already had discussions with some additional states that seemed almost ready and very interested but weren't able to meet our timeframe, so we're trying to get those in place. So, we will be implementing some new pilot projects in this next phase.

The other thing, which I had suggested that we did and I think is really great is not only to evaluate what's being done but develop a toolkit to help others who want to...other states and providers who want to connect the information from the PDMPs to be able to do so based on the learning's from both the Workgroups as well as from the pilots.

So, the contractor will be developing a toolkit to help others kind of get over the hump and be able to connect the data. So, we have a short timeframe to do all of that, there is only another 6 months that we were able to extend it for, so, hopefully, we will at the end have both some good data about how it has...I'm hoping we'll have data on how it's changed the prescribing practices, some lessons learned from, you know, how to do things better as well as a toolkit to help others who want to go down this journey even if we're not supporting it through this contract and through the pilots.

There was some suggestion, which Gayle mentioned about, is there a way to push this along with Meaningful Use? And it was just something that came up in a discussion and I would love to...you know, if folks have more thoughts about that I would be interested in hearing about and if there's something we could do since we've just started the second phase of this contract to make that possible, if that's something folks are interested in I would be open to hearing about that.

And then, lastly, I would just love to hear from you all if there are particular programs or projects that ONC is doing that you would like updates on. First of all you can tell me now but you're always welcome to e-mail me and let me know if there is something particularly you'd like an update on and either I can get some information and give a brief overview or we can bring in whoever the project lead is on it to give a more thorough briefing on it if folks want an in depth update on a particular project, that's it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, thanks, Jodi. Is that a start on it Gayle? Update and transparency?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Update, yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Why don't you go ahead?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you, Paul. Yes and thank you Jodi. Really it sounds like the ONC, as always, is very, very busy and doing lots of good things and certainly I do want to comment on the PDMP. I think this is a good...that Meaningful Use is certainly the correct mechanism to help encourage the use of the PDMP and that can be accomplished in many ways, just even, you know, when you go and enter an order for a narcotic or any of the schedule 2, 3 or 4 drugs to pull up an alert or even just give you the website and have a link to the website so that before you write the script you actually go to the website and you look and see, you know, what the history is on it, so it can be done rather simply I would think, but that there may be better mechanisms as well.

So, a pilot is certainly a good way to do this. I think that's an excellent, excellent way, but on some of the other things that you all are doing, I think the safety issue, I know we had a public hearing I think maybe last year on safety issues as I remember and as that report comes out I would think that would be a very important thing for not just a report presented but for major discussion in this committee.

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

So, one thing I will say which I didn't mention is that when we put out our plan we will accept comments on the plan which is what we did with our strategic plan and so if folks in the committee are interested in having a discussion once we put out the plan, either at a Workgroup or the full committee, whatever you think would be most appropriate, that would be great, so let us know.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

The meeting that you're doing this fall is that here in DC?

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

The one with FDA will be in DC it will actually be out at FDA headquarters.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

And are committee members invited to that?

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

It's open to the public so anybody is available to attend and if folks want we can make sure that when that becomes...

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Can you notify everybody...?

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

We can give notice to everybody and you do have to register just because they want to make sure, you know, they don't exceed fire code with the number of people who attend, but it's free and open to the public.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So, two of the things that you gave updates, you know, the strategic plan updates would be an appropriate ONC update and the other is the EHR safety plan that will be coming out, if that could be included in the reports when they become available.

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yeah.

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Yeah, I would say...I mean, as soon as...once we have reports available we'll make sure that we...you know, if we know something is being released we'll put that on the agenda, but if there is something that is ongoing that you all would like to just know what the status is of it, we've done that before, please don't hesitate to let me know.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Sometimes we don't know what we don't know, but...

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Right, right I know, but absolutely, I will make sure that we have that on the agenda for the month as those come out.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Great, thank you. Other comments/questions? All right, well this maybe a first really getting out early, but, why don't we open it up to public comment now I think for our second phase.

Public Comment

MacKenzie Robertson – Office of the National Coordinator

Operator, can you please open up the lines for our second public comment period of the day and I will ask if there is anyone in the room that would like to give public comment, if you could please come up to the table.

Alan Merritt – Altarum Institute

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

Robin Raiford – Advisory Board Company

Thanks, Hi, Robin Raiford from the Advisory Board I just want to share some thanks to the group for keeping the eye on the prize and keeping going despite all of these things flying at you, it gives me something to look at at night besides the ads on TV which I just think are getting relentless here in the DC area for the next month to go forward and thanks for the one year heads up of how I'm going to get Stage 3 on a poster, I'm not sure, but I've been asked a million times what happened to the poster for Stage 1 to Stage 2, it is out there, anybody out there in internet land if you just Google Meaningful Use White Board or Meaningful Use Pocket Guide it is out there and it's out in the hallway here, but it's getting pretty big. I think Stage 3 is going to be a bus route.

And, I think, Elizabeth has left and I'll have to send her an e-mail to let her know, I did have a humbling experience last week in front of some CIOs that were looking at Stage 2 and everything and we were talking about the tornado exemption if you got a payment adjustment or whatever and who was sitting in there was the CIO who was over the hospital that got flattened in Joplin, Missouri and he came up to me afterward and he said "I just want to let you know we still met Meaningful Use despite that." So, there are hard fast folks out there and 10,000 people have downloaded that poster from the NPRM. So, good job in just, you know, Paul, you especially, I mean, you know, going on from AHIC in a multiyear commitment here to the country keeping it going. So, thanks.

MacKenzie Robertson – Office of the National Coordinator

Are there any public comments on the phone?

Alan Merritt – Altarum Institute

We have no comments at this time.

MacKenzie Robertson – Office of the National Coordinator

All right, Paul, I'll turn it back to you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, thank you everyone for another productive meeting and getting through the draft comments for the Request for Comment and we will see you on November 7th back in the same place, thank you.

MacKenzie Robertson – Office of the National Coordinator

November 7th is at the Omni Shoreham Hotel.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yeah, same city.

Public Comment

1. Jim Thompson: USA languages 2-6 are Spanish (28M speakers), Cantonese, French, German and Tagalog (all under 2M speakers). Would there be any instances where anything other than Spanish would be required to meet the requirement on Slide 24?