

HIT Policy Committee Final Transcript September 14, 2011

Judy Sparrow – Office of the National Coordinator – Executive Director

Good Morning everybody and welcome to the 27th meeting of the HIT Policy Committee. This is a Federal Advisory Committee which means there will be opportunity at the end of the meeting for the public to make comment. Also, the minutes of the transcript of the meeting will be posted on the ONC website and just a reminder for committee members to please identify yourselves when you're speaking so members of the audience on the web and on the phone can understand who is speaking. Let me go around the room now and introduce members of the table starting on my right.

Jodi Daniel – Office of the National Coordinator

Jodi Daniel – Office of the National Coordinator

Robert Tagalicod – Centers for Medicare & Medicaid Services

Robert Tagalicod – Centers for Medicare & Medicaid Services

Larry Wolf - Kindred Healthcare

Larry Wolf - Kindred Healthcare

Deven McGraw - Center for Democracy & Technology

Deven McGraw - Center for Democracy & Technology

David Lansky – Pacific Business Group on Health

David Lansky – Pacific Business Group on Health

Judy Faulkner – Epic

Judy Faulkner – Epic

Paul Egerman – Software Entrepreneur

Paul Egerman – Software Entrepreneur

Paul Tang – Palo Alto Medical Foundation

Paul Tang – Palo Alto Medical Foundation

Neil Calman – Institute for Family Health

Neil Calman – Institute for Family Health

Gayle Harrell – Representative State of Florida

Gayle Harrell – Representative State of Florida

Marc Probst – Intermountain Healthcare

Marc Probst – Intermountain Healthcare

Christine Bechtel – National Partnership for Women & Families

Christine Bechtel – National Partnership for Women & Families

Art Davidson – Denver Public Health – Denver Health

Art Davidson – Denver Public Health – Denver Health

Madhulika Agarwal – Department of Veterans Affairs

Madhulika Agarwal – Department of Veterans Affairs

Scott White – 1199 SEIU

Scott White – 1199 SEIU

Judy Sparrow – Office of the National Coordinator – Executive Director

And I believe we have a number of members on the telephone Farzad Mostashari?

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

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. Connie Delaney? Charles Kennedy? Is anyone else on the line please? All right with that I'll turn it over to Dr. Mostashari for opening remarks.

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

Good morning. Good morning. It's an exciting time, we have, this is National Health IT Week and for the first time ever we have a presidential proclamation that acknowledges the importance of health IT and its place in having the kind of healthcare delivery that we want and our patients deserve. It also marks that on Monday we launched the consumer eHealth part of ONCs activities, but more importantly we recognize and brought together leaders across the country who are making it easier for people who want to get their own information to do that, and we clarified that, we heard it from Leon Rodriguez, the new Director of the Office of Civil Rights, that it's their right, but more than just their right that it is a key step towards giving consumers giving patients really the tools to become more empowered and more engaged consumers of healthcare, managing their own health, being better partners in taking the care with their providers and helping with coordination of care. We also announced the Notice of Proposed Rulemaking...CMS and others that clarifies that the HIPPA rights to obtain a copy of your own records or covered entities does apply to laboratories, this is obviously going to go through the rulemaking process and we'll hear a lot but our, the administration's position, going in position, is that patients should have a right to their own information from laboratories as well from providers and health plans.

We heard pledges on Monday from a wide range of organizations not just those who are holders of data, but also from groups like a consumers union and AARP, and the Nursing Association who stated strongly, and I think this was, of all the announcements, maybe the most potentially transformative was they pledged to reach out to their 3 million nurses in the country and engage them and help them be the soldiers in the field who engage consumers and fulfill the traditional roll that nurses have always played as advocates for patients.

