

HIT Policy Committee Transcript March 14, 2013

Attendance

The following Committee members attended this meeting:

- Farzad Mostashari
- Paul Tang
- David Bates
- Christine Bechtel
- Christopher Boone
- Arthur Davidson
- Paul Egerman
- Connie White Delaney
- Judith Faulkner
- Gayle Harrell
- Charles Kennedy
- David Lansky
- Deven McGraw
- Marc Probst
- Joshua Sharfstein
- Joe Francis for Madhulika Agarwal

The following Committee members did not attend this meeting:

- Neil Calman
- Richard Chapman
- Frank Nemec
- Latanya Sweeney
- Scott White
- Patrick Conway
- Thomas Greig
- Robert Tagalicod

Presentation

MacKenzie Robertson – Office of the National Coordinator

Thank you. Good morning, everybody. This is MacKenzie Robertson in the Office of the National Coordinator for Health IT. Welcome to the 46th meeting of the HIT Policy Committee. This is a public meeting being held virtually, and there is time for public comment built into the agenda. We only have one time for public comments, since it is a shortened schedule, and each public comment will be limited to three minutes.

The meeting is also being transcribed and recorded, so for the sake of the transcript, I would just remind everyone, if you can please identify yourself before speaking. And since this is a virtual call, I'll also remind all the participants, please don't put the phone on hold. We will hear your hold music come through the line. If you could please just disconnect and then call back in.

And lastly, the hashtag for the meeting is #HITPolicy, for anyone that will be tweeting. And with that, I will go into the roll call. Farzad Mostashari? Paul Tang?

Paul Tang – Palo Alto Medical Foundation

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Paul. David Bates?

David Bates – Brigham and Women's Hospital

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, David. Christine Bechtel?

Christine Bechtel – National Partnership for Women & Families

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Christine. Christopher Boone?

Christopher Boone – Avalere Health

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Christopher. Neil Calman? Richard Chapman? Art Davidson?

Arthur Davidson – Denver Public Health Department

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Art. Connie Delaney?

Connie Delaney – University of Minnesota/School of Nursing

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Connie. Paul Egerman?

Paul Egerman – Businessman/Entrepreneur

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Paul. Judy Faulkner?

Judith Faulkner – Epic Systems Corporation

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Judy. Gayle Harrell?

Gayle Harrell – Florida State Legislator

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Gayle. Charles Kennedy? David Lansky?

David Lansky – Pacific Business Group on Health

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, David. Deven McGraw?

Deven McGraw – Center for Democracy & Technology

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Deven. Frank Nemecek? Marc Probst?

Marc Probst – Intermountain Healthcare

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Marks. Josh Sharfstein?

Joshua Sharfstein – Department of Health & Mental Hygiene, Maryland

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Josh. Latanya Sweeney? Scott White? Joe Francis for Madhulika Agarwal?

Joe Francis – Department of Veterans Affairs

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Joe. Patrick Conway? Thomas Greig? Robert Tagalicod? Okay. With that, I will turn the agenda over to you, Paul.

Paul Tang – Palo Alto Medical Foundation

Great. Thank you very much, MacKenzie, and welcome, everyone, to this abbreviated session. Thanks for changing your travel plans. We're doing our part to contribute to the \$85 billion sequester. The first thing I'd like to do is have the privilege of announcing that Deven McGraw has been reappointed to our committee, so thank you, Deven.

Deven McGraw – Center for Democracy & Technology

Thanks, Paul.

Paul Tang – Palo Alto Medical Foundation

Secondly, I want to see if there's – people have had a chance to review the minutes, and entertain a motion to approve them.

Gayle Harrell – Florida State Legislator

So moved. Gayle Harrell.

Paul Tang – Palo Alto Medical Foundation

Second? A second?

Arthur Davidson – Denver Public Health Department

This is Art. Second.

Paul Tang – Palo Alto Medical Foundation

Thank you. And any discussions or amendments? If not, then all approve – all approve?

Several

Aye.

Paul Tang – Palo Alto Medical Foundation

Any oppose or abstain? Thank you. So the minutes are adopted. And let me just quickly go over the abbreviated agenda. We'll start out with Robert Anthony giving us an update from CMS. We're coming to the end of our second year in the meaningful use incentive program. Then Farzad will be joining a bit later, and he may or may not be able to join us right before the privacy and security Tiger Team update, followed by an HIE hearing report out. The hearing occurred end of January, and Claudia Williams will be doing that. And then we'll conclude our formal part with the ONC update by Jodi Daniel and Doug Fridsma. And at the end, as always, we'll have an opportunity for public comment.

We'll be – next month, we'll be covering some of our initial responses to the RFC for meaningful use programs, so we'll start reviewing those comments and the revisions based on that. Any other updates to the agenda? Okay. Let's start out with Rob Anthony and our update from CMS.

Robert Anthony – CMS

Thanks, Paul. Are there – oh, there we go. So I assume that I will just say advance to next slide and we'll go through this. I want to do a little bit of an update as far as actual numbers go, but I also want to do a little something different. We have talked about looking at some of the numbers from year one versus year two, and we have at least a top line summary of that when we go into attestation. So I do want to emphasize that we have a number of slides here that are for everybody's sort of edification. I'm more than happy if people want to reach out to me afterwards. My email is on the last slide, if anybody wants me to follow up on something. But for the most part, a lot of this I'm going to go through really quickly.

So if we can go through the next slide, the first thing I want to cover is the registration of payment data. If we look at the next slide, you can see that registration is – continues at the normal pace. Next slide. There we go. January, we had over 17,000 people come in to register, which puts us at a total of over 370,000 providers registered for the program. Next slide.

I did want to highlight – normally, we do a – more of a breakdown here with Medicare individually and then by specialty and by month, and all of that information is available on our website in the monthly report, but because of the numbers that we're going to go through today, I didn't want to put everything here. That is all, however, available on the website. I did want to, however, highlight the Medicaid. There have been some questions ongoing about, you know, meaningful use versus AIU, and I wanted to highlight here that we are definitely seeing a pickup in the number of people who are coming in for meaningful use on the Medicaid side. Obviously, we still have the largest number of folks who are – came in – came in for Medicaid payments for Adopt/Implement/Upgrade, but you can see here that to date we have 7,500 – almost 7,500 providers on the Medicaid side who have done meaningful use, and 6,400 of those are eligible professionals. So we're definitely starting to see something of a transition from AIU to meaningful use on the Medicaid side. Next slide.

So overall, I think we saw some of this in the rough figures when we talked last month. We are at a little over \$11.7 billion paid through the end of January. We do expect that number to go up. We have broken it down by payments by program year here, so you can see what those fall into, and you can see that 2012 so far is a much larger year than 2011 was. We do expect, as I said, that number to go up, because we are still processing some of the eligible professionals who have come in in February. So we'll have more complete 2012 numbers as we move forward. Next slide.

I think the exciting thing here is that as of the end of January, we have passed 210,000 unique providers paid. That's eligible professionals and eligible hospitals. It is a total of over 200,000 eligible professionals that have been paid through the program so far, and as I said, February was the last month that people could come in and attest to the 2012 program year, so we expect that number to continue to grow as we move forward and process all of those 2012 attestations as well.

We're already seeing some people come in for 2013. You can see it's a small number in that middle column there, but we've already got some Medicaid eligible professionals come in for obviously AIU at this point in time, and also 12 hospitals that have come in, and these would have to be new hospitals that came in and did their 90 day attestation. Next slide.

So overall, this is where we are at the end of January. I do expect that you will see another updated February report that is posted to our website in the next few days, so you'll see some of those numbers go up. But as of the end of January, we were at almost 85 percent of hospitals registered for the program out of a total of 5,011. Next slide.

And over 73 of hospitals paid, either under Medicare, Medicaid, and the vast majority of them have been paid under both programs, which of course means that the vast majority of that 73 percent have actually achieved meaningful use, which is encouraging. Next slide.

We have a large number of eligible professionals registered. Obviously, that blue portion there is the portion that have not yet registered, out of the total denominator of over 527,000, but it does mean that we have over 2/3rds of eligible professionals registered for the program as of the end of January. Next slide.

And although we haven't got quite that number paid, we do still have a significant number that have been paid. Almost 40 percent have been paid under Medicare, Medicaid, or the Medicaid Advantage organization, out of eligible professionals. Next slide.

So this is just our by the numbers, to reiterate where we are with a number of these things. As I said, over 73 percent of all eligible hospitals have received an incentive payment under either meaningful use or Adopt/Implement/Upgrade. The vast majority of them are meaningful users. Approximately 35 percent, a little over 1 out of every 3 Medicare EPs are now meaningful users of EHRs, and approximately 40 percent, 2 out of every 5 EPs, have made a financial commitment to an EHR through either Medicare or Medicaid. And this is a figure at the bottom that seems to have stabilized over the last few months, that the number – the percentage of Medicare EPs that are receiving incentives who are non-primary care, specialists, is 58 percent. Next slide.

So this is what February is shaping up to look like, and we'll have a little bit more information on the website in a few days, I hope, with a updated February report. But February was a bit month, as we expected. A lot of Medicare EPs came in and attested in those – that final month. We paid \$700 – roughly \$725 million in February, which will bring the life to date of the program to a little over \$12 billion. Next slide.

And we do – you can see a large number of Medicare EPs, over 27,000 in February alone, a total of over 33,000 unique providers paid in February, which brings us pretty close to 220,000 unique providers for February. Now again, these are draft estimates. You'll see some more updated figures when the final report is released. Next slide.

So I want to go through some of the attestation data in a little bit of a different way. There is our normal aggregate attestation data that we've been providing by objective, and it provides performance data and exclusion data, deferral data, for both core and menu objectives for EPs and hospitals, and that is all still there and for everybody to look at. There hasn't been a major fluctuation as we've moved forward. But what I did want to take a look at, if we can flip to the next slide, we have in here over 190,000 EPs, over 2,700 hospitals. We have a pretty sizeable number of both year one and year two, so 2011 and 2012 participants.

And I wanted to take at least a top line look at performance from the first 90 days and performance for returning providers as well, so we could see what that looked like. So next slide is our – next slide.

W

Hey, Rob, before you go off that slide, just a – it says that 213 EPs submitted unsuccessfully, but 231 resubmitted.

Robert Anthony – CMS

Could we back up to that? I think that may be a transposition of numbers. I'll have to go back and check on it. Back up again, please. Yeah. Yeah. I think that's a transposition of numbers. I'll go back and verify that.

W

That'd be great.

Robert Anthony – CMS

Next slide. So this is our standard, and we haven't seen a whole lot of change here. There has been some change as we've moved forward with, you know, the least popular menu objectives, or the menu objectives that are deferred the most for EPs. Unfortunately, I think we've got some things that have been switched for hospitals and EPs here. So advanced directives for hospitals has moved into the most popular list for hospitals. The least popular for EPs, we've got transition of care and patient reminders. Another one that pops up in and out of that is sometimes patient education, as some people will remember, but we've seen this fairly consistent throughout. We haven't seen a huge change in at least the bottom or top deferred menu objectives. Next slide.

So what we have here is for both EPs and hospitals a comparison of 90 day performance data. One of the questions that sort of came up as we looked at data, or one of the things we wanted to take a look at, is were the early adopters, people who came in at the very beginning of the program in 2011 and did their 90 days in 2011, would their performance be significantly different from the folks who came in for their first year in 2012?

And if we go to the next slide – next slide. Okay. I'm not sure if everybody's getting the lag or if it's just me.

MacKenzie Robertson – Office of the National Coordinator

No, we are, too. It looks frozen.

Robert Anthony – CMS

Okay. Here we are. So this will show the – for EPs 2011 versus 2012, 90 day, so these are all people who came in for their first year for 90 days. It's just comparison of the people who came in 2011 versus the one who came in 2012. Obviously, you can see in 2011 we had far fewer people come in, but if you look across these, I think that what we're seeing overall is not for the most part a huge difference in performance. We're still seeing consistently high performance, and that's what we have here. We have performance, the average numerator/denominator score that we're seeing across these different core menu objectives. I haven't included – at this point in time, we don't have the deferral and the exclusion information, but we'll be looking more at that.

And if we go on to the next slide with menu objectives, you can see that that continues to hold true there. We're still seeing consistently very high performance from EPs regardless of what year they came in.

Joe Francis – Department of Veterans Affairs

Robert, this is Joe Francis. I didn't see CQMs on this list. Is it still too early to assess?

Robert Anthony – CMS

The clinical quality measure data as far as performance?

Joe Francis – Department of Veterans Affairs

Yes.

Robert Anthony – CMS

I would have to defer to our colleagues in the Centers for Clinical Standards and Quality. I know that there are some issues regarding the quality of that data, and I think we've talked about some of that before, where the computation of the data, the actual calculation of individual quality measures, is not something that is – the accuracy of it is not incorporated into certification currently for EHRs. So I don't know at this point in time what they are planning to do as far as analysis overall of that quality measure data. I do know that they have more confidence as we head into 2014, and we are certifying the accuracy of that quality measure calculation, that they are planning to do more with that data.

Joe Francis – Department of Veterans Affairs

Right. And actually, I wasn't expecting to see aggregate performance information. I was just interested in seeing what the scope of the landscape was in terms of some of the challenges, because I recall a last year presentation that you gave, that that was one of the more, you know, problematic aspects for implementation.

Robert Anthony – CMS

Yeah. At this point in time, we were just looking at performance data from 2011 versus 2012. It wasn't necessarily taking a look at challenges, and this wasn't a survey in any way. This is literally information that we've pulled from the various attestations from our NLR to take a look at performance versus various years.

Joe Francis – Department of Veterans Affairs

Okay. But we're assuming that the folks that are attesting are also transmitting data?

Robert Anthony – CMS

No. At this point in time, not everybody is – do you mean submitting electronically?

Joe Francis – Department of Veterans Affairs

Correct.

Robert Anthony – CMS

At this point in time, no. We have a very small number of people who are actually participating in the electronic transmission of the quality measure data. There's of course the pilot for eligible professionals through PQRS, and then the hospital has a reporting pilot as well. And right now, it's a small number relative to the whole of eligible professionals who are actually electronically submitting their quality measure data. Obviously, as we move into 2014, that'll be a require for anybody who's a returning provider. But right now, it isn't a requirement.

Joe Francis – Department of Veterans Affairs

Excellent. That was exactly what I was looking for.

Paul Tang – Palo Alto Medical Foundation

And Rob, this is Paul Tang. On the – similarly, on the immunization and syndromic surveillance submission, I think in stage one they were just – the requirement was testing.

Robert Anthony – CMS

Correct.

Paul Tang – Palo Alto Medical Foundation

So are these submissions actual submissions and receipt?

Robert Anthony – CMS

Not necessarily. What we ask is for people to verify that they have tested, and if they have tested, that they continue – if they have tested and been successful, that they continue to submit to those registries. The measurement in stage one is just that they have tested that submission.

