

**HIT Policy Committee  
Transcript  
September 6, 2012**

**Attendance**

The following Committee members were in attendance at this meeting:

Farzad Mostashari  
Paul Tang  
Christine Bechtel  
Neil Calman  
Terry Cullen (alternate for Madhulika Agarwal)  
Art Davidson  
Connie Delaney  
Judy Faulkner  
Thomas Grieg  
Gayle Harrell  
David Lansky  
Deven McGraw  
Marc Probst  
Joshua Sharfstein  
Robert Tagalicod  
Scott White

The following Committee members did not attend this meeting:

David Bates  
Richard Chapman  
Patrick Conway  
Paul Egerman  
Charles Kennedy  
Frank Nemec  
Latanya Sweeney

**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 40th meeting of the HIT Policy Committee, drum roll. Should we have black balloons everywhere? This is a public meeting and there will be time for public comment built into the agenda and the meeting is also being transcribed, so please make sure to identify yourself before speaking. I will now take roll call. Farzad Mostashari?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Present.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Farzad. Paul Tang?

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

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Paul. Madhulika Agarwal? David Bates? Christine Bechtel?

**Christine Bechtel – National Partnership for Women & Families – Vice President**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Christine. Neil Calman?

**Neil Calman, MD – The Institute for Family Health – President and Cofounder**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

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

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Art. Connie Delaney?

**Connie White Delaney, PhD, RN – University of Minnesota/School of Nursing – Dean**

Here.

**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. Thomas Grieg? Gayle Harrell?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Gayle. Charles Kennedy? David Lansky?

**David Lansky, PhD – Pacific Business Group on Health – President and CEO**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks David. Deven McGraw? I know she will be attending a little bit later. Frank Nemec?  
Marc Probst?

**Marc Probst – Intermountain Healthcare – CIO**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Marc. Josh Sharfstein?

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

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Josh. Latanya Sweeney? Robert Tagalicod?

**Robert Tagalicod – Director, Office of eHealth Standards & Services, Centers for Medicare & Medicaid Services**

Here on the line.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Robert. And Scott White?

**Scott White – 1199 SEIU United Healthcare Workers East**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Scott. Okay, I will now turn the agenda over to Dr. Mostashari.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Thank you MacKenzie. And I should also mention that our transition from Mary Jo to MacKenzie is now completed and MacKenzie will...Mary Jo is celebrating...and thanks again to Mary Jo, and just a reminder that going forward, MacKenzie will be our primary point of contact for all things FACA, including the nomination process, the Committee and Workgroup meetings and all the day to day functionings, but Mary Jo will still be available to her, in our Senior Policy Advisor role. So, thank you Mary Jo.

Well, the big news since we last spoke was the release of the Stage 2 Meaningful Use and the certification criteria and standards. And I guess if I had to summarize, one of the main take away, I hope, and what I think Industry perceived was, was not much news because it was so largely predictable based on all the discussions that we have had in the past forty Policy Committee meetings. And that is bad for journalism, good for policy-making and good for vendor preparedness, I hope. Vendors have been hard to work already, working on what was large predictable and anticipated as the result of that. And I think it is important for us to recognize that that roadmap takes time to get to and making sure there are no quick turns or changes in direction, I think, is important to lay that more or less predictable roadmap out there. That having been said, the...I think if for people who are not followers of, well, what words changed between the NPRM, you know, where's the track changes version of what changed between the NPRM and the final rule. For the vast majority of doctors and hospitals and

consumers and all the other folks in the larger stakeholder community, I think the big message, the big shift, the big step-up between where we were in Stage 1 and Stage 2 is how much more we can do on standards-based exchange and interoperability now than we could two years ago. Where it was not clearly for lack of having high expectations, we had great expectations and aspirations, we recognized from the beginning that meaningful use is really about both adoption and use of systems within settings, which is incredibly important, and results in incredible advances in quality and safety and efficiency. But also in interoperability and exchange of that information between sites of care.

It was just that what we could do, what the industry was ready to do, what providers could feasibly be asked to do two years ago was pretty low. And so in the Meaningful Use Stage 1 rules, we ended up at a place where it was tests of exchange, not actual exchange. That expectation, that ability has now changed where we are pushing forward for 2014 saying, there has to be actual exchange, actual exchange with Public Health, actual exchange between providers, actual exchange with the patient. So, that is, I think, a big step forward. The other is in the extent to which in the certification and standards side, your compatriots over there on the standards side have been very busy and with the over one thousand participants in consensus, accelerating consensus, we now have really significantly different place where there are...there is now consensus on a single format for sharing patient summary records with single vocabularies and terminologies to be used for really many of the major categories of basic information that need to be made liquid. That we do have, finally, ubiquitous availability of the standard for exchanging information over the Internet securely between different electronic health records.

But that is not enough. That is fantastic, it is really a mark of the progress we have made, but we also recognized after Stage 1, that we need to toughen up how the testing for that interoperability is done, and to move from simple conformance to actual functional interoperability testing. And we are going to be working with NIST and again with the community, to get feedback and input on those testing scripts and testing tools. And I think what's pretty clear is that around things like quality measurement, around things like interoperability, we're going to see much more demanding expectations in terms of what the vendors are going to have to do to actually get certified to interoperability and that will be important. So, as we turn the corner on meaningful use, on the exchange and interoperability side, I think at just the right time to be able to provide that foundation, that continued foundation for what we as a country need to do to provide the kind of coordinated care, the kind of value as a whole, to be able to take care of the whole person, not just individual fragmented tasks within that person's healthcare journey. So, that I think is going to be...continue to be an enduring legacy of the Health IT Incentive Program. That's...I think the other key point that a lot of folks have picked up on is, while there were flexibilities in accommodations made to where we are, the feet on the ground part, while we keep our eyes on where we need to go, making sure, as the Policy Committee recommended, that there is sufficient time between the final rules are out and when the final, the last opportunity for providers to have implemented those upgraded, newly certified systems and the 90 day reporting period in 2014, is going to be, I think, an important added 9 months of potential flexibility, as you'll hear from Rob. So, we set high goals, but we also provide, and there is...I counted easily 16 examples of where there have been flexibility accommodations made so that people can get on the escalator and not fall off, as we move up, upward always. So the flexibility, I think, was another take home.

And then finally, there are many areas where there were lots of disagreements and no... I think no area was I think more conceptually separated than the issue of provider accountability for patient actions. And on that, I think everybody, I hope, feels that we truly... it was some tough policy decisions to be made, and we truly understood both perspectives on this, but ultimately, I think it was important to affirm that concept, that it is important, the provider does play an important role in ensuring that patients actually engage with these tools and are indeed in a unique position to do so. And, we created, I think, some flexibility and we reduced the threshold down to what clearly should be achievable, but we kept that principle in place, and I think it is an important principle. So, that's I guess my take-away from where we are in Stage 2, at a higher level, and we will turn it over to Paul.

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

All right. Thank you Farzad. Also, I want to extend our congratulations to you and the Department and CMS for really a great set of final rules for Stage 2. As you said, it is really a platform, a springboard for what we want to do in Stage 3 and beyond, and really working on the outcomes. And I think, looking at the results that we are going to hear about where you have taken us to this point, it has been a tremendous journey and one that has really catapulted the country for moving to use these tools. So, thank you so much.

Want to open up with the important thing about lunch, so, before you is a menu that if you could turn in, we'll have some of the lunches delivered for lunch, and that will help us with the timing point of view. The other piece is the minutes. And I have a few that I forgot to send over to MacKenzie, edits, just sort of technical edits, but are there any other comments about the minutes that were sent out earlier? Hearing none, any movement to approve them?

**W**

So moved.

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

And second? And all in favor?

**W**

Aye.

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

And then opposed? Okay, so moved. Okay. Today is a very full agenda and we are going to start off where Farzad started, which is Meaningful Use Stage 2. And we are going to hear from the Rob and Steve Show on what the final rules are for Stage 2, and the objectives and certification. After lunch, we will return and hear about a topic we have talked about before, which is a cry from everyone including vendors, about the need for value set standards. And NLM has taken up that charge, and we are going to hear from Jamie Ferguson and Betsy Humphreys about this important activity over at NLM. Then, hear from... about the national strategy for trusted identities in cyberspace from Jeremy Grant at NIST and Devin McGraw is going to bring us our final recommendations from the Tiger Team about Trusted Identity in Cyberspace as applied to our work. I will then give a brief update on some of the work that is going on in our workgroups of this committee and we will conclude with an update from ONC with

Farzad and Jody. And then we will have public comments before we adjourn. Any other comments about the agenda? Wonderful. So now, without further ado, we have the Rob and

Steve Show and we are going to hear about the final rules of Meaningful Use stage 2 both from the objectives and quality measures and the certification criteria. Rob?

**Robert Anthony – Centers for Medicare & Medicaid**

Thank you, Paul. Steve and I are going to start selling T-shirts in the lobby after shows (laughter). I am going to do, obviously, a brief overview of what is in the CMS Stage 2 Meaningful Use Rule. Most of you are more familiar than most of the audiences that I do this for, so, I'm going to try and move sort of quickly through this, so that Steve has time to do his end of things. I have probably stolen enough time from him in the past on other presentations.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

You are...today.

**Robert Anthony – Centers for Medicare & Medicaid**

Thank you. But, if at any point there is anybody who needs a quick clarification on anything or if I am moving too fast or something, please feel free to stop me and I will be happy to fill in the blanks. So, these are for the folks who are downloading the presentation and playing along at home. These are links to the display rules for both CMS and ONC. You can also find these on our website, the CMS.gov/EHR/incentive/Programs website we have a Stage 2 tab that links to both the CMS Meaningful Use and the ONC standards and certification rule.

Even though we call this the Stage 2 Rule, there are actually a number of things in this that are not specific to Stage 2, and I always try to make this distinction for folks. There is obviously the Stage 2 Meaningful Use overview. As many of you know, we introduced a number of changes retroactively to Stage 1. There is new clinical quality measures and reporting beginning in 2014 for everyone, regardless of whether they are Stage 1 or Stage 2. And then if course, we detailed the payment adjustments on

hardships, how we will look at those periods and how we will apply them. And then finally there are some Medicaid program changes, specifically some changes to patient volume calculation.

So the thing we are...we received a lot of public comments on, and the thing we keep getting asked about with Stage 2 is what we have done as far as eligibility? I think everybody in this room knows, the

Eligibility for the program really is determined by HITECH and is determined by Congress.

Congress has not made any changes to the HITECH Act, so we really did not have any ability to expand to other providers or other organizations or other institutions. What we were able to look at is the hospital-based EP definition, and what we have provided for in Stage 2 is a potential redetermination of hospital-based status under a very specific set of circumstances. For the vast majority of providers, this is not going to change. It is still be hospital-based definition of 90% or more of your covered professional services in an inpatient or emergency department, makes you hospital-based, and therefore you are not eligible to participate, with the theory being that most of those providers would be using the hospitals EHR and the hospital is getting the incentive payment.

However, there are some EP's who work within a hospital environment who are funding a completely separate certified HER, neonatologists come to mind for some of this. So, if during an application process those EP's can show that they are funding everything related to that certified EHR including the supporting hardware, they are not getting reimbursement from the hospital for doing that and they are using that EHR in lieu of the hospitals certified EHR, then they could potentially be determined to be non-hospital-based and then participate for an

incentive payment. That application process is not up yet, but we will have more information on our website when we do have that.

This may be the easiest part for most of you, since you are intimately familiar with meaningful use and Stage 2. Obviously, this is the slide that we show everybody else in Stage II, focusing on advanced clinical processes and everybody asks, well what is going to happen with Stage 3 in improved outcomes to which I say the rule has only been out 2-1/2 weeks. But, as many people know we had proposed in the

NPRM and we finalized here, the delay to 2014 at the earliest for Stage 2. We have clarified for folks that everybody is going to begin at Stage I, you are going to get mostly two years of Stage 1 before moving onto Stage 2. But for folks who were the early meaningful users in 2011, they are going to get an extra year at those Stage 1 requirement, again to provide that extra time. The same works for hospitals, except that they work on the fiscal year. In 2014 as Farzad said, we have adopted a reporting period on the Medicare side of 3 months. This is a one-time for 2014 only, to provide maximum flexibility and avoid the, what I have been calling the funnel effect of too many people trying to come in all once. Hopefully, this allows people to stagger in on board for certified EHR a little bit more easily, since everybody will be going to 2014 certified EHR. On the Medicaid side...I am sorry, on the Medicare side; it is 3 months key to the quarter. That is because the how our quality reporting systems work. On the Medicaid side, it is any 90 days within either the calendar or fiscal year.

Some basic things that changed and did not change in this, we proposed and finalized the change to how menu objective exclusions work. Currently, you can actually select a menu objective and exclude from it, even if there are other menu objectives on which you can report. We are eliminating that beginning in 2014 for both Stage 1 and Stage 2. If you are able to report on another menu objective, then you have to attempt to report on it. This does not affect the number of exclusions that people can claim. If they claim more than the number they are required to report on, that is perfectly fine. They can still meet meaningful use that way. This just prevents people from choosing something that they know that they can exclude from when there are other things they know that they can do.

On the no change side, obviously meaningful use is meeting the measures of the objectives that is what it comes down to. The other thing that did not change is the threshold for locations with certified EHR

Technology, you have to have 50% of your patient encounters at locations that are equipped with certified EHR technology to be able to participate in the program. And if you have that 50% of your encounters at the locations, you can limit your denominators for meaningful use to just those locations with certified EHR technology. This is consistent with the policy we have in place right now.

We did allow for batch reporting in the Stage 2 final rule. We did not implement the group demonstration, group average; I try not to call it group reporting because people get confused between the two of these. But, essentially, we had identified a number of operational concerns system-wide with implementing a group average where everybody kind of gets averaged out for all of their numerators and denominators into a single thing and reports as one group. What we will allow, however, is a batch reporting system that will begin in 2014, that will allow groups to submit attestation information on an individual EP basis, so it will still have each individual EP and numerator and denominator, and they would upload that to our attestation system, which would allow large...well large practices and small practices to submit all that information at once

rather than going through the attestation system individually for each EP, and we think that's going to reduce a lot of burden of reporting for practices.

So this is the part that is not terribly surprising to most of the folks here. We did keep the core and menu structure as we proposed in the NPRM. We did keep the total number of objectives the same. As many of you know, we eliminated some objectives, we combined some objectives, we subsumed some objectives like problem list and med list and med allergy list under other objectives, the summary of care, transitions of care. As Farzad said earlier, the big thing to take note of is that not much has changed from the NPRM. We tweaked, because of public comments, so there are some thresholds that changed. There are certainly some standards and methods that changed, but for the most part, what we proposed in the Stage 2 NPRM is what you end up seeing here. Obviously, the big focuses for Stage 2 for us were on patient engagement and on electronic exchange of information. So, in patient engagement we do have the requirements for patient action as part of certain objectives. The 5% of patients sending a secure message to their EP, 5% of patients accessing their health information online, that view online, download and transmit objective for both EPs and hospitals. We did start at more than 10%, we received a lot of feedback from folks who were concerned that providers in certain areas might not be able to meet even the 10%, so we did lower this to 5%, which we believe is achievable.

We did provide an exclusion, which we had not previously propose in the NPRM, that is based on broadband availability in the providers county and we did that for several objectives as we moved forward through Stage 2. We are really focused here on the actual use cases of electronic information exchange as we talked about before with summary of care after a transition of care. We had started with one set of measures and with public comments, we altered this to try to still preserve the idea of electronic transmittal and still try to preserve the capability of EHRs to send information outside of closed networks. And what we have ended up with is these three measures for that particular objective, still providing a summary of care for more than 50% of transitions of care and referrals. And again that includes objectives that we may no longer be individually tracking, but med list, problem list and med allergy list are things that would have to be maintained regularly in order to be able to meet this. Ten percent of those transitions of care have to be exchanged electronically, transmitted electronically and at least one of those electronic transmittals has to actually be sent to somebody who has a different EHR vendor. Or failing that, there will be a designated test EHR to which...with which people can successfully exchange in order to meet that measure. We think that the vast majority of the people will be able to meet that in the first case with just their normal course of transmitting information about patients. But for people who may be in a high concentration area of a particular EHR vendor and may not be able to have the opportunity, there is the possibility of the test EHR.

So as I said, the next few slides are really core and menu for EPs and for hospitals. I will not go through each of these for those of you who are playing along at home. We did put in bold type the areas that had changed from Stage 1. So for example, if you look at the recording demographics in Stage 1, that objective was...the measure was for more than 50% of unique patients, we have moved in Stage 2 to a higher threshold for more than 80% of patients and that is why more than 80% is in bold. And this is true throughout all of these. You will see on this slide number 10 and number 15 are the patient access and summary of care that we just discussed. Number 13 is the secure messaging. The 13 is a new one for the core as we indicated that it would be. On the menu objective, probably the biggest change to note here from the Stage 2 NPRM is the re-addition of progress notes. We had not originally proposed it as an objective. We had sought comment on it and we received a great deal of public comment from people saying that they believed that electronic progress notes were an important and valuable part of EHR, so we have added that back in as a menu objective for both EPs and hospitals.

On the hospital side, again you are not going to notice a huge change from what was proposed. EMAR is the electronic medication administration record, the medication tracking that we had introduced in the Stage 2 NPRM. We did finalize as the core and of course, number 9 and 12 here are the patient access and summary of care similar to what you saw on the EP side. Again, we added progress notes here as one of the menu objectives, finalized the objective for providing structured electronic lab results to EPs as a menu objective. But other than that, you are not seeing any dramatic changes from what was proposed in Stage 2. Similarly, most of the changes we introduced for Stage 1 are things we had covered in the proposed rule, nothing particularly surprising here. We are changing the denominator to add an option for Stage I for computerized provider order entry, currently it's unique patients with at least one medication in their medication list that's caused some difficulty and confusion for folks, so we are providing the option beginning in 2013 and beyond, of limiting this to a strict number of orders during the EHR reporting period, and of course the numerator would be the number of medication orders with CPOE. Vital signs, as we had indicated in the NPRM, we are changing age limits to be more in line with the American Pediatric Association recommendations and we are splitting the exclusions so that currently it is all three elements of blood pressure, height, and weight if a provider considers them not relevant to their scope of practice. Now, of course, you can still claim that exclusion but you could claim an exclusion specifically for blood pressure or specifically for height and weight, if you feel these are not relevant. Again, those will be optional in 2013, but will be required starting in 2014.

We are eliminating the test of electronic transmission of key clinical information that will be effective starting in 2013. Again, we are focusing on the actual use cases in Stage 2 of health information exchange. This turned out to be a very difficult concept for providers to grasp. It led to the generation of many FAQs and much consternation on the part of providers. And then finally, this particular change for Stage 1 is actually to align us with what will be in the 2014 certified EHR capabilities as we move towards providing patients information online, so that they can view it, download it and transmit it. The legacy objectives in Stage 1 of providing patients with any e-copy of health or discharge information upon request, or the menu objective for EPs of providing online access, we did not want to continue to maintain those, so we will actually replace those objectives with the new Stage 1 objective of providing patients that ability to view, download, and transmit. However, for Stage 1 there will not be that patient access requirement, there will not be the requirement that you have in Stage 2 that 5% of patients actually access the information. It is just making the information available online for patients for more than 50% of patients. And again, that will start in 2014 to align with the 2014 certified EHR capabilities.

And then finally, we did make an addition for Public Health objectives, all of those to add language except where prohibited. There are some local and state guidelines or regulations that prohibit certain providers from reporting certain information to certain Public Health registries and it put them in a little bit of a Catch-22 where they were required to do it for meaningful use but couldn't because of state and local regulations. So we have just added that language, functionally nothing else changes about those objectives.

So as I said, clinical quality measures are changing for everyone beginning in 2014. This is again to align with the adoption by everybody of the new 2014 certified EHR. With the adoption of 2014 certified EHR, everybody can be on the updated electronic specifications for CQMs. So everybody, regardless of stage, will begin reporting clinical quality measures in the same way beginning in 2014. In 2013, clinical quality measure reporting will be the same as it is now. There are the three core and three alternate core for EP's and 15 required for eligible hospitals and CAH's. There will still be the reporting methods of attestation, and we have a couple of e-reporting pilots for EP's and hospitals that they can continue with and of course, Medicaid providers would continue to submit their clinical quality measure data to their state. We will not be updating the electronic specifications for CQM's for 2013. We have heard a lot about that, but we know that most vendors will be focused on developing 2014 technology and not updating the electronic specifications in their products, so we did not feel we could require it at this time. The other thing that is provided for in this Stage 2 rule is flexibility in allowing people to implement, if they are able to implement their 2014 certified EHR early. If you get something in the last six months of 2013, for example, we would still want people to be able to use that certified EHR to report clinical quality measures. There will be a great deal of crossover between clinical quality measures as they currently exist and what we'll see in 2014 and we'll indicate which of those can be selected from to attest using the new technology, if you happen to get it early in 2013.

We did remove clinical quality measure reporting as an objective, we indicated that we would. It is not that it is eliminated as a requirement for meaningful use; it just was sort of a redundant objective to ask people to report on. We were asking them to report do you plan on attesting to your clinical quality measure data and then several screens later we actually asked them to attest to it. We figured we would find that out when they submitted the data. One of the things we are introducing for clinical quality measure reporting beginning in 2014 is that at least 3 of the 6 health and human services national quality strategy domains will have to be represented in the choices that are made of clinical quality measures. Everybody, I think is familiar with those NQS domains. We will post on our website, and I think the goal is in October, which of the clinical quality measures will match up to which of the NQS domain, so that people have an idea what to select from.

As we have discussed a few times before, alignment was the main goal with clinical quality measures. This time around, we were trying to get to the idea of reporting from the same measure sets for the same programs, to reduce burden on providers for both collection and reporting. We may not have gotten to one submission for everything, but we are getting pretty close to it. Obviously, there are a number of different quality measure reporting's in addition to the EHR incentive programs on the hospital side. There is the inpatient quality reporting, there is the physician quality reporting system, CHIPRA and ACO's. And as you will see, we have harmonized some of the reporting methods that people can use, and I will go through those in a couple of minutes.