We also, boy there's a lot going on this week, on Monday, sorry on Tuesday, yesterday, we also saw the launch of the Million Hearts Campaign. We've been, in this committee we have talked a lot about what our goals are for, concrete goals, for the framework for Meaningful Use and for the HITECH implementation and reducing avoidable deaths, premature deaths, was clearly one of highest priorities for us and it was reflected in the structure of Meaningful Use and in the detailed requirements for Meaningful Use and with the recognition that it's heart disease, cardiovascular disease, heart attacks and strokes that make up the largest portion of avoidable deaths and that we are not doing enough as a country to take steps that we all know, that a 3rd year medical student knows, are the things that we should be doing and yet we collectively provide those services, provide those outcomes for our patients only less than half the time.

So the Million Hearts Campaign I think underscores its focus and energy to that vision that we have had and links us to a much broader public and private campaign to focus like a laser beam on cardiovascular disease. What are the implications of this? Well one of the things that was mentioned was harmonizing quality measures, taking aspirin, blood pressure, cholesterol, and smoking quality measures, and making sure that no matter what the program is, no matter what the, whether it's across the range of Medicare Programs, whether it's across states, whether it's for private plans, that they will say let's use, if there's a core to quality measurement, let's make sure that these key measures that relate to cardiovascular

prevention are in that core and let's try to define them the same way across different programs. So that's the vision, it will take time of course to realize that, but there's a clear commitment on the part both of the private sector and public sector to do so.

So, very exciting week here that and plans that we're...I want to take this moment to, you know, we are always looking forward, looking up at the, up the hill that we have to climb, the mountains beyond mountains that become visible but once in a while it's good to look back and take a breath, enjoy the view, look at the vistas that are spread out before us and it is remarkable, truly remarkable how in such a short time since, really if we think about, since the launch of, for example the health IT incentive payments, how fundamental a change is coming to the delivery of healthcare and in a way that is thoughtful, that is, takes into account the kind of care we really want to see not just to focus on the technology.

And as we take a look back and recognize that this committee itself was only created recently, although I'm sure for many of the members it seems like they've been taking part of these meetings forever. I want to recognize one person who really has been the heart and soul of this Federal Advisory Committee on the Health IT Standards Committee and that's Judy Sparrow, who really was there from the beginning, and as many of you have grown to know and appreciate the amazing work she does with the committees, with the chairs and co-chairs, with the agendas, with the membership and keeping the process going as only somebody who truly believes in the process, truly believes in the open democratic and transparent and inclusive process that, of government getting advice from the best minds in the world and in the private sector, and making our policies, our regulations better through listening, and she has been a believer in that all of her long career in the federal government and she is retiring at the end of this month. So we want to stop and pause and let us applaud Judy for her service.

(Applause)

Judy Sparrow – Office of the National Coordinator – Executive Director

And I won't take up any more of the agenda, but I really could not have said that better myself on what this committee has done and what it continues to do and I would just add one more thing, to me the civility with which they have conducted their affairs has just been outstanding, I mean it's a real lesson on how government and private sector can work together in a very meaningful way. Thank you all very much; it's been an honor and a pleasure, thank you.

(Applause)

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

The work will go on and we are grateful to have Mary Jo Deering who many of you also know and also has been a long-time true believer in the federal government of working with the private sector, working with researchers, working with many of you here for many, many years and has been an active part of so many of the workgroups and everything from the early days with Meaningful Use to more recently the governance and privacy and security work that we've been doing. So, Mary Jo has graciously agreed to step in during the transition period while we look for a, try to look for someone who can permanently fill the shoes that Judy Sparrow leaves. Thank you also to Mary Jo.

(Applause)

That's it. Thank you.

Paul Tang – Palo Alto Medical Foundation

All right, thank you very much Farzad and congratulations again for all the events happening and especially the Monday Consumer Health IT Summit that really went off very well and it's a good start to embracing the consumer participation in health and this entire initiative. So, thanks Farzad and good luck on your, I think you're in Oregon right?

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

Yes.

Paul Tang – Palo Alto Medical Foundation

Your Oregon activities. Maybe from the top of Mount Hood.

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

I'll be sending out some tweets so you all can follow what's going on here.

Paul Tang – Palo Alto Medical Foundation

Thank you. And Claudia or Hunt are you on the line?