Paul Tang – Palo Alto Medical Foundation

So when you list immunization submission, 35 percent, is that test – attestation of testing, or is that actual ongoing submission?

Robert Anthony – CMS

It's the actual number of people who have tested that submission.

Paul Tang – Palo Alto Medical Foundation

Okay. Okay. Thank you.

Robert Anthony – CMS

So you can see on menu objectives, we're also still seeing consistently fairly high – there are some fluctuations, but I think nothing that – here that is statistically significant.

If we go to the next slide, we have a little bit more data, because we do have a number of hospitals that have come in new for 2013. So you can see a third column there of 2013. It is a smaller number at this point in time, but again, as we look across these different core and menu objectives, we're not seeing a huge spike or drop anywhere, all still very consistently high, especially relative to the required measure threshold, which gives us some confidence that people, no matter where they're starting in stage one, whether they were an early adopter or whether they're a later adopter, still seem to be implementing and scoring consistently high, and it does seem to support the idea that once people implement, they implement throughout. They don't – they don't necessarily just record to the particular measure of the objective. They implement for their practice or their hospital. Next slide.

And the same is true – this is the menu slide for – or menu objectives for hospitals. Now there is some fluctuation in the bottom three public health submission measures, immunization registries, reportable lab results, syndromic surveillance. Some of that is certainly a change from what databases were available from 2011 to 2012 to 2013 for people to submit to. Some of it is I think, as you can see in 2013, it seems to be more of a fluctuation, but if you look at 2012, I think as we get more of an end there, as we get more of a denominator, we may see that flatten out a little bit. But again, you have a choice as a hospital for submitting to two out of three of these. So this may represent what is available to people to submit at the time, more than anything else. Next slide.

We also wanted to take a look at least at a top line at returning providers' performance data. So it's one thing to have somebody come in for 90 days of meaningful use. Obviously, 90 days to a full year is a larger hurdle, and we wanted to see whether that type of performance significantly differs. Once you implement for a 90 day period, does that implementation continue, and does it continue strong, or does a year provide more challenges to people?

So we took a look at both EPs and hospitals, and if we go to the next slide, this is core objectives for first versus second year. So again, this is your first year of 90 days, and then these are returning EPs who did a full year in 2012. Obviously, I don't have – we don't have complete information at this point in time, which is why the number of attestations in 2012 is lower than what you got in 2011, where we're still processing some of those 2012 EP attestations.

But as you can see, it is still consistently high across the board. If anything, we do see a slight increase as we move to a full year. Some of it is not particularly statistically significant. Obviously, moving one percentage point on maintaining problem list doesn't necessarily mean a whole lot, but four percentages points on CPOE, four and a half on ePrescribing, a fairly significant jump, almost six percent, on clinical summaries, some to be at least some indication that as they move into a second year, that work flow becomes something a little bit more routine, and they're actually performing these at even a slightly higher level than they began.

If we move on to the next slide, you'll see that menu objective performance is roughly the same. Again, some of this isn't necessarily statistically significant. We're not seeing a huge jump in say medication reconciliation, but we do see a nearly seven percent jump in providing patient reminders, a significant jump in patient specific education resources, and at least a slight jump in some of the immunization registry data submission, although that may also be a reflection of what databases were available to submit to.

We see similar on the hospital side, if we move to the next slide. So again, some of this isn't statistically significant. We see some slight bumps. We see some slight drops. Overall, hospitals did begin performance at a slightly higher level than eligible professionals did, on average. So when you start that near the top, it is not always easier to get closer. So some of this is slight rise, slight drop. Most of it is a fraction of a percentage point.

If we could move to the next slide, and that is true again on the menu objectives side. We do see some fluctuation in, again, the public health agency submission, but that is probably reflective of what's available at the time, more than anything. Next slide.

Joe Francis – Department of Veterans Affairs

By the way, Robert, on that last one, I was little surprised – you know, I'm not so sure that that four percent drop would be just statistical variation. I wonder if there are related to state budgets some particular gaps there, infrastructure gaps at the local level, that we should be cognizant of as we move forward.

Robert Anthony – CMS

You mean in regards to the public health?

Joe Francis – Department of Veterans Affairs

That is correct. You know, and particularly in light of the additional stresses and strains that I'm sure states will be feeling during these months of the sequester.

Gayle Harrell – Florida State Legislator

And this is Gayle. I'd like to add on to that. Also, you've got a lot of implementation of _____ going on on the ACA at state levels, and resources being consumed there. So there's going to be – this is a time when states are having a difficult time making – you know, opening up those registries and putting the infrastructure in place, you know, for the public health surveillance.

Robert Anthony – CMS

Yeah. I think there are a number of factors that probably have an influence here, and I think you're absolutely right. We're going to continue to see fluctuation in that area, as they – states face different challenges, either bringing things online or maintaining some of those databases.

So the rest of this is our typical aggregate performance data, and I will not go through all of these slides. They're there for everybody to take a look at. We haven't seen a huge jump or drop in the overall performance. This aggregate performance data is life to date for both eligible professionals and hospitals, so it represents everybody from the beginning of the program into that average, which is why we're not seeing a whole lot of fluctuation as we move forward.

We do in this – if we go to the next slide – we do in this of course provide exclusion and deferral information, and we'll be looking at some of that exclusion and deferral information for – in the same way as we just looked at some other information as we move forward, both for folks in their first year, so people in their first 90 days, and for returning providers, to see how often people, for example, switch menu items from first year to second year, to take a look at whether deferral rates stay fairly high on the same objectives from 2011 to 2012 to 2013, and that will inform us, I think, a little bit more about the readiness of people as we start looking at stage two.

So again, there's all of this information here. There is more detailed payment information on our website, and we'll have an updated February report within a few days on the website as well. I'm happy to take any other questions.

Paul Tang – Palo Alto Medical Foundation

Thanks, Rob. Very interesting. I'll note for the committee that _____ will be coming back to you with some new approaches to meaningful use stage three based on the comments, but one of the things to note from these reports that Rob has been giving us is one, as people enter into the program, you find that they blow right past the thresholds that are set. And what's nice about Rob's comparison is they did that in 2011, they do that in 2012, and in the early hospitals, even in 2013. And the other thing that was important about today's presentation is – and when you switch from 90 days to a whole reporting year, they maintain the high performance.

So a couple of assumptions we've had is one, people don't stop just at the minimum threshold, and two, that they don't give up once they've achieved some qualifying stage. And that is some of the assumptions we were using and hoping that would bear out, and this is a really good confirmation of that, to consolidate some of our meaningful use objectives, with that assumption that people are just not going to stop performing, and to make a shift towards outcomes, because people are now getting these basics under their wing. So we'll be following up with that next month. But thank you, Rob. Any other questions or comments on the material that Rob presented?

Christine Bechtel – National Partnership for Women & Families

Yes. Christine. Rob, you had a slide a couple back where you talked about 35 percent of EPs are meaningful users, and I think the slide said 73 percent of hospitals received a payment.

Robert Anthony – CMS

Correct.

Christine Bechtel – National Partnership for Women & Families

Is there a reason that you don't have hospitals as meet – you know, sort of characterized as meaningful users, as opposed to receiving a payment? Is there a difference between the two?

Robert Anthony – CMS

We did that to bundle everybody who kind of falls into the category, because there are some hospitals who have done just AIU, so they just received an Adopt/Implement/Upgrade payment through Medicaid. However, the vast, vast majority of hospitals are meaningful users, and have received a payment under both Medicare and Medicaid. So if we were to actually break that 73 percent out, I don't know the exact number, but I would guesstimate off the top of my head that 71, 72 percent of all hospitals are actually meaningful users.

Christine Bechtel – National Partnership for Women & Families

Okay.

Robert Anthony – CMS

But the number who have just received an AIU payment is actually very, very small.

Christine Bechtel – National Partnership for Women & Families

Oh, okay. That helps. And so when you say 35 percent of EPs are meaningful users, you mean they've successfully completed stage one?

Robert Anthony – CMS

Yeah. Thirty-five percent of Medicare EPs. Yes. They have – they have actually done either a 90 day or they've done returning as well.

Gayle Harrell – Florida State Legislator

This is Gayle Harrell. I have a question also.

Paul Tang – Palo Alto Medical Foundation

Yes. Go ahead, Gayle.

Gayle Harrell – Florida State Legislator

On the registered eligible hospitals, we have 15 percent that are not registered. Have you done an analysis to find out who they are, and perhaps why they have not taken this first step?

Robert Anthony – CMS

You know, we're doing some of that now. We are starting to put together some survey information to get a better look at providers who have either not chosen to take part in the program yet, or providers who may have – and there are some – who have come in for year one but not necessarily returned for year two, and we want to see why that might be and what those particular challenges are.

I do know that looking at some of the REC data that we have, that we do know that there are some rural hospitals, for example, that are facing a bigger hurdle trying to onboard a lot of this. So there are definitely some that are in that boat. We have heard anecdotally that there are some smaller hospitals that have not necessarily been prioritized as far as implementing actual EHRs in their – in their hospitals from a vendor perspective, so there are certainly some that are just not on the list yet, and have experienced challenges getting that implemented. But we'll have a little bit more information I think as we move forward, looking at some of that.

Gayle Harrell – Florida State Legislator

I think that's very critical, that we have some analysis as to why some of the hospitals are not there, and, you know, what can be done to assist them. I think that is critical, especially on these small rural hospitals.

Robert Anthony – CMS

Absolutely. Absolutely. And I think that's what we're hoping to do with some of the survey and – hopefully, in the ONC update, some of the folks there can also answer some of the questions of what they're seeing for rural hospitals from an REC perspective.

Gayle Harrell – Florida State Legislator

Do you have a breakdown state by state on eligible providers? When you have 60 percent that, you know, are not paid at this point, do we know where – are there certain areas that those are more prevalent? Do we have any demographics whatever of people – of eligible providers who have not made the jump, the leap of faith?

Robert Anthony – CMS

We do have that information, and we can try to pull some of that together for the next presentation.

Gayle Harrell – Florida State Legislator

I think that's also a very key question that needs to be answered, who is not participating, and where are they.

Robert Anthony – CMS

Yeah. And we do try to focus on some of that as well. I almost wish I had Matt Kendall from ONC on the line with me so that we could talk about some of the states in which we have done particular challenge grants, or we have tried to focus participation, especially on the Medicaid side, to get providers involved. And there are a few key states that we've targeted to do that, and he could talk a little bit more about what the progress has been in those particular areas. Perhaps for our next meeting we can pull that together.

Judy Murphy

Rob, this is Judy Murphy. I think that would be a great idea, because there is a lot of activity going on between CMS and ONC specifically related to things like rural and then targeted at particular states. An update would be great.

Robert Anthony – CMS

Yeah.

Paul Tang – Palo Alto Medical Foundation

If I recall, when we did the update with the RECs, something like the – you know, the folks that have been working with the RECs had about twice, I think it was, the rate of successful attestation. So, you know, indicating that they're quite effective.

Judy Murphy

That's accurate. And there was a GOA report related to that as well.

Paul Tang – Palo Alto Medical Foundation

So we have a good mechanism to reach out. Maybe we – there can be even more people that are touched. Other questions/comments? It's really good to hear the success of this program. It really has created quite an inflection point. There's areas that we need to reach out even further, as Gayle points out, but the uptake and the success people are having with them, in terms of the process change, as I say, and states do want to move over more towards outcome, but it's very encouraging. So thank you, Rob, as always.

Robert Anthony – CMS

Thank you.

Paul Tang – Palo Alto Medical Foundation

Has Farzad joined yet?

Mackenzie Robertson – Office of the National Coordinator

He has not, Paul.

Paul Tang – Palo Alto Medical Foundation

Okay. So we'll move on to the Privacy and Security Tiger Team update, and we have the returning dynamic duo. And this – privacy and security is such a challenging area where we have lots of new issues that come up as we transition from the tethered – the paper-tethered world to this electronic world, and we just have such a wonderful Tiger Team led by Deven and Paul Egerman to walk us through these tough issues, and are really making progress, and these things are – these are the kinds of recommendations that can benefit us all in the country. So I'll turn it over to both Deven and Paul Egerman.

Paul Egerman – Businessman/Entrepreneur

Well, that gives us pressure to do a good presentation.

Paul Tang – Palo Alto Medical Foundation

Yeah.

[Laughter]

Deven McGraw – Center for Democracy & Technology

Yes, it does, but it's also much appreciated. Thank you very much, Paul. We are going to be talking about policies related to queries for patient health data and the obligations on the data holder to respond. Next slide, please. I just want to acknowledge the terrific contributions of our Tiger Team. We have some pretty intense discussions on nearly all of these topics, but this one in particular has been a challenge but also very interesting one. Next slide, please.

We want to start by laying out some of the background with respect to what we just shorthand call query and response. And first of all, you know, we're not writing on a blank slate here. They're – query and response happens among different healthcare providers on a fairly regular basis, maybe not as much as we would like, but it's – but it does happen. A lot of it happens on paper through fax and the mail, or through verbally on the telephone, conveyance of information, but also in terms of folks who were early adopters of electronic medical records. Some of this is happening already, but not as regularly. And so there are in fact some new challenges and questions that frequently come up when you're automating this process of requesting information about a patient and then getting something back.

We do have laws already in place. HIPAA regulates when a healthcare provider is permitted to disclose identifiable health information, which is in HIPAA language known as PHI or protected health information, and this includes in response to a query or a request for data, as well as in the circumstance where the – where the exchange of information is initiated by the data holder.

The rules under HIPAA permit a provider to disclose information under a range of circumstances, but they don't require providers to do so. They really – the rules leave the judgment up to the provider to make in terms of sort of when data will be released. And of course, there also frequently are state or other laws that may provide some requirements on providers in terms of when data can be disclosed. Next slide.

So with all of this – I'm just going to go ahead and start while we wait for the slide to come up. With all of this background, it's not our goal, nor do we necessarily have the authority, to sort of change the law around when providers disclose. So we are instead looking at reducing any potential real or perceived barriers, such as by providing some clarification around the law that really enables providers to be able to respond to a query in a way that's consistent with their professional ethical obligations and the law.

And what we're going to do today is just give you a report on the general approach that we're taking to these issues and sort of the status of our discussions to date. It would be nice if there's time to get some feedback from other members of the Policy Committee. It's our intent to provide you with our initial file recommendations on this topic at the April meeting. Next slide.

So in terms of how we approached these issues, because, you know, the sort of general term of query and response could encompass, you know, a lot of different scenarios, but it's always helpful when you're having discussions about privacy policy to be able to focus on some very common use cases, in particular tied to meaningful use requirements, in order to sort of ground the discussion and enable you to focus.