But beginning in 2014, every Medicare eligible provider beyond their second year of participation, will begin electronically reporting their clinical quality measure data. We will talk about the methods for that electronic reporting. If you are in your first year of participation, you will still attest through the web-based attestation. Medicaid providers, of course, will continue to submit their CQM data to their state and states do have an option as far as implementing electronic reporting. And as I said, we will have a finalized list of the clinical quality measures and their e-specifications and their associated NQS domains on our website, we are shooting for October for that. The other thing we will publish at that time is a recommended core set of clinical quality measures for eligible professionals. There will be two sets, one that focuses on adult populations and one that focuses on pediatric populations. And these really focus on high priority health conditions like blood pressure management.

So this is before 2014 currently and what will happen beginning in 2014, on the left is the three core and three alternate three menu, fifteen for hospitals beginning in 2014. EP's will report on nine out of a selection of sixty-four clinical quality measures. They will have to represent three

of the six national quality strategy domains in that selection and of course, they can select from a recommended core set of clinical quality measures. Eligible hospitals will report on sixteen out of a selection of twenty-nine clinical quality measures and they have the same requirement for representing three of the six national quality strategy domains.

This is a very busy chart with a lot of words on it, but I am going to boil it down for you in about forty-five seconds. Essentially, the first line says that in your first year as an eligible professional, you will report your clinical quality measure data through attestation to our website. Once you get beyond your first year, you will have multiple options of how to electronically report your clinical quality measure data. Beginning in 2014, there will be a submission method, a CMS designated system, where you would submit aggregate data basically numerator denominator exclusion numbers for each CQM similar to what you manually input into the attestation module now. There will also be the opportunity to do patient-level sample data that is submitted through the physician quality reporting system. You can either do that individually through the PQRS EHR reporting option, or you could report as a group, participate under the PQRS group reporting option and it would satisfy both the EHR incentive program and the PQRS program for reporting. EP's who are participating in an ACO will also be able to submit electronically through the measures for ACO's and be deemed to have met both EHR incentive program and their ACO quality measure reporting.

Hospitals will have a similar structure. There will be obviously in the first year attestation reporting, but there will be a CMS designated system through which aggregate information can be reported. There will also be a manner similar to what exists now for the hospital e-reporting pilot. There will be all patient or all payer patient level sample data that will be submitted electronically and it will satisfy the hospital in-patient quality reporting as well.

And these next two slides really do not say anything except that there is not been a change in the timing of clinical quality measures. Your first year of meaningful use is 90 days, just as it's meaningful use for 90 days, it's clinical quality measures for 90 days, it's one year after that. Except for 2014, where we have these special three-month or ninety-day reporting period. On the Medicare side, if you are participating it is a three-month reporting period. It has to be keyed to the particular quarters.

We do detail the payment adjustments and hardship exceptions. These are required by the HITECH Act, and they are required to take effect immediately beginning in 2015. One thing that we did clarify for people, and I always make a point, is that people can participate on either the Medicare or Medicaid side, especially EP's who could be eligible for both programs. They are likely going to opt for the Medicaid participation because the incentives are higher. However, they have to actually demonstrate meaningful use to avoid a payment adjustment. If they receive and adopt, implement or upgrade payment in one of the years that we are specifying, that does not qualify them to avoid a payment adjustment. The law is clear that it is for meaningful use.

This will initially seem a little confusing, but it actually turns out to be fairly simple. We had to apply a prospective approach to payment adjustments. In other words, we had to look back at a previous period of meaningful use to determine the pay...whether you were a meaningful user for a payment adjustment year. This is because with each piece we have to with EP's, begin applying the payment adjustment on January 1, 2015 and rather than going through and doing claims reprocessing, which can be an incredibly burdensome process for providers and an incredibly costly process for taxpayers, we are looking back at either a full year or 90-day reporting period prior to the actual payment adjustment year. If you are an EP who has demonstrated meaningful use in 2011 or 2012, we are going to look to 2013 in that first payment adjustment year, to see that you were a meaningful user. Obviously in 2016 we will look back at 2014 and we will just look for that special three-month EHR reporting period. But as you can

see, each year we look back at a different period, and that answers the question that we got from a lot of people about whether EP's would have to demonstrate once that they were meaningful user to avoid a payment adjustment or whether they would have to continuously show that they are meaningful users to avoid a payment adjustment. You do have to continually show that you are a meaningful user to avoid payment adjustments. And obviously, we do expect that there are going to be other providers who begin to participate later, who will want to avoid payment adjustments as well.

If 2013 is your first year of meaningful use that is okay. We just look for your first year 90-day reporting period within 2013 and then we will look for full-year reporting periods after that. And then finally, if 2014 is your first year for meaningful use that is also fine. We will just look for a 90-day period within 2014; however, we do need time to process prior to that January 1, 2015 onset deadline, when we have to apply payment adjustments. We stipulate that we need a three-month period, which means that EP's have to attest no later than October 1 of 2014. That means they will essentially have to begin their 90-day reporting time no later than July 1 of that year. Eligible hospitals work the exact same way. They just work on a fiscal year. So 2015, we are going to look back for either a full year or 90-day reporting period during the 2013 fiscal year. Hospitals also have to demonstrate meaningful use every year to avoid the payment adjustments. Again, if they are first-time meaningful users in 2014, we will look for the 90-day period in 2014, but we need time to reprocess before we begin the 2015 fiscal year, so we have a three-month period, which means that hospitals have to attest no later than July 1 of 2014.

Critical access hospitals get paid a little bit differently. They get paid based on reasonable cost of cost reports that are filed after the actual reporting period. Therefore, we can apply the payment adjustment period to the actual reporting period that is in their cost report. If that does not make sense to you, I can try and explain it a different way, but essentially we get their paperwork later, so we can look at their same year information, which is exactly what we are going to do. But, CAH's do have to continue to demonstrate again, like eligible hospitals.

There are several categories of hardship exceptions that we introduced. For the most part these are by application, except for one particular instance, which I will talk about in a second. The first three categories are similar across all providers, EP's, eligible hospitals and critical access hospitals. There is one based on infrastructure. If it's a provider that is in an area without sufficient Internet access or has insurmountable barriers to Internet access, newly practicing providers, EPs can get a time-limited two-year exception, hospitals can get a time limited one-year exception. And then of course, unforeseen circumstances -- if you get hit by a hurricane and if it makes it impossible for you to achieve meaningful use, the last thing we would want to do is assign a payment adjustment.

The fourth and fifth categories are specific to eligible professionals. They are eligible professionals that can demonstrate that they both lack face-to-face and telemedicine interaction with patients and they lack a need for follow-up with patients. And then the fifth category is for EP's who work at multiple locations who can demonstrate that they really lack of control over the availability of EHR in those locations. For EP's who are in anesthesiology, radiology, or pathology, they will automatically receive the hardship exception, based on that fourth criteria of lacking face-to-face or telemedicine interaction and lacking follow up need. We did solicit comments on this; we received plenty of public comment on it indicating that there was a great deal of challenges for these three specialties. These three specialties, these providers will have to have the appropriate specialty code prior in PECOS prior to July 1 of that year preceding the payment adjustment, that will automatically trigger our system to not apply the payment

adjustment. We will be releasing information about exactly what those PECOS codes are and where they have to go. And before anybody asks, because I get this question now in every webinar when I do not say it, it does not preclude anesthesiologists, radiologists or pathologists from participating. They can participate if they so choose; it just prevents them from being levied with a payment adjustment.

There are a couple of Medicaid specific changes and if anybody is interested in the details about this, there are several FAQs under the Stage 2 tab of our website that talk specifically about it. But essentially, they relate to calculation of patient volume and expansion of some encounters that can be used in the patient volume calculation and some flexibility in the look back period for that patient volume calculation. We think this is going to allow more eligible professionals to qualify under Medicaid and of course, incentives are higher for the EP's under Medicaid. And then finally, as we had indicated, we did make 12 Children's Hospitals eligible, that had been inadvertently excluded because of a lack of a CMS certification number within this final rule. So, this is a direct link to our Stage 2 tab on our website. We do have links to both of the federal registers for folks who feel I did not go into enough detail or that I just talked really, really fast. There are tip sheets for each of these areas covered that we covered that do an overview of Stage 2 Meaningful Use requirements, of what 2014 CQM measure reporting will be, how we are doing payment adjustments and hardship exceptions, there's one for both EP's and hospitals; Stage 1 changes that we've finalized here. And then there are actually two tables that compare core and menu for EP's and hospitals of Stage I to Stage 2, in case you need a handy reference on those. All right, I think I did that pretty fast.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

You know, I am going to have to wipe the shock and awe from my face. Usually how the Rob and Steve Show goes is that Rob talks normal and then I talk like the guy that reads the disclaimer at the end of the commercial [laughter]. So, I do not even know what I am going to do with all this free time. Hopefully it will be a good experience, educational. I will try to tease out some things in ONC's rule and I have one slide that I have built recently for animation. So, for those that are listening over the webcast, that have tuned into our prior webinars at the National eHealth Collaborative, lessons learned, questions answered and asked, have re-jiggered the presentation a little bit to make it more efficient and will be trying to step through at the Policy Committee here, a few high points that I think are relevant to the discussions that you all and your workgroups have had versus for the Standards Committee, I will be doing more of a deep dive, and it will actually be flipped to be the Steve and Rob Show at that point, where I will give your Standards Committee colleagues a deeper look our rule.

First and foremost, just wanted to thank the Policy Committee for commenting as well as all of you in your individual capacities and the folks that are behind me and the folks that are listening. I think Rob would agree that we saw an evolution in the comments that we received, much more focused, much more detailed, a lot of deeper understanding about the program and how it affects different stakeholder groups. And so I think that really helped us make the rules better. Just from an understandable type of perspective as well as addressing a lot of the concerns that were raised in the public comment period. And I think we saw that on both rules, roughly got about the same number of comments I would say, they were just higher-quality comments compared to the last time around. So that really helped us in the regulatory process.

The other thing, which is more for my federal colleagues who are listening, we recognize the time constraints that we were under and I think the rule is just to give people a little bit more sense of context, to bring this back up again. We published, together, the proposed rules two months later than we did at the last cycle. Because last time around they came out December 30

and they were issued for public inspection. The 28th of February is when they were issued this time around. And so, we literally shaved off weeks, if not a month or two, from the final rule period in getting this one issue. And so it was real committed...steadfast commitment for us in the department to get these rules out as soon as possible. So, there was a lot of blood, sweat and tears, more sweat and late hours to get these rules done, but that really reflects our commitment to get the rules out so that the time that folks really requested, we could make available as much as we could, to catch up. So, we are here presenting at the September meeting, and not the October meeting because of that commitment. And I do not want folks to lose sight of that effort on behalf of us as public service, you know, career feds. And the commitment of our leadership at the political level as well to really...and our colleagues at OMB, who, without them, we would also not be here. So I mean across the board, there was a large commitment throughout the administration to get this done and to get this out and that really should go recognized, I think.

So, diving in the top part of my...I will read the title on my slides, because we have a little cut-off here. The major themes that you will see in our standards and certification criteria final rule, enhancing standards-based exchange, Farzad touched on that in his opening remarks. Promoting EHR technology, safety and security and enabling greater patient engagement, so that is really our part of supporting what providers need to achieve through Meaningful Use Stage 2.

Introducing greater transparency to the certification process. I will cover some of those points later. And then overall, finding additional ways to reduce regulatory burden and introduce new flexibilities to our regulatory framework. So, just a quick note, there are a number of slides in my deck that are just going to be for your reference, for other peoples reference for download to review later, for view and download later or transmission to a third party. I will try to work in some jokes.

The point here to keep in mind is that the scope of our rule is a technical one and it really informs the specific capabilities that EHR technology must include and how it needs to perform in order to get certified, and it does not specify how it needs to be used, that is why Rob is here. Because that is what meaningful use really explains is the behavior, how EHR technology, certified EHR technology, needs to be used in order for incentives to be received. And so, we do a three-legged race every time we put these rules together. And if you read ONC's rule as a way, as a proxy for how the EHR technology should be used, it can result in some misinterpretation. So you really need to read them together, it is a pairing and that really, I just wanted to lay out as we go forward. Always one of those opportunities for a public service announcement type of thing, in terms of how to rules interact.

So, I have some comparison slides, this one's going to be for your reference, comparing the NPRM to the final. Again, like Farzad mentioned, not too much has changed, a little bit hard to see the colors, from at least back here. But, there are a number of certification criteria that we had bucketed in the NPRM and largely we kept them pretty much the same in the final rule. At the lower level, we did make a lot of clarifying changes as well as alterations to the certification criteria in response to public comment.

The next three slides that I have just are for your reference. We have three categories of certification criteria, hopefully pretty self-explanatory, new, revised and unchanged. And the new ones, we just have some strikeouts and additions in terms of the table here. So we added two to the new, we struck one and, going forward, will have the revised certification criteria. We actually...I'll probably skip to this next slide. We added some from the unchanged back into the revised category because some of the changes that we made in terms of clarifying the final rule, resulted in us determining that in meeting our interpretation of what revised meant, they fell into this category now, and would be necessary to be revisited for certification. So, those are the ones that are in this light yellowy-orange color that were struck. They got moved back into the revised table of certification criteria. The other two got struck for other reasons, more detail in the proposed rule.

One important point before I leave this slide is that the ones that are in black, bold are eligible for what we call Gap Certification. And so that means that previously issued test results can be used for 2014 edition certification and that hopefully will it introduce some efficiency over time. Hopefully we will not have as much of a refresh of our certification criteria as we did this time around and you can see on a sliding scale those that are eligible for Gap Certification increasing, and those that are in the bucket of new and revised being limited to a smaller set of certification criteria.

So, the meat of my presentation for you all really revolves around the revised definition of certified EHR technology. And I use this slide to some degree in my presentation on the NPRM just to do a little compare and contrast. The 2010 final rule really established a static definition for certified EHR technology that was driven by the number of certification criteria that we adopted for each of the settings, the ambulatory setting or the inpatient setting. We proposed in our proposed rule was a more dynamic definition that would be reflective of and driven by meaningful use, and the stage of meaningful use that a provider would need to meet. And that is this bull's-eye diagram that we use as an illustration of what that dynamic definition looks like. This is a really important aspect of the added flexibility to our regulatory framework. And I have a number of images, some of which I will go into greater detail, others I will leave to your reference that help explain this concept, because it is a new concept and it's important for people to understand how much flexibility there now exists in our regulatory framework.

Okay, so just some other big picture concepts. Again, new regulatory flexibilities. The biggest difference here is that the number of certification criteria to which EHR technology would need to be certified, is driven by meaningful use. And that is going to affect the quantity of EHR...or the number of certification criteria that are included and capabilities in EHR technology that different providers adopt, based on the stage of meaningful use that they seek to meet. So, there are really two views for the Certified EHR Technology definition, and there is a quick pause, that is the CEHRT abbreviation that you see now, that we have used to shorten everything. For eligible providers, the EP's, EH's, critical access hospitals, now the rule, and what we set in our rule is really relied upon in CMS's rule from the certified EHR technology definition perspective. It is about having EHR technology certified to what we call the base EHR definition, and I will go into that in a second. And just enough 2014 edition certification criteria to support their achievement of the meaningful use stage that they seek to meet. On the flipside, the definition also informs EHR technology developers and it offers them an opportunity to rethink the different scopes of certification for their EHR technology, based on this new flexibility that they will be able to seek. And so, it introduces what I have been calling the potential for these right size certifications and the scope of the right sized certified EHR technology based on the scope of practice and the stage that their customers will be seeking to achieve. And that is really where the different quantity of EHR...certification criteria to which EHR technology would need to be certified.

One example here, just to marry it, is that because there is no longer this finite number of certification criteria to which EHR technology would need to be certified, on the eligible hospital side for Stage 2, there is the much commented on menu objective of hospitals reporting electronic laboratory results to eligible professionals. Under this new regulatory framework, eligible hospitals would not need to have EHR technology certified to that capability, if they were not intending to meet that meaningful use objective. And EHR technology developers would not need to get certified to that capability if their customers would not intend to meet that objective either. As opposed to the prior definition that we established driven by certification criteria, they would have to have all of the EHR technology certified to all those certification criteria. So that is just one example of how this plays out, especially on the menu side.

The same instance would be true for exclusions related to the core objectives. You take some of my favorite examples, you know chiropractors or dentists, and they have different scopes of practice. If there is a specific EHR technology developer that serves those as customers, the EHR technology developer will no longer need to just get certified simply for their customers to meet the definition of certified EHR technology. And their customers will still be able to meet the certified EHR technology definition, having EHR technology that is no longer certified to support those objectives that they can meet an exclusion for. So, e-Prescribing for dentists, I'm sorry, e-Prescribing for chiropractors, public health reporting for dentists, things they will be able to meet legitimately through an exclusion for meaningful use, they don't need to have EHR technology certified to it and the vendors that support them don't need to go through the process to get certified to it either. So, that's a lot of the new flexibility that's introduced and that's why it's really...I'll hammer home, the driven by meaningful use component and folks need to understand how those two interact.

So, there are a couple of general points to remember. There are two types of certifications that can be issued, there is the complete EHR certification, which is EHR, certified to all of the mandatory criteria that we have adopted and then there is the EHR module certification, and that essentially is anything less than a complete EHR certification. So it can be ranging from one-certification criteria in theory to all the way up to "N" minus one certification criteria... The scope of...EHR technology represents only those capabilities for which certification was sought and granted. And another point that I think, I've heard in terms of comments that folks may misunderstand, EHR technology developers get to choose the type of certification sought, either complete EHR or EHR module, and the scope of that certification, whether it be seeking numerous different EHR modules that each have been certified to a different number of certification criteria or whether it be getting certified as a...seeking a complete EHR certification.

So, given this new regulatory flexibility, given this new framework that we have established, what is the exciting part here? What is going to get folks out of bed? The new part that I will hammer home here for folks is that under the prior regulatory framework, you had to have a complete EHR or an equivalent combination of EHR modules that each met the same number of certification criteria. I have a good example, hopefully, that will make this...bring this home for folks. Under the new regulatory framework under the EHR module category, you could have a combination of EHR modules or now a single EHR module that is certified to a limited number of certification criteria that will get you across the finish line for the Stage of meaningful use that a provider would seek to meet. And so that's a big difference in the regulatory framework compared to the final rule from 2010.

So, the bull's-eye that I showed earlier, at the center of it is this Base EHR definition, and these are fundamental capabilities that everyone's EHR technology would need to be certified in order to meet the Base EHR definition. And then as you get out to these outer rings, the second and third ring, that is where the dynamic aspect of meaningful use kicks in, based on the stage of meaningful use and the exclusions that providers can meet. So the Base EHR definition, a

couple of quick points and this gets to some of the regulatory nuances. It is a definition, it is not meant to be interpreted as a type of EHR technology that needs to exist, it is not meant to represent a single EHR technology, it is meant to be a step along the way for providers to determine whether or not they have EHR technology that meets the overall definition of certified EHR technology. And so it is meant to be treated like a checklist. There is also part of the Base EHR definition, clinical quality measure requirements, that I am not reflecting here, but in large part, this represents 20 certification criteria that are universally applicable, that will need to be included in everyone's certified EHR technology in order for them to meet that definition. So everyone pretty much starts here.

And I have an info-graphic that helps describe this as well. The first five rows here on this table are rooted in statute, the HITECH Act, Congress provided us these capabilities that EHR technology would need to include. We assigned this minimum set of certification criteria to those capabilities and then the last row, the sixth row, is the row that we added as part of the regulatory process. Okay, so here is where the animation kicks in. Let me just get to my slide. I do not even have any notes for this, so I how do I know I am advancing. The 2010 final rule in this upper swim lane represents the kind of driven by certification criteria policy that we had. And so, on the right-hand side, in this blue square, in order to meet the certified EHR technology definition for the ambulatory setting, it needed to be certified to a finite quantity of certification criteria, it would be 32 certification criteria. Now, for an EP trying to achieve Meaningful Use Stage I, in theory they would only need EHR technology certified to 27 certification criteria, assuming that they could not exclude any core and that they were deferring five menu objectives. And so what that created was a mismatch between the certification criteria that we required to meet the definition and the capabilities that the EP at a minimum would need to meet meaningful use. Now, to illustrate the 2012 flexibilities, how the new final rule policy really shakes out, is that...sorry, the other example here is the combination of EHR modules, same size as that square, has to cover 32 certification criteria, again creates a mismatch. Getting down to the 2012 final rule policy, we have an EP as an example. Based on the stage of meaningful use that they seek to meet, it is going to be variable. The minimum number of certification criteria that they are going to need to have in their EHR technology. On the ambulatory side, the same driven by meaningful use process. And so what happens is, ring, ring, you know, that's where you ring the bell, we've got what I like to call right sized certified EHR technology or certified EHR modules. And they will be able to have a single module based on the stage of meaningful use that they need to meet, that really fits their needs. The same would be true for a combination, an equivalent combination, of EHR modules. They could, in theory, be certified by the EHR technology developer based on their customer's needs, based on the stage of meaningful use that they seek to meet, to have those capabilities that just fit their needs.

Now, this is on paper, this is the regulatory analysis of how the framework works. What we can step to is really the reality sized, and this is what it may look like for an eligible provider based on what the EHR technology developer actually gets certified. There may be an extra certification criteria or two, but they may not have necessarily determined that they wanted to use to meet meaningful use. But that is what the EHR technology developer got certified and so that is what is available for them to choose to meet meaningful use. The same would be true from an EHR module perspective. It is a tighter fit, but there may be something that hangs off the edge a little bit in terms of above and beyond what they require. So, I hope that helps to show the regulatory framework and how it is evolved to introduce this new flexibility. And so it really requires understanding this interdependence and the two views, a. For the EHR technology developers to understand they have a lot of room to run and get different types of EHR modules certified going forward, different types of scopes for their EHR modules to make it available to their customers and for their customers to know, on the eligible professional, eligible hospital side, that this new framework offers this availability and this flexibility.