Claudia Williams – Office of the National Coordinator

I'm on the line.

Paul Tang – Palo Alto Medical Foundation

Great. I know you have a hard stop so we'll go ahead and continue with your part of the program.

Claudia Williams – Office of the National Coordinator

Great and I'm also from Oregon here and delighted to be joining all of you. I just want to, just check, Hunt are you on the line as well?

Hunt Blair – Deputy Commissioner Division Health Reform Department of Vermont Health Access – Medicaid

I am, good morning.

Claudia Williams – Office of the National Coordinator

Fabulous. Okay. So what we wanted to do this morning in just a short period is give an update on experience and challenges and sort of the bends and the curve we see in the HIE program and then really give Hunt a chance to talk about not just implementation of the HIE and HITECH programs in Vermont but also how they're knitting together that work with the health reform and healthcare transformation work they're doing in a state and I think Hunt has a couple of slides to share and a lot of insights as well. So, I'll just speak for a few minutes, Hunt for a few as well, and then we'll hopefully, a bit of time for questions at the end.

So, I think, as we talked about before, and really thanks to the work all of you have done, the goal of the grant program is not in any way distinct from Meaningful Use. We are completely driven by the objective of getting supporting providers, small providers, large providers, hospitals, in achieving the Meaningful Use objectives, the exchange objectives. So, if you think about the priorities that we're focusing on their lab exchange, care summary exchange, supporting pharmacies in participating in ePrescribing, and public health reporting. And so, you know, the last year has really been about helping, working with states to get really concrete, tangible implementation plans against these basic objectives.

So today I want to just focus on the second, care summary exchange, and really I'm using that term to lump together, you know, hospitals sending discharge summaries and the requirement that docs feel to share care summaries as well. So, if you remember from our, where we ended in MU Stage 1 it was that you could use many different methods to achieve that simple sharing of a care summary or collective transition, but we're really trying to do is drive ahead to what we expect to be, you know, hope to be the requirement that that be and electronic exchange of information.

So, let's now look at the landscape for a minute. You know, we have real capacity developing, HIO capacity developing in a lot of communities, certainly hospitals have developed their own exchange capabilities often with their docs, but what's interesting is if you look at the, ask the question, can Dr. Smith and Dr. Jones send each other information about a patient as the patient is transitioning to have a

test, to get a referral, whatever, you know, very few of those existing...support that capacity. In many cases what we have is the aggregation of hospital data that can be queried by a doc, but really no way for two docs to share information. And nationally, we know that about 22% of hospitals are currently exchanging clinical information with unaffiliated providers. And yet this basic challenge that that kind of very fundamental task, of exchanging information, having information follow patients within or through the system, we have a lot of gaps in being able to achieve that. And that's a big part of the implementation list right now.

So, as I've mentioned before about four main states or so, it changes a little bit day to day, have direct strategies, are thinking about how to use the direct protocols in particular to support the basic question of how Dr. Smith and Dr. Jones can share information about a patient as that patient moves through the healthcare system.

And, so I want to talk a little bit about the kinds of approaches and strategies they are using and some of the challenges we're seeing as we move forward with that look. So, I think the kinds of strategies we see really vary depending on the existing capacity within this space. So, in a lot of places like in Texas we see...of the data. If you look at the map of Texas you see the whole western front, Lubbock and...area very little capacity to exchange information, lots of, you know, merging areas in the city areas of Houston and Dallas, and Austin and those areas, but very little capacity in the west. So, you know, a lot of states are thinking about their direct strategies as a way to get the last mile to the small providers if the...states that exist in this place. Not just, obviously, in those rural areas, but also in urban areas where people don't have HIO or HIE capacity.

Second, you know, we're seeing states like Tennessee, a variety of states, where there are nodes that exchange that are quite, quite well developed but there hasn't historically, Indiana is an example, in a way to allow exchange across those nodes. So I'm a doc in one, Rio, you're in another one, highly exchanging information, so also is direct to really being thought about as a way, a lightweight way to enable that kind of node to node data, and it may not actually root through to Rio itself but maybe something we do directly with direct but a way to move across the nodes and get information flowing literally across the state.