So we're really looking at three specific scenarios or use cases that we want to provide some recommendations around. And I'll just describe all three scenarios to you now, and then go in a little bit more detail on the first scenario, because that's really provided the basis for much of our discussion to date.

Scenario one is what's called targeted query for direct treatment in a circumstance where the law is basically HIPAA. There aren't any additional privacy laws that would apply. And again, since it's for treatment, and direct treatment is really treatment of the patient whose record is being sought in the query, HIPAA would allow you to disclose information to somebody who requests for direct treatment purposes without necessarily needing to get the consent or authorization of the patient ahead of time.

The second scenario ratchets that up a bit. It's still targeted query, but it's controlled – but there are other privacy laws that are also in place, such as ones that might require specific authorization of the patient. And then scenario three is non-targeted queries.

Next slide. Let me tell you what this – what scenario one means, what we mean when we say targeted query for direct treatment. In this scenario, the query is called targeted because you have some knowledge of who – the provider that you're seeking the record from. And so in this scenario, you have a provider who requests PHI from another external provider about a particular patient for direct treatment purposes, and it's controlled by HIPAA. So again, it's targeted because you know who the provider is. You either got that information from the patient or you know it from some other source.

You'll see on a later slide that in scenario three, we talk about what's called non-targeted query, which is you know the patient, but you actually don't know who the provider is where she has been seen previously, and that could be more than one provider. We're framing that as non-targeted query.

But for now, we're going to focus on sort of where we've made some progress with respect to this particular scenario, targeted query for direct treatment where HIPAA controls, and we'll start into that discussion with the next slide.

So first, we started by having a sort of basic grounding of what the existing obligations of a data holder and the requester are in a scenario where you've got a query for direct treatment purposes. You know, the data holder is going to need some reasonable assurance of who the request – you know, of the requester's identity. Is the requester who they say they are, and is there in fact a direct treatment relationship with the patient, which in most cases provides the authorization to be able to disclose the data?

Then the data holder has to essentially make the decision about whether to release data, again, consistent with whatever legal obligations they have to abide by. In this case, it's HIPAA. And then they have to send the data on the right patient, and they have to send it securely.

The requester, on the other hand, in response to these data holder obligations, because the law really talks about what the data holder can disclose and the circumstances under which she can disclose it, you know, the requester is going to have to need to present some identity credentials, I am who I say I am, provide some indication or assurance that that treatment relationship exists, and that information, you know, about who the patient is that they are requesting has to be sent in a secure manner, and be enough to enable the data holder to locate the record. Next slide.

So in response to those existing obligations and our goal of trying to provide some clarity to, you know, sort of both ends of a query and response in terms of satisfying legal and professional obligations, we started with a series of six questions that we thought we would ideally need to answer, and one is what would support reasonable reliance by a data holder that in fact the request is who they say they are, the identity question? And there are probably a range of responses to this, including, you know, do they have a DIRECT certificate for the direct program? Are they members in a network that the data holder trusts, or do they have a preexisting relationship where they have built up some basis for trusting that that credential is attached to the right person?

Second question. What would support reasonable reliance by the data holder that the requester has or is in the process of establishing a direct treatment relationship with the patient and is otherwise authorized to be able to obtain that data? And again, this is one where there's probably a range of possible responses. Does the data holder actually know the requester, and trust him or her? Is there – are they part of a network where attestation to a treatment relationship is required, and there's some sort of network governance that forms a basis for trust, such as, you know, you might get in trouble, you might get kicked out of a network if you're false – if you are found to be falsely attesting to treatment relationships?

Patient consent, some indication that the patient wants this data or notes that there's a treatment relationship here, is another basis for reasonable reliance by the data holder that the treatment relationship exists. So this is a circumstance where patient consent would not necessarily be required from a legal standpoint, but it's – but in some cases can often be helpful in supporting the existence of a treatment relationship, and then reasonable reliance by the data holder that that treatment relationship exists. And then, of course, you know, the knowledge on the part of the data holder that that treatment relationship exists, which can come from many sources. Next slide.

The third question is one of – that gets to, you know, what – making the decision to disclose the information. Actually, the next two questions deal with making the decision to disclose the information. And we first asked if it mattered if the data holder was making a human decision to disclose in each and every instance, as opposed to having the response being automated in some way. And we said yes. I mean, at least that's where we are right now. Again, we're – these are not final recommendations. We're still working on wordsmithing. But the general consensus has been yes, this matters, and in effect, the data holder needs to establish some policies to govern when they want to automate response and under what circumstances.

And then we asked to what extent does automation trigger the need for meaningful choice by patients? I'm not sure what happened to the spacing on this slide, but essentially, we were looking back to original recommendations that we did on consent that the Policy Committee endorsed. These are back from the summer of 2010, where we said that where the – you know, the data holder no longer is in control of decisions to exchange information or share information from their records, that those circumstances could trigger a need to seek meaningful choice from the patient before their data would be accessed in those types of models.

And our thought here was that, you know, data holders can in fact automate their decisions, such as by establishing an algorithm, if they still maintain the ability to make those choices about automation and disclosing PHI. Then meaningful choice would apply when the data holder no longer has the capacity to decide, to make decisions about automation, for example. And we're still in the process of finalizing these recommendations and wordsmithing them, but that's the general gist of where we've arrived so far on this automation question. Next slide.

So the next two issues are about sort of what patient identifying information is to be presented as part of a query in order to facilitate matching. That's number four. Ideally, no more, but also no less, than what is needed to accurately match the query to the right patient data. We're going to be pulling up some of the recommendations that we've made previously on matching accuracy. For example, use of a particular data field is not required, and instead, you know, entities should focus on improving their rates of matching accuracy. We'll have more on this as part of the final recommendations, but our thought was that we could not be necessarily prescriptive here, other than to say, you know, there needs to be a way of sort of getting this right on the part of the data holder, certainly, because it would be a breach for them to respond with a record that wasn't the right one potentially.

On the other hand, you don't want to have so much data be packed into the query that it's essentially arguably too much data, and is also exposing more than might be necessary. So we're still chewing on the particular wording of this, but, you know, I think the sweet spot we're trying to hit is the no more and no less than is needed to hit that accurate match.

How should data holders respond to a query? Well, more than anything, we don't want queries to just disappear into thin air. Data holders should respond to queries in a timely manner by providing either some or all of the requested content or some sort of response indicating that the content requested is not available or cannot be exchanged. And we're looking to some of the language of the DURSA, which is the agreement that's part of eHealth Exchange, which also used to be known as NHIN or NwHIN Exchange. Since so many organizations have signed on to and used that language, it's going to be very helpful I think for us in formulating our response here. Next slide.

And then the last question that we began chewing on, under scenario one, again, is in a query response situation, should there be a requirement to account for and log the query and the disclosures in response, and then to share that log with the patient upon request? And our initial recommendation here, which we just landed on a couple of days ago, is yes, certainly with respect to the data holder, the data holder should log both the query – again, from an outside organization, and the response. And then that information should be available to the patient upon request. And, you know, certainly the folks with technical expertise on the phones thought that this was a technical capability that could be built in as part of a query response capability generally.

We began discussion of whether the request should also be required to log the query, and we were not able to resolve that. You know, there were some folks who felt like requesters could certainly do that as a matter of internal policy, but shouldn't be required to, and others who thought that they should, and we just ran out of time to finish that discussion. And certainly, if committee members have any feedback on that particular question, or any others, we'd be interested in hearing it. Next slide.

So those were the six questions that we began to develop responses for, focusing on scenario one, which is targeted query for direct treatment in a circumstance where HIPAA controls. Then what we plan to do next is to finalize the wording on those questions, and then move – and then take a look at scenario two, which is a circumstance when you're likely needing to get the consent or authorization from the patient prior to disclosure, due to application of another law, and what – in what ways does that change any of the responses to any of the prior six questions? And then scenario three involves the non-targeted query, which is, again, a circumstance where – and it's – but still focusing on direct treatment. That's the circumstance where you don't know who the provider is – or who the provider is or who the providers are who might hold information about the patient, and you need to do the query using some sort of record locator service, master patient index, and PCAST called it a DEAS, in order to find the sources of the record.

So I want to – I'm going to – we're done with the presentation, although I want to stop and see if Paul Egerman wants to – make sure that – see if I've left anything out or add some thoughts of his own.

Paul Egerman – Businessman/Entrepreneur

Thanks, Deven. That was a great job of taking us through a fairly complicated issue. The big – the comment that you made earlier is important to remember, which is basically, you know, healthcare organizations are doing this all the time now in various ways. You know, HIM departments will fax lab results to another organization or physician when they ask for it. And so there is a lot of sort of question/query response going on, and the challenging part is to understand, well, when you do that with – in an automated way with an EHR talking to another EHR, or perhaps talking with something – communicating with some intermediary organization, you know, what are the additional policy issues?

And so we wanted to present this to you – we've had some spirited discussions in our Tiger Team – just to see if the Policy Committee members have any reactions to our work so far.

Paul Tang – Palo Alto Medical Foundation

This is Paul. I want to thank the Tiger Team again for – what's always nice is not only are there meaningful recommendations, but the clarity with which the issues are articulated helps us understand them better. So thanks again to the Tiger Team.

I have a question on – and it was so clear, the way you laid out these scenarios and discussed the scenario one in detail. One of the key things is whether in both your meaningful choice, is when the data holder does or does not have a choice in responding to a query. So we understand how HIPAA is permissive does not require disclosing records. If – in one case, if a vendor organized HIE network makes a contractual obligation of all the people who participate in that network, and removes that meaningful choice – in other words, the data holders, the individuals who would be responding to queries, no longer – must automatically respond to a query, does that invoke meaningful choice, then? Is that a scenario that you looked at?

Deven McGraw – Center for Democracy & Technology

So I think – I think it would. You know, we'd have to go back to the Tiger Team. We did spend some time on our last call talking about different query network models that exist today, and while we can't say that we, you know, sort of have the whole universe represented in the room, we do have a couple of them. And the Tiger Team members were comfortable with language that said, you know, that the decision maker – I want to – actually, it would be good to go back to that slide. Let me just find which one it is on the deck. That as long as the data holder still makes the decision about automating, that that sort of satisfies the – you know, the obligate – you know, our previous consent requirements, where it really focused on whether you still had the capacity to make decisions about record disclosures.

But you could decide to automate those decisions if you wanted to, because you were still making a decision in that circumstance. The decision is sort of wholly taken away from you, which, you know, one might argue in the scenario that you raised that that – that you don't have the decision-making capacity anymore, and you're sort of forced to give it up, that you would then – you know, that meaningful choice might attach.

But, you know, I think probably what it comes down to is what constitutes, you know, a decision on a data holder to automate, and is signing up for a network where you agree to make your records available to be queried, does that still give you decision-making capacity, or does it not?

Paul Egerman – Businessman/Entrepreneur

This is Paul. I mean – I mean the other Paul. What Deven said is correct. One way to think about it, again, is to think about how it might currently work in a non-automated way, whereas an organization may have a HIM department that would respond to these kinds of requests, and presumably have some policies about who they respond to –

Deven McGraw – Center for Democracy & Technology

Exactly.

Paul Egerman – Businessman/Entrepreneur

– and who they don't. And if you simply electronically automate those policies, then you retain a sense of control.

Deven McGraw – Center for Democracy & Technology

Yes.

Paul Egerman – Businessman/Entrepreneur

And it's fundamentally – the concepts of then meaningful choice would not apply. If, however, it's broader than that, you sort of lose that sense of control over who has access, the meaningful choice probably would apply.

Paul Tang – Palo Alto Medical Foundation

I think that's clear. I think in the case that I'm thinking about, you've lost the choice because you either – so you want to exchange, then you must – you must give up your choice, and that's – so I think your policy statement here is very clear. Other comments or questions about the presentation and where they are at this point?

Judith Faulkner – Epic Systems Corporation

Sure. This is Judy, and following up a little bit with what Paul said, I did think it was interesting that the patients who showed up at that all-day meeting, I don't know, a month ago, a few weeks ago, in DC, all said that the choice should be the patients', and they couldn't think of any reason why a provider would not send their data if the patient wanted it. So I think that has to be thought of as well.

Paul Tang – Palo Alto Medical Foundation

Any other questions, comments?

Joe Francis – Department of Veterans Affairs

Yes. Paul and Deven, this is Joe Francis from VA. I actually have a fairly extensive list of comments from our privacy and security people, which not to prolong this call, I will just send on electronically for the group to review. I would just say that one recommendation that my folks are ____ make to the Tiger Team is to really consider some of the new challenges that come with the electronic automation and some of the things that were not considered in your review or enumerated here, such as, you know, the myriad of state laws, and their patchwork quilt of requirements. They also ask that you take a look at some of the ONC standards and interoperability framework work on data segmentation for privacy, which apparently completed its work recently, and other things.

Deven McGraw – Center for Democracy & Technology

Yeah. Joe, that's – this is Deven. That is totally relevant to scenario two, so the comments from the VA are absolutely timely, and we'd love to get them.

Joe Francis – Department of Veterans Affairs

Yeah. And we similarly had this question about what you meant about that comment in 3B on slide nine, meaningful choice recommendations.

Paul Egerman – Businessman/Entrepreneur

That's right. And again, Joe, your comments are timely, because we are just about to start on scenario two, where we deal with some of the state laws and some of the issues that you call segmentation, which also could be involved in the state laws.

Joe Francis – Department of Veterans Affairs

All right. Very good. So we're just ____ in the next scope of work.

[Laughter]

Paul Egerman – Businessman/Entrepreneur

We need that information, so very helpful.

Paul Tang – Palo Alto Medical Foundation

Any other comments/questions? Well, thanks again to the Tiger Team. It's wonderful to have you elucidate the issues, and to give some very, very thoughtful recommendations. So we look forward to scenario two and three, and finals on scenario one.

Deven McGraw – Center for Democracy & Technology

Thank you very much.

MacKenzie Robertson – Office of the National Coordinator

Paul, this is MacKenzie. Farzad has joined the call.

Paul Tang – Palo Alto Medical Foundation

Great. And this is why we have Deven continuing on the committee.

[Laughter]

Paul Tang – Palo Alto Medical Foundation

Farzad, we announced the pleasure of having –

Farzad Mostashari – Office of the National Coordinator, HHS

Yes.

Paul Tang – Palo Alto Medical Foundation

– Deven continue on the committee, because _____ –

Farzad Mostashari – Office of the National Coordinator, HHS

Virtue, they say, Deven, is its own punishment.

[Laughter]

Deven McGraw – Center for Democracy & Technology

Well, clearly I must like – I like doing this work, even though it's not easy.