So, to relay it and align it with the EHR reporting period and the effective dates, there are now three options prior to 2014 for eligible providers to meet the certified EHR technology definition. The first two, options one and two, were in our proposed rule. And the first is largely means you use what you've got through the 2011...with 2011 edition EHR technology, certified to the entire set, the entire suite, throughout the 2013 EHR reporting period. So, you can use what you have got throughout the entire period and then you have this flexible window in 2014, to make the transition to the 2014 edition EHR technology. So, that is a connection, a really important one, for folks to understand, you can use what you have got all the way through 2013, and then make the migration to 2014 edition EHR technology.

Number two, for those people that have EHR technology developers that are really going forward, getting new EHR modules certified, we recognize that there would be this transition period and allowed for a hybrid of 2011 edition or equivalent 2014 edition EHR technology to be part of their mix. It is anchored to the 2011 edition prior static definition for certified EHR technology philosophy, but if they already have 2011 edition, they have already met that static definition and this is a way for them to start getting 2014-edition EHR technology into the mix. The third is the new flexibility that we added in as an earlier adoption aspect, that is reflective of what we proposed for 2014 and beyond, which is, you can jump ahead; you can get your 2014 edition EHR technology and rely on this new dynamic definition early. And so you can straightaway adopt solely 2014 edition EHR technology using this new dynamic definition and meet Meaningful Use Stage I in 2013, largely to meet the definition of the certified EHR technology.

So, the principle behind after and beginning in 2014 is that, there's a single set of certification criteria that have now been certified to a common set of new adopted vocabulary standards, content exchange standards, transport standards. Everyone has EHR technology at the same level of interoperability, with the same capabilities to execute exchange. And that is a really important point, as we have providers seeking to achieve different forms of meaningful use using EHR technology differently, but the principle behind this is that everyone seeking to achieve meaningful use should use the same tools and should have the same EHR technology available to them. It is really the amount of utilization that they need to do and to prove to meet either Stage 1 or Stage 2 increases over time. And so that is one of the big differences in how the rules marry together.

This is a for your reference, it is very detailed. I tried to spell things out just to show the difference scopes and number of certification criteria to which EHR technology would need to be certified in order to meet the certified EHR technology definition, as well as how many certification criteria would be necessary at a minimum to meet either Meaningful Use Stage 1 or Meaningful Use Stage 2. And to also show that the certification criteria are really a subset of all the capabilities that will exist in someone's EHR technology and certification does not cover the entire scope of the universe of EHR technology capabilities that exist.

Here is another example, I will attribute this to your colleague, friend, Micky Tripathi, in his presentation, which really helped hammer home, I think a concept. This is a bar chart example of quantity. So, the Y-axis would be the number of certification criteria to which EHR technology would need to be certified. And I will just jump to bullet three, four, five and six. This shows the different quantity, the number of certification criteria to which different eligible professionals EHR technology would need to be certified in order for them to continue to meet the certified EHR technology definition. So, bubble four is an example where you've got an eligible professional, for instance, that works in a scope of practice that can meet MU core exclusions, so their MU core and the quantity, the number of certification criteria to which their EHR technology would need to be certified is less than what someone that couldn't meet any of those exclusions would need to be certified as well.

Also wanted to show that I did not touch on in detail, on a prior slide, the Base EHR again is a definition and so, different EHR technology developers, different vendors, could provide capabilities that satisfy those certification criteria in combination, in order for someone to meet that definition. And so, again, it doesn't need to be a single EHR technology that gets certified as a "Base EHR," it's more along the lines of those capabilities need to exist in their EHR technology and can be provided by different EHR modules.

So, the other thing, as Rob likes to mention, in terms of Meaningful Use Stage 1, was part of their final rule and modifications there. We also made modifications to our certification program and this largely affects technology developers to make the certification process more efficient, to reduce some regulatory burdens. One thing that we changed, which is minor, but for folks to keep in mind, we had originally proposed a framework that had a temporary certification program and a permanent program.

Starting on October 4, when this final rule becomes effective, the temporary certification program will sunset and the permanent program, which we will now rename the ONC HIT Certification Program, will be the only program up and running. And it will follow that two-part process of getting tested first, bringing those test results to a certification body and getting the certification body to evaluate those certification results.

So, there are some new certification criteria that we included in our rule that apply as a part of the certification process. I will highlight two. We proposed three certification criteria related to...in the safety umbrella. We finalized two out of three of those certification criteria. The first being the safety enhanced design one which requires user-centered design to have been applied to the medication related certification criteria or however many of those certification criteria that are a part of an EHR technology that's presented. As well as EHR technology developers to identify the quality management system or the variability of the quality management systems that they use in developing their EHR technology and the capabilities for certification is required. The other two points that we include that are responsibilities of the ONC authorize certification bodies, ONC ACB's, related to price transparency. And so, the ONC ACB's are required, as a part of the kind of smart labeling/smart disclosure requirements that we already include for a number of the other facets, that EHR technology developers need to disclose, they will have to notify eligible providers about the additional types of cost. Not the actual dollar value, but the types of cost either a one-time, ongoing, or both, that affect the complete EHR, EHR module total cost of ownership for the purpose of achieving meaningful use.

And so, to give you an example, if an EHR technology is certified for the view, download, transmit to a third-party capability, the EHR technology developer needs to prove that those capabilities function in accordance with the certification criteria. But if there is an ongoing monthly subscription cost in order for the provider to actually continue to host that online

availability, that would be the type of cost that would need to be disclosed. And so, it is more so along the lines to show that there are other costs that are involved in implementing EHR technology that has been certified, that go along with the process. And that was some of the feedback that we received from stakeholders that may have been caught off guard. Other instances would be a one-time fee or one-time cost to create an interface to interact with the state Public Health. Sometimes...that is not something that we can get down into the level for certification and so at that level we want to make sure that it is a smart disclosure, providers are aware that there are other costs...types of cost that could be involved in implementing their EHR technology.

The other relates to test result transparency. And this really plays on the separation between testing and certification as a part of the certification process now. And that the EHR technology developers would first need to go to an accredited testing lab to get tested and it will essentially, for lack of a better term, generate a report card in terms of the testing results that have been issued to the EHR technology that they will take to the certification body to get certified. That test report card will be...ONC ACB's will need to submit a hyperlink of those test report cards to ONC and that will be available as a part of the...accessible through the certified HIT product list. So, for those that need or feel a need to dig into how upon implementation, you know, I am tripping up on something. How did the EHR technology developer get certified? That will be a part of the test results that will show the process by which they got tested.

So anticipated timeline, this is something that I got a lot of questions about at my prior webinar. I wanted to hone in a little bit more on some details. The final rules are issued, so we are past August. Through September and October, this is really where it starts to heat up. And the big picture point here to emphasize is that this is not going to be a serial process, this is a parallel process. This is a heavily engaged process and this is to ensure that EHR technology developers and the public are fully engaged. And the one other thing I think to mention here is that the first time around there were areas in terms of the expediency in which we needed to get the program up, and which the test procedures needed to get written and developed, and that we had to make a decision to prioritize a certain level of rigor that would be involved in testing and certification. So, this time around there is an emphasis on increasing the rigor, having electronic test tools where they are available, to make them available for certain of the certification criteria, having more detailed test procedures to provide that additional rigor through the testing and certification process.

And so, this is really a joint effort between CMS, ONC, and NIST in getting these test procedures developed. You know, there is obviously a large portion that revolves around clinical quality measures, that working with our colleagues at NIST and CMS to emphasize, and a lot of the other test procedures that need to be put together for the 2014 edition. Now, the other thing to keep in mind is that we already had a large set of certification criteria for which test procedures were developed. And so, some of which that are in the unchanged, test procedures are not going to change very much at all. Others that are in the revised, some of the revised did not really change all that much. And so, there are a number of test procedures that I think will fall on these initial waves that will be coming out, that will not be too much of a big change or hurdle for EHR technology developers to wrap their heads around. But, like before two years ago, there will be this kind of schedule, regularized weekly waves of test procedures to limit the amount of drinking that someone needs to do from the fire-hose in order to provide feedback. And there will be opportunities for folks to engage themselves with the electronic test tools as well.

All that leading up...you know, there will be public comment the same as that I went through before leading up to testing workshop that would be held in the November time period, at which time afterwards the test procedures would be finalized, the test tools will be cemented and the National Coordinator has a responsibility to approve the 2014 edition test procedures. They

would then be issued, made publicly available. The accredited testing labs would need to familiarize themselves with those procedures, as well as electronic test tools. So, all of these things are going to be heavily threaded together and the bottom line is that the timeline is structured in a way to provide EHR technology developers the ability to become fully engaged in the test procedure process. As well as most importantly, to be fully prepared by the time the testing and certification process becomes available and commences. And so it is not going...it is not going to be the serial aspect. It is really meant to get them up and running, to know what They are going to face in the testing process as soon as it becomes available.

So, these are other just other materials for folks that are on the webinar that are watching. They are available on our website, four different types of bull's-eye diagrams that assign the certification criteria to those rings for meaningful use. This other one is a new one that we created to really figure out, and I will credit Wes Rishel. When I tweeted about the availability of the info-graphics, he said to me, "I don't know whose doing your messaging, but you should have said, got CEHRT as a play on, you know, got milk. So, I will try to use that, but a plug to Wes for pointing me in messaging direction.

The thing to note here is that if you adopt a complete EHR, and this is the stage one version in the info-graphic. Then there is really not too much else that you need to do in terms of thinking. Because it really provides overall assurance that you have of got EHR technology that you will need to meet meaningful use. As you go down, and I am sorry for the people behind me who cannot really see it...it is not too crisp on the screen here. The green box is the Base EHR definition everyone starts with that. The next box is a part of the Base EHR definition which reflects the minimum number of clinical quality measures to which an EP or eligible hospital, critical access hospital's EHR technology will need to be certified. So that was a minimum threshold that we set in the Base EHR definition to make sure that folks would have what they needed to meet meaningful use. And then the third and fourth box are really those that ensure that they can make sure that they have EHR technology that's been certified to certification criteria to support those correlated objectives and measures that they seek to achieve for meaningful use. This is again just an example. We broke that larger, more detailed info-graphic down into those that are specific to eligible professionals or eligible hospitals.

And that wraps up my prepared remarks. Check back to our website there. There will be other things we'll be putting together like the grid that we produced the last time around comparing the meaningful use objective and measures to our certification criteria. As well as what I am calling the "standards hub" which would be a webpage that has for all of the publishers of the standards that we've adopted in our final rule; URLs and hyperlinks to the documentation and the standards that are included, so people don't need to hunt and peck and search around for all the documents that we reference. So that is one of the things we are going to be making available. Obviously again, shout out to the HL7 folks for their announcement. That will be another thing that I think will help greatly contribute to the availability and accessibility through our website, to have these standards. So, I believe that wraps up the Rob and Steve Show. Signing off or available for listener feedback.

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

Thank you so much both Rob and Steve. I mean, that was very comprehensive, yet brief and very informative. And we will want to take the opportunity to thank Farzad and the Department and CMS for such a close working relationship with your FACA committees, with the HIT Policy and the HIT Standards Committee. It's been a very productive relationship and there's been a lot of exchange in the little news is good news kind of outcome that you portrayed at, I think, the NPRM, where at least you were saying predictability is one of the things that we need, particularly now, as we build towards...on this trajectory towards Stage 3 and beyond. But, it has been a wonderful collaboration, so thank you. Want to open it up to the committee members for questions and comments. It looks like David has the first one.

**David Lansky, PhD – Pacific Business Group on Health – President and CEO**

Thank you, Paul. Thank you, Rob and Steve, great show. I...first of all, obviously want to complement and thank you both and everybody working with you to get us this far this fast. I know the pressure has been huge and the complexity, as we just saw, is daunting. But I had three things that surfaced for me as I listened to the presentation. I will try to make my three comments brief. And all of them were basically about what is our role as a Policy Committee, given the introduction of the changes in both the certification side and the objective side for Stage 2, especially as we look towards Stage 3, which is where we are now turning our lens. Sorry to tell you we are now going already for the next round, no breathing space.

So first, I think on the certification stuff, two thoughts I had at the big picture level. One is a level up, I think, from Steve's presentation, and one is a level down. On the level up, I guess I'd appreciate your reactions and thoughts on where we are in conceptualizing an information technology network environment in which certified EHRs sit, and which will, I think we probably all assume that looking forward five years or whatever number, the concept of an EHR product which is going to be fully contained, longitudinal health record with all the capabilities to manage someone's health is not realistic. And we are going to have a large network of nodes contributing data and functionality to the management of the patient and the communication of information to the public.

And I know part of the modularization component that you described, Steve, is a way to get there. But, I worry that we have to so specify the certification standards for each element of the infrastructure that it is untenable. As the infrastructure gets more diverse, pluralistic, complex and the nodes are mobile and personal and distributed and so on and so forth. So, I guess I wonder what we can do as a committee over the next year, as we look at Stage 3, to support the process of articulating the network and making sure we do not try to over-specify everything from the federal level. And, what you have seen in the work so far that would help us do our job to support you in doing that. And I think particularly we want to allow for the interoperability among the nodes, we want to allow for the construction of a longitudinal patient view somewhere in the cloud, not necessarily in every office and every hospital, although maybe that is an answer. And we want to allow for population view, as well as a longitudinal personal view. So, I know it is a big question and we will not answer it today, but we probably need a process by which we think about the answer to that question and do not get overly bogged down in the technical specs for every single node. That is my fear.

My second question is really a level down. Where are we in facilitating what Paul and I have both been talking about as plug and play analytics? How do we allow for this distributed network to accept inputs like knowledge assets, I think someone called them in one of our meetings, whether it's CDSS rules, whether it's quality measures specifications, whether it's benchmarking and quality improvement feedback, Farzad and they were just talking about. That is all going to come from sort of outside the health management patient level structure which is where we're again focused at a micro-level on the patient level and clinical management. But all the knowledge assets of the world have to be brought to bear. And that interface between the knowledge assets and clinical care system seems to me we are not doing...I am not quite clear what our strategy is to connect those two environments to each other.

And the third question I have is really about the quality measurement platform, which of course I am particularly concerned about as a purchase representative here. And there I think my question...my fear is about this word alignment that we are very enthusiastic about. And I worry particularly where the alignment strategy is to map the meaningful use quality measurement work to the old world quality measures like PQRS. And I understand CMS has a number of regulatory and programmatic objectives, but I really am concerned and what we've already learned from the Stage 1 reports from the field, is that we can't sort of drag the EHR advanced, more sophisticated clinical world back into the old world and be...in a very productive way. And I would much rather see us think about meaningful use, quality measures pulling us forward, than trying to address what I consider inadequate standards of PQRS to drive clinical quality forward. So, I am worried that we have to not align to the old world, but we actually have to create a model that pulls the old mechanisms forward. So, I will stop there, but your comments on the first two questions I would appreciate.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Let me take Steve off the hook there. You know, at its heart the certification program is tied in what it is required to do to the Health IT Incentive Program, which is for doctors and hospitals to earn incentive payments for the meaningful use of electronic health records. So that defines a clear boundary of what is in scope for the regulatory approach to certification. And I think that the conceptual framework that we have here is that we have to make sure that we stay true to that, but also permit and increasingly liberate both data going out of those transactional systems, but also information and intelligence coming back into them.

So, I don't think that the future, the question you asked, you know, how does this relate to all the other nodes that are going to be added to this, the analytics, the mobile patient engagement tools, all the other things that can come around this, the profiling, the hot-spotting. I think one way to go here might be to say, well that increasingly gets piled in under certified EHR technology. But as you point out, this probably leads to kind of an untenable growth of the concept. The other is to kind of keep the core, what's core, and then we can have...I mean, this committee has settled on some things being core, like quality measurement is core, Even though it could have been decided that that's, well actually legally, it was actually in statute that quality measurement is in there, right. But, that is, one would argue, well that's, you know, a population feature, it is not just transactional clinical care. And the electronic health records indeed will need to have some population functionality. But it does not have to be everything.

So I think that our task is to make sure that we make...do a very good job of identifying what is meaningful use of electronic health records. And based on that, what should be a certification process for electronic health records for doctors and hospitals. But also to make sure that they are porous, and they are porous not in a random way, but in a rigorous way, so that there can be interfaces, there can be API's, there can be data going out, and I think this is the part that you are focusing on appropriately. So, increasingly you are going to want to take those knowledge assets, and be able to integrate them into the transactional workflows. It is not tenable for us, if we're thinking about accountable care organizations to say, doctors use, hospitals use this clinical information system for all of their workflows and then we're going to have this separate thing off to the side, where you go to log into a portal to look at your, you know, your care gaps. That is not going to work. People are really going to need to integrate those care gaps into the transactional workflows. And I think it gets to, and they're all related right, the quality measurement is a platform, the decision support that are executable and the registry functions that flow from those, those really all need to be able to be interfaced with the electronic health record. And I see that as being, probably from a technical and industry point of view, one of the

most challenging things we're going to take on is how do you take those and integrate them in. So, I think that actually gets to both points to a bit.

On the quality measure alignment, Patrick is not here, Patrick Conway. He apologized to me for that today, but I think we have to...there has been progress made, I guess I would say and Rob, if you want to comment more on...if you look at the specific quality measures that this committee, and I think David you had a big part in identifying some of the next generation of quality measures, whether it's closing the referral loop, whether it's looking at some of the patient engagement or the drug measures. Some of the next generation of quality measures that were developed because of the Meaningful Use Program, are now going to make their way back into those other programs. And I think that ultimately is alignment should not be a one-way street, nor do I think it is a one-way street. I think we're going to pull but we need to stay tethered, because we can't totally detach, I think from the perspective of the providers and the hospitals, they can't really have two totally separate systems, one based in the old and the other in the new, without a connection between them. So yes, we will be held back somewhat, but we can also pull forward, if we can remain tethered is kind of my generalization.

**Robert Anthony – Centers for Medicare & Medicaid**

Yeah, I think we are looking at an aligning forward. I think we are trying to do that as much as possible. I absolutely understand the concern. The balance for us is trying to move forward both system-wise and with the actual measure sets. You cannot leave those programs behind, those other programs we have to figure out how they intersect, because some of those other programs are also mandated programs. So the effort is to really see, and you will see this I think very much on the PQRS side, where the actual measure sets between EHR Incentive and PQRS will be aligned, so that we are not having a separate set when you are reporting under one method and a different set when you are reporting under this method.

**David Lansky, PhD – Pacific Business Group on Health – President and CEO**

Can I make one other point Paul?

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

Yes, certainly.

**David Lansky, PhD – Pacific Business Group on Health – President and CEO**

One thing that I recommend is that we consider in this committee, maybe in February or thereabouts, having a session or part of the session on this question of the quality measures and where they are going, and what we can do in Stage 3. By then we will have enough input from the requests for comment that I know Paul's committee is going to put out in November, and I think this is a very serious question. My constituency, if you would like, the purchasers of health care, are really concerned we are looking at a 2015 time frame for Stage 2 activity, which is then six years since the 2009 launch of our program and that statute, and the measures we are talking about for 2015, are not adequate. And I think we counted on the \$29 billion dollars on this program and this committee, to drive an agenda that was much more aggressive over those six years than what we're going to have. So I think this committee needs to take a look at that and say are we really where we need to be, especially if we're now talking about 2016-2017 Stage 3, I think has to be much more aggressive in the measures and try to avoid the potential for rolling back to a program that was not very effective, and make sure we build one that is effective.

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

Good, thank you. Deven?

**Deven McGraw – Center for Democracy & Technology – Director**

Just, one question is a pretty simple question and then the other one is probably a little bit more complicated. The simple one is, with respect to the first measure within the information exchange bucket of three, which, by the way, I like the option that you came up with for dealing with the exchange with at least one other different vendor. The first measure of sending summary care record for more than 50% of transitions or care referrals, that one does not emphasize that it has to be done electronically. And yet you are supposed to also be using Certified EHR technology to do that measure. So, how do you see providers meeting that measure if they are not sending it electronically?

**Robert Anthony – Centers for Medicare & Medicaid**

Yeah, I am sorry. We place most of the emphasis for the electronic exchange in that second measure, which is the 10% of that. That 50% is sort of, however you are getting across the finish line, I guess.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, okay.

**Robert Anthony – Centers for Medicare & Medicaid**

It has almost tiered down in a way. You have your 50% that however it gets across the finish line, whether that is forwarding something the way that it is now. You see in the current objective where it can actually be passed on to the next provider. Electronically counts as a part of that as well, that direct electronic exchange is even a...more of a subset beneath that with somebody who has a different network altogether. So, whether it is something that you are physically handing off, whether it is something that you are doing electronic exchange through a closed network, whatever you are using to get that across the finish line.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Might be around prescriptions and electronic prescribing. So, the information about what was done has to come from the system. But the system can also keep track of what is printed; it can keep track of what is faxed. So, it does have to be through...the reporting has to be through the system, but the 10% is what has to be sent electronically using the standards. The 50% could include the system keeping track of that

they printed it and sent it or that they faxed it, or other ways.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay. Okay.

**Robert Anthony – Centers for Medicare & Medicaid**

Which is the current way that that objective is for Stage 1, it is consistent with what we are doing in Stage 1 now. The addition is those last two measures.\

**Deven McGraw – Center for Democracy & Technology – Director**

Got it. Got it. Yeah, that was more clarification. The second question is on minors and access to minor's information through the view, download and transmit capability. And I'm well aware of the sensitivities around minor's health data, particularly for conditions where under certain state laws, minors have the capacity to their own treatment and therefore, hold the privacy right essentially, and therefore can have the ability to make sure their parents don't see it, if that's their desire to do so. What I was a little dismayed by was a sort of dismissal of the possibility that in some circumstances an entity that serves adolescents, might actually want to allow adolescents to have their own portals, and to allow that to count. Versus the option that seemed to be the only one discussed which is that you can put the information in a parent portal and allow count that as access for...I mean, I read it to mean you could allow that to count as access for the minor as a patient, as long as, you know, you obviously have to comply with the law that covers you that might restrict your ability to make certain pieces of information available through that

Portal, that might be seen by a guardian. So, my sense is that whatever option a healthcare provider chooses to serve their patient base, with respect to the EDT, ought to count. And obviously they're well aware of sort of their legal obligations with respect to what type of data can be exposed to a parent or guardian in the case of a more mature minor seeking the types of care for which they often can consent on their own.