And, finally, and this is I think really interesting, it's also being launched as a way to jump start a more robust exchange approach or be a complement to that. So for instance, in Rhode Island, working with their kind of well-developed policy infrastructure and their opting consent approach they're basically enabling docs using their EHRs when they send a care summary to another doc for a patient transition, another copy of that message can be sent through the kind of consent filter and then populate the repository they use for query. So, we sort of see these 3 modalities of use of direct going on right now and lots of interesting experiences and challenges and exciting success in all three.

Another strategy that states are using is really starting with those local...or local HIOs and asking how can we more rapidly build the capacity for getting some basic MU requirements within those places where trust is already developing where there's a business case that's underway and in many cases states are directly funding or supporting those local efforts. I think some of the opportunities we see are really, again, to focus on Meaningful Use and that has sometimes been a bit of a challenge because, you know, communities come in with their own preferences and ideas to where they want to go and I think part of the art is finding ways to build a pathway both to get to MU exchange requirements, which I think are the basic fundamental building blocks, but also have an approach to get to the things, the hopes and needs you have moving forward.

I think what we're seeing that's quite interesting for those states that are pursuing this model, and again Texas is an example, and in some ways Rhode Island is, there are a variety of others, is actually defining the qualification criteria both from a privacy and security stand-point and also from an interoperability stand-point. So things like, you know, what are the basic standards you need to have developed, what are the baseline policy requirements that we want of these different qualified entities, how is it again that you will share information not just within but also across, and as you can see when you start asking those questions those are a very parallel set of questions that we've been asking about NwHIN governance

through this body. So we're really quickly not just trying to support those efforts but also learn what they're doing, what their experience has been and trying to feed that information back into our governance work.

So, I know we just have about 50 more minutes, so what I want to do now is transition directly to Hunt and the work he is going to share about Vermont and the progress they're making there, and then when he's done let's open for questions, hopefully we'll have a few minutes at the end. So thank you very much and Hunt I pass the baton to you.

Hunt Blair – Deputy Commissioner Division Health Reform Department of Vermont Health Access – Medicaid

Great. Thank you very much Claudia. Good morning everyone thanks for the opportunity to join you virtually. I'm with...out here in Oregon at the kick off their HIE big strategy launch in session today that we're excited to participate in. I would also mention that Vermont participated Monday in an event around putting the I in H. and took the Blue Button Pledge and I'll talk a little bit about that as we go forward.

As many of you know it's actually and artifact of Vermont's State Health Reform Legislation that I'm required to use this slide in every presentation that I do. I'm not going to go too far on this, but just to make a simple obvious, but I think very important point, is that as we're building out the distributed network of health information exchange I think this is particularly important given the points that Farzad raised earlier about getting the individual in H, but all of the nodes in the distributed network of HIE are equal, at least at the metaphoric level. I certainly understand that at the technology level it's a little bit more complicated than this drawing indicates, but I think that, you know, it's important to recognize that part of what we're doing is leveling the information exchange playing field, you know, doctors, hospitals, insurers, individuals all on an equal footing, and that that flattening effect really, you know, it's something that is important, but it does run against the typical hierarchy of the healthcare business model and so HIE is by its very nature disruptive to the ecosystem, but certainly I think disruptive in a creative way.

So, in Vermont we really, health reform is our main HIE use case as H has been embedded in health reform really from the outset. We look at H and HIE to enable the kind of communication and linkages between the various components and elements of the healthcare system that are currently all too frequently not as tightly integrated and knit together as they ought to be. So we have a couple of core design principles, first that all Vermonters should have their own blueprint for health as the name of our approach, a blueprint, primary care medical home, that all of those medical homes are connected through something that we call community health teams that provide linkages not just for subpopulations and specialized groups but really for all the general population to be the glue connecting primary care with the rest of the healthcare and social services system with a goal and a phrase that I've stolen from colleagues in Minnesota "that fragmentation of care should be a never event." And that really, that logic, building that kind of system that extends in our case not just to healthcare per se but to the entire states enterprise and our Human Services Program and we really feel that HIE is the vehicle that can ensure that kind of connectivity and communication.