Farzad Mostashari – Office of the National Coordinator, HHS

Thank you. Thank you so much. I am calling in from off site, and sorry I couldn't join earlier. I just wanted to do some brief reflections on what we heard and saw at HIMS last week, and it was really quite remarkable to see, I think, in a way the industry responding to the market forces around interoperability and exchange. That was – that to me was pretty clear, and a clear reflection that the – not just the shift in the technology and standards looking forward to 2014 and stage two, but the shift in payment and what the customers are asking for has created I think a much stronger interest and commitment to providing interoperability and exchange for – on the part of the vendors.

It was also interesting to see how concepts like patient engagement or business intelligence analytics, ACO enablement, population health management, are beginning to, to various stages, migrate away from being buzzwords to being solutions that are – that are – you know, kind of folks are settling down a bit, and less buzz, perhaps, around them, but more, you know – less smoke, but maybe more fire in those concepts. Maybe patient engagement is still most – I don't think people really have settled down in terms of understanding what that's really going to mean, but there's certainly, again, an understanding that this is going to be pretty important.

I was also heartened by talking to a lot of the implementers from hospitals and practices and so forth, that unlike previous years, the discussion was not so much, you know, is having a, you know, problem list a good thing or not a good thing, but much more practical, you know, commitment to and progress on the path, and now beginning to discuss the next stage of issues, you know? Okay, I have a problem list. That's a given. You have a problem list. That's a given. We're going to be exchanging problem lists. That's next year. But wait a minute. Am I thinking about problem list the same way you're thinking about problem list?

So those are I think the new conversations that we're having, conversations around what do you do about, you know – someone's coined data trickles, when information gets passed back and forth, and even after correction, rears its old head up again, and proliferates. These are challenges that we are going to face as we make progress on exchange of information. And I think it's a good thing, good to have such problems, because it shows how much progress has been made.

So again, I think the message from Marilyn Tavenner at HIMS was pretty – was pretty clear and compelling. Twenty thirteen is the year of implementation, of finishing stage one strong, and some remarkable statistics, continuing on that, really amazingly hard work it's taken to get to this point. And in 2013, really pushing on implementation of stage two capabilities, and the – and beyond, but really focusing on what we need to do.

We also heard that we are – announced that the – in reflection of that focus on implementation and on stage two, and recognizing that we do need to learn from what's working and what's not working in stage two, that, you know, that we aren't going to be doing the rulemaking for stage three until next year. So 2013, you have a little more time in the Policy Committee, which I'm sure will be – will be welcome, and the Standards Committee will have a little more time in terms of having – being able to step up to the next level of standards.

How exactly – when the rules go out, and the implications that I'm sure that a little people are interested in for timing, we are not commenting on at this time in terms – and there's no decisions about what the implications of this are going to be in terms of stage three. But we are saying let's spend 2013 focused on really learning about what's happening and improving what's happening also, including on the program integrity side.

So that's all I wanted to reflect back on, on HIMS '13, and keep the progress moving ahead.

Paul Tang – Palo Alto Medical Foundation

Thank you, Farzad. Any comments/questions there?

Charles Kennedy – Aetna

Hey, Farzad. This is Charles. I was there as well, and I was really surprised as a health plan how many – surprised in a pleasant way how many of the EMR vendors were moving into kind of the population-based management space, and in many ways, they're starting to enable what I would say is things that a health plan will traditionally do. So I think – I think we're in for some really interesting times, and I think there's some real, you know, market shift that we're going to see play out in terms of traditional competitors moving into spaces they've never been in before, and new competitors challenging established ones in spaces they thought they owned.

Gayle Harrell – Florida State Legislator

And this is Gayle. I'd like to comment on that. I was very impressed with the real push on analytics. I think that's the new space you're talking about. And as you say, the more competition there is, I think the better they become, you know, and the use of analytics becomes. As we move into different payment models, I think – and ACO development and whatever, that will become even more important.

Paul Tang – Palo Alto Medical Foundation

Thank you. All right. We are so on time. So we're ready to progress on to the – an update from the Health Information Exchange Hearing that occurred at the end of January, and Claudia Williams will take us through that. This is another area of great concentration in terms of one of our focal areas for this year, and we're trying to understand what is happening in the field and how can we effect any policy changes that would facilitate this exchange.

Farzad Mostashari – Office of the National Coordinator, HHS

Actually, before – Paul, if I may, before we move on, the other – the other announcement that caught a lot of attention was about – on the CommonWell – I don't know if you had a chance to discuss it already.

Paul Tang – Palo Alto Medical Foundation

No, we did not.

Farzad Mostashari – Office of the National Coordinator, HHS

The – and I think a lot of folks are still trying to figure out what the it is on that, and I've heard very different things in the descriptions of the – what the activity is actually, and the initiative is actually. So I wonder if we could have – if a committee's interested, we could deputize somebody to look into what is really being proposed and report back to the Policy Committee.

[Crosstalk]

Farzad Mostashari – Office of the National Coordinator, HHS

Interest in hearing more about this?

Christine Bechtel – National Partnership for Women & Families

Farzad, can you say more about what it is? I just missed the first part of –

Farzad Mostashari – Office of the National Coordinator, HHS

Oh, just in terms of having somebody, and I'm thinking someone like Paul Egerman –

[Laughter]

Deven McGraw – Center for Democracy & Technology

He's a good candidate.

Farzad Mostashari – Office of the National Coordinator, HHS

More virtue being punished, looking into the – what is – kind of what is new and what is being proposed, in fact. And we've heard, you know, everything from standards to governance to exchange to key distribution for identity management to record locator. Obviously, it has important implications for the conversation we've just had about consent management, for example. So I thought it would be, instead of kind of having a discussion of it without the benefit of having a little bit of investigation, we would deputize someone to talk to some of the key players and do a little, you know, getting under the hood, and then report back to the Policy Committee.

Paul Egerman – Businessman/Entrepreneur

Sure. Happy to help.

Farzad Mostashari – Office of the National Coordinator, HHS

Thank you.

Paul Tang – Palo Alto Medical Foundation

Wonderful. Thanks, Paul.

Charles Kennedy – Aetna

Paul, this is Charles. I'd be happy to help as well.

Paul Tang – Palo Alto Medical Foundation

Great. Thanks, Charles. Anything more, Farzad?

Farzad Mostashari – Office of the National Coordinator, HHS

And then the last thing, I think we mentioned this, but just in case we haven't, as I was talking about the business case for information exchange and interoperability, we also took I think a big step forward in a joint announcement with CMS and ONC about our policy intent to use all available payment and policy levers to encourage data sharing over data hoarding, to make sure that it's never profitable to hold data and not share it for – if the patient needs it to move for best treatment.

And so we, along with CMS, we have proposed a number of potential seeking comments on a number of potential payment and policy actions that we – the administration could take to change the context and make it ever more profitable to exchange and share information rather than hoard it, and we would love everybody on the committee to spread the word about the RFIs, and make clear that everyone understands both our policy intent and our openness to hearing about ways in which potentially we have perverse incentives in place, and how to turn them into virtuous incentives around data sharing.

And I know that time is tight. It's only a 45-day window. But I'm wondering, Paul, if this is something the Policy Committee might be interested in providing us some recommendations and feedback on as a group as opposed to individually.

Paul Tang – Palo Alto Medical Foundation

Yes. That would be – we'd be happy to do that. One of the thoughts was possibly the certification adoption workgroup taking that on, because they're so unbusy right now.

[Laughter]

Paul Tang – Palo Alto Medical Foundation

Anyhow, I'll follow up with Nicky, who chairs that group, and see if that group could take that on. But it's absolutely front and center in terms of facilitating and even encouraging health information exchange.

MacKenzie Robertson – Office of the National Coordinator

Paul, this is MacKenzie. I think you meant the information exchange workgroup.

Paul Tang – Palo Alto Medical Foundation

I'm sorry. I did.

[Laughter]

Deven McGraw – Center for Democracy & Technology

Yeah, that's what I was going to say. It seems more appropriate for them. But, you know, I feel like I'm signing somebody else up for more work, since I'm only a member of that committee. I don't chair it anymore.

Paul Tang – Palo Alto Medical Foundation

So hopefully Nicky's on the – on the line, and can hear the origins of this. But we'll follow up.

Farzad Mostashari – Office of the National Coordinator, HHS

I'd better – I'd better stop talking before we _____.

[Laughter]

Paul Tang – Palo Alto Medical Foundation

All righty. Well, thank you, and I think now we can move on to the HIE hearing report out with Claudia Williams.

Claudia Williams – Office of the National Coordinator

Great. Thanks so much, and I'll be – I guess we're all virtual, but maybe just ask my ONC colleagues to flip the slides as I move forward. I'm without a computer right now.

So on January 29th, this is – it's not the first time, one of the first times, that the Standards and Policy Committee convened a hearing together with Farzad and the two chairs chairing the group, and really wanting to get a complete picture of what is the state of exchange today in terms of the kinds of business practices we're seeing, the patterns we're seeing and volume we're seeing of exchange, and the kinds of emerging technical business as well as governance issues that might create a roadmap of work for both this committee as well as for ONC itself. It was a very full day. It was a very interesting day, and I'll be sharing some of those key takeaways.

So first slide on key takeaways, I think one thing, and Nicky did a masterful job I think of synthesizing and summarizing the state of the world today. If you haven't looked at his deck, I strongly encourage you to do that. You know, there's a lot of exchange happening. Three vendors just along those three – Cerner, ECW, and Epic are each exchanging millions of patient records a month, often within their own networks, but I think about a third of Epic's exchanges are with outside vendors as well.

ePrescribing, as we've shown before through the Surescripts network, has really I would say exceeded our expectations in terms of the take-up from docs and the percentage of pharmacies participating, and just in the HIE program alone, where we monitor the amount of exchange occurring that's helped or supported by the grant funding, transactions went from 80 million in quarter 2 to – let me see if I can find this – to over I think it was 150 million in quarter 4. Let me confirm that number.

And so we are just seeing both I think rapid acceleration of a very diverse range of sources of exchange, and really a lot of growth. At the same time, these patterns describe what's been a really fundamental shift in thinking from one where we imagined there would be a single entity in a region or in a state or even at the national level that would be the sort of sole provider of HIE for everyone, providing soup to nuts governance, soup to nuts standards. Folks would need to buy onto that. And certainly we are seeing in some regions that kind of fundamental sort of infrastructure provided in one place.

But as we talk to folks through the hearing, and as we talk to ACOs and folks from vendors and others, really what we're seeing is a very different approach – Nicky called HIE 2.0 – that's focusing much more on the verb HIE, and where the market needs are bubbling up through the demands of customers, with a diverse set of needs that folks may be getting some from their EHR vendors, some from their analytics companies, some maybe from a regional HIE.

In this case, there's really not a single killer use case, the way I think we thought at one point a query would be, but people are looking for functionality that's going to be cheap enough to be very scalable, but also where the workflow is good enough that likewise it can be very scalable. So a real focus on give me what I can get now, make it really work in my workflow, and make it affordable enough that I can just start using it broadly right now.

So we heard a lot about the business drivers from payment reform, and I'll talk about that a little bit more on the next slide. So next slide, please.

So I think one of the really most fundamental takeaways we were hearing is how strongly within the context of new payment models exchange is not a nice to have but a complete requirement. And some of the data that were shared both in the hearing and outside I think really bring home that point. Atrius, which is a pioneer in Massachusetts that presented, said that 40 percent of their – of the admissions from their patients are within their network, but a full 60 percent are outside. So they're going to need to have a way to exchange information, not just in the tightly controlled, very integrated technical infrastructure they're creating, but frankly, across the whole healthcare market.

We also heard earlier from a pioneer in New York that 50 percent of the attributed lives – the high cost attributed lives, so they're a Medicare pioneer, have – are dual, Medicare and Medicaid eligible. So I think we're painting a picture of the need to have exchange services that can serve a full marketplace of participants that will include primary care, long term care, behavioral health, care managers, and the hospital, where some folks will be part of a very tight network that perhaps has the same platform, and a bunch of folks are frankly going to be outside of that.

We also heard a lot of discussion about interoperability and exchange and standards, and I think a strong message that meaningful use, especially stage two, whose effects haven't completely obviously hit in the marketplace or in the behavior of providers, is taking fundamental important steps towards enabling a basic national dial tone, but that as we continue to work on implementation and the kind of real world gritty implementation, not in – just to get certified, but really to make exchange work across vendors and across providers, we're going to be unearthing new kinds of issues that need to be resolved. An example of that was the easy exchange of certificates for DIRECT. Another was, you know, maybe we need more definition around CPDAs.

And we'll be having to find a way to provide that additional definition and that additional specificity, not necessarily in the regs, but also through implementation guidance and workgroups and collective discussion as we go forward. I think there was a real – a very strong desire for more forums in which people could share what's working, but also collectively solve the kinds of implementation gritty problems that they're facing on the ground.

The last panel of the day focused on the third model that we've always talked about in our HIE strategy, which is patient-mediated exchange, and we heard from PHR perspectives as well as businesses like care planners that are trying to get patients' clinical information so that they can coordinate care, share information back with providers. And again, I think we heard that people feel like we're on a real – a tipping point in terms of not just the need for patient engagement driven by payment reform and other things, but fundamentally a new world of data liquidity in which patients really could in an automated way have their medical information go from an EHR into a platform of their own choosing.

And I think we had vendors announcing as part of the Blue Button effort at HIMSS that – three vendors announcing that they are going to be supporting an automated triggered flow of information to patients' end points that they pick in this – in this calendar year, which is, you know, not required in meaningful use, but is an incredibly helpful implementation step to really allow that kind of data liquidity for patients. Next page, please.

Key – let's see. So we should be on key activities now. So I just wanted to mention a few activities and initiatives at ONC that I think really map back to what we heard at the hearing, and I'm sure others, when we – we'll have plenty – hopefully plenty of time for questions and comments, others will have other things they want to share as well.

First, you know, as we think about our work to do over the course of the next year, I think a big task is to make stage two work and have it serve as the sort of data liquidity innovation and exchange engine, not solving all problems, but helping really simplify and reduce the cost of exchange across the nation so all kinds of other use cases can be possible. And those really fall into technical governance and business case kinds of challenges.

So on the technical end, I want to highlight two things on this slide. One is guidelines that will soon be coming out from ONC to help folks see how they can implement stage two in a way that will really easily allow a HISP to HISP exchange, so that any provider could literally send information to any other provider in stage two in a trusted and secure way. And so I think there were a couple of pieces that were not addressed in the direct _____ around, you know, just authentication of the end using providers, as well as how we're going to exchange those digital certificates. So we're hoping that this guidance will be very, very helpful for implementers in the field.

Secondly, and Farzad really discussed it already, the business case for exchange, we have to make it profitable to share information, and not profitable to not share information. And so the CMS/ONC RFI that's calling on all of you to give input on what are the policy levers that we can pull at both the federal and as well as the state level. And then finally, the funding, we will be soon making a funding announcement for the government FOA that calls on existing governance entities to come forward with proposed scopes of work, and this is very much in line with I think work Jodi will be talking about later in the update for ONC, where ONC has a range of activities to really support strong governance over the course of the next year, working with many, many partners in the field.