**Robert Anthony – Centers for Medicare & Medicaid**

I do not think that is radically different than our intention with that. I think that we were trying to get to a point where we know there are certain legal ramifications and we were trying to say; that you are...we are not in this, in meaningful use, trying to go beyond or around those particular legal ramifications. I think that...and this likely could be a good topic for an FAQ where we clarify guidance for folks as we move forward. But, when we look at areas like that, I think we could absolutely see putting patient information

for the adolescent onto a portal for the adolescent for their access, counting as something that goes into the numerator for that objective. I do not think there's any issue with that.

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah, I think an FAQ would totally clear that up, because that was the impression I got, but I just wanted to be clear. All right, thank you.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Deven, the other context where this comes up is in the after visit summary, where we've heard from many providers of care to adolescence, that there may be good reason for the provider to be able to modify or redact portions of that after visit summary information on there. And it was with an eye towards that, that in certification, we included a requirement that the products permit the end user to edit and customize the after visit summary. Steve, do you want to...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

That sums it up.

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

Okay, Neil, Josh and then Christine.

**Neil Calman, MD – The Institute for Family Health – President and Cofounder**

So this question is for Steve. I am trying to understand this option that you've now allowed providers, in terms of eliminating what used to be a package of functionality, so that if a provider in the community was buying a certified EHR, they could be confident that it would do all of the things that they might want to do today, tomorrow or next week in relationship to meaningful use. And now it sounds to me like a provider purchasing a system may not do that and that there's some new twist, to sort of people buying electronic health record systems, that they sort of have to figure out not only does the system do what they want it to do now, even though it's certified. But, maybe it can't do syndromic surveillance and maybe it can't do some of the optional things that today aren't relevant to them, but tomorrow might required or not required by us, but maybe part of what the community requires. And I guess, one I am trying to understand the rationale for doing that; it sounds like we took something that was fairly simple and made it complicated. In order to make it easier for the vendors, we have now made it more difficult for the community to really understand what they are buying. And then I guess secondly, if we have done that, how do we...what do we tell people, because everybody is going to be certified. How do people know that they are buying a product that is not necessarily certified to all of the things that meaningful use might want them to do. Or do I have this totally wrong?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

No. I mean, I appreciate your question. And so, we do, I think as Farzad has mentioned previously in other cases, we do have to weigh added flexibility with complexity, and how that can introduce complexity. Here, we really do this for providers and because the definition that we said is use by meaningful use. So, when it comes down to the meaningful use of certified EHR technology, CMS defers to our definition, in our rule. So, we really set the definition for eligible professionals, eligible hospitals, and critical access hospitals in ONC's rule. And that is why I tried to emphasize that it has two views.

To your point, it has really...if they want ultimate assurance that they have capabilities to meet meaningful use that have been certified, then they could adopt a complete EHR...let me be more precise. They can adopt EHR technology that has a complete EHR certification and that scope is representative of all the certification criteria that we require for certification. That would allow them to meaningful use certified capabilities. It does not mean that the EHR technology developer, if they choose not to get a complete EHR, could continue to include the syndromic surveillance capability, and they can use it in their community. It just means that what they had approved for certification is reduced to what they would absolutely need to have certified to meet meaningful use. So, I want to try to emphasize, that was that massive square diagram. That the scope of the capabilities for which certification is required is anchored to meaningful use and the objectives that it needs to support. And what we have done is shrunk the scope of what at a minimum is required for certification in order for people to have "certified capabilities to meet an objective and measure." An EHR technology developer then can continue to include a whole suite of other capabilities that the customers may use in whatever jurisdiction that they are in. They would not need to be certified in that case, in order for them to continue to use them. If they wanted to meet meaningful use, to meet family health history, that would need to be certified. But if they just want to have that capability, the vendor could get...you know, include that in their product, but not get it certified. I thought I had you at hello.

(Laughter)

**Neil Calman, MD – The Institute for Family Health – President and Cofounder**

Not get that...so, it would still be certified, but that function would...that particular function would not be certified.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Correct. Yeah.

**Neil Calman, MD – The Institute for Family Health – President and Cofounder**

So, they might not be doing...collecting family history the way we want them to, but there still...but they still could be collecting it. And then, that could not be chosen by a particular provider then as one of their menu options. So they are putting in family history, but they cannot choose that one because that particular EHR vendor has chosen not to do family history the way everybody else in the country is going to be doing family history. I guess that is what I am trying to...it does not make sense to me.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

So, if a provider chooses to, they can always get a complete EHR.

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

And the scenario you just described Neil is not a complete EHR, correct.

**Neil Calman, MD – The Institute for Family Health – President and Cofounder**

But how do they know that?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Well, there's labeling. So on the CHPL, there's a selector...there's a radio button that says, you want to look for complete EHR's, here's the list of the complete EHR's that have been certified, if that's what you want, right?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

That is also one of the things that the ERH technology developers are required to disclose, if they have gotten a complete EHR or an EHR module certified. And in the case of an EHR module, each of the certification criteria to which it was certified.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information**

So, in terms of...terms, it really gives yes, more responsibility to the provider, for making sure that they are choosing, but we are giving them the information tools they need to make that choice. If they are a dentist who says, “I will never use that,” then this gives them the right and the ability to not buy a system that does a bunch of stuff that they are never going to use and they do not want it, they do not want to pay for. But, they still have the information if they choose to, to buy a complete EHR. So this really was done in response to comments from providers, not vendors, who said, “We want to only buy what we need.”

**Neil Calman, MD – The Institute for Family Health – President and Cofounder**

But, let me just follow up. If you really want to do it for providers, what you do is you say that vendors have to be able to sell products that don't necessarily have all the modules, but to have a vendor do things in a nonstandard format doesn't make sense to me. Because providers are going to end up with things that they do not know this year they are going to need next year. And they are going to be done in a non-certified way. I think that's the thing...you know, when you look at the...I guess I just feel like we have made things more difficult for the providers. And yes, they should not be forced to buy things they do not need, but that is not up to us. That is up to the way you know, vendors sell their products, whether they sell them all at once. I guess I am concerned that non-certified functionality. People say sure we can do family history, sure we can capture progress notes, sure we can do registries, but they're not going to be done in ways that everybody else is doing them, and then they end up having this stuff, but it's not really going to get them where they need to go. So, a caution there.

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

Josh?

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

Thanks. And first, just want to congratulate everyone who has worked on this. I have been involved in regulatory processes at the federal level that are measured in decades. (Laughter)

**Robert Anthony – Centers for Medicare & Medicaid**

Sometimes that is how it felt.

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

And then you have meetings where people say, but are we really ready to move forward now, even though the original proposal was in the 70's. So, I really do appreciate everything that is gone on. I have two sets of questions. The first is very specific, the second a little bit more general. And, I apologize if I am totally ignorant with the first, but for the first set relates about clinical quality measures. When those get reported in, you get the data from the practices, is that Medicare only or is that everyone?

**Robert Anthony – Centers for Medicare & Medicaid**

It is all payers.

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

It is all payers. Will that be publically available by practice, do you anticipate?

**Robert Anthony – Centers for Medicare & Medicaid**

The clinical quality measure data?

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

Um hm.

**Robert Anthony – Centers for Medicare & Medicaid**

I do not believe that it is published by practice or anything that is identifiable at this point.

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

There is no plan or...

**Robert Anthony – Centers for Medicare & Medicaid**

We certainly do not do it as part of the EHR Incentive program. We actually do not make any data at this point in time that is identifiable by provider available, other than what we were congressionally mandated to do, which is, "Who has received a payment." We do provide some public use files that provide the numerator and denominator information that is de-identified for...and it provides some other things like specialty and things like that, for meaningful use data. At this point in time, with clinical quality measure data, we are not doing that.

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

Okay. I mean, CMS does a lot of identifiable information around the hospital quality and other things, but this has not crossed into that discussion at all.

**Robert Anthony – Centers for Medicare & Medicaid**

No.

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

Okay. And I guess related to that is whether CMS is anticipating or...you know, once you start getting in from a whole lot of providers, whether that data would be made available to Public Health at the state or local level, to be helpful. I mean, many of the measures are really relevant for public health.

**Robert Anthony – Centers for Medicare & Medicaid**

That is a conversation we have not had yet. It is certainly possible that we will go in that direction, it is just a conversation we have not had yet. Farzad it obviously itching to say something though.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

My comment for Secretary Sharfstein is that states actually have a right under Medicaid Incentive Program...

**Robert Anthony – Centers for Medicare & Medicaid**

Thank you...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

...to receive the quality information from those. And I think something that would be interesting for you to help catalyze among your peers is what use will states could put that information for use for, particularly for the most vulnerable populations on the Medicaid site. So, part of this, I think, is the pull as well as the push. So, I think it is fantastic that you are expressing pull, that desire to want to see this information, and to use this information. But I think it needs to be a little bit more prevalent.

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

Sure. I just wanted to understand what the status of the discussion of that was. I mean, clearly, the Medicaid data, we will have the ability to use, but the Medicare data is pretty helpful also in this. And there is, in the field, quite a lot of understanding of the benefits of public reporting around things. Second question. Health Information Exchanges, what role, if any, do you see for health information exchanges to help in Meaningful Use world as it now exists for Stage 2, understanding that there are some places where you don't have health information exchanges, it's not necessary, but in a state like Maryland, where we have a pretty robust health information exchange, how would you see that kind of fitting in with this?

**Robert Anthony – Centers for Medicare & Medicaid**

I think we have a very, speaking of robust, a very robust discussion about this within the Stage 2 final rule about the use of health information exchanges, specifically for electronic exchange of the summary of care documents. I think in those areas where there are those robust networks developed, that's absolutely going to be that facilitator for most people and it makes it easy to meet both the second and third measure of electronic exchange in exchanging outside of a particular network. I do not know if you want to talk a little bit more about exchanges, I know that you are a little deeper into it than...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Sure. So technically speaking, in order for providers to meet meaningful use, they have to use certified EHR technologies, it is the rule. And exchanges can and have been certified to be essentially modules. The deal with the exchange aspect and that a provider could choose to use to satisfy their meaningful use requirements. So one way to accomplish that, and it's quite straightforward, is for a health information exchange service provider to become certified as meeting the exchange requirements for meaningful use and then any provider who uses that, could list the information exchange service provider as the means. The other...and there are both requirements around they can meet the certification requirements, both to the direct protocols as well as the query for SOAP based protocols, the SOAP base is for the secure query. The other provision though, that we permitted in the meaningful use rule was they either use certified EHR technology or, I forgot the exact language, but it was something around, any entities that have been...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Participate in the exchange.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

...participate in the exchange. The Nationwide Health Information Network. So, and we will have a little bit more discussion about this later today. If, at some point, we do have a designation, a national designation, for organizations that are part of the Nationwide Health Information Network, then those organizations could also...the providers could also meet meaningful use by the exchange requirements by using those organizations.

**M**

Thank you.

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

Good, thank you. I have Christine, Art, Terry, Judy.

**Christine Bechtel – National Partnership for Women & Families – Vice President**

Thank you. And thank you very much for your presentation and all your guys work on this. I have a couple of questions. One is I want to come back very briefly and say something about the quality measures piece of this. I share very much David's concern about the robustness of the measures that are in the other programs to which meaningful use is being aligned, PQRS, etcetera, etcetera, and I think another reason to be concerned is that those programs are not all payer data. So, that is a challenge because they are Medicare only, and when you report quality measures only on your Medicare patients, then I think we lose an opportunity. So I do think that if there is going to continue to be alignment, that the Policy Committee probably needs to engage in looking at PQRS and those other programs on the measures that are in them. But I also want to just say that we had a proposal that was discussed at length in the Policy Committee and came through the Quality Measures Workgroup, whereby meaningful use could actually serve as a pipeline for developing some of those more robust measures, by having clinicians working with their specialty societies and others to really actually design and test measures, which would really cut the cycle time for developing those measures greatly in the field. So, this may be more of a thing, you know, comment for Farzad, but I really hope you guys are giving serious consideration of how to put that into play, sooner rather than later so that we really have a better pipeline for getting those measures.

I do have a question on view, download, transmit, and I think it is a certification rule question. So, you know, buck up. And that is, so if I am a specialist, I am going to give you the construct in which I am thinking about it. If I am a specialist and my patient already has let's say a portal or a personal health record elsewhere, and that patient says, "Well I don't really...look, I don't really need you to give me portal access, I just need you to send it to me and here is where I want it. I want it either to go on my primary care doctor portal or in my HealthVault account or whatever. Are there technical requirements in the certification rule that would permit that? Or is every specialist and clinician going to have to set up a portal, so the patients would be the one that would then download and send it to wherever it is that they want?  
(Indiscernible-multiple speakers, laughter)

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

I have to consult with my...

**Robert Anthony – Centers for Medicare & Medicaid**

Steve, I am going to advise you not to answer that question...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, and the reason why I was talking to Rob quickly, I mean, this is a clear interdependence between the rules, in terms of for meaningful use its patient action.

**Christine Bechtel – National Partnership for Women & Families – Vice President**

I know.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, on the certification side, the EHR technology that a provider has has to have been certified to that. It does not necessarily require that they have their own individual portal, as part of their EHR technology; they could rely on a third party. That would be an aggregate, for numerous providers to have signed up with that third party that had gotten certified as a module, in most cases, that they have an affiliation with, etcetera, which is part of their overall “certified EHR technology.” It would be interesting if a patient had an account with that same vendor, for a lack of a better word, where they would kind of send it to themselves or not. But, in the case where its two different entities, then they would be able to access that information and transmit it to the location of their choice, if that...you know, all that connection etcetera is available.

**Christine Bechtel – National Partnership for Women & Families – Vice President**

That is very helpful.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

So in other words, if the specialist has an EHR, a vendor who doesn't want to get into the whole portal business, they could rely on a personal health record provider to send it to them and for them to then be the portal and the view, and the whatever that the patient...

**Christine Bechtel – National Partnership for Women & Families – Vice President**

Okay, perfect. So my last question, actually I have two and I think they are correct. One is, Rob you talked about exceptions in, and you have named three specialties, and basically said they are not subject to the penalty. Just a quick clarification, what if they decide to go out...to try for meaningful use and they do not successfully attest. Do they get penalized?

**Robert Anthony – Centers for Medicare & Medicaid**

No.

**Christine Bechtel – National Partnership for Women & Families – Vice President**

So they can get free money, no penalty. I just want to make sure I am getting that.

**Robert Anthony – Centers for Medicare & Medicaid**

That would be one way to characterize it; it is not the way I would choose to. I would say that also as we draw attention to in the rule, that this right now for those exceptions, are time limited. We are going to be looking at this again as we move forward for Stage 3. So, this is not a forever and go for it kind of deal for just these specialties.

**Christine Bechtel – National Partnership for Women & Families – Vice President**

Well, that helps. But good job Bobby and guys. Last question, communications preferences, I think this is back to Steve. I mean, it is sort of both of you, right. So, in the rule, in the policy rule, CMS essentially says we have eliminated it as an objective because we believe there are other things like patient reminders you cannot do without collecting communications preferences. But, in the certification rule, no offense, but it's so unclear, I just couldn't really understand that component because on one hand it says, yes, your technology has to be able to collect communication preferences, it wasn't clear to me what that meant. But on the other hand, we think that in future rules; we should make sure in 20 whatever, that we should collect. So I am confused. And what we intended, anyway, around that was communication preferences that's not just like a field for your e-mail address and your mailing address, but rather, if I am getting...if you're reminding me about an appointment, I'd prefer you e-mail it to me, but if you're giving me lab results or, you know, communicating about some other issue, I'd prefer regular mail. I mean, that was the intent and I do not see that that is in there technically. It is not in there as policy requirement for the use, but I cannot see that it is also in there technically.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, patient preference only applies in the ambulatory setting, and that is where it is assigned as a field that needs to be captured. Now how, for a lack of a better word, how dumb or smart the patient's preference capture is programmed in, at a minimum, preferences need to be captured, and I think we gave some examples of like e-mail, text, regular mail, etcetera, that would need to be things that could be captured by the EHR technology to represent the patient's preference. It would be above and beyond current scope or, to I think segregate the type of...the reason why and what type of preference would be assigned to, the reason or the purpose for the communication. That does not preclude EHR technology developers today from doing so, and I think this may get to a point that David was making earlier as well, there is a constant policy tension of, and I think right for the committee to consider. If it is not part of the certification, it is never going to happen, if that is the philosophy that is approached. Or, if it's certification needs to address a minimum, to make sure people are doing it, and then let the industry innovate above and beyond that. So, it is a constant tension that we have. If that is a policy direction that the committee would like to go on and recommend, then that certainly could be considered. But again, if it is...

**Christine Bechtel – National Partnership for Women & Families – Vice President**

Right, okay. So I'll just make the brief point that we actually did recommend that direction and I think I would at least disagree with CMS's determination that people will do it anyway in the absence of a policy requirement to do that, primarily because that's not the culture of the health-care system when it comes to that kind of flexibility and patient centeredness. So, I will just throw that out there as something I think we probably missed on this one, and need to pick it up again in Stage 3. Thank you.

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

Okay, we only have ten minutes, so try to be brief. Art?

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

Yes, thank you. Excellent presentation and you guys have working very hard, and all of your staff. I wanted to go back to a point that you mentioned earlier Steve, about this price transparency. I think that is excellent that that be there. Have we, in the exchange of information that we talked about with another vendor; do we anticipate that there will be a price associated with that?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Um, I mean...

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

A cost...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

There could be a cost associated with whatever type of exchange that they may seek to participate in, if it is somewhere in their state, it may not be. It depends on, I guess, the model that participation is. But

EHR technology will not necessarily have that capability straight away, you know, all the way from end to end.

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

So we think that the vendor would have to inform the purchaser that this is a potential cost.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Yeah, I mean, if you are in Colorado, right. So CORHIO, if they want to connect to CORHIO, and there's a cost to connect to CORHIO, it would be a potential cost associated...you know, whoever their HER technology developer would say do you want to do beyond what we have, that you could incur a potential cost for us to connect you to CORHIO.

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

Go back to the example that you gave Steve of speaking with the state health department about some exchange. It just seems like we are trying to do so much alignment here, alignment of issues related to CMS and how CMS is working with ONC and NIST. And you are example kind of pointed to me that I do not know whether there is enough alignment of what is going on at ONC, and maybe CDC. And how CDC pays for, or provides money to states to do surveillance. And that now we have potentially...we already know we have many states and localities that have different requirements. It seems like we should be pushing for that alignment as well in public health, so that price transparency example you gave is not something that we continue to talk about in Stage 3 and beyond.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Yeah, I mean, I don't know if Rob wants to...we worked, I can tell we worked a lot with our CDC colleagues on all the public health objectives and measures, including the new cancer registry reporting one as well, and I think it's a fair point that we discuss with them in great detail about...those aren't entities that are eligible to receive incentives, right.

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

Right.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, how CDC can best use its policy levers and other procurement opportunities, etcetera, to align the programs together to support provider's achievement to get data to public health which public health wants.

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

Right, thank you.

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

Terry.

**Terry Cullen – HIS/HHS**

Mine is pretty quick. First off, I want to echo amazing, amazing. And I really like the graphics, I love the little stuff going on there. And I want to follow up on what David and Neil said, because I think that this is really important, this concept of modularity versus an integrated system, especially as we have looked towards the plug-and-play analytics. So what I would see, and some of this is informed by what Colonel Greig and I have been working on in the IEHR is this concept of a SOA-based architecture, really plug-and-play whatever you want to plug-and-play. But with the understanding that the specifications to plug-and-play are public and they are standard. So, I think we may be getting ahead of ourselves, to some extent. We're going to allow modularity, but we really, I don't know, have gone into what are...so we published some messaging standards, but have we published enough standards to not be in this caveat emptor position where the physician is going to have to figure out whether this is going to plug-and-play, because I will tell you the physicians aren't going to be able to do that. So, as we move towards Stage 3, I am really supportive of modular certification. I think it gets us where we need to go from an architecture perspective, but we have got to get ahead of this somehow, and I do not know that we can actually wait two years, so...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Yeah...I do not have anything in specific to respond. I think the one concept that I have been trying to communicate as I had in some of my slides here, that I would say I didn't communicate as clearly last time around, is the types of certification issued, being the complete EHR certification or the EHR module certification. And in the...I probably took for granted that everyone thought, "Oh, he's talking in regulatory-ese, so I can understand his regulatory-ese." We capitalize them as terms of our proper nouns, and they have a specific regulatory meaning and the module term, capital "M" EHR module has a specific regulatory connotation that is not the same as lower case "m" that other people may use. And so, it is representative of the certification criteria to which an EHR technology is certified. And that is what the capital "M" EHR module certification is meant to be. Just using the opportunity to help explain that, but it is in the same vein there to make available as part of the regulatory framework these concepts like the personal health record application that could get certified as a capital "M" EHR module or, to some of David's points as well. We broke the certification criteria for clinical quality measures into three separate certification criteria, thus allowing for...so capture...put simply, capture, calculate and reporting. So the calculation, the deep analytics if you want to call it that, could be separately certified by some data quality thing in the cloud, and everyone could use that as their EHR module, as part of their certified EHR technology.

**Terry Cullen – HIS/HHS**

So, let me just make one comment and it goes back to what Farzad said, is that the one problem with that issue, you don't want to at the point of care decouple...you can decouple the transaction...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Yes.

**Terry Cullen – HIS/HHS**

...but you do not want to decouple what the provider sees. So, you do not want them having to do access and verify on another thing, so...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Right, excellent.

**Terry Cullen – HIS/HHS**

...I think we just...and we are not going to resolve this here, but I think we need to be attentive to this as we move forward.

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

Thank you. Judy.