So I will stop there, and certainly I'm happy to take questions, but also if we have time, MacKenzie, rather – I'm sure others may have takeaways that they want to share, having participated in the hearing.

Paul Tang – Palo Alto Medical Foundation

Thank you very much, Claudia. Comments or questions from the group?

Joe Francis – Department of Veterans Affairs

This is Joe Francis from VA. I mean, we heartily support this work, and as you know, a number of our people are working closely to support standards and interoperability. Just a thought. You know, in addition to the providers' perspective that is so out in center here for better care coordination, I think there's also an aspect that's going to become more poignant after 2014, and that's a payer perspective for coordination of benefits.

There are tens of millions of Americans that will be eligible for coverage under parallel and overlapping programs, whether it's Medicare, Medicaid, Indian Health Service, HERSA, VA, DOD, and now commercial payers, if they have to go and get coverage for their families. And I think that there's some significant savings from looking more carefully at what people get under different reimbursement structures. And so hopefully that's going to be a future consideration for the group.

Paul Tang – Palo Alto Medical Foundation

Thank you. Other comments?

Paul Egerman – Businessman/Entrepreneur

Yes. Claudia, this is the other Paul. You made a comment about giving incentives for healthcare organizations to participate in exchange. It seems to me, to the extent that patients are aware of what is happening, that the patients will be a very useful – have a useful impact in this process. I think the patient would be very upset, pick up on something that Judy said earlier, very upset to hear that their provider either declines to participate in some exchange activity or is unable to participate.

Claudia Williams – Office of the National Coordinator

Paul, do you have specific recommendations for activities or actions to kind of trigger that?

Paul Egerman – Businessman/Entrepreneur

My answer is no, other than to – other than to somehow put forward the idea of simply transparency to patients about what is happening for – and also what is not happening.

Gayle Harrell – Florida State Legislator

This is Gayle. I'd like to make a comment on that as well.

Paul Tang – Palo Alto Medical Foundation

Yeah. Go ahead, Gayle.

Gayle Harrell – Florida State Legislator

I think, you know, that is part of the role that I think ONC needs to play in really informing patients in a very public way about health information exchange. I think that is – that is key, not only in building trust in the system, but also making sure patients are definitely part of it, and they put that push on things as well.

Deven McGraw – Center for Democracy & Technology

Gayle, this is Deven. You should see some of the videos actually that the consumer office within ONC has helped put together to try to explain to people, and it may not have been just the office. I mean, they had a whole day on consumer engagement recently where they sort of unveiled some of those resources, and they're actually really good. So, I mean, you know, you can't substitute for conversations that people have with the providers that they trust, but it sure is helpful to have resources that –

Gayle Harrell – Florida State Legislator

Absolutely.

Deven McGraw – Center for Democracy & Technology

– help. Yeah.

Gayle Harrell – Florida State Legislator

Absolutely. I think that's key.

[Crosstalk]

Paul Tang – Palo Alto Medical Foundation

And for those who had the opportunity to hear Marilyn talk at HIMSS, she started out with her own anecdote about having to prepare herself for, you know, seeing another provider, and explaining why she needed such and such, or actually something that didn't work out before. And to her amazement, this provider already had access to that, and so she didn't have to give her whole story. So there's plenty of these stories around.

Joshua Sharfstein – Department of Health & Mental Hygiene, Maryland

Yeah. This is Josh Sharfstein from Maryland. I think that we've definitely heard that from consumers, and I just also would echo what Claudia said about payment reform driving a lot of interest, the fact that we readmissions incentives are pretty intense in Maryland. We don't – it's all payer and differently designed so that they're very intense. It's led to a lot of engagement by hospitals and the HIE, and it's also generated a lot of interest in the automatic notifications to primary care doctors. The primary care doctors are interested in, you know, hooking up, so that they can find out where their patients are, so that they can do better under medical home incentives. So I would certainly echo Claudia's thoughts about that.

Paul Tang – Palo Alto Medical Foundation

Thank you. Other comments? Well, I think the word out – the word is out about how valuable this is, and we just need to align all of our policies, and importantly, our payment incentives, so that at the very least, there's no punishment for doing this exchange.

Claudia Williams – Office of the National Coordinator

And Paul, maybe – I'm not certain, and maybe MacKenzie can fill us in about other groups, but the IE workgroup will be explicitly looking at the RFI and providing comments as soon as it flows through the Policy Committee. So like in other cases where we ask for comments, there will be a great opportunity to get formal, focused feedback from all of you as well.

Paul Tang – Palo Alto Medical Foundation

Great. Okay. Well, why don't we move on into the ONC update? And I don't know whether Jodi or Doug is going to start us off there.

Jodi Daniel – Office of the National Coordinator

This is Jodi. Can you hear me?

Deven McGraw – Center for Democracy & Technology

Not very well.

Paul Tang – Palo Alto Medical Foundation

We can barely hear you.

MacKenzie Robertson – Office of the National Coordinator

Can you move a little bit closer to the phone, Jodi?

Jodi Daniel – Office of the National Coordinator

Can you hear me now?

MacKenzie Robertson – Office of the National Coordinator

Yes.

Jodi Daniel – Office of the National Coordinator

Okay. Sorry. I thought I had taken it off speaker, but I hadn't. Great. So can you get the slides up? Okay. So I'm going to give just a brief overview of some activities that are going on, including with the FACAs as well as some of the rest of the activities going on in ONC that I think you all might be interested in. So we'll advance to the next slide. Next slide, please.

Okay. So here's a list of the topics I will cover. Let's jump right in. I'll go to the next slide. Okay. So first, I'm going to start with an update on some of the FACA activities, particularly this new FDASIA workgroup, and I'll tell folks what that is. First, again, just provide my congratulations to Deven on her reappointment to the Policy Committee. It was long in coming, but it's great to have her continuing for – with us on this endeavor.

I also wanted to give an update on a couple of the other workgroups that we have been trying to get kicked off. So we have just formed our consumer empowerment workgroups, both for the Policy Committee and for the Standards Committee. The first consumer empowerment workgroup meeting is scheduled for Tuesday, March 19th, from 3:00 to 4:00, and the first consumer empowerment workgroup for the Standards Committee is scheduled for Thursday, March 21st, from 11:00 to 12:00 PM. So those'll just be initial meetings where folks will sort of start to get to know each other, and we'll start tackling – identifying what are the issues that the workgroups are going to be taking on to start off with.

We also announced that we'll have an accountable care workgroup for the Health IT Policy Committee, and we did get nominations and have been in the process of identifying members for that workgroup, and inviting members. We will continue to do that in the next week, and we hope to hold a first meeting either later this month or early in April for the accountable care workgroup of the Policy Committee. We will make sure to update the website regularly with new workgroups and the information about those new workgroups, so stay tuned.

I wanted to spend a little time, though, talking about this new workgroup which we haven't talked about. This is the – another workgroup for the Health IT Policy Committee, and we've talked with Paul about this. It's called the FDASIA workgroup. So FDASIA stands for the FDA Safety and Innovation Act. This was passed late last summer, and in that – in that statute, there was a provision that required ONC to work with FDA and FCC, the Federal Communications Committee, to provide recommendations and a report to Congress on a risk-based regulatory framework for promoting both safety and innovation of health IT, including mobile medical devices, and that also reduced regulatory duplication.

They asked us to get expert input from a variety of stakeholders, and suggested that we could form a workgroup if we wished. We thought the best way to do that was to form a workgroup under the Policy Committee, because we already have this great body of folks who are – of experts who are looking at issues regarding health IT and policy, and we thought that we could form a workgroup under this committee that can provide that kind of input to us as we're developing this report with recommendations.

So that's kind of the background of why we're putting together this committee and what the charge will be. So we are looking for them to give us advice through the Policy Committee on how we should be thinking about these recommendations. We put out a request for nomination. The application period just closed on March 8th, and we're in the process of digesting over 200 applications that we received for participation in that workgroup. We are looking at all the categories that were set forth in the statute to make sure we have good representation from a variety of different stakeholders, some of which are the kinds of folks that are represented on the Health IT Policy Committee, and some are going to be providing new perspectives that we may not already have on this committee. So we're in the process of reviewing applications, and we hope to kick off that committee in April.

The report from HHS is due in early 2014, so this will be an aggressive timeframe, and we're going to be looking for lots of interest from the committee, from the workgroup, as well as trying to find creative ways to get broader stakeholder input, because there seems to be a lot of interest in this topic. Okay. Next slide, please. Next slide, please. Okay. Well, I'll start talking. Oh, here we go.

So governance. I wanted to give a little bit of an update, and then talk about an announcement we just made. So we've talked with this committee about governance of health information exchange more broadly, and about our goals of increasing trust of exchange, increasing interoperability, and reducing cost and complexity of exchange. As we've talked with you about, we are not pursuing a regulatory approach at this time, but we are pursuing a series of activities that we think will help support governance of health information exchange and support some of the good work that's already going on, while also giving ONC's perspective and policy views on the topic.

So we've said that we'll be doing a series of actions. First, we said we would put out a framework with policy – kind of policy guidelines or policy principles regarding health information exchange and governance. We have announced the availability of funding for grants to address some key issues and challenges that we know are out there with respect to governance and health information exchange. We will be doing ongoing monitoring of the market of – for health information exchange, as well as governance, to see if there are any activities we're – that would benefit from federal activity, whether there are any challenges with respect to trust or use of data, all of those sorts of things. So we'll kind of monitor the market to see if what we're doing is helping, if there are other things that we should be doing, if there are things we shouldn't be doing, and where we can be most effective.

And the fourth that I want to spend a little time on is talking about our actions to convene some of the stakeholders that we've heard from in our RFI to make sure we understand some of the issues that are coming up, best practices, etcetera.

So NeHC, the National eHealth Collaborative, which is ONC's grantee, announced the launch of the National HIE Governance Forum. The forum is designed to convene key stakeholder governance entities to address cross-cutting governance issues among various exchange approaches. We expect that the participants will include organizations whose decisions establish the policies and practices for a given community of exchange partners, and will provide an opportunity for sharing of information across those different entities based on their experiences and their challenges.

The forum is designed to identify key issues and common problems in the governance of health information exchange, as well as the best ways to address them. And what we hope to do is use this both as an opportunity for dialogue, collaboration, learning, as well as identifying best practices that can help others who are trying to address some of those same issues.

So we will be looking very closely with NeHC on this. They will be the entity that is doing the convening, but ONC is working hand in glove as the – with NeHC as our grantee in setting this up. We are asking interested organizations to apply by March 15th to NeHC, and there is a website listed here with more information. So folks who are interested can go on that – on the NeHC website and get some more information about the forum. Okay. Next slide, please.

So I mentioned last meeting, last month, about the Achieving eHealth Equity Summit, and I know this was an interest when we talked about our work plan earlier this year, so I wanted to come back and just tell folks what some of the takeaways were. So we hosted this summit at the White House on February 21st. It was sponsored by ONC, the HHS Office of Minority Health, and ZeroDivide. And the purpose was really to focus on how we could achieve eHealth equity through policy and action for underserved populations.

So some of the key takeaways and opportunities were as follows. First, that partnering is key to building or developing culturally competent solutions, and that we have to partner with those who have the money, technology, and passion, that this is hard, but it's imperative. That – also that we should look outside of healthcare for partners to build sustainable eHealth ecosystems, and not just within the healthcare system. That community-based organizations need to do a better job of documenting their effectiveness, and so there could be some opportunities there.

That we need to figure out how to take some of the successes that there are, some success projects to scale. So looking at some bright spots on figuring out how we can scale those activities. To increase awareness of and build demand for eHealth or patient-centered technology, and that communities need to be involved in designing the solutions toward eHealth equity.

So those were some of the key takeaways and opportunities. It was a great discussion. I was not there, but I heard from my colleagues about the discussion and the richness of discussion that occurred. A couple of the next steps. There's an intent to reconvene the group via webcast for a deeper dive into what is working, so trying to figure out what is out there, what are the bright spots, and where are there opportunities to build on those. And there will be a public distribution of the proceedings in April of 2013. So we will make that available on our website and folks can take a look at that. Next slide, please.

So just to keep the excitement going and show the diversity of work we're doing, we go from HIE governance to eHealth equity, and now we're on prescription drug monitoring programs, or PDMPs. So we have been – ONC has been collaborating with SAMSA, CDC, and ONDCP, the Office of the National Drug Control Policy – I think I might have gotten that right – ONDCP, over at the White House, on looking at how we can link prescription drug monitoring program data to EHRs so that that data is available in real time to those who are either prescribing medications or dispensing medications.

So we've had a series of pilots, six pilot sites, and the pilots were integrating existing technologies and trying to connect them with the PDMP data. The goal is to try to figure out how to bring this more into the physicians' normal workflow at the point of care. We have known that the prescription drug monitoring data was not always available to physicians when they needed it, when they were writing their prescriptions, and they would often find out after the patient had left that there might have been a problem that they should have addressed when the patient was there.

So the goal here was to try to make that information available to help affect clinical decision making, so that providers are aware of the information that's in the PDMP databases in making those decisions, and either can affect their clinical decision-making either positively or negatively. And we did hear of folks who either – providers who were in the pilots who chose not to prescribe because of the data they received, as well as confirming that it was appropriate to prescribe, because they were confident that the person was not abusing the prescription drugs that they were being prescribed. So it actually supported prescribers in making the right clinical decisions with respect to prescribing controlled substances in the pilots that we've seen.

So we had pilots in a number of locations. So we had two in Indiana, one in the ED and one provider setting, one in Michigan that was with providers, one in North Dakota, which was with pharmacies, one in Ohio with providers, and one in Washington State.

The results. We had a variety of different ways that we – that the different pilots were incorporating the prescription drug monitoring data into the workflow of prescribers and dispensers. We did find that in the pilots, 98 to 100 percent of prescribers and dispensers reported that the PDMP data was now easier to access. The prescribers and dispensers did feel that the PDMP data was acceptable for clinical use, that the users were better informed, and that the availability of the information positively impacted their care.

And one specific example in the Indiana ED pilot, it showed that there was an impact to the number of prescriptions written. So 58 percent reduced either the prescriptions or the numbers of pills dispensed, and 7 percent increased either the prescription or the number of pills dispensed. So we saw both folks using the information to change their prescribing practices both in – positive and negatively. And also, I encourage folks to look at our website. We have the information about the pilots up on our website, and we will be making more resources available for folks who are interested in how to incorporate PDMP data into clinical decision-making on our website. So stay tuned for some more, and please check out that website. Next slide, please.

Okay. So we are going to try, starting next meeting, to have somebody from our – from our data shop to provide updates on the data and the statistics that they are finding for adoption and – as well as other interesting data points that the Policy Committee might be interested in. Unfortunately, we didn't have anybody who was available today, so I'm going to be doing my best to give you that update. But in the future, what we'll try to do is have Mike Furokova or somebody on his team provide those updates, along with the CMS updates on the data for the meaningful use program, so stay tuned for that.

We do have two new data briefs on hospital adoption for health IT. One was an overall adoption rate, and the other was acute care hospital adoption rates to meet meaningful use. So some of the key statistics, and I do encourage folks to look at the links here for more details if you are interested in that, but from 2008 to 2012, hospitals' capability to meet each of the 7 meaningful use objectives grew significantly, with increases ranging from 32 percent to 157 percent.

Hospital adoption of CPOE for medication orders showed the highest growth between 2008 and 2012, increasing by 167 percent. And the percent of hospitals possessing a certified EHR jumped by 18 percent between 2011 and 2012, so from 72 percent to 85 percent. I don't have a lot more details on these data briefs. I do encourage folks to look at the data briefs themselves, and like I said, we'll have Mike Furokova or somebody on his team here next time who can provide more richness of the data and some of the nuances of what they found in those data briefs.

Judy Murphy

Jodi, this is Judy Murphy. I just want to jump I and say the source of this data is the American Hospital Association annual survey. Many of you are probably familiar with it. It's done in fall. And there's been an IT supplement I think for something like five years or so, and this data was extracted from the IT supplement. Sixty-three percent of the hospitals in the United States respond to that survey, and that is, you know, statistically significant, to be able to be extrapolated and say that's, you know, pretty much what's happening in the industry at all hospitals.

Jodi Daniel – Office of the National Coordinator

Great. Thank you, Judy. I appreciate the additional information. Okay. And last slide, please. Farzad talked about the advancing interoperability in health information exchange RFI. I just wanted to put this slide up so people can see the link to the – to the RFI, and highlight that the deadline for comments is April 21st. So we look forward to both the Policy Committee's input on that, as well as the general public's input on that. And that's all I've got. Thank you.

Paul Tang – Palo Alto Medical Foundation

Thank you, Jodi. Any questions for Jodi?

Christine Bechtel – National Partnership for Women & Families

Jodi, it's Christine Bechtel. I just have a quick – I think it's more of a suggestion. I – the hospital data briefs are really helpful. I think where the – where I start to get very confused, though, is, you know, we had Anthony earlier talking about, you know, 73 percent of hospitals have been paid, but then we have 85 percent here saying they possess a certified EHR. There's some – I don't know if there's a way that we could, maybe when Mike comes next month or whatever, help us understand the relationship between the two data sets. Is it different denominators? Is it, you know, whatever? I don't know. It's just – there seems to be a lot of different numbers with some pretty nuanced explanations as to why they're different, but it starts to get a little confusing.

Jodi Daniel – Office of the National Coordinator

Sure thing, Christine. That makes sense. You know, obviously, it does take time for folks who adopt or possess a certified EHR to then actually come into compliance with all of the meaningful use requirements, so I'm assuming that there is some discrepancy because of that. But we'd be happy to ask Mike to clarify.

Christine Bechtel – National Partnership for Women & Families

Yeah. I assume that's right, too. I just didn't know if – well, if it's all hospitals in the United States, are they all also EHs, right? Because some –

Jodi Daniel – Office of the National Coordinator

Right. Some are not.

Christine Bechtel – National Partnership for Women & Families

Right. Some are not, and I don't – but I don't know how many, and same thing for EPs, although your data brief isn't on EPs. But that would be like really helpful, to help us take a good look at both data sets.

Jodi Daniel – Office of the National Coordinator

Okay. Will do.

Gayle Harrell – Florida State Legislator

This is Gayle. I'd just like to make one comment about the PDMPs, if possible.

Jodi Daniel – Office of the National Coordinator

Sure.

Gayle Harrell – Florida State Legislator

You know, I – this is such an important tool, and I would just love to see there be some discussion about building links within EHRs so physicians don't have to go outside their EHRs to get that information. I think that is a key component in really encouraging physicians to use this. What we're finding in Florida is we only have one or two percent of physicians who are accessing the PDMP.

Jodi Daniel – Office of the National Coordinator

Great. That's helpful, Gayle. I think – I'm trying to remember if we included a – I think we included a question in our request for comments, the Policy Committee's request for comments, about using EHRs – building in the capability for the EHRs to access the PDMP data. I think some of the challenge we heard back was just that there was such variability among the – among the different state programs. That said, we are working with our contractor, and we – on standards work, to try to make this information more consumable by EHRs. So I think it's a really good comment, and it's something we're working on.

I'm wondering if folks would be interested when this project is over – I think it ends at the end of March – perhaps next month we can have the contractors come in and just give an overview of the project and some of the findings that they had? Would that be helpful?

Gayle Harrell – Florida State Legislator

Yes. That would be very, very helpful, because we are trying to do everything in the State of Florida to encourage physicians to use the PDMP, but it's become problematic in that it's really not being used.

Jodi Daniel – Office of the National Coordinator

Okay. All right. Well, why don't we – we'll take that as an action item. We'll try to get somebody in to give an update on the project and what has been done, where there's still opportunity, and how folks can – you know, how we can help folks in the future.

Gayle Harrell – Florida State Legislator

Thank you.

Jodi Daniel – Office of the National Coordinator

Great.

Paul Tang – Palo Alto Medical Foundation

Thank you. Other comments/questions? Okay. Thanks, Jodi.

Jodi Daniel – Office of the National Coordinator

Thank you.

Paul Tang – Palo Alto Medical Foundation

Why don't we turn to Doug?

Doug Fridsma – Office of the National Coordinator

Okay. Thanks so much, Paul. I just have just a couple of slides. They're very dense. I expect that people can take a look at the slides at their leisure. This is – if we can go to the next slide, what we have here is sort of our portfolio snapshot of the activities that are going on within the S&I framework. I think it's important to note that many of these activities, we are working to try to figure out in relationship to meaningful use stage three how we can prioritize the work going forward and make sure that we're supporting those things that are going to be important, getting into the next suite of functionality that we need to have.

If you take a look at the list of the projects, the top three, the DIRECT project, transition of care, and laboratory results interface, have all been adopted as part of meaningful use stage two, and so we're working very closely with the community to begin supporting the implementation and use of these standards. And so part of our efforts within the standards and interoperability framework is actually to stand up a series of forums and discussion groups that are not directed so much towards the standards folks, that are – that have developed the implementation specifications and the standards, but actually, to get feedback from the community so that as they develop the transitions of care and the consolidated CDA technology and incorporate that into the electronic health records, as we find potential challenges there or things that we need to improve, we'll have a mechanism to learn from those implementations to support that, to provide best guidance and best practice for how those get implemented, and then to feed that back into the standards process, should it be necessary to do an update or a refinement.

That's true, I think, both of the DIRECT project, the transitions of care, and the laboratory results interface activities, and we're working very closely with the standards development organizations and community experts to make sure that we have adequate support for the implementation of these standards, because one of our key goals in 2013 and 2014 is really to make sure that the implementation of meaningful use stage two is something that is successful for the industry, and something that we can make sure that we learn from and refine as we think about future stages in meaningful use.

The remaining set of initiatives within the portfolio are at different stages of maturation. I think there was a mention of the data segmentation for privacy activity. That actually has gone quite well. There are actual pilots and tests that are out there. At the HIMS demonstration just last week, there was a commercial vendor that had actually adopted some of those specifications and was demonstrating how they could incorporate that in the way they protect information and exchange it on behalf of patients and providers.

I'm skipping QueryHealth and public health reporting for right now, because I'm going to talk about that in relationship to our most recent initiative that's coming out. ESMD is a project that is being supported and led by CMS. It's an effort to really help with the fraud and detection audit piece, and make sure that we have sufficient integration of the standards and specifications that allow us to not only do clinical documentation and the like, but also to provide things like an author of record, which is a digital signature that can be applied to a document or to a request, and also working very closely with them to figure out the right way to integrate our transport standards like direct into this process. So Melanie Combs-Dyer has been a real thought leader with that, and we've been working very closely with CMS in this particular activity.

The longitudinal care – coordination of care project is one that has been primarily driven by the community. This is one that we've provided sort of a minimum level of support, but I must admit, this is a community that is incredibly enthusiastic, and an important community for us not to forget. Many of the providers in long term care facilities may not be eligible for incentive pay, but they don't want to be left out of the ecosystem of health information exchange. And so they've been focused on care plans and other things that are on the list of priorities for the HIT Policy Committee, really trying to get to the point where we have not just free text descriptions of those care plans, but the ability to take a look at the individual elements of that care plan, and be able to route and use that information electronically.

The laboratory orders interface is a project that's nearly completed. It's gone through a series of ballots, and the ballot reconciliation in the standards development organizations are starting to be finalized. The reason that this one is important is that if you take the laboratory orders interface and you combine it with laboratory results, you actually can have that 360 that we'd like to see, where a physician can order a laboratory test electronically, it is transmitted to the laboratory for analysis, and then what comes back is an electronic feed that is in the laboratory results interface standard.

And so they've made significant effort there. There's also this notion of collecting what are the most common orderable tests, and that may vary from a laboratory system to a laboratory system, but coming up with a compendium, if you will, or a standard way of describing what can be ordered, is another part of that particular project that I think, with both an automatic way of ordering, a way of describing the things that can be ordered, and getting those information back in an electronic format, provides a really nice ecosystem, if you will, that connects the EHR to our laboratory systems.

The last three initiatives, the Health eDecisions, Automate Blue Button, and Structure Data Capture, are some of the most recent things that we've been working on. Health eDecisions is an activity that is being supported by CMS and directed by Jacob Reider and his team. It's an effort to be able to reduce the burden it takes to share best practice and clinical guidelines so that those things can be described and then imported into an electronic health record for incorporation in clinical decision support rules.

They're also working on a way that would allow an electronic health record not so much to support the decision logic, but actually to go and query a service that says, I have a patient in front of me whose diabetes is out of control, and they're on the following medications. What would be best practice for me to be able to monitor this patient effectively, and then to be able to get recommendations back on that particular server.

So there's a lot of activities that are ongoing there. They're working with HL7 to create a standard that meets that particular use case, and they've gone through their first ballot cycle. They've got some other activities underway as well that will allow consistency of how you ask that question that I think will support a variety of other activities as well.

The Automate Blue Button is one that was – a project that was primarily directed through three of our Presidential Innovation Fellows that were working with ONC for the past six months. They've recently completed the work there, but this was an effort to really take a series of the building blocks that we have in our portfolio of standards, assemble them together to solve the problem of how do we meet the meaningful use requirement of view, download, and transmit?

And so by combining the Blue Button specifications with the standard that we use for clinical summaries, and then tying that together with the DIRECT protocol, they were able to describe and pilot a implementation guide that took those three building blocks, put them together into an implementation guide, and satisfied the requirements of the view/download/transmit requirement of meaningful use stage two.

The last initiative, and this is the one that's the most recent one, is something that we're calling Structure Data Capture, and what we're trying to do in this situation or in this particular project is to try to figure out how we can link together data that's collected for purposes of, for example, clinical research, or data that needs to be captured for patient safety reporting, and supplement that with electronic – with information that's drawn from the electronic health record.

And so the Structure Data Capture is to create essentially a standard way of describing much more atomic data elements, in some sense responsive to some of the activities of PCAST that we've heard about in the last year, but to create the metadata that you need to capture a small chunk of data, what we're calling a data element, or a common data element, if people agree that that's a way to do things, but to be able to capture that and then allow electronic health records to interact with both an individual common data element as well as collections of common data elements that would allow us to simply and easily integrate things like clinical research capabilities into an electronic health record by being able to sort of put up a case report form, or put up a quality improvement study data collection – set of data elements, and to integrate that with the electronic health record.

We've just started this about two or three weeks ago, and they're making good progress in sort of defining that syntax for what that more atomic data element might look like. This is a project that we've got a number of collaborators on. We're working with ASPE here, and HHS, as well as with the National Library of Medicine, to help us with kind of organizing and structuring this, and with AHRQ, because they have an interest in seeing if this could be used for reporting patient safety events as well.

So there's – we're leveraging the QueryHealth activities and the public health reporting activities to help support some of the Structure Data Capture. And so some of those activities are getting folded into those activities. So that gives you a sense for the kinds of things that are going on right now in accelerating the standards and where we are with some of the pilots and activities that are relevant there. We can go to the next slide. Can we go to the next slide? There we go.

Now this is a very detailed slide. Essentially, I tried to take six or seven slides that we presented to the HIT Standards Committee and distill down some of the activity that we need to do in the course of the next year or so in terms of making advancements towards interoperability and information exchange. The things that are listed on this – on this list, though, were not generated by ONC. These really are a derivative of the work that was – and the priorities that came from the HIT Policy Committee, that we then distilled that down, and to say what are the technical specifications and standards that we would need to be able to support some of those policy objectives.

And as you can see, you guys are very ambitious in some of the policy objectives, because there's a lot of information that's listed on this particular set of activities. I think – I wanted to present this essentially to the HIT Policy Committee because I think one of the things that we're going to want to do is that this work plan is a draft. It's a living document. And over the course of the next couple of months, as we begin to tick away the low hanging fruit and bring this stuff together, it'll be important that we have a dialogue between the HIT Standards Committee and the Policy Committee so that if we identify a particular standard that we say, this is an easy one for us, and we think we can add this functionality, we can talk to you about that and help us prioritize.

If there's something else that you say is – that we say, this is going to be hard, it's going to take us a lot of work, we need to then have a conversation with you as well to see how can we prioritize this. Is there an incremental path, if you will, to getting to those things? And so there's a whole host of activities. We're in the process right now of kind of beginning to do the analysis, and working with the HIT Standards Committee to make sure that we can start answering some of the questions around the technical capabilities necessary to support the HIT Policy Committee goals.

So if you look at the near-term things, we want to take a look at standards that might support additional transport mechanisms of data to and from patients, and so that may include not only the direct specification of web services, but enhancements to those, and maybe some additional ways of doing transport that are related to REST or the way in which webpages work.

We really think that we need to do some work on supporting image exchange, and I think one of the things that the HIT Standards Committee is going to be working on is really understanding what the use case is. What is the problem that we're trying to solve? Because I think there are some times where we say, well, this is for – the kinds of standards that we would use, if what we're doing is treatment planning for radiation therapy, versus sharing a JPEG to be able to talk to the patient about their broken clavicle, those are very, very different use cases that require very different kinds of standards. And so we need to get clarity on what we want to do on an incremental path to – and that's a conversation that I think will be joint with the HIT Policy and Standards Committees.

We've got a whole host of things to address, current gaps that we've already talked a little bit about with our standards and interoperability framework activities, so things around laboratory orders, formularies of things that you can order from the labs, or formularies of medications that you can order, how to be – how to be – how to cancel transactions, medications for ePrescribing, discharge medications for ePrescribing, genomic data.