**Judy Faulkner – EPIC Systems – Founder**

Okay, thanks. First, on the graphics, I did like them too and I think the one that says, "start here," you should make it into a board game. (Laughter)

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

It is a little bit of Chutes and Ladders like...

**Deven McGraw – Center for Democracy & Technology – Director**

Chutes and Ladders, yeah.

**Judy Faulkner – EPIC Systems – Founder**

Secondly, Christine not's here, but I wanted to mention her comment about the patient being able to pick which ways they want to have communication. I do not think that is a vendor thing as much as a patient thing. If I am a patient, I do not mind being asked the question, "how would you like communication?" But if I am asked, "What do you want for scheduling, for lab results, for provider communication, for bills, for announcements, for summaries," I am going to say, "Stop it." So, I wonder if we are really appealing to a very small number of patients who might want different ones in different ways, and maybe it should not all be separated, because it might just be overkill to the patient.

Thirdly I want to comment on what Neil said, because I just still find that a little challenging. See if I have this right. So you have a complete EHR, and perhaps the organization does not want to use it for say oncology, they have a different system. Then the oncology system is the modular and the rest, is it still complete or is it not complete anymore?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

That is the...that is actually a really good question because, in response to public comment, the...sorry if I am going to dig deep a little bit here to explain it. But, the complete EHR certification again is representative of a certain set of certification criteria and what we did in response to public comment was, to make the cancer registry reporting certification criteria optional. So, if you get a complete EHR certification, that will not include necessarily, unless the vendor goes ahead and gets above and beyond certified to those two certification criteria, those capabilities.

**Judy Faulkner – EPIC Systems – Founder**

Well then let us pick something that is not optional, sorry, that was a bad example then.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

It was a...

**Judy Faulkner – EPIC Systems – Founder**

So let us say that the vendor does have all of the components, but there is one piece not optional...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

...right...

**Judy Faulkner – EPIC Systems – Founder**

... that the provider chooses not to use. That department wants whatever it has been using. Then, is that whatever...let us just assume it was oncology, just to use a word. And is that oncology module then, assuming it was required, the module...certified as the module and what about the rest of it. If the rest of it did have everything, are they still certified as a complete EHR or are they then a module? That is...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Yeah, so we do not break out the world like that. What gets presented for certification gets issued the complete EHR certification.

**Judy Faulkner – EPIC Systems – Founder**

Okay. So then that becomes that. Then what if the complete EHR is issued as an EHR, but the...I mean, is able to sold, but it also sells by components. So you have a vendor who has 30 components, the provider buys two of them, and uses lots of other stuff, the mix and match. Then does that vendor get counted as a complete or does that vendor get count...in other words, where is that slippery slope? You take off one, they are still complete, you take off two, and they are still complete...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

No. Yeah see, it does not work like that.

**Judy Faulkner – EPIC Systems – Founder**

But what if it is just one or two modules that are bought then is it complete or not complete? Slippery slope.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

You have to look at it from the provider perspective. If it is complete, it is complete and that is all it can be. Um...

**Judy Faulkner – EPIC Systems – Founder**

So even if the provider is buying only one module from that vendor to fit within everything else, say that module is lab. That lab...that vendor then is counted as a complete, even though just lab is sold.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

No. You have to go through the, I guess the lifecycle where EHR technology developer brings forward some EHR technology that is capable of doing “X” capabilities.

**Judy Faulkner – EPIC Systems – Founder**

Yeah, so it is capable of doing everything say.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, if it is capable of doing everything, then it gets issued a complete EHR certification.

**Judy Faulkner – EPIC Systems – Founder**

Right.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

And that is...if one...go ahead.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

The vendor, if they wish to marked individual modules, even though they have a complete EHR, may choose to get...go to their ATCB, or...certificate body, and get individual modules also certified as modules with numbers for...to be made available for purchase.

**Judy Faulkner – EPIC Systems – Founder**

Okay.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

And that would be how the mix and...thank you for jumping me ahead, you know, so I guess as it would play out under the new regulatory framework, for EHR technology developers who address the full scope, the advisable approach would be to get an EHR module certified...you could get a complete EHR certification, and that would be fine. Or if you want, from the provider's perspective, make it available for them to pick and choose those pieces that they want to implement and get that “right size.”

**Judy Faulkner – EPIC Systems – Founder**

Sure. Then you will have that modular.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Then you could get a base...you could get EHR technology certified to meet the 20 base certification criteria, Base EHR certification criteria and then figure out the scope of other EHR modules that would be issued, you know, two capabilities for this EHR module, three capabilities for that EHR module, that the provider could then add to the Base.

**Judy Faulkner – EPIC Systems – Founder**

So, how do you publish that when you publish the statistics, if you have a vendor who does both, do you combine them together when you say hospitals, so you have EP and then you have the hospitals, do you combine them together or do you separate them out?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, maybe if I can answer it a slightly different way. The certified HIT products list will list each individual certification issued and behind that, when you click through, the certification criteria to which that product was certified. When a provider generates the CMS EHID number, it amalgamates, conglom...it combines all of those separate products, if they pick separate products, together to represent one single number. So then CMS gets that one single number that they can then decouple again, if they have combined multiple products. And the public use file, I think...Is it split out?

**Robert Anthony – Centers for Medicare & Medicaid**

Yeah, actually the public use file takes that CMS certification number, and keys it to all of the individual products that might be under that certification number, so you have a representation of what vendor

products are being used throughout.

**Judy Faulkner – EPIC Systems – Founder**

Thank you.

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

Final question, Gayle.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Yes, thank you Paul. And I hate to be...sit here and have the last question and stand in between you and lunch. But, I do have a couple of things I want to say. First of all, I want to say thank you for that delineation of different specialties. I think that is very, very important for people not to be penalized if they simply do not have the ne...they do not have the capability of doing something. So, I think that is extremely important. I share Neil's concern about the use of the modules. I think this is going to take a very...for small practices, probably unlikely that they would do it. Perhaps this is only geared to hospitals or very, very large practices or ACOs or whatever, to have the capability to deal with the module question and putting together the various pieces. I would be concerned that someone might go out and purchase modules and not be able, at the end of the day, to meet meaningful use. So, I think it is going to be a role for our reqs to make sure that those smaller practices have the capability of understanding the implications of that. So, as we move forward, if we want to make sure that that is a component within a req, that they understand the role of the modules. Because you will have practices buying things that think that they are going to meet meaningful use at the end of the day, they are not. So, that is always a very significant fear for me, hearing from all those small practices all the time.

The other question that I want to raise, that I have not had any conversation, and I don't know, in the slides there was nothing specifically addressing the privacy and security issues that we have really been discussing. And I do not know if I want to defer to when Deven you talk...but that is going to be geared strictly to Stage 3. And, I know I'm hearing from our...from the different states that are implementing their health information exchanges and specifically about what

certificates are going to be required for whether you've got an organizational certificate for direct or whether we're going to allow HISP certificates for that health information exchange set up by the states. Are you addressing that at all? I haven't gotten through all 700 pages yet, but if you could perhaps talk a little bit more directly on exchange, specific to direct and specific to state health information exchanges.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, the rules do not specifically get into that level of implementation detail. With respect to the grantees that we have, we have issued guidance through the state HIE grantees to help them wade through those issues. I do not know the specifics of that guidance, but I know it addressed some of those questions that you have asked. So, we have provided our grantees some additional insights, but that is not a kind of core component of...

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

It is not a core component of that, but I do have some very specific things that the state of Florida has asked me to address, and perhaps I can do that...not take your lunchtime, but I will do that off-line with you Steve, on some of the things that they are very specific about.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Okay. I am happy to help.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Okay, thank you.

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

Great. Thank you. I do want to thank Rob and Steve for a great presentation and for discussion. So, thank you so much. And for all the work behind it for sure. So, we are going to transition over to, I think to Rob to deliver the CMS update.

**Robert Anthony – Centers for Medicare & Medicaid**

An encore presentation. I am actually the thing standing between everybody and lunch. So, I am going to actually make this relatively short. I know that you have some other agenda items. And honestly, once we get again into the percentages on the different objectives, you will see that once again, very little has changed. So just to go quickly through the registration and payment data. We have 271,000 providers through the end of July. I am sorry, but this early we do not actually have an August report available yet. So, I am going to do my typical, what we have now and our best-guessed estimate for what we will have at the end of August. But, we are tracking very much monthly registrations, what we have been seeing, the last time we spoke to you, we had the May report available and at that point there were about 10,300. So, we are seeing the same level of registration as we go along here, and as you can see from this report, it has been fairly throughout 2012. As of the end of July, there had been \$3.2 billion dollars in Medicare EHR incentive payments to a little over 68,000 providers that is an increase over when we had talked in May of about \$2.8 billion. Again, monthly totals are tracking about the same. In July we had about 190 million in incentive payments. When last we spoke in May, it was about a \$168 million. So again, we are seeing the same. The slots here, the pecking order for different specialties under Medicare, and just a reminder that we really only have the specialty designation under Medicare, have not moved. The numbers keep increasing, but the actual positions and the numbers within them have stayed relatively the same. Every once in a while, dermatology and endocrinology change positions at the bottom, but, otherwise, we are seeing about the same ratio of specialists throughout, as we are proceeding further down the path with meaningful use.

And this is just a breakdown by month, for those who are keeping score, of the individual payments. The one thing that we are seeing, we had a slight dip in May. I think that we

probably were transitioning over from folks that were in 2011 to folks who are doing their first 90 days in 2012. We fully anticipate that we are going to continue to see the type of numbers that we see in June and July until the end of the year, and then as we did last year, with 2011, we will see December of 2012, and then January and February, and probably into March since that represents February attestations as well. A lot of people who are returning for their second year of meaningful use will be doing their full year attestations in January/February and then again, we expect a fair number of folks to come in at the end of the year for their first time for 90 days as well.

In May, for Medicaid we had about 132 million total, it's 173 million as of July, which puts us at 3.1 billion in Medicaid incentive payments through July. As you can see, it continues to be primarily folks who are participating on the adopt, implement, upgrade side. Again, we anticipate seeing a larger number of meaningful users coming in towards the end of 2012. But keep in mind that since Medicaid does not require consecutive years of participation, it is very possible that we'll end up with folks who came in in 2011 with adopt, implement, upgrade, and may not actually be successful meaningful users until later years in the program. This is a breakdown of just numbers paid by month, and you can see, it has been fairly consistent for Medicaid throughout 2012. So we are at, as of the end of July, over 130,000 providers paid, over...well, almost 6.6 billion dollars in incentive payments issued. In May we were at about 113,000 providers paid. So, we've seen in the last couple of months, close to 20,000 added to that.

We did a little bit of a break breakdown of this last time and for reasons that I cannot fathom, there is one number on here that keeps switching from a percentage to a decimal, so excuse me. But, this is representational of the number of hospitals that have been registered and paid out of the entire pool of hospitals. There are 5,011 total eligible hospitals, at this point in time we have 76.9 percent who have actually registered for the program. Out of that, we have 54 percent that have actually been paid, so that leaves us a small gap of 22 percent there who have registered but not been paid, and we do have pretty good indication that we'll see many of them come in towards the end of this year.

This is eligible professionals registered. There are 521,600 total eligible professionals that we estimated for the program, we are now at a point where 51 percent, a little over 51 percent, one out of every two eligible professionals has registered for the program. About 34 percent of those are Medicaid, 16 percent...I am sorry 34 percent are Medicare, 16 percent are Medicaid. And in the paid category, we still have more registered and paid, although we are continuing to go up on this. At this point in time, we have 23 percent of eligible professionals paid, who have received a payment under either Medicare or Medicaid, which is closing in pretty rapidly on one in every four who are participating, having received an incentive payment. So, in less than 24 months, we have a pretty good number of people who are participating. So by the numbers, we broke this down last time, we've got 55 percent of all eligible hospitals have made that financial commitment to an EHR, one out of every five Medicare EPs are meaningful users, one out of four Medicare and Medicaid EPs have made a financial commitment to an EHR. That number, that percentage of specialists, non-primary care eligible professionals, and again we only have the Medicare to judge by, we only have specialty information on those, remains constant at 58 percent, but it is an indication that we have a large number of specialists who are continuing to participate in the program.

As we move into August, this is shaping up to be a month in line with what we saw previously, about 11,000 providers paid, which will bring us above 140,000 participating providers. We

expect close to half a billion dollars in incentive payments and that should say August, not May of 2012, which will bring us knocking on the door of nearly 7 billion in incentive payments that will be issued as of the end of that last month.

So, as we go into this data analysis, I will just preface it by saying that nothing much has changed here. We seem to have a previous slide on this, I am going to see if this appended to the end. Okay, we seem to have a previous deck on this. I will point out where there are differences and will give you the new deck to upload. Actually, for this data analysis, we have a little over 87,000 EPs who had attested. The vast majority had been successful; there are only 258 that had been unsuccessful out of that, and out of that, 186 resubmitted, so you can see we have a very small number who have not been successful. One thousand six hundred and seventy-eight hospitals had attested all of them had been successful. You will see actually, when we give the new deck, that absolutely nothing has changed in this slide. The most popular menu objectives remain advanced directives, drug formulary and clinical lab test results for hospitals. Drug formulary, immunization registry and patient lists for EPs. The least popular menu objectives are the transition of care summaries and patient reminders for EPs, transition of care summaries and syndromic surveillance for hospitals. As always, there is little difference between eligible professional performance and hospital performance. There is little difference among specialties in performance over all. However, there is a difference in the exclusions that are claimed and the deferrals of menu objectives.

That top bullet, we continue to append, but I would say that you are coming to the tail end of our actually including that. I am sorry; the top bullet on mine is slightly different. The on average, all thresholds are greatly exceeded. We do have providers who are on the borderline. We had previously had...or we have on the new one a bullet that says that this shows our earliest adopters, and that is not necessarily indicative of what the overall performance is, but as we move into August, we are no longer looking at just the early adopters. We are looking at people who may still be in their first year of meaningful use, obviously, but they are not necessarily the people who are at the beginning of the curve. And yet we are still continuing to see very high performance across the board on all of these objectives. Obviously, we will be better informed when we have people who are returning in 2012, and we can do a comparison of meaningful use in a second full year period versus a first 90-day period. But so far, the more people come in, the more these thresholds stay the same.

So, this will give us at least an opportunity to highlight what the differences are between these, and the differences are absolutely none. There have not been no changes whatsoever in any of the recording objectives for problem list, med list or any of the others, nor has there been any change for EPs under exclusions or smoking status. As you can see, these continue to be 90 percent. The really critical problem list, medication list and med allergy list continue to be even higher than that. We have seen, overall, a slight dip in sending...the performance on sending reminders to patients and, I should probably remind everybody at this point that performance is an indication of the average percentage. Again, the average numerator over the average denominator. Exclusions are the percentage of providers who have actually claimed the exclusion for that particular objective. Deferrals are the percentage of providers who have deferred, not chosen, that particular menu objective as part of their menu set. Where you see not applicable under performance, it is an indication that it is a yes/no objective. Obviously where you see a not applicable under exclusion, there is not an exclusion and when you see a not applicable under deferral, it is an indication that it is a core objective, and they cannot defer it.

So, these do continue to be incredibly high. There has been a slight dip in the sending reminders to patients, it has been trending downward a little bit. But still the measure of this is a very low measure at 10 percent, so to see 61 percent is still far and above what the requirement is. You can see that these have continued to be very high, patient education is still low here, but again, it

has a 10 percent requirement threshold, so 49 percent is far and above what we see. The deferrals on patient education resources and timely electronic access are actually trending slightly downward. It is not very significant, it is a couple of percentage points, but it does mean that more people are selecting those as menu objectives as we are moving forward. The same is true of the medication reconciliation deferral. The summary of care continues to be fairly high, but the deferral rate has trended downward a couple of points for medication reconciliation. It is worth noting on both this previous slide and on this later slide that even when...when people are actually selecting these objectives and they are implementing these as part of the menu, they are doing quite well on performance. And this has held relatively true, as we have looked at the public health objectives for both EP's and hospitals. The exclusion and deferral rates fluctuate fairly, but the performance rates stay about the same. In this case, because these are not numerator/denominator, it is the percentage of providers who actually conducted a test for performance.

Hospital tends to be the same; there is not a radical difference in performance. All of the recording objectives are very high, CPOE, advanced directives, incorporating lab results, very high. We are seeing that the number...the percentage exclusions for e-Copy of health information and e-Copy of discharge instructions is trending downward. Again, it is not a huge leap downward, but it is a step down. So we have to assume that more patients know to ask for this information and as you can see with 95 percent, on the new slide it is 96 percent of e-Copy health information performance. When people are asking for it they are by and large getting it. Again, we see the similar trend here with medication reconciliation and summary of care, high deferral rates, but when they are choosing those, the performance on them is relatively high. And then again, for public health objectives for hospitals, we see a fluctuation in exclusion and deferral, but by and large, the performance rates have been fairly steady.

So that was my long way of saying not much has changed in what we've seen data-wise, although in this case, the longer we go with saying that not much has changed, the more encouraging that trend actually is because it's an indication that more and more providers are coming in and yet everybody is performing at a statistically high level.

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

Very good. Thank you Rob. Any comments from the committee. Terry?

**Terry Cullen – HIS/HHS**

I had one question. In the Medicaid enrollment -- do you break out pediatricians?

**Robert Anthony – Centers for Medicare & Medicaid**

We have not broken out pediatricians.

**Terry Cullen – HIS/HHS**

Do you have any concept what is going on there?

**Robert Anthony – Centers for Medicare & Medicaid**

Not off the top of my head. I can certainly take a look at it and see if we cannot pull out some information on it for the next time that we talk.

**Terry Cullen – HIS/HHS**

Thanks.

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

Anything else? Well good. Thank you very much Rob for your usual great presentation on the update. We are now up to 7 billion dollars, over half the hospitals, a quarter of the docs at least have made financial commitments. Really very encouraging. So, we will break for lunch until one o'clock. Thank you.

**MacKenzie Robertson – Office of the National Coordinator**

Could everyone please take their seats and we will get started. Can everyone please take their seats and operator, can you please get ready to open the lines back up.

**Operator**

Lines are open.

**MacKenzie Robertson – Office of the National Coordinator**

Could everyone please take their seats and I will turn it back over to Paul.

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

Good. Thank you MacKenzie. Welcome back after lunch. We have four more topics to go. We're going to start out with Jamie Ferguson and I think Betsy Humphreys is on the phone to talk about the new Value Set Authority Center hosted by the NLM, which, as I say, is a response a need that we all have, both on the provider side and the vendor side in terms of standardized values and somebody who manages this and maintains it. Jamie and Betsy.

**Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy**

Betsy, are you on the phone there?

**Betsy Humphreys – Deputy Director – National Library of Medicine**

I am on the phone.

**Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy**

Great. Hi, I am Jamie Ferguson, the Chair of the Vocabulary Task Force of the Health IT Standards Committee and Betsy Humphreys from the National Library of Medicine, my co-chair, is on the phone. We are here today to talk about the Values Set Authority Center of the NLM, which solves problems of clinicians and vendors for the adoption of standard vocabularies in meaningful use. We are also going to talk about the convergent medical terminology or CMT, which are convenience subsets that are based primarily on SNOMED CT and they are downloadable from the National Library of Medicine. And these subsets are extremely useful for quality measure developers as well as other users of the standard vocabularies and they make use of the...of some of the powerful features of SNOMED.

So I wanted to start out with this page of definitions here. So the way we define a value set is that it is essentially the whole universe of codes, terms or concepts for a particular purpose. So, a value set is definitive, it is complete and comprehensive for that purpose. And an example of a value set would be the enumerated list of codes that are used when calculating a quality measure. I want to contrast that to a convenience subset or subsets. So subsets are essentially implementation artifacts that are useful for the adoption of standard vocabularies. And so examples of subsets would be, say, the top 1200 lab order codes...most frequently used lab tests, or the cardiology problem list subset of concepts that are used by cardiologists. So those are examples of convenience subsets. I just wanted to make the distinction between those two, because we are going to talk about both of these things and do not want them to be confused. So, going on to talk about the current value set plans, I/m going to turn it over to Betsy.

### **Betsy Humphreys – Deputy Director – National Library of Medicine**

Okay. So, the slide that you are looking at is basically summarizing previous recommendations and how the current HHS value set plans implementation activity responds to them. And I'll just quickly go through this, first to say that the NLM in collaboration with CMS and ONC, and for certain aspects of this also ARC, is actively bringing these capabilities up now and they will be available to the community very shortly, but, they're not there right...you can't access them right now. So in essence, the recommendation says we need a single federal office or agency that should be responsible for this and enumerated these specific functions that should be carried out, and this slide summarizes in essence, who has the lead for what of these activities.

So in terms of identifying exactly what sets are needed, who will produce and maintain each set. And that would involve how we will go from where we are today to the elimination and avoidance of duplication of value sets for the same purpose in the future. For the purpose of meaningful use, CMS has the lead, ONC is there with them and NLM is providing support in terms of identification where, for example, producing information that would show where there is duplication or where there is close coordination and so forth, that might be needed to move to a better state.

In terms of determining dissemination schedule and update frequency, again, this is joint responsibility with CMS taking the lead, because they have laws and regulations that affect some of this, obviously. ONC and NLM are also in the mix in terms of what is possible and how this interdigitates with the updates of the underlying terminologies. And NLM will be taking the lead in terms of establishing and making available standard formats for production and dissemination. And I know that there has been discussion, and obviously you all know work going on at the Mayo about CTS2 being one of the methods of dissemination of these, and that is being worked on as well out there.

Then, we will be managing the processes for review, validation, approval and publication of the sets. And this is essentially the making sure that the final sets are accurate in terms of the terminology, up to date and so forth, before they're published. This testing here does not refer to the actual testing in the field of whether the measure works, is valid, and is implementable, that is a testing that would sort of be involved earlier in the process in terms of development of the actual measures and the value sets. Then we will be responsible for ensuring that we have robust infrastructure for the sets and we will also, also I think probably in conjunction with CMS and ONC, be trying to establish related education, communication and outreach. I am happy to say that CMS has generously transferred funds to the National Library of Medicine to support this work in fiscal 2012, and we anticipate that they may likely to be able to do the same for the next couple of fiscal years.

Can we have the next slide? So again, in terms of the infrastructure for development, maintenance, and dissemination. This is NLM; we will be working on these things. We are going to establish a central repository with download capabilities and feedback loop mechanisms for the dissemination of these meaningful use vocabularies as a whole, where we already in essence do that. We are going to have API's from the Value Set Authority Center as we do for the entire vocabularies. So this will enable alternative distribution mechanisms that may be appropriate for particular groups, but the value sets, the authoritative version, will come from our Authority Center and will sort of be the ground truth for what the value set is.

We are going to eventually support the use of our tools and repository for both the meaningful use subsets...value sets and also others that may be being used for purposes that are not subject to the regulation, in order to enable sharing of those and research and development and help for EHR implementers outside of the meaningful use requirements and there will be obviously different control mechanisms over those that are the required ones for use under meaningful use and others that may have value for implementers and users. And, we are going to provide access, again, via APIs to all of the data that we make available and this will enable the development of, we hope, many useful sets of tools and implementing in EHRs from involving the value sets. I should say that there is a lot of the process that we're building and a lot of what is engaged in this entire effort, which might be...certainly would be called development in new territory and new processes and so forth. So, we will all be learning as we go along and we'll be very interested in getting good and frank feedback about what is available as it becomes available and how we can improve it and make it more useful to the whole community. Back to you, Jamie.

### **Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy**

Okay, thanks Betsy. And so, in considering how to best move forward for the use of value sets, particularly for quality measures in meaningful use, the Standards Committee, actually this is the identical slide that was used in the Standards Committee when we made this recommendation which was about two months ago. So it should now say, new guidance and approved Standards Committee guidance to measure developers, because it was approved by the Committee. We saw problems with the adoption of the some of the standard vocabularies, and a few cases in which quality measure developers were in essence creating new burdens of documentation on providers by inventing new SNOMED concepts, for example, that exactly fit the purpose of the measure, but that wouldn't otherwise be used in normal medical record documentation. And so, the essence of this guidance is that the e-Measure developers, in particular, should rely upon existing medical record documentation and coding in the standards, instead of requiring new or different documentation, except where there is a policy reason to use the quality measure as a forcing function, essentially to force new documentation practices. But that there needed to be some policy review of those cases and not have it be an artifact of the measure development process in and of itself.

Developers of e-Measures also should first use and look to the use of the standard vocabularies as they are already used in certified EHR technology. And in fact, there's plenty of evidence, which I'm about to talk about in just a sec, about how the standard vocabularies are already in use. So that measure developers can then look at what codes and terms are already used in medical record systems, so that they could then develop measures that actually could be reliable e-Measures, rather than inventing new things that aren't going to actually be documented otherwise.

And so, that brings me up to the convergent medical terminology or CMT. This was an open-source donation from Kaiser Permanente a couple of years ago that was scheduled to be delivered to the SNOMED authority, which is the IHTSDO, the International Healthcare Terminology Standards Development Organization and the National Library of Medicine. The content, because it is largely based on SNOMED, is reviewed for adherence to the editorial guidelines and applicability, both internationally and here in the US. So, it's reviewed internationally by the IHTSDO and reviewed here in the US by the

National Library of Medicine, and most of the CMT content actually is in the SNOMED international release. So, as it was donated, it was then...most of this is actually part of the international SNOMED and some of it is also part of the US extension to SNOMED. CMT also includes the cross-maps from SNOMED to other standard vocabularies including ICD-9, ICD 10 CM, laboratory LOINC, and medication terminologies as they may apply to the different concepts.

On this slide, you can see a listing of the different clinical domains where the CMT content is available. And so, I guess the first point here is that there are a lot of different subsets that are already freely available as download files from the National Library of Medicine. Most of these subsets, as I mentioned, are in the international release of SNOMED CT, but a little bit of these

subsets is in the US extension of SNOMED CT, if there is a concept that's applicable in the US that doesn't have an international counterpart. Just briefly, and so this is not intended to be an eye chart, but you do have this in the materials. The example here, and I've got a couple of different excerpts to show, essentially to show that in addition to the standard vocabulary terms and codes, there are clinician-friendly display names that can be used instead of displaying the fully specified standard SNOMED description. And there are also, in these download files, patient-friendly display names that can be used. So for example, a patient would see heart attack instead of acute myocardial infarction. Or acute MI would be the patient... would be the clinician preferred term. And so the idea is that the same code is associated with different descriptions, depending on who the user is or depending on who is viewing the electronic health record. And this also demonstrates that the cross-maps ICD-9 and ICD 10 are built in.

Now this is another excerpt, and I do not expect it to be read, except perhaps by a couple who may be interested, but the point here is that SNOMED CT is not just a bunch of random codes for random medical concepts. It is based on a powerful description logic and so using the SNOMED CT description logic for population analytics, uniquely enables advanced queries against EMR data. So this is very useful for quality assessment purposes, for decision support analysis as well as for clinical guidelines development.

Now I think that... actually, I have already mentioned how the CMT subsets can be useful. And so I want to focus back for just a minute on the use of CMT for the quality measures. Now in the first place, these subsets are actually... they have been developed for almost 20 years. They are currently in use by over 65,000 physicians and nurses for documentation in tens of millions of electronic medical records. And so, these are standard terminology subsets that... again that integrate the clinician and user terminology as well as the patient-facing preferred terms and allow the use of SNOMED. So, this is an example; when we went back to the recommendation of the Standards Committee to the e-Measure developers to use data that's already out there, this is an example of that kind of data that's being made available from the National Library of Medicine. I'd love to take questions or comments.

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

Good. Thank you. Thanks Jamie and Betsy. Art?

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

Thank you for the presentation. I just have a question, but have either of you thought about, since you just described how this is applicable for population health measures, I think I heard that, quality metrics and decision support. The need for public health to do...to receive electronic lab reports from providers or to be part...to contribute to registries is an example, also, of population health. I wonder if NLM has been thinking how they might support these more public health oriented efforts. I see a lot here about how this could be offering assistance for population health, but more to the very specific public health efforts around when I should report, what are and that the diseases that are reportable in my state or my jurisdiction. What are the data that should be reported as a part of that electronic laboratory report or others that might be developed as a part of specialized registries or other registries that have been cited in Stage 2 recently.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

This is Betty Humphreys. Let me just say that NLM works closely with the CDC and the PHIN VADS group there on just these issues. And they have been leading excellent efforts to come up with subsets that address just those things. That is, the reportable diseases in all the states, NLM has collaborated with a variety of groups in terms of coming up with specific code sets and subsets that relate to newborn screening. And there certainly has been a lot of joint work related to laboratory reporting implementation guides and so forth.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Betsy, if I may add, the CDC and CSTE did provide the...what used to be called the Dwyer tables, the matrix that lists reportable conditions...nationally notifiable conditions crosswalk to the specific LOINC codes, and I believe SNOMED codes as well, that are involved in that. So it is, I believe, as Betsy's pointing out, that's maintained in the PHIN VADS as opposed to with the NIH NLM repository. But I think clearly they could be linked together, but it is currently available, that mapping table.

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

So, in terms of the recommendation two of 2010 slide that you have there, this central repository download capability, do we think ultimately that will be at NLM or that will be at CDC?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

For the public-health...

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

For the public health vocabulary sets.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

This is Betty Humphreys again. I think the feeling is that eventually all the values sets would be available from NLM, but the PHIN VADS distribution, which is very specialized for the public health community, would also continue to be available. So, for certain users in public health departments and so forth that are particularly focused there, they would have a view of the world and access to the information that was particularly relevant to them. For other users, potentially hospitals or other groups where they are interested in the public health reporting but also in many other aspects of this as well, the value sets would also be available from NLM.

**Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

Thank you, Betty.

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

David.

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

Thanks Jamie and Betsy, I appreciate this update. It raises a couple of questions for me. One is about, you talked some about the measure, the encouragement from the Standards Committee to the measure developer community to utilize these as a primary source in developing future measures. And I wonder what you've heard from them. Just in some ways I think we heard it in the Quality Measures Workgroup from the Vendor Tiger Team we have that they really wanted this framework to be developed. I haven't heard from the measurement community whether this works for them and I wonder what you've heard from the field, so to speak, about whether they're capable of adopting the recommendations you guys made to them.

Secondly, what's the...I see that you referenced here the 65,000 clinicians using the tool set, but I wonder what you think the pace of adoption will be generally across the country through the overall EHR program and what is the expected pace of adoption and the expected reaction from the measurement community? Tell us about the likelihood of using this as a basis of measures that are in general use, in what timeframe, what is the right path by which this would be generally accepted? Then the last thing I'm curious about, I'm sort of worried about granularity and in some ways I understand the impetus to get...if ICD-10 and other tools, to get more and more granular and precise in the clinical terminology. And then from the point of the view of users, you have the problem of aggregating to concepts that make sense to people in making decisions for themselves, in a variety of ways. And outside of this specific bedside context, all the other users will have a real hard time with this data until you do, as you suggested at the end Jaime, aggregate it up to other concepts. And I'm just wondering what the sort of state of discussion is about how these highly granular representations end up being standardized in their public expression?

**Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy**

Well, thanks for those questions. So first of all, on the measure developer reaction, I would say thus far, particularly in the NQF, the reaction has been very positive to this kind of development. And I think this is seen as a helpful step, and I don't know, Paul, if you want to comment on that as well.

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

Well, it is one of the missing links in the so called quality data model, where we're trying to standardize both the value sets and the expression of quality measures in a way that could be reused, instead of every measure developer developing yet another concept to put in their definition. So this was something we saw as a hole, and then Jamie presented this at NQF and thought wow, the HIT Policy Committee needs to hear about this.

**Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy**

So thanks. And so then David, also on the pace of adoption, I mean, I think that this is just a part and parcel of meaningful use. And so it seems to me that the idea of having the NLM as the one-stop shop where all the different vocabulary resources are available can only improve the adoption of the standard vocabularies, as is required in meaningful use and in fact, expanded beyond those specific requirements for other benefits.

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

Could you also add a word on how this can tie into the measure-authoring tool?

**Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy**

I'm not sure I'm the right person to address the...sort of the next steps on the measure authoring tool itself.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

Jamie, I think I can answer this, at a high level, anyway. This is Betty. Basically, we are expecting...we are going to have APIs for submission of value sets and validation of value sets, as well as extraction of value sets, to use as the basis for updating or creating new ones. So, what we are expecting is that something like the measure...the measure-authoring tool, people...no doubt some...we expect people to continue to use it and we are in expectation that there will be a useful interface between it and the Value Set Authority Center, both for submitting and validating things that were created elsewhere and for extracting things that could be used as the basis for developing other measures. There will be also be as this progresses at NLM, native authoring capability at NLM for those who may want to create value sets either for measures or for other purposes. But we will continue to support the notion that people would be using...could easily be using external tools and then need to use our validation techniques and submit things, in essence in batch.

**Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy**

Thanks. And then David, just on your last question about sort of the granularity versus looking at things at the aggregate level, I think that this is exactly why SNOMED is so important. Because SNOMED allows for accurate, repeatable, reliable, aggregation through what we are calling subsumption queries. So for example, instead of all of those different flavors of myocardial infarction that were shown on that eye chart, you could simply query for all cases of everything that's subsumed under acute MI. And so the SNOMED vocabulary allows for that to happen in a completely reliable way, so according to whatever point in the hierarchy...in the SNOMED hierarchy you want to operate at, that's the level you can operate at, regardless of essentially what level of granularity it was originally documented in. The other thing is, so, again back to just that cardiology example. You could look at all cases using negation, you can look for, for example, all cases of coronary artery disease in non-transplanted hearts, and things like that. So, there are a variety of very powerful features from using the features of SNOMED.

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

So, I think we're way over. Do you have something really quick, because you were next up, so I'll just give you...

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Just one very quick question. I think this is a very important addition to everything we are doing, but when you're talk about developing these sets and also with the measure community, who is the ultimate arbiter at the end of the day? Who is responsible? Is it the Library of Medicine? Is it...who is going to...is it the measurement community as we develop and move down this whole line? Who has the ultimate responsibility if we are talking about establishing open consensus in getting to the end result here? Who is taking...who is in control of this and do we as a committee have input into that?

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

I, um, is it Betty that wants to handle that one?

**Betsy Humphreys – Deputy Director – National Library of Medicine**

I will start this way. For that value sets that are required for meaningful use, it will be CMS in combination with ONC that will in essence be the final arbiter of what is going to be used in meaningful use. But their...the measures that are being selected are developed by different measure stewards and the issue of what goes in a measure and how we move to less potential overlap and better coordination maybe than we have now, and I know we have a lot now, is going to be an activity led, as far as meaningful use is concerned, by CMS and ONC. NLM's role in it is to say look, this thing that you came up with does not pass validation. That is, there are some internal consistencies, it just is not accurate as a value set of this particular standard vocabulary, and therefore...or, there seem to be incongruities in it. And then it goes back to the measure developer to say, well what did you really intend and these are the problems we have identified and how can we work together to figure out how to fix them? But, the authority about what is covered in it is handled by someone else. We are just saying in the end, this thing needs some correction because it is not valid the way you have put it out...the underlying standard vocabulary.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

That could present, you know as we go down the whole road of clinical quality measures being built into meaningful use, I can see problems developing with that, if you don't eventually have someone who is the ultimate authority there.\

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Gayle, I think that what the NLM is doing, and correct me if I am wrong Betsy and Jamie, is their saying, for example, if a quality measure has the concept of ischemic vascular disease, what are all the SNOMED codes that would rule up to that concept of ischemic vascular disease? And that may change over time, and there may be new things that are added to that. That is not something the Policy Committee... I mean, that is a much lower level of granularity that the Policy Committee would ever get involved with and I think we want to have the people who are the experts in the terminology deal with what they are the experts on. And I think for us, on the quality measurement really, this can help us have quality measures that are more accurate, more meaningful and not having to go through regulations to change a specification that says, you know, ischemic vascular disease is defined exactly thus. You let that part

evolve more rapidly and be updated without us having to get involved. And I see that as all just a good thing. I think that's good keeping the swim lanes clear rather than actually potentially contradictory.

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

Good. Thank you very much, Jamie and Betsy. Very interesting project. Okay, I apologize, we are running behind. I have five minutes that I will give up and will send you out the updates in e-mail.

Next is Jeremy Grant from NIST, talking about the national strategy for trusted identities in cyberspace. Thanks Jeremy.

**Jeremy Grant – National Institute of Standards and Technology, Senior Executive Advisor, National Strategy for Trusted Identities in Cyberspace (NSTIC) Program**

Thanks. Good afternoon everybody. Thanks for the invitation to come talk to you today. So I wanted to talk a little bit about the topic of identity in cyberspace. And how some of the work that we are leading out of NIST in support of the White House's national strategy for trusted identity in cyberspace can help to solve some of the identity authentication and security challenges that you are facing within the Health IT community, and hopefully improve trust for health information exchange.

So, for starters, imagine if we were in a place four years from now where 80% of doctors and patients in the marketplace were carrying a secured credential, say bound to a smart phone, although it wouldn't necessarily have to be, but that is one scenario, that they could use this for both identification and authentication. And all across the health ecosystem, organizations could trust this credential in lieu of existing user name and password systems. This solution would be interoperable with your login systems that you are using today, which would mean you would not have to be issuing new credentials. It would support multifactor authentication for enhanced security and getting people away from password management. It would be tied to some sort of a robust identity proofing mechanism, ensuring that individuals in fact are who they claim to be. And you would have baked in rules and technologies in the system in order to protect security and privacy.

What would this mean for improved security? Well, just a couple of things to consider, if you look, last year there was a report that the Secret Service does in partnership with Verizon, looking at data breach vectors of attack. Five of the top six vectors of attack last year, in 2011, data breaches were tied to passwords. In addition to the security challenges with our password-based systems, we have got weak identity systems today, really make it impossible nineteen years after the famous New Yorker cartoon was published where the dog is on the computer and talks to his friend the dog about, "the great thing about the Internet is, nobody knows you're a dog. That really hasn't changed much today. And, if you do not actually know who is a dog on the Internet, it really sort of hinders what kind of service can be offered online, particularly when you look at high value or high risk types of transactions like those involved in healthcare. We also think this is an area that could help to break down barriers to exchange of health information, offering a choice of proven, easy to use identity solutions for health providers, helping to streamline workflow practices by eliminating the multiple user IDs and passwords that people have to manage today, and helping to secure access for patients to their own information. I was sent a great new study this morning, I tend to collect studies on problems with passwords and what people think of them. And there was a new study that was actually published as a part of the Harris Pole, which suggested that 38% of adults in this country are more hopeful that we can achieve world peace than that they can actually remember all of their passwords. So, when we are contemplating how to roll out new services, and potentially asking people to create new passwords, that might even be more complex and difficult to remember than the ones that they have today, that is something to keep in mind.

So, the national strategy for trusted identities in cyberspace outlines the path forward to try and address some of these issues. The background of it dates back to 2009 Cyberspace Policy Review that was conducted when the president took office, which called for the creation of a cybersecurity-focused identity management vision and strategy. That looked not only at the intersection of cybersecurity and identity, which I think is kind of an easy one to understand, but specifically called out a need to address privacy and civil liberties interests up front and look for a ways to potentially leverage some new privacy enhancing technologies for the benefit of the nation. At the core of the NSTIC is a call for what's dubbed the identity ecosystem, essentially a marketplace, an online environment where both individuals and organizations can better trust each other because they are following a set of agreed-upon standards and policies to obtain and authenticate their digital identities. And there are four guiding principles that are running throughout the NSTIC, which are: That the solutions that emerge from this marketplace we are hoping to catalyze in partnership with private sector partners. It needs to privacy enhancing and voluntary, they need to be secure and resilient, they need to be interoperable and need to be cost effective and easy to use.

And the NSTIC goal, and we always...I always highlight when I show this slide of January 1, 2016, because I think we can actually demonstrate some real improvements much sooner than that. But that there is an identity ecosystem where anybody in the country can choose from among multiple identity providers and different types of better digital credentials for online transactions that are more convenient, secure and privacy enhancing. So some of the benefits, illustrated here for the health environment would be: Streamline provider access to multiple systems. Enabling secure online patient access to health information. Improving care through better exchange of electronic medical records. And an ability to actually allow individuals to tie certain attributes about themselves to an identity claim or potentially having not even share everything about themselves, but only particular attributes. This provides the foundation to enhanced privacy.

Drilling down just a little bit more on the privacy guiding principle, privacy and civil liberties are really fundamental and really quite pervasive throughout the NSTIC. Increasing privacy is really something that is a core focus, particularly looking for ways to minimize sharing of unnecessary information. Really shifting the focus from, "hey, you are registering in the new system, let's get every information piece that we can about you," to, "what are those specific attributes that we actually need to know in order to process the transaction?" And, it does prescribe adherence to eight fair information practice principles as minimum standards for organizations participating in

the implementation of the Strategy, to ensure that you really have things like data minimization, notice, choice, appeals and things like that. It is also worth noting that NSTIC is voluntary and private sector led. This is not a government run ID program, in fact, it is really the antithesis of that. Individuals can choose not to participate and those who do should be able to choose from a variety of different public and private sector identity providers. There is also no central database that is being created with this, it is really an effort again to catalyze the marketplace that consumers can use, rather than having the government actually keep track of these transactions, the variety...most of which we really don't care about anyway.

And it does look for ways to preserve anonymity, realizing that both the ability to be anonymous online as well as operating under a pseudonym at times, has really helped to support the growth of the Internet, enables free speech and freedom of association online and there is nothing we are trying to do with this initiative to impact that.

So what NSTIC calls for at the end of the day is for the private sector to lead the effort. While the government produced the Strategy, it is very clear when the White House was putting it together, that if the government actually tried to mandate specific solutions, let alone get into the business of issuing credentials, we would probably fail, for a number of reasons. One, we have gotten into this space before and haven't done very well. Beyond that, I think there is a recognition that the private sector is really in the best position to drive the technologies and solutions. The amount of innovation going on among entrepreneurs in the private sector right now, in this space, is really quite stellar. And worst thing for the government to do...the worst thing that the government could do, would be to prescribe a specific set of solutions and not anticipate the next thing that's coming down the road. We also think that the private sector is in a much better position to ensure that whatever these solutions are that they are deployed in the identity ecosystem, offer improved online trust and better customer experiences. Again, we don't really want to be in the design phase of this from the government side.

What we are looking to do from the government side is provide support. We have been working for the last year to help develop a private sector led governance model, the Identity Ecosystem Steering Group that launched last month in Chicago. In the next couple of weeks we will be announcing somewhere between nine and ten million dollars' worth of pilot programs that will help to stimulate the marketplace. And while we have not announced them yet, I can say that at least one of them will focus on the healthcare sector, and will hopefully be of some excitement to the community. Because we are at NIST, we are facilitating...we are in a position to help facilitating and lead development of interoperable standards to support the ecosystem.

Understanding also that barriers that are out there to this marketplace existing are not just technical set of challenges, but also a lot of issues on policy, things like, what happens if one of these systems breaks, who gets sued and who is liable? Or, what should the baseline privacy rules be? The government wants to look to be able to provide clarity on some of these major policy issues that have never been addressed during previous attempts to really tackle digital identity and which will need to be for a marketplace to flourish. And finally, because we are the government and we buy a lot of stuff, including things that need authentication online, we want to be an early adopter to stimulate demand.

So, it is important when talking about NSTIC, to talk about the fact that it is a Strategy document. It is essentially an aspirational paper that lays out what the world should look like within a few years. And so when agencies are being directed to try and align with the Strategy, or folks like Farzad and his team at ONC are asked to make sure that they take a look at this when they are looking at how we should handle identity and security within health IT, I always like to point out this is a Strategy and the things that we are talking about do not necessarily exist the way we envision they will. But, there are some things that do exist today in the government, particularly FICAM Trust Framework Providers, which are offering solutions today. A background on this is that FICAM was a committee, Federal Identity and Access Management Committee set up under the Federal CIO Council several years ago to essentially look at how you could take some of the concepts of third-party credentials being issued not by government agencies, but by our partners and get them through an accreditation process to ensure that they actually meet security and privacy standards that agencies can use today.