These are all things that are currently under analysis to try to figure out which ones are going to be easy, which ones are going to be hard, and which ones have the highest value for us to continue our work. And we're also looking at standards as well with NIST for securing data at rest, especially genomic and consumer downloads. These are things that I think we want to get in play early, get some decisions made, and then we can move on to some of the other things.

In Q2, which is just around the corner, we're trying to make sure that we can support the consolidated CDA and the transitions of care, and it may be that we need to think about creating ways to export this information for a longitudinal care record, and what would be necessary to do that. Advanced directives, clearly an important aspect that we need to take a look at. And things that will help us programmatically connect different EHRs or different functions using what we call APIs, or application programming interfaces, that allow us to more tightly connect modules or components of an electronic health record.

We're – we think that quality is going to be important, and so looking at some of our standards that were developed as part of QueryHealth and our work with Jacob Reider on the standards to support quality measures and reporting are going to be an important thing that we need to refine and consider how to get those things through ballots and the standards development organizations so that they'd be suitable for adoption within the certification program.

Again, clinical decision support, which is sort of the other side of that same coin around quality, how we can best do that. And we've got, again, activities underway that we need to assess over the course of the summer.

Standards which support defect reporting to patient safety organizations, and those that are there to support registries, are going to be part of this Structure Data Capture initiative that we're working on as well.

We've got a number of different things, work that's been in the state HIE in Q3, that we can talk about closed loop referral, record locator services, which I think will be interesting in Q3, given particularly some of the work that's going on with the CommonWell that was announced last week, and work to help support that targeted query, the work that's been keyed up now by the Tiger Team, to make sure that we've got the appropriate standards to help support those kind of targeted query and response activities. And you can see that both in the provider and patient identities, as well as in the pull and push activities that we might have.

We talked a little bit about the long-term care activities, and that standards to record care plans and care teams is underway. We hope that by Q3 we can make a report about that. We've got some existing work around data segmentation that we think needs to be reviewed, and get recommendations about how best to proceed. And then standards that will support clinical documentation, problem lists, computer assisted coding, and the like, I think are going to be important.

Finally, rounding out the year, we need to make sure that we've got standards that support measurement of EHR usability, and we'll work very closely with NIST and Jacob Reider and the Chief Medical Office to make sure that we have ways of assessing usability. Now that may not be a standard in the traditional sense, but we certainly want to have some consistency or a way in which we can support EHR usability.

We've got patient generated data, and there's work ongoing within HL7 right now to make sure that we can note when there is data that's been generated by the – by patients, and leverage some of our existing standards. And we want to make sure that we include consumer device data, and there's work with the FDA to develop unique device identifiers. How to include that, as well as consumer devices, into this ecosystem, is a discussion that will happen later in the summer.

And then we've got standards to support digital signatures, standards that will – that will help us integrate with some of the NSTIC activities, and then we talked a little bit about this, which support the query of data within an organization and targeted query for patient data.

So we've got a lot of activities. Much of this is stuff that's already in flight, that we just need to be able to bring back to the HIT Standards Committee. But we'll be working I think very closely with the HIT Policy Committee to make sure that the things that we're doing are going to be supportive of our policy objectives that we have within this committee as well.

And so with that, I guess we can go to the last slide and open it up for questions.

Paul Tang – Palo Alto Medical Foundation

Thank you, Doug. I wonder if I could make a couple of comments? One, as you list – what Doug just presented were activities that were stimulated by actions or discussions at the HIT Policy Committee, and it sort of reminds me, this is a committee that was set up in HITECH, a committee of private sector volunteers, along with their federal liaisons, that are incredibly dedicated and passionate about this work, and it's a lot of it. I'm not sure if the statement ____ full-time job, I think it is a full-time job to do this work.

And I just want to tip my hat to all of you on this committee that are putting this much time, this much energy, and this much dedication into this work, because I think it's incredibly meaningful. And so thank you.

And the second comment I want to make is having to do with working with Farzad and the incredible team he's put together in the ONC. Part of why we're so busy in this committee is we're trying to keep up with what ONC is doing, and part of what it's doing is responding to the challenges that – more importantly, the opportunities in reforming and transforming the health system. Part of the ground work was laid in HITECH and then followed up with ACA, but this – for many of us who've been in this for a long time, this is an incredible opportunity, and a once in a generation chance to make a big difference. We're not the difference that's being made. We're putting in an infrastructure that is so enabling and so empowering, either to the professional team, the healthcare professionals, or to the patients. And I just think it's incredibly rewarding.

So I want to thank the department – the Office of the National Coordinator for the incredible work that goes in by the staff. I mean, and talking to some of the folks there who've been career professionals, and in other departments, this is an – this is really a unique department, works so hard and so quickly on so many things, that – you just heard Jodi and Doug update on the tip of the iceberg of what's going on. I just had to say it in response to just what we're hearing in terms of what's going on, the quality of the work, and the meaningfulness of the work. It's just so impressive. So just wanted to start out that way and acknowledge both this committee and the members of it, as well as the office. So thanks.

I do have one question on the matrix you – sort of the work plan you described, Doug, for the HIT Standards Committee. One of the things that would be helpful, it was really an incredibly helpful summary in terms of all of these standards activities, sort of in response, and you can recognize that from recommendations from the Policy Committee, or things related to meaningful use. One thing that would help us is maybe at some point some kind of description of timeline on when the deliverables would be. That helps us figure out when is – when are the standards ready to be incorporated into, for example, meaningful use requirements. So that would be something, you know, maybe in the future you could help us with.

But thanks to both Jodi and Doug for this wonderful summary of activities going on and some of the opportunities we have to interact. Let me open it up again for comments and questions in response to the update.

Judith Faulkner – Epic Systems Corporation

This is Judy. I've got a question, Doug, about a couple of things. When you put on there things like data segmentation and usability and the quarters that you're going to work on them, in my mind, maybe I'm wrong, but I don't know that the Policy Committee has decided policy on data segmentation and usability. So please correct me if I'm wrong. But how does it get to the Standards Committee if it didn't go through the Policy Committee?

Doug Fridsma – Office of the National Coordinator

Well, I think, you know, there have been some ongoing activities in the standards world. Certainly the data segmentation activity is something that Joy Pritts and her office, we're working very closely with her to help support that. SAMSA has been deeply engaged with those as well. I think part of what we want to do, and this is true I think of the usability activities as well, is that we just sort of teed up some opportunities to have that discussion about what we've done so far and kind of what the capabilities are with regard to both the data segmentation work, as well as what are different ways that we could work towards usability.

As I said, usability was something that came up that I think needs to have a discussion within the HIT Standards Committee. One would hope in the work that we do between both the Standards and the Policy Committee, that we'll have a handshake with this, that in fact things will get teed up by the Policy Committee that will lead to a conversation with the Standards Committee, and we'll be able to go back and forth, as opposed to having the Policy Committee sort of work in a waterfall mode, where they would come up with all of their recommendations and then charge the Standards Committee to simply implement.

I think that dialogue back and forth is really what I'm hoping to achieve, and it's the reason why I wanted you folks to know what's going on in the HIT Standards Committee, so that we can begin and have that dialogue.

Judith Faulkner – Epic Systems Corporation

So this is still kind of confusing to me, because it seems different from what the two committees were originally established for.

Deven McGraw – Center for Democracy & Technology

I don't – can I interrupt? This is Deven.

Judith Faulkner – Epic Systems Corporation

Yeah, sure.

Deven McGraw – Center for Democracy & Technology

So we expressly acknowledged as a committee when we dealt with the issue of consent that there already was existing policy on the book in the form of law that required the patient's authorization for certain types of data, even in circumstances where other types of data could flow without necessarily having to get the patient's authorization first. So given that there already in fact is policy on the books, and it's legally required of a number of providers to have – to seek that authorization, there – that was the point at which we had the data segmentation hearing about existing technologies and acknowledged that more work needed to be done on the technical/standards side in order to give providers the tools that they might need in order to comply with legal obligations they already had.

Judith Faulkner – Epic Systems Corporation

Yeah. I remember that.

Deven McGraw – Center for Democracy & Technology

Yeah. So I would argue in fact that the S&I work and the pilot on data segmentation is a follow-on to compliance with – you know, facilitating – giving providers some capabilities they could use to comply with their existing legal obligations.

Arthur Davidson – Denver Public Health Department

Paul, this is Art. Didn't we have a discussion when we had the presentation about PCAST that we were working going to work as a Policy Committee to support some of the ideas there, and to explore those that we had not yet felt we fully understood? I thought the work that Doug's describing fits under that.

Paul Tang – Palo Alto Medical Foundation

I think that's truth. I think both of these comments, Deven's and yours, are relevant to this.

[Crosstalk]

Paul Egerman – Businessman/Entrepreneur

Yeah. And this is the other Paul. The PCAST recommendation was really to do testing and pilots. It was not – I mean, there were recommendations as it related to metadata. There were – that the Standards Committee were supposed to respond to, and they certainly did. And they responded in a really aggressive and impressive way. The PCAST recommendations did not include any policy recommendations relating to data segmentation. I mean, the PCAST ones that came from the Policy Committee.

Paul Tang – Palo Alto Medical Foundation

Right. So I think the question that Judy's presenting, Doug, is this is exploratory work. It's not a implementation. Is that right? Or potentially exploratory in conjunction with pilots?

Doug Fridsma – Office of the National Coordinator

We've been working very closely I think with Joy's group, and, you know, it's the reason that we have these conversations, is so that we can get input on the broad range of activities that are ongoing. Even with regard to the Structure Data Capture initiatives, we've always talked about stage three and future – and subsequent stages, to try to get to a learning healthcare system, and to try to incorporate clinical research in the activities that an EHR might be able to accomplish.

So we've taken a look at those things, and we've been working on trying to make – to be responsive. Sometimes it's easier for us to take a look and see how we can support some of those activities with our pilots and some of the work that's going on in the standards and then feed it back to the HIT Standards Committee and the Policy Committee and to really get that input to see whether we're on track, or whether there's additional work that needs to be done, or whether there's a different direction that needs to be taken. So in some sense, the transparency is helpful, because it makes sure that we're – we've got some of that dialogue that's occurring.

Paul Tang – Palo Alto Medical Foundation

So is it the sense of the group that we need a little bit more dialogue about this? I think what Deven is saying is there's a certain amount of segmentation, now that's a bigger level of segmentation that – than – it's a bigger section versus a granular segmentation on each data element, that has to be – that is required by some state laws, for example. And I think what Judy is alluding to is the more finely granular segmentation that could in principle go down to the data level. And then what Paul was saying is we hadn't made a policy recommendation about how granular to be, and I think the way it was left is that ONC would look at what are the standards needed and do some pilots about how feasible it is even to get granular. Is that a summary of where we are? And then the next question is is there further discussion the group would like to have to go back and forth between the Policy Committee and the Standards and/or – and ONC?

Paul Egerman – Businessman/Entrepreneur

And Paul, the other comment that I think Judy is raising, at least that I'm hearing, is not just data segmentation. It's the relationship between the Policy Committee and the Standards Committee. As I understand, the HITECH legislation is a – like a waterfall.

Paul Tang – Palo Alto Medical Foundation

Right.

Paul Egerman – Businessman/Entrepreneur

In other words, the Policy Committee decides and directs the Standards Committee as to what to do. This seems like there's a lot going on that we're just being informed, and that feels like a different approach.

Judith Faulkner – Epic Systems Corporation

That's it. That's exactly what I'm saying, Paul. Thank you.

Paul Tang – Palo Alto Medical Foundation

Okay.

Jodi Daniel – Office of the National Coordinator

This is Jodi Daniel. Both committees do make recommendations to ONC, so we don't have the Policy Committee directing the Standards Committee to take action based on the statute, but advisory committees make advice to us. There can be something that, you know, that ONC might ask – can ask of the Standards Committee even if the Policy Committee hasn't made a recommendation, if there's something that ONC wants feedback on. So generally yes, if we are – we have been having the Policy Committee sort of weigh in on the policy direction, and then – and using that as direction for the Standards Committee. But it's not – it's not the only – it doesn't mean that the Standards Committee can't talk about other things that we want feedback on that aren't – that haven't been specifically either addressed or resolved at the Policy Committee level. We do try to make the connection, but there can be some exceptions to that as well. So I just wanted to make sure that, you know, folks understand just how the committees relate to us and each other.

Judith Faulkner – Epic Systems Corporation

This is Judy again. I can understand that there's some exceptions, but it seems like there's a lot of big ones, and that's where I'm coming from. Usability, for example, is another very big one. I – maybe I'm forgetting, but I don't think – I don't recall the Policy Committee making policy on usability. Did we? And if so, then how do we get standards set on usability? Because I'm getting quite confused by that.

Paul Egerman – Businessman/Entrepreneur

And this is Paul. I mean, ___ also to what you just said, Jodi, and if there's places where there's exceptions or where you've made requests to the Standards Committee, I think you should tell us so that we can understand that. It doesn't feel like that's what's going on here, but maybe it is.

Paul Tang – Palo Alto Medical Foundation

I think in this – this is Paul Tang. In this particular issue, so data segmentation particularly as it relates to privacy, we do have another – I don't know what kind of – I don't know whether it's a ___ or just some advisory committee, but – so PCAST weighs in on this particular thing. So there's something where I think ONC is getting some input from multiple sources, so I can see how that's a little bit of an exception.

Paul Egerman – Businessman/Entrepreneur

But the PCAST situation is interesting because indeed, that was one of the pieces of feedback that came from the PCAST report, which was that there was a technical solution being offered in the absence of thinking through the policy implications.

Paul Tang – Palo Alto Medical Foundation

Right.

Paul Egerman – Businessman/Entrepreneur

And that's – it's a fundamental issue that you run into, where, you know, the standards people and the technical people may think that they have a great idea as to how to do something, and they may indeed have a very good idea as to how to do it, but it's just an issue of process that we should be deciding the policy part thoughtfully and carefully first.

Paul Tang – Palo Alto Medical Foundation

So is this something – is this a particular issue, data segmentation, something the Policy Committee would like to discuss further and potentially even with the Standards Committee chair or something, and ONC, to hash out a little bit more of the issues?

Judith Faulkner – Epic Systems Corporation

Can I raise it one level up first?

Paul Tang – Palo Alto Medical Foundation

Okay. Sure.

Judith Faulkner – Epic Systems Corporation

And that is should the Policy Committee be looking at the Standards Committee's standard setting and decide if in fact we think there are certain areas that it feels like there needs to be more discussion, they're big issues, and the Policy Committee should weigh in before the Standards Committee sets standards? And then going down from that, then we get to your question, which is then what about data segmentation?