So, you have this process that is in place right now for the agencies to actually be able to leverage commercially issued digital identities and credentials. The government essentially crafted what is a government-approved profile of widely used commercial identity protocols like open ID and SAML that are designed to maximize the security and privacy options that are available in each of those. And it has privacy criteria that are based on the FIPS that are included in NSTIC. To date we have had four non-federal organizations that the General Services Administration has accredited as Trust Framework Providers, who are essentially then accredited to assess and accredit commercial identity providers who then embrace these government profiles and abide by the privacy criteria, and those are Kantara, Safe BioPharma, InCommon, which generally serves the Research University Community and the Open Identity Exchange, which is an organization made up of...largely of major commercial technology and Telecom and data brokers such as Verizon, AT&T, Google, PayPal, and companies like Experian or Equifax. So, we have a framework today that is actually in place for agencies to be use these solutions and in fact,

many of them have started to. So the good news, because of this work that FICAM has done, is that there is an emerging marketplace for FICAM approved, multi-factor authentication credentials today. I talked before about the problems with passwords and the need to try and get people, particularly for sensitive transactions, to support some sort of multi-factor authentication. It really makes it much more difficult to hack into a system. Three years ago, if you looked at the marketplace, there was not a whole lot, the solutions that were out there were limited to a few technologies and form factors that some thought were a little clunky and there was no accreditation process for the government to actually bless these solutions as being ready for government use. Today we have a marketplace that is producing a wide range of new solutions, a lot of them tied to the explosion of smart phones in everybody's pockets. It really helped me to smash through a lot of previous cost and usability challenges, making strong authentication much easier to deploy and to use. And the FICAM Trust Framework provider certification process puts a foundation that is out there that not only the government, but a number of private sector entities are looking at as a certification process for multi-factor authentication solutions.

So, talking a little bit about the health space. It is worth highlighting some key drivers and some developments in the marketplace the last couple of years that I think it is worth this committee taking notice of. Starting in March of 2010, when the Drug Enforcement Administration's e-Prescribe rule specifically called out a NIST publication, special publication 800-63-1. Essentially this is the NIST guidance of Federal agencies for electronic authentication online. And called out a level of assurance 3, which looks to multi-factor authentication combined with some sort of robust identity proofing, as what the standard will be for physicians to actually electronically prescribe certain classes of controlled substances. That followed last year when NIST recognized GSA's FICAM Trust Framework Provider adoption process as the only certification process that we recognize, as a way to actually accredit solutions against 800-63-1.

GSA, late last year and early this spring, certified both Kantara and Safe BioPharma as the very first two trust framework providers for non-PKI based LOA3. Again, that is multi-factor. Verizon became the very first certified identity provider, they were followed by Experian as a provider. They actually just announced two months ago that they had gotten their certification. And also of note, CMS outlined its plans this past February to support all FICAM-approved external credential providers.

So, this sort of leads to some interesting developments. In the short term, what this means is that a physician who has a credential that he is using for e-Prescribe, will also be able to use that same certified credential for transaction completely unrelated to e-Prescribe, when he or she actually logs in for a transaction with CMS. So, understanding that you now have reuse of the credential, essentially a federation that has been stood up between CMS and the e-Prescribe vendors. Long-term why not look to actually leverage that same credential elsewhere in the health ecosystem, particularly when you are looking for ways to help healthcare providers actually ensure that there is secure access to the health IT systems that we are starting to deploy across the country? It is not too hard to say you should look to the credential that somebody is already carrying in their own pocket that they might be using for other transactions. Supporting this kind of standards-based approach really promotes a virtuous circle. The more certified credential providers that go into the market, the more electronic health record systems are going to be able to actually accept these certified credentials. And of course, the more people that are accepting them, there is a better business case for new credential providers to enter the market, innovate around the edges, compete on things like cost and other features which, again, leads to more certified credential providers. So, we think there are some good things going on in the market already, just by virtue of e-Prescribe saying that they want to leverage the NIST standard that is out there today. You have seen a number of other companies start to dip their toe in the market and look at getting certified to support this as well.

In terms of our next steps. Everything we are doing with NSTIC is really focused on healthcare only as one domain, although it is certainly an important one that we are focused on this. I mentioned earlier that we convened a new Identity Ecosystem Steering Group last month in Chicago. More than 300 organizations and companies as well as 230 individuals signed up to participate. We funded the creation of the steering group through a two-year grant, to a consulting firm that is essentially serving as the administrator for it and there are more details on this at [www.IDecosystem.org](http://www.IDecosystem.org). At the initial meeting one of the things that happened right away was a number of the healthcare stakeholders set up a specific health domain working group and asked for ONC to participate, and we have been in touch Farzad and Joy and others about that and they have pledged to participate, which generated much excitement among the group. But the Steering Group is really tasked with trying to convene stakeholders to craft the standards and policies that will actually lead to a framework that can enable this identity ecosystem that the Strategy envisions.

Beyond that, I mentioned we are very close to awarding some pilots later this month. We really tried to take in the pilots out federal funding opportunity a challenge-based approach that identified a lot of the barriers that the marketplace has failed to overcome when it comes to strong authentication. And actually challenged bidders to come up with innovative solutions that could smash through the barriers and provide a foundation that we could start to build better authentication solutions. We are quite excited about the pilots and we will be able to talk more in a couple of weeks, when they are actually announced. And finally, it is worth talking,

government is making a very conscious effort to be an early adopter of these solutions to stimulate demand. So I talked before about what is happening with e-Prescribe and CMS. Across the government there is a White House driven effort to ensure that there is actually alignment in external-facing applications with the FICAM program the GSA has set up to actually make use of these accredited credential providers. There is also a White House initiative to create what has been dubbed, “The Federal Cloud Credential Exchange,” essentially a single cloud hub that would make it very easy for agencies to integrate with third-party credential providers, leveraging some cloud solutions that are out there, that can really do it quite easily for the marketplace today.

So, I would be happy to answer any of your questions that you might have. Before I do, a few ways that we can help IT and stakeholders can and should look to support the Strategy. One, join the Steering Group. As I mentioned, you have got a number of folks who are already looking within the health community to try and make this one of the first market segments that is a leader, using strong federated identity. Mark Coderre, who is in the information and security team at Aetna is actually one of our management council members that was elected by his peers. And there are some others in the group with strong health experience as well. Talk about the value of what this to your colleagues. And also look to potentially support NSTIC pilots that we announce in a couple of weeks by volunteering to have your organizations be a relying party with some of the credentialing solutions that will be deployed. We have had at least a couple of presumptive awardees that will be looking for additional parties that will test out the solutions, and we would love to see something there. Beyond that, look for ways to be early adopters and feel free to reach out to us, we do like to hear from you. So, with that, I know we are short on time. I am happy to take any questions and my contact information is up on the screen as well.

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

Okay. Thanks, Jeremy. I think I am going to encourage people to take advantage of the contact information because we are running quite short of time. Thanks very much.

**Jeremy Grant – National Institute of Standards and Technology, Senior Executive Advisor, National Strategy for Trusted Identities in Cyberspace (NSTIC) Program**

Sure.

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

And next Deven’s going to present the work of the Tiger Team related to this topic.

**Deven McGraw – Center for Democracy & Technology – Director**

(Indiscernible) All right, thanks very much. We are...this is essentially a follow-up from the set of recommendations that we began to present to the Policy Committee at our last meeting. So, I am going to try to go through the slides a little more quickly. There is certainly more information on the slides for those of you who want it, and it is always nice to be able to follow-up a presentation that was on the exact same topic that you were presenting on. It helps things go much more quickly. So again, these recommendations are focused on this identity issue, which is the question of are you who you claim to be when you are accessing data. And we focused, at least for this round of recommendations, on provider users of electronic health records and provider access to healthcare data of physicians as well as staff, operating on their own or behalf of the provider. We will taking up this issue with respect to patient access to health information, and in fact, we have a hearing that we are going to do on this issue which will be a web-based hearing that will take place on October 15. So, it is coming...so, patient stuff is coming, but in the meantime, we are going to take the provider slice of the pie first.

So, in the last Policy Committee meeting, we came to you with a set of recommendations that said there ought to be a required level of authentication of LOA 3, which is multi-factor, which is username and password plus something that you have, another token that proves that when you are accessing data, that you are who you say you are. For remote access to health information. And we conceded at the time that we did not have sufficient time as a Tiger Team prior to our last meeting to sort of fully define what was meant by remote, and we wanted to get a sense from all of you about whether you were on board with the concept of requiring multi-factor authentication for remote access, should we come back to you with some better definition of remote. So, here we are with a better definition for remote, to complete the circle and hopefully get these recommendations finalized.

So, what we said is that remote access really includes the following scenario. So when the access of the provider user is coming from outside of an organization or entities own private network, where the access is coming from an IP address that is not really recognized as being part of the organization or the entity, or that is considered to be outside of the organization or entities compliance environment. What they deem themselves to be legally responsible for. Or, the access is coming across a network, any part of which is or could be insecure, such as access across an open Internet or using an unsecure wireless connection. In these remote circumstances, we are recommending that there be a minimum requirement for multi-factor authentication that meets the NIST level of assurance 3 that is the standard that most folks shoot for from an authentication standpoint.

And what that means is, the authentication piece of it, the identity proofing, as we have on another slide, the first issuance of the credential to the provider user. We are not necessarily recommending that that has to meet a certain NIST level requirement, because, you know, we do not have any evidence that providers are not doing a sufficiently good job at issuing initial credentials to their users. This is really about when that user is trying to access information from outside of the organization, outside of the organization's compliance environment in a remote way, can they prove in fact that they are who they say they are through the authentication portion? And it really ought to be more than username and password.

User name and password can be one factor, but there really ought to be that second factor. And that can be as simple as if, in fact, the access is coming through a device that is...that may not be sort of owned by the facility, but the facility is aware of and is registered to it. So say you have got a physician user who routinely logs in using a mobile device remotely from home. That device can be registered with the facility and then when the physician seeks to authenticate herself into the system, the device is recognized, the physician user puts the password in and the access is granted.

So, the NIST levels have gotten much...NIST levels and technology advancements, quite frankly, have made the ability to do multi-factor authentication frankly much easier. It is not easier to spoof, because if that were the case, then it would not meet a higher level of assurance. But it is easier to take care of. And Jeremy in his presentation, mentioned the sort of single issue password that shows up on your phone, that it is one-time only that you enter. And that is another way to authenticate yourself. So again, we are sort of narrowing our focus on remote access, defining it to be those circumstances where the risk that the person on the other end of the transaction may not be who they say they are is higher than in the sort of normal circumstance of access within an organization. And that is what we are focusing on. So, let me just quickly go through the other pieces of this, which we had previously introduced at the last meeting, but I want to make sure, to give at least a summary of the complete picture here.

What we are recommending in terms of what constitutes remote access requiring multi-factor authentication is really sort of a minimum, organizations always have their obligations under the HIPAA

security rules to do risk assessments and identify additional risks that may constitute a need for a higher level of authentication for their users. So, we always want to be mindful of that, that what we are doing is trying to raise the floor, not necessarily creating a ceiling. The identity proofing piece, as I mentioned before, we are not recommending be at a certain level, because based on what we know from the hearing that we held, we are not having issues with people being improperly identity proofed at the front end. We are applying this to clinical users, anyone who is credentialed to access health data on the provider end. Again, we will get to patients in the next phase. We also want to acknowledge that the technology options for doing credentialing really continue to evolve, and this should be a field that we continue to monitor over time, to make sure that the policy is keeping track...is keeping up with innovation rather than lagging behind.

And we also really do think that the work that is going on with NSTIC could be incredibly value to this effort. And, in many respects, probably what we are doing is sort of setting....raising up the bar a bit in anticipation that NSTIC will enable us to raise it even higher, and will enable physician credentials issued in one organization, or by a credentialing issuer to be used in multiple places. Making it thereby even easier for people to be credentialed at a high level of assurance for multiple types of healthcare transactions. And then there is also the possibility that you can use that credential not just to pass on proof of your identity, but also to pass on important attributes like licensure for types of transactions where that piece of information might be important to be able to convey with the credential.

And then, as always, we have been relying on NIST for setting the standards for identity proofing. We are always eager to sort of see these publications continue to be updated and the more that they can be mindful of the challenges that occur in the healthcare sector, the better. And so we have a little bit of a plug in there for updates to 800-63-1, to look at maybe some unique needs in the healthcare environment. And that is it. I think I might have talked faster than Steve Posnack.

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

We are good. Questions? This is something we are going to vote on. So questions, clarifications, comments? So, I think you delivered your homework.

**Deven McGraw – Center for Democracy & Technology – Director**

I think this might be the first time it has ever happened. Well, you know, it does help to have two shots at it.

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

Yeah, to have your tutorial.

**Deven McGraw – Center for Democracy & Technology – Director**

And Jeremy going before me.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I just want to underscore and put together kind of what we heard, initially from Jeremy who basically said that the capabilities to do this in a scalable way, in an affordable way, that can be used by multiple relying parties, is really rapidly changing and improving and accelerating. And then the second part, as Deven said, we do face real security concerns and threats and making sure that we have at least closed this door by ensuring the identity of those who have online remote access to electronic health records, just kind of makes sense. And I think it may be the time is ripe to do this. Gayle?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

I just want to add my two cents, I cannot let privacy and security go by with putting in my two cents on this. And I know I have concerns being expressed at my local level, at my state level and my HIE on some of the costs that are going to be involved in this. And I have to say, that I am in total support of this and I think the Tiger Team has done an excellent job in discussing, ad nauseum at times, on various aspects of LOA this and LOA that. But, what is key to this is that when you get the private sector innovation, that it is going to make this less expensive as we go down the road. I think the cost to...as we stand up these HIEs across the country, I think the costs are going to go down and that in the long-term, the public acceptance is going to go up. So, it is worth the investment in setting this high bar, setting the level that we need to set, in order to build that public trust. So, I highly recommend that we vote positively on this.

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

Would you like to move so?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

I move so.

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

Is there a second?

**M**

Second.

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

And any other discussion? All in favor?

**M/F**

Aye.

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

Any opposed? Or abstain? There you go. Thanks Deven.

**Deven McGraw – Center for Democracy & Technology – Director**

Thank you.

**M**

Thank you Deven

**Deven McGraw – Center for Democracy & Technology – Director**

Thanks also to my Tiger Team, we really did put this one through the wringer.

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

Okay, well I think that brings us to our ONC update and Jodi was going to start off and then Farzad wanted to talk about some other matters.

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

Where is Jodi? Oh.

**Jodi Daniel – Office of the National Coordinator – Director of Policy & Research**

Okay, good afternoon. I am going to start with just a couple of updates for folks and then I am going to turn it over to Farzad for a bit and then he will punt it back to me. So, we will do a little tag team here. Actually, let me just do the update first. So there are a couple of things I wanted to announce to folks. First, we had a vacancy on the Health IT Policy Committee for a few months, since Adam Clark's departure. He filled the vacancy for advocates for patients and consumers and the GAO has just announced this afternoon, that they have named a replacement for Adam Clark. The Comptroller General announced that Christopher Boone, from the American Heart Association, will fill this vacancy. He is Director of Outpatient Quality and Health IT at the American Heart association. And he will serve in Adam Clark's role. That appointment goes through April of 2013 and then he would be eligible for another three year appointment after that. So, hopefully we will be able to have him come to our next meeting. So, it is up on GAO's website if people want more information about that, but, we have a replacement for Adam. So, that is the first point that I wanted to make.

The second, I wanted to just mention our Consumer e-Health Program. We actually have, on Monday, the anniversary event from the launch of our Consumer e-Health Program. So, it is very exciting, we have made a lot of progress in the last year, as evidenced by first, and importantly, our meaningful use regulations and the prominence of some of the consumer and family engagement requirements in meaningful use as well as in our standards rules. As well as the success of our Pledge Program. I do not know the exact number of people we have...organizations we have now in the Pledge Program, but the last number I remember seeing was about 375. So, it is quite a large and growing group of organizations that are pledging to help patients have more easy electronic access to their health information. So, that is very exciting. I understand that our event is already filled up, but I believe that folks are able to listen in via the web, so, please do so.

In light of that, I also wanted to mention that we have talked about performing a consumer empowerment workgroup of the Health IT Policy Committee, as well as one for the Health IT Standards Committee. And we will...there will still be a patient and family subgroup of the Meaningful Use Workgroup focused on the meaningful use provisions. But there seem to be other issues that were coming up with respect to consumer e-Health and consumer-facing tools, and as patients are getting access to their records, how they are managing that information and the tools, like PHRs, for helping them do so. And so, we will be trying to stand up a workgroup on consumer empowerment and we will be looking for a broad and diverse set of stakeholders to serve on that workgroup. We are also, in order to get a broad and diverse group of stakeholders, we are in the process of working on a way of getting folks who are interested in participating on our workgroups, including that one. But as vacancies open up on others, to identify themselves by providing a nomination and information about themselves on our website, that is not up and running yet, but we are hoping it will be soon. And we will be using that process to try to collect a diverse set of stakeholders for these consumer workgroups as well. So hopefully we will have that up and running soon and we will talk more about that and hopefully we will be able to announce it at our consumer event on Monday. So with that, I will turn it back over to Farzad.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Thank you Jodi. I wanted to give the Policy Committee and the broader community an update on Request For Information that we have put out earlier this summer. In terms of the potential regulatory approach to establishing kind of validation of organizations in the Nationwide Health Information Network. And what might be some of the conditions for trusted exchange that those organizations might need and sixty-six other questions that we posed. And I wanted to just take a minute to remind us about kind of what are the goals of that? Why we did that? And what are we thinking now about the best way to accomplish those goals, given the feedback we have received. And Jodi will walk us through some of the more detailed responses to the RFIs. The overarching goal, of course, for us all remains that information follow the patient where and when it needs to go, across those geographic and vendor and organizational boundaries. We know that the current state of care coordination and information exchange, anyone who has been a patient or loved a patient or cared for a patient, knows that it is far from ideal. And that in addition to the technical challenges to interoperability, there may be something else that is hindering the development of really a marketplace, a trusted marketplace for information exchange services. And those that we have talked about have been the rules of the road, that if I am a provider who wants to purchase services from a health information exchange service provider, do I have confidence that they...that I can buy their services, that they are going to be following the right rules of the road.

And if I am a health information exchange provider, and I want to exchange information with somebody else, to have an assurance that they will be following similar rules of the road, and reduce the need for negotiations; time consuming, expense adding negotiations around privacy policy, security policies, interoperability and even business practices. So, in our RFI we proposed, again, a voluntary structure, where there would be a regulatory validation, accreditation, certification, rather involved process for the potential conditions for trusted exchange, that covered those technical, the security and business practices. And we also asked whether the time was right for implementing such a regulatory framework for establishing, for evolving and for enforcing these conditions.

I want to thank everyone here. We had a lot of discussions with some Policy Committee, many of you independently submitted comments on and responded to our Request For Information. We got over 140 comments from the public, and they were quite detailed, and they really told a story. First and foremost, we heard interestingly that we had done this because we expected that there would be a big demand for such a validation process. It was interesting, what we heard was actually, listen guys, there is a lot happening, there is a lot of good information exchange that is occurring today, perhaps more than is widely appreciated. And what we heard was that these activities are quite diverse in their architecture and in their business models. And one concern that we heard across almost every response was that regulation at this time may actually slow the development of trusted exchange, if it is implemented prematurely.

So, our goal is to increase information exchange, not to hobble it or hinder it in anyway, and it was something that we have to listen to carefully. One of the things we heard was, and there is some recent news and announcements that tie into this, for example, the NwHIN exchange spinning off into a public/private partnership, in healthy ways. And potentially those emerging governance activities could serve, instead of freezing everything in place while people wait for the regulations to come out in the NPRM and the comments on the NPRM and then a final rule. Maybe we can just move ahead with offering, and I will get to how to accomplish the goals in a non-regulatory way. But the suggestion was, there is a lot that is already happening. If we take the direct project, and there have been a lot of questions, Gayle just referenced them about, exactly how might the certificates work and how this. Well the direct community spun off an existing governance body called Direct Trust, and they are working through a lot of the issues and we have been able to offer guidance to our state health information exchange grantees that direct trust has now taken on board.

So the concern was really, that as we are accelerating the implementation and expectations for standards based exchange in Stage 2, that we could ill afford a pause while a regulatory process takes its course. And, as a result, we have decided that now is not the time, probably, to pursue a regulatory approach that follows what we laid out in the RFI. So, what can we do to help? One thing we heard was that we should provide that framework of the enduring principles, policy principles to guide those emerging governance models. And we will do that. Indeed, the Policy Committee has already provided much of those policy principles that we can affirm as the foundation. We heard that we should identify and shine a light on those good practices that support robust, secure information exchange, some of the emerging governance models, to more actively engage with them. And we will do that. We heard we should build on existing approaches, particularly on interoperability, to take real interoperability problems and use non-regulatory approaches, convening approaches, as well as our certification program, to address those real interoperability issues. And we will do that. We heard we should build on existing regulatory frameworks around consumer protections and privacy, and not duplicate regulations as they relate to, for example, intermediaries. So, we should do that. And I want to assure you that as we continue to follow the approach that we have laid out here to try to take what steps we can, whether it is through working with the existing governance entities that are out there, issuing the guidance and clarity around that, solving real interoperability problems, providing those models and best practices. We are going to learn and we are going to continue to monitor what is happening.