Deven McGraw – Center for Democracy & Technology

This is Deven. I suggest that we take a look – I'm not adverse to having that conversation, but I suggest we do so in a very informed way, which is a more complete understanding of the statutory language in terms of authorities and responsibilities, as well as maybe people understanding sort of what we have already said on the issue of – on the policy issues related to special protections around certain types of data, and what technical capabilities might be either helpful or required in order to allow meeting that.

I sort of feel like, you know, we've got law on the books here, and a bunch of providers that are responsible for complying with that. I have a hard time seeing how – which we all expressly acknowledged in Policy Committee letters that went up to Dr. Blumenthal at the time regarding consent, and that were the precursor to the data segmentation initiative to start with.

So I'm just a little – I'm not certain what else there is for us to do about it, given that people with higher authority than us have already decided to create laws that require special protections for certain types of data.

Jodi Daniel – Office of the National Coordinator

Yeah. When we – this is Jodi again. When we look at – I mean, we look very strongly, as you all know, at the advice we get from you all as well as from the Standards Committee, and then there are lots of other things that are influencing the decisions we are making about how – the policies we're setting, as well as the way we're using our resources, you know, either looking ahead at some things that we think are important, or that are important for other parts of the department. Like Deven is saying, there are other laws that are in place that we know we need to address, or things we're hearing from folks that are trying to actually – who are in the trenches trying to implement some of the important work that we're trying to promote.

So, you know, I don't want to suggest – I do want to suggest that your input has a huge impact on the policy and the directions we take, and you've seen that in many of our regulations, etcetera. But there are also other things that we're taking into account in making decisions about how – you know, what direction we're taking on different things. Or there may be some other priorities that the department has that we are following through on, or that we might want the Standards Committee's input on, etcetera.

So it's not this – you know, I don't see, you know, that the Standards Committee can't do any work unless the Policy Committee says so. We're charging the Standards Committee, and we are using the input of the Policy Committee, as a very, very significant driver of that, but not the only driver.

So we can talk – I mean, I think – I would be happy to go back and, you know, talk about the advisory committees and the – you know, kind of what the charges are and that sort of thing, but, you know, I don't want folks to walk away thinking that, you know, that folks can't act unless we have a recommendation from the Policy Committee in that direction. It is a very important directive, but not the only one.

Paul Egerman – Businessman/Entrepreneur

So Jodi, has ONC asked the Standards Committee to work on data segmentation and on usability standards?

Deven McGraw – Center for Democracy & Technology

That's why – Paul, I'm – that's why I'm saying we should uncover the letters that we've already written on –

Paul Egerman – Businessman/Entrepreneur

No, but what I'm – Deven, what I'm understanding from what Jodi is saying is regardless of the letters, ONC may still be asking the Standards Committee to do something, which is perfectly fine. So I'm trying to understand are they doing that. Are they asking them to do these areas, usability and data segmentation? And it's okay if they are. I'm just curious to know if they are.

Jodi Daniel – Office of the National Coordinator

If we have specifically charged the Standards Committee on those topics?

Paul Egerman – Businessman/Entrepreneur

Yes.

Jodi Daniel – Office of the National Coordinator

Doug, do you want to address that?

Doug Fridsma – Office of the National Coordinator

We've been working very closely with SAMSA and the Chief Privacy Officer's office to come up with some of the technical specifications that help support kind of existing law. I think our goal is that because there are some technical specifications invested in that, we would like to get the input from the HIT Standards Committee to take a look at the work and to see if it fits into our portfolio of other standards that are there.

So in fact, most of the work that's happened within the standards and interoperability framework has been funded through SAMSA, and has been a great collaboration between my office, Joy Pritts' office, and the folks at SAMSA. So we just want the HIT Standards Committee to take a look at what's been done and to provide us their input and feedback about that.

With regards to usability, that's certainly something that we have heard, both from the HIT Policy Committee and others. There's been work with NIST to try to develop some criteria. We've been working very closely with the industry to get feedback about the best ways to handle that. And certainly for meaningful use stage two, there was the requirement to use sort of – or to at least document the design process, and to move towards more user-centered design processes.

I think, again, there's a lot of different ways that you could handle that. It would be useful to get lots of perspectives, and one perspective might be to talk to the HIT Standards Committee and see, well, what are the different ways that we might be able to do this?

Judith Faulkner – Epic Systems Corporation

This is Judy again, and I am concerned that if in fact what is designed for both usability and data segmentation is stuff that the vendors – well, first of all, usability, should it be designed by government committees is a really interesting question. And data segmentation, is it going to be technically feasible, that was one of the things that – are we beating the pilot on that? In other words, are we waiting until we are seeing in fact it really does work before we make the rules up to say this is what you need to do?

Jodi Daniel – Office of the National Coordinator

I'll start on the usability one. I don't think – and remember that the Standards Committee is only advisory to us. They are not creating standards. They don't get to set the rules. They are just giving us input into our thinking. So, you know, so I just want to make sure there's a clear sense that we are – you know, the Standards Committee does not set the standards, and then that's, you know, gospel.

That said, you know, so the issue about whether or not – you know, what we do with the input, and whether or not – what the government's role is in that, and how we address usability I think is still an open question, and we could have that conversation in the policy committee as well if folks want to. We did also hear about usability in the IOM report about safety, so it's something that we're hearing about from multiple different places, including, you know, a pretty significant and notable organization that we actually charged with giving us input on safety. It was something that they had included in their recommendation.

So it's – I think it's valid that we're asking for input on usability. The question about what we do with that, I think, Judy, is a really important one, and is something that we could talk about in the Policy Committee, if folks are interested.

Paul Egerman – Businessman/Entrepreneur

I think folks are interested –

[Crosstalk]

Jodi Daniel – Office of the National Coordinator

It sounds like.

[Laughter]

Jodi Daniel – Office of the National Coordinator

I'm hearing that.

Paul Tang – Palo Alto Medical Foundation

Well, so I'll just respond a little bit on usability. I think usability is something we've raised, certainly in meaningful use, and as Jodi pointed out, it was certainly raised in the IOM report on patient safety related to EHRs, and it's certainly probably the biggest thing we hear from the users, so the end customers of these systems. So I think we have asked for – we didn't have any bright ideas on how would you, quote, test for it. I know we said we can't prescribe the design for it, but you can – well, within stage two is you can – you can at least hear from vendors on how they're incorporating user-centered design in the product.

So it is an issue, and we have as a Policy Committee said that it's something we need to pay attention to. Right now, we're still looking for the most effective way to do it, and the least burdensome way. So I think that's something that did come from the Policy Committee.

So the discussion seems to be more – now are folks comfortable in – I'd like to hear from some other members of the committee as well – with Jodi's explanation, which is yes, in the statute, it does talk about HIT Policy Committee setting some of the priorities and asking for further input on some of these to the HIT Standards Committee. As Jodi pointed out, the Standards Committee also – it's advisory to ONC, and ONC can ask it for additional input and advice as well. Are people – is that a satisfactory answer, or is there further discussion you'd like to have in a different – in an upcoming meeting?

Christine Bechtel – National Partnership for Women & Families

Paul, this is Christine. I'm satisfied with that. I think that is very consistent with what the law says. I think part of the reason many people think there is sort of a cascade effect is because the law does task the Policy Committee with recommending a priority order of standards, implementation specs, and certification criteria, and it does sort of charge the Policy – I mean, the Standards Committee with, you know, responding to that, in a sense. But Jodi's right. It's a federal advisory committee, and we make recommendations, and, you know, the federal government can ask us to work on anything at any time.

So I'm fine with that. I think that it's less about what the law says and probably more about the – you know, the communication back and forth and the hands off, and not, you know, maybe giving the Standards Committee a huge hunk at one – you know, time, but being able to _____ that workflow back and forth, at least in a way that the Policy Committee understands. And so I think, you know, ONC has done a good job of late having Doug and his colleagues come and tell us what the Standards Committee is doing, and I think that's something that would be helpful to continue.

I think what probably – my sense is, what's a little bit new here is just that there's a lot that we're like, oh, because the work planning process was, I think, Jodi, fairly recently done, in the last couple of months.

Jodi Daniel – Office of the National Coordinator

Mm-hmm.

Christine Bechtel – National Partnership for Women & Families

You know, _____ presented that to us. So it feels like it's new, but it's a result of _____ process. So I'm fine with, you know, with proceeding.

Paul Tang – Palo Alto Medical Foundation

Other comments? And I'll come back to Judy and Paul on whether you'd like to talk further about – so it's not about whether Standards Committee can give advice on something separately, but if there's some concern that's raised about an activity, and if ONC would like to have further input from the Policy Committee, we can certainly discuss that.

Judith Faulkner – Epic Systems Corporation

I think it would be good to discuss, Paul, because I think it's really a matter of degrees that we're talking about, and what is each committee's purpose, as at least we see it, so that we have an understanding about that. So I think it'd be a good thing to discuss in the committee meeting.

Paul Tang – Palo Alto Medical Foundation

Okay. Jodi, what do you think about that? Are there –

Jodi Daniel – Office of the National Coordinator

Yeah. That's fine. Or, I mean, the other thing we could do is we could have a – just an administrative meeting to talk about, you know, how we – you know, what the authorities are and how – you know, kind of the process of getting things in and out of the committees, and passing things from one to the other, with ONC input in that. So either way. I mean, we could do it in a committee meeting, or if it's more efficient, we can also do an administrative call, perhaps. I defer to MacKenzie on that. But I think we probably could do that, if it's just about kind of the workflows and the authorities.

Paul Tang – Palo Alto Medical Foundation

So let me make – and I was thinking about that as well. Let me make one more clarification with Judy and Paul, who raised this. Is this more about the process or is it the topic that you're more concerned about? Because I think those are two different things.

Paul Egerman – Businessman/Entrepreneur

And my answer is yes.

Paul Tang – Palo Alto Medical Foundation

Okay.

Paul Egerman – Businessman/Entrepreneur

It's really both.

Paul Tang – Palo Alto Medical Foundation

Okay.

Paul Egerman – Businessman/Entrepreneur

It's both a process issue and – these are – it's like a pun. These are sensitive topics ____.

Paul Tang – Palo Alto Medical Foundation

Yeah. They are.

Paul Egerman – Businessman/Entrepreneur

Segmentation, the usability one, they're – it's both.

Paul Tang – Palo Alto Medical Foundation

Okay. So let me try this. Let's first start with the process piece, then, and let me take Jodi's suggestion that we have an administrative meeting just to understand the process, and as Deven said, let's make sure we understand what's in the statute. But it's – I think all that's been clarified during this discussion. But let's have an administrative meeting about the relationship with – this ____ committee, ONC, and the Standards Committee, and how we manage that. And then if there are leftover concerns about the topic, then let's figure out in the – in the full committee meeting how to – how to address those. And we are – we do serve at the pleasure of ONC, so they can say, you know, whether they would like some additional input on these two particular topics. Is that agreeable? To try the process first, to make sure we have a common understanding about that, and then deal with the substantive topics?

Paul Egerman – Businessman/Entrepreneur

Yep.

Judith Faulkner – Epic Systems Corporation

Yep. That sounds good.

Paul Tang – Palo Alto Medical Foundation

Okay. Thank you. Any other discussion about – related to the ONC updates? Well, thank you for both the updates and for the subsequent discussion, and we'd like to keep aligned both in the process and the topics. There are lots of these meaty topics, and we want to make sure that we're giving the best advice we can with the diverse representation we have.

All right. Why don't we open up for public comment, please?

Public Comment

MacKenzie Robertson – Office of the National Coordinator

Operator, can you please open the lines for public comment? And I'll just remind all the public commenters, it is a public comment portion. It's not necessarily required that the committee provide a response. And your comments will also be limited to three minutes, and I will be announcing when your time is expired. Thank you.

Operator:

If you are on the phone and would like to make a public comment, please press star one at this time. If you are listening via your computer speakers, you may dial 1-877-705-6006 and press star 1 to be placed in the comment queue. We have Josh Rising. Please proceed with your comment.

Josh Rising – Pew Charitable Trusts

Hi. Thank you very much. My name is Josh Rising. I'm the director of the Medical Device Initiative at the Pew Charitable Trusts. As you know, the FDA is developing a unique device identifier, or UDI, system for medical devices that will serve as the cornerstone for significant improvements in medical device safety and post-marketing surveillance. This UDI system will benefit patients, clinicians, and public health officials by providing for more rapid identification of medical devices associated with adverse events, assisting with prompt and efficient resolution of device recalls, delivering an easily accessible source of definitive device identification, and increasing efficiency through a more accurate accounting of the devices used.

However, to realize these important public health goals, healthcare providers and hospitals must incorporate UDI into clinical practice. Given the importance of this objective and uncertainty around whether providers will incorporate the UDI into electronic health records, we urge the Health IT Policy Committee to recommend that ONC and CMS include the capture of UDI for implanted devices as a stage three core meaningful use objective under the improving quality, safety, and reducing health disparities section.

Additionally, we also look forward to working with the HIT Standards Committee on our recommendation to capture UDIs in the next update of the EHR standards and certification regulations.

Further, while we support meaningful use proposed objective SGRP408 to electronically transmit adverse event reports to the FDA and CDC from the EHR, we believe the Health IT Policy Committee should recommend this criteria in stage three, and not as a future stage objective. This objective should also clarify that adverse event reports for medical devices include the UDI of the associated medical device.

Prompt accomplishment of these goals related to UDI and improving the post-marketing surveillance of medical devices will require recognition from outside experts, such as this committee, of the importance of UDI adoption in improving patient outcomes. Thank you very much for considering our comments.

MacKenzie Robertson – Office of the National Coordinator

Thank you. Are there any more public comments?

Operator:

We have no more comments at this time.

MacKenzie Robertson – Office of the National Coordinator

Okay, Paul.

Paul Tang – Palo Alto Medical Foundation

Yep. Thanks, MacKenzie, and thanks to the committee members, again, for making changes to their travel plans and for fully participating on this virtual meeting. And we look forward to our meeting in person in April, where we will have quite a hearty agenda. Thank you.

David Bates – Brigham and Women's Hospital

Paul, could I just make one last comment?

Paul Tang – Palo Alto Medical Foundation

Yeah. _____.

David Bates – Brigham and Women's Hospital

This is David Bates. I just want to say that I strongly support the last comment. It's very exciting to see the UDI finally come of age. We heard _____ yesterday at a meeting in Washington from Tom Gross from the FDA about this, and I'd like to see us move forward with this.

Paul Tang – Palo Alto Medical Foundation

Okay. Thank you. All right. So thank you, everyone, for your participation, and we'll look forward to all the work that's going to go on between now and then, including the response to the RFI, and we'll see you in April. Thanks.

MacKenzie Robertson – Office of the National Coordinator

Thank you, everybody.

Deven McGraw – Center for Democracy & Technology

Thank you. Bye bye.