And if at some point it turns out people are coming to us and saying, no, no, no, we really do want...we want this, right? If there are systemic issues, problems that...market breakdowns, that are actual proven systemic problems, let me assure you, our proclivity, our tendency, our instincts are towards action. And sometimes we have to have the better part of valor is knowing when not to act, however much it goes against our general feelings about, "we need to do something." But we need to do something, we are going to do something, and if it ever turns out that that we...it makes sense to go back to a regulatory approach, whether it was what was outlined in the RFI or a modification of it, you are going to be the first to hear. Because, we are going to come back to the policy committee, we are going to review what we have learned, what are we seeing and we are going to take it up again. So, there are not going to be any surprises in this, as in anything else, and I just wanted to let you know that we want to let everybody know really, in terms of what we are thinking, based on the feedback that we got from that Request For Information. So, let me turn it over to Jodi. Yes Judy, why don't you hear from Jodi first, in terms of some of the more details of what we heard, and then we will get to the questions.

**Jodi Daniel – Office of the National Coordinator – Director of Policy & Research**

Thank you Farzad. So, some of what I am going to say is repetitive, but I will go into a little bit more detail and MacKenzie is handing out the slide deck now. So, I am going to sort of walk through our goals, what we were trying to do, what we heard and where we are going, in a little bit more depth and kind of highlight some of the comments we specifically heard in thinking through our next steps. So, what were ONC's goals. So of course, our goal is to improve health information exchange to support patient care, but what are goals with respect to governance and health information exchange.

So, we are focused on strengthening interoperability, particularly at the implementation level. When we look at the health care...the health information exchange market, we want to facilitate the emergence of this market, in a way that syncs with payment reforms. We wanted to try to reduce some of the risk, the cost, the complexity of exchange in order to do so. We are also focused on fostering trust, both among providers, as well as consumers, about the exchange

services they use, and about the information that is being shared across those services. So, we are very much focused on those protections, in order to enable providers to feel comfortable with sharing the confidential information they hold about patients, and for patients to feel comfortable about their information being exchanged. And we also wanted to promote effective relationships between intermediaries, between those providing information exchange services, so that information was not just locked in to particular providers that could access that particular intermediaries systems.

So, leads very much toward what problems are we trying to solve. So, we know that data has historically not moved well across organizational, vendor and geographic boundaries. And, we want to resolve this, in order to improve patient care as well as payment and delivery reform. So, the problems we are trying to solve were to help facilitate trust relationships between entities that are difficult and costly and take time to build and nurture. We are trying to address the fact that there are some business practices or revenue models that may lead to silos of information as opposed to information that follows the patients. That existing models that support exchange, which there are and which we learned about a lot more in our...in the comments we got back, are not always sufficiently recognized or replicated, and folks are not necessarily learning from successes or the lessons from each other. And that implementation guides with respect to technical standards are not always sufficiently specified to lead to interoperability. So, this is the nutshell.

In one slide, what we put in our RFI, it really is...it was pretty simple. It is only one slide. We proposed a voluntary governance framework established through a new regulation that focused on the entities that facilitate electronic health information exchange. So that was sort of the context that we were working within. In order to do that, in order to establish a governance framework, we had proposed establishing a set of conditions, rules of the road as they were, which would be conditions for trusted exchange, CTEs. And they were in three areas. First were safeguards, so privacy and security, second was interoperability and the third were business process. We proposed a validation process for entities to demonstrate conformance to these conditions for trusted exchange. We proposed a process to update and retire those CTEs, as well as to classify the readiness of technical standards and implementation specifications to support the interoperability related CTEs. And then finally, we proposed approaches for monitoring and transparent oversight of the activities of these validated entities. So that is what folks were reacting to when they gave us their comments.

So what did we hear. So, these are some of the themes that we heard in the comments that we received. First that health information exchange is in its infancy and that regulations can stifle an emerging market. This is a point that Farzad made. We heard from folks that our goal should not be...that our role should not be to regulate, but to guide the market while ensuring basic protection through existing regulatory frameworks. And some of the specific comments we heard were to avoid freezing the market or causing development...a developing industry to stop and wait for regulations, as Farzad said. When we regulate, we go into our process of trying to develop the rules, and while we are in active rule making, we are not as open to input, other than through the formal comment process as we could otherwise be in a less formal process. So, folks were telling us that they would be sort of stifled while we were in the rule making process and would not move forward.

We heard from some HIE's that there may be some...that our approach may lead to some negative impact in the development of successful health information exchange initiatives, that were already working, but may not have been completely aligned with the conditions that we had

established. We have heard from an insurer that the market...that the criteria could deter new entrance to the market. So not only those that were already farther along and may or may not have been perfectly aligned with our conditions for trusted exchange, but that new entrants may be deterred from offering services that may help to support electronic health information exchange. We heard that we should be thinking more about a lighter handed superstructure sort of at this principle level, that Farzad mentioned, and then permitting the private sector to carry out the design and operationalization of programs for certification, accreditation and audit. And this was from one of those intermediary type governance like organizations that have been forming, that we heard that from. And again, we heard we should be thinking about the overall policy goals and establishing those and the framework within which folks that are providing these services can operate.

We also heard that a number of organizations and entities are already testing some good practices for the exchange of information. And that we may slow the expansion of some of these efforts to try new things and try new practices that may actually improve the way health information exchange is taking place. We

heard a lot that we needed...that ONC needed a better understanding of how exchange efforts currently are working and also to help promote others in understanding their successes and failures, and encouraging these service providers to build on each other's good examples. And we also heard, again, this is back to this being sort of in its infancy, is that this is new territory, there is a lot that is going on that is working well and we should let that happen. So, again, we heard from a lot of HIE's that this is not necessary at this time, that there are some activities going on, let us see how things develop. We heard that ONC should leverage the work and engage stakeholders that are playing in this space, in a meaningful way and build consensus among those stakeholders. We heard from some folks that we should seek additional stakeholder input through town hall meetings or forums or other mechanisms. So, a lot of folks who said, listen to what...listen to us, let us help you think this through, let us tell you what we are doing. Help us to figure out how we can share our lessons learned with each other. And, there are a lot of folks who are just getting their sea legs and trying to figure this stuff out and were concerned that we would be rocking the boat so much that they might not be able to sail safely across to the other shore.

And then lastly, we did hear that there were specific interoperability challenges that could be tackled through non-regulatory approaches or that can be built upon existing approaches related to interoperability. Specifically we heard from a commenter that promoting and adopting interoperability standards before adopting a governance model would make more sense. We heard that there should be an emphasis on use of standards and implementation guidance, and that rule making should not address Federal development and management of technical CTEs or standards, including implementation guidance and operating rules. So, we heard a lot of folks who had some good ideas about what we should be doing, where there were opportunities for us to help support this emerging market, while not interfering with some of the good things that are currently happening.

So, ONC's approach. This is the public process, I think at its best. We put out a Request For Information and we got good information and we are acting on that information, and we are listening. And there are often times when folks do not quite understand what we are doing or why the government takes a particular action in this case. We did not come out with an NPRM, we came out with an RFI because we really wanted input and we really wanted to understand if the direction we were going made sense. And that is what lead us to our proposed approach. So, four points to our proposed approach. Lead through action, lead through guidance, engage, listen and learn, and monitor the marketplace. So, I will walk through each one.

So, lead through action. We heard a lot of using the available levers to directly accomplish some of our specific goals. Folks told us, particularly in the area of standards, that we should be using the existing levels and some of the existing approaches that are already under way. Same thing with respect to consumer protections. We...in the Stage 2, we have set up the infrastructure for...of health information exchange and we should be building on that. With respect to leading through guidance, Farzad mentioned disseminating a framework of principles for folks to align with. So, we do have a lot of the emerging activities with respect to health information exchange, and there are folks who are looking for guidance and would like to know how they can develop trusted exchange. So developing sort of that high level policy objectives and a framework of principles for folks to operate within. We are available. We also will be making good practices and models that folks are using available, and helping to figure out how to facilitate the sharing of information across different entities that are either just starting to provide health information exchange services and those that are much more established. So we will be taking steps to facilitate that dialogue between health information exchange providers so that...as well as making some of these good or best practices available for folks to look at, as they are setting their own path.

Number three I think is probably the most important thing we will be doing, in many ways, because I think it will help us figure out whether we are on the right path and whether there are things that we need to do down the road. So engage, listen and learn. We really are going to proactively encourage and engage with communities and stakeholders that are offering solutions for exchange. We had folks telling us that they wanted to come together to figure out how to solve some of the challenges that are occurring and we are looking at ways to partner with different organizations that are serving in either governance like roles or in providing health information exchange services, to help us understand what is currently going on and for us to help bring those folks together and be sort of a convener of stature for those different stakeholders. And then finally, monitoring. So, we will monitor the marketplace for a variety of things; for any abuses or market failures, which is where government often plays a role in stepping in, but also for exchange successes, gaps in what may be going on in the marketplace, etcetera, as well as consumer and provider attitudes. I started with talking about the goal of...one of our goals of trust both for consumers as well as providers, and monitoring how consumers and providers are seeing health information exchange and their attitudes toward that and whether or not we need to step in to address concerns on either the consumer or provider side. So, with that, I will open it up for questions.

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

Go ahead Judy.

**Judy Faulkner – EPIC Systems – Founder**

Well, I think it is probably good not to make it regulatory. I do think though it is good to have guidance, because the three things that slow down vendor to vendor interoperability are having the lawyers and compliance officers have to meet one by one with every place the patient goes. Now that might not be too hard in the community, where you have a few different vendors who can...who work with a few different organizations and those organizations can get together. But if I am from Madison and I get sick in Washington, DC, likely that is not going to happen. So, that is one problem. The second is the authentication certificates and the third is the phone book, how do they even know to send things back and forth. So, I think it is fine not to be regulatory, but I think if there are a couple of samples or guides that you publish, and that the vendors can perhaps pick one or two of them, or maybe just take it from being a six month back and forth between the lawyers and get it down to a day. That would be so helpful, so that they can start, they can just agree that they disagree on one or two things and then work that out, rather than, and in many cases, they do not even know where to start, so helping them start.

**Jodi Daniel – Office of the National Coordinator – Director of Policy & Research**

Are there particular issues that seem to be the biggest sticking points in those relationships?

**Judy Faulkner – EPIC Systems – Founder**

I can get back to you on that one Jodi. Because I know we have rules of the road that everybody agrees to the same thing, and it makes it so easy. So, how do we make it easy? You know, you hear all the time that the vendors are not cooperative, but, I do not think that is the problem, they just do not have this groundwork here.. So, I think it would be fine, in fact, even good, not to have it be regulatory. The difficulty that you are going to get though, I think, is going to be, what is the word when it goes from one to another to another?

**Jodi Daniel – Office of the National Coordinator – Director of Policy & Research**

Chain of trust?

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

Chain of trust or transitive?

**Judy Faulkner – EPIC Systems – Founder**

Yeah, the transitivity of it. So right now, if a single vendor can know that everyone in the entire organization has signed the same rules, and that they know that if they send information, if they send information to B and B sends it on to C, the same rules will be followed. You are going to run into transitivity problems if, in fact, you do not have absolute agreement to the exact same rules. Because then how do you tell everybody that when you send your data to this particular place that has not followed the same rules, they may send it differently anywhere else. So, you have got a real transitivity problem there. The other two certificates of authentication and the phone book I think are slightly easier to solve, but they are also there.

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

Deven.

**Deven McGraw – Center for Democracy & Technology – Director**

So I think I want to push back a little bit on the concept that regulation stifle innovation. I think it is kind of popular rhetoric these days and it is not always true. It depends on the regulation. How quickly it can get out and finalized, the extent of which it is flexible enough to allow for guidance for ongoing implementation. So, we have this little backhand...that we do at CDT, the job killing privacy regulations. Right, that regulation is job killing by definition, that regulation stifles innovation by definition. So, I just want to take a moment to say that I do not agree with that conceptually. Having said that, I think I completely understand why when taking the RFI and when sort of off the table is a viable vehicle for getting good policy guidance and good adherence to standards out there, does make sense to me. I think we have some other potentially more effective vehicles for getting good policy and good best practices adopted. And some of them we have utilized well, such as through the certification standards and the meaningful use objectives, and some of the guidance that has gone out.

But other tools, quite frankly, I think we could use a little more effectively, and specifically I am talking about guidance under the HIPAA Privacy and Security Regulations. I mean, I am also not for duplicative requirements on folks and so to the extent that we were sort of looking at some of us, we are looking to NwHIN as a way to sort of elevate the field on some privacy and security issues. It was never the most desirable way to get that done, in my view point. And we have many more effective ways of getting that done through an industry that has already become accustomed with dealing with HIPAA privacy and security rules, that is seeking more certainty in how to comply with HIPAA privacy and security rules and wants to be in compliance with those rules, for the most part.

So let us use those more, and not necessarily through regulatory changes, but more FAQs and guidance, so people have a more clear understanding of what is expected of them and that we can allow the innovations and technology to be incorporated into what we ask of people on a regular basis. So again, I understand that is totally not in ONC's hands, so this is maybe a little bit of a bully pulpit moment. But I do think that we have not leveraged that vehicle enough and could and should and we would not need NwHIN governance nearly as much or at all, to address some of those privacy and security related trust issues if we had that other vehicle.

**Terry Cullen – HIS/HHS**

And I think that is exactly consistent with what we heard, and I think that is a path that we will pursue...

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

Gayle.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Thank you. And I am...actually, I am delighted to hear this. Surprising you with all I say about privacy and security, I am delighted to hear about this. I much prefer to see to let markets develop and things happen. However, I do see the need for the guidance for some consistency and one thing that you have left out of this, I think, is transparency. I think you need to put another bullet in there that says transparency. And that is where, when people put those rules on the road, Judy as you are talking about, in a very public place, and you also encourage private certification bodies to stand up, like JCAHO and things of that sort. And you have...you wind up with a community out there that comes together and develops the rules of the road themselves, you can be actually much more ineffective. And much more...and develop that public trust, that chain of trust that is necessary. When you get the private entities and those groups, those different exchanges that are standing up, we have some input through our state exchanges that...there is money involved and strings come with...money comes with strings. So you have some input on that, but it is much better in the long run to have those private groups that become the certification bodies, that become those arbiters of the rules of the road by consensus of those being governed, that it works much better in the long run.

But I would absolutely saw you have got to have transparency in this whole thing and that is a key element to making it work. This is without...when you do not have a rule come down, yes it

may take longer for things to evolve in the long run, but it will be better at the end of the day, I think. So, we are in a transition period now and the more we can encourage those individual...and you have a convener role in that, I believe to come together, to put together a working group, maybe under the auspices of this committee of HIEs and state level HIEs, and bring them together, so you can start that process. But without that, there are a lot of things happening out there that are uncoordinated.

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

Thanks Gayle. David?

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

Yeah, I think I am in the same place as everybody, although I have a suggestion or two. I am not sure that this is a case where the best policy development strategy is to listen to the marketplace, because we have a historic failure in the marketplace to address the needs. And I think there is an opportunity here, along the lines everyone has said, not to necessarily take a regulatory approach, but to take a stronger approach along the lines of what you have outlined. And I would suggest, I think consistent with Gayle’s point, that the monitoring bullet you have down here be a much a stronger, maybe even a principal one and that I think there is an opportunity for you all, going back to your slide two Jodi, where you list your goals. Almost every one of the goals there could be a metric, which you guys could monitor and say, Are we achieving the interoperability goals we hope for through marked action, through the informal guidance we promulgate. Or at what point are these metrics not moving and we need to trigger some kind of action, convening or other regulatory action that moves it forward.

And I would tie those, as they are framed here they are good, you could also go to the national quality strategy goals or others, that are really the public goods that we are all aspiring to. This may not be achieved by the current state of payment incentives and the private market that is in place, which has been a historic frustration around interoperability. So I think you could shape the guidance that you promulgate around those public good goals, not just the private exchange goals, which may all satisfy themselves without our doing anything. And I would actually be interested if we could develop a set of use cases around those public goods of data exchange, information exchange, which we could track over time. And let your guidance speak to those public good use cases, whether they are the public health objectives or the care coordination objectives or the accountable care evolution objectives, etcetera, patient engagement objectives, that may not be satisfied by the private market in the term that we all want them to be.

**Jodi Daniel – Office of the National Coordinator – Director of Policy & Research**

That was very helpful, thank you.

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

I think I was next. As you stated your goals Farzad, and listed on the slide, I thought that was a fairly foolproof argument on the actions you proposed, or that you were seeking to proposed, or you were seeking interest in. And clearly this group, I think largely supported, we answered all the 66 questions and largely in support of the idea, because trust really is central and trust is not nearly widespread in the current market as it exists. To Deven’s point, I do not think everyone even understands or interprets HIPAA correctly, to even know how to use...leverage it and use that tool to further this activity. I am a little nervous, I do not know who wrote in the comments that, it could be...you referred a lot to the HIE

Organizations, and are we hearing from the people who have to participate or indirectly participate with their data, the consumers and patients. Do they feel safe enough, which was the heart of the matter, to have their data flowing around according to individual and heterogeneous rules? So that was, I thought, the crux of why you thought it would be better if you came out

now with maybe what is cast as regulation, but as people are saying, I do not know that it...regulation.

But I would argue, of your steps and guidance, maybe to be much stronger and make it model, maybe not that you create, but you convene. So that there is a strong model out there, and it can be voluntary, but there is a good housekeeping seal of approval, so people who subscribe to and commit to that, have something to go towards. But more importantly, that patients could feel more comfortable about, I can understand this and I then I can understand who puts this up and what does it mean, in a uniform way, to get to Judy's transparency and transitivity. Because there are a number of members of a given cooperative and it is the trust and the compliance is only as good as the weakest link. And I thought one of your goals was to actually have a floor of what...below which you could not pass.

So I think there are a lot of good attributes that were there, perhaps regulation or at least the way it was interpreted as being regulation, and you may not even have meant it as being truly regulatory. But, I think there needs...I mean, as a personal opinion, it seems like a uniform set of...a model would be helpful to us all, and get us all off the starting gate. So yes, there is some activity going on in the country but clearly it is not at all widespread and the people who are most at risk, I think, are individuals. And so that is who you sought to protect and I think we still have that need, at least. Judy.

#### **Judy Faulkner – EPIC Systems – Founder**

I want to give a...the conflict between transparency and transitivity, and also I like the idea that you have a model, it is a single one, and that you keep it very simple and it is the floor. Then, here is the problem. Let us say that you went to St. Mary's, and the rules were fifteen different items, and that was published, here are the fifteen things. And St. Mary's sends it to Methodist with those fifteen. But then Methodist sends it on to Mercy and it is the same fifteen, except they have changed two and seven. And then Mercy sends it on to Metro, and it is the same fifteen, except they have changed two, seven, eight and eleven. What is transparency for when you first possess it, it does not exist. You do not have it any more, so you are misleading that patient as to what happens to that patient's data. And that is why I think with the transitivity, unless you have just a few, very simple, important rules, like you won't use the data for commercial purposes, just a very few, simple rules, and those are what you show in transparency, it is not going to work.

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

Any other comments?

#### **Judy Faulkner – EPIC Systems – Founder**

I have one comment to follow up on that Gayle and to say what you said. Actually that allows the private marketplace to distinguish in a business proposal why you would do A or B and so, if there is a floor, and then there is choice involved, it actually can stimulate the private marketplace, and meet the same goals, with this ability to expand on it. So. I am not surprised that this was the feedback. The first thought I remember when I was at HHS we had discussions about this and I think it is a sense of regulatory environment, which is not really the goal, and also, Paul to go to what you said, who responded? You know, capture the patient voice.

### **Terry Cullen – HIS/HHS**

I think also, one of the things up our regulatory approach is that...it was still a voluntary approach. So the strength of the regulation is not the same as if you have a mandatory approach. But, the challenge of the regulation and not being able to iterate quickly, is still there. So, we sort of had a regulation that kind of locked in the rules, at least for some period of time, which could, in fact, make it hard for somebody to operate. But yet, it still was a voluntary program. So, we are trying to figure out how we can get through to the best of both worlds in moving forward, understanding that we want to be more nimble, that we still want to have some models for folks to work within and help to address some of the challenges that we identified. But still do so in a way that allows us to be a little bit more nimble and to not set rules that we realize, after we put out the rules, you know, six months later that it actually raised some challenges and we have to go and re-regulate.

### **Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Our hope is that we will put out guidance that will be embraced by a broad group of information exchange groups that will ask convening and governance and that that brand will emerge. And that information exchanges around the country will say, "I want that brand," and the purchasers of those services will say, "I only want to purchase from someone who meets that brand." And the consumers will have that confidence that their information is...but that we can do it in a much more agile way that if we tried to put out an NPRM, and then get the comments and do a final rule and all that. And by the time you...you know, then Stage 2 will be upon us before we know it. So, just to be quite clear, our goal is to get to trusted exchange as quickly as we can, and we think this is the best way to get there.

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

Art.

### **Arthur Davidson, MD, MSPH – Denver Public Health Department – Director**

Yes. I like this approach. I want to go back to what something that David said about slide two. These might be converted into some metrics to follow. It seems like some of these goals, there are levers already. We spent a few minutes, a short time with Deven presenting, and the prior presentation, about how are we are going to do authentication. So, some of these pieces are already there and I think it would be helpful to maybe create a matrix that says, here is one where we do have a lever, here is one where we do not, we are going to the market to help us. Because we do want to get to a point of trusted exchange and I think the goals here are the right goals. It is just how we move down this path.

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

Anything else? Thank you, thanks for the follow up on that and thanks for the discussion again. I think this will all point us in a good direction and we are happy to help in any way we can. Okay, I think we are at the point for public comment.

## **Public Comment**

### **MacKenzie Robertson – Office of the National Coordinator**

Operator, can you please open the lines for public comment? And while they are queuing up anyone on the phone, if there is anyone in the room that would like to give a public comment, if you can please come up to the table.

### **Alan Merritt – Altarum Institute**

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

### **MacKenzie Robertson – Office of the National Coordinator**

I do not see any public comment in the room, is there any public comment on the phone line?

**Operator**

No comments on the line.

**MacKenzie Robertson – Office of the National Coordinator**

Okay. Thank you.

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

Well thank you everyone for a very productive and vigorous discussion today. And I will remind you that next month we will be revisiting Stage 3 recommendations prior to...pre-RFC. You can tell, there are a number of questions that we have, we will be seeking public comment on, but will go through this committee first, before we put it out. So thank you very much, and see you next month.