So, I indicate here in the slide it seems to be just the Vermont way that we, we're just all about integration, about pulling things together, systemness has been from the very outset in Vermont, modern era of Vermont Health Reform, a key design principle, and as we've evolved through the years another important principle related to HIE is that the more we're really building a fully integrated technical infrastructure. So, just a click in the slide here. So, I'm not going to go through this in detail, but just to say that the components of our model, are these advanced primary care medical homes, the community health team, and then targeted services for complex cases that, again are all linked and that what we use is the information technology, a combination really of direct, of the exchange and of web based clinical data repository to ensure communication across that spectrum.

So, turning for a moment to how we're integrating this with the state and there's a, I'm going to do the 30 second version of a much longer presentation, is that we're taking very seriously the CMS charge in the 7 standards and conditions to really look towards leveraging and re-using our IT artifacts. So, we're standing up our core enterprise resources in the state that will include both a master persons index and a

state provider directory, we'll be utilizing these for our eligibility system, for our MMIS Medicaid Claims System, and for the new insurance exchange and importantly for our conversation here, also supporting the health information exchange network.

So, what you can see building out here is our blueprint IT systems, the clinical data repository that links to the community health teams, also the infrastructure for our public health and then obviously connecting all of that, and I know this is a little hard to see, but basically what all those pink boxes are, are the various providers and we've taken the approach, in Vermont, that we're not just connecting eligible hospitals and eligible providers, but we're connecting everything, so long-term care, mental health, home health, and significantly also human service providers, we have a really, a very exciting innovative program where the community health teams themselves are being expanded to have staff who are located at public and nonprofit, and housing sites where they're able to help coordinate care there and of course are instrumental for keeping people at home longer and having much better transitions when they do go into the hospital or rehab when they come back to be, again as fully integrated and connected as possible.

We also have, as part of this infrastructure, evaluation and analytics. We are a state with a Multi-Payer Claims Database. We have partnered with the University of Vermont on an informatics platform that brings together both claims data and clinical data for analysis of both the blueprint and also for doing modeling for the future global budget and single system enterprises that we're moving toward. And okay, so, the final point that I wanted to make because Claudia invited me to say anything beyond HIE is, that this is a slide or table that many of you have seen. I'll just say, very briefly, that I think it's a great opportunity, as we look at all of federal health reform and the great work that is being done by various federal partners, to really drive alignment, not just the quality measures and quality metrics, as Farzad was eluding to earlier, but really how the key data elements are recorded in electronic health records.

Now, if we have through the EHR certification process for instance, the opportunity to have certain key data elements, blood pressure for instance, recorded not as text but as computable values in every EHR then that's going to really provide us with an incredible power in terms of being able to compare and contrast the clinical data that is coming out of this ultra-large scale system of ubiquitous health information exchange that we're building. So with that I'll conclude my remarks and again, thanks very much for the opportunity to share what we're doing in Vermont.

Paul Tang – Palo Alto Medical Foundation

All right. Thank you both to Claudia and Hunt. And I'd like to open it up for any comments or questions from the committee. Paul Egeman?

Paul Egeman – Businessman/Entrepreneur

Great job. This is Paul Egeman. Thank you very much Claudia and Hunt and great presentation and first I want to compliment you Hunt and the people of Vermont for including the insurance exchange in your overall architecture with health information exchange and I think that's great. I just had a question, Hunt, which is how are you financed other than ONC grants?

Hunt Blair – Deputy Commissioner Division Health Reform Department of Vermont Health Access – Medicaid

Excellent question. So, back in 2008 the legislator in Vermont passed what we call the H assessment it's a 2/10 of 1% fee on top of all major medical claims, so what we do take the data that comes in to the Multi-Payer Claims Database for the prior year and generate a report and then invoice on a quarterly basis all carriers that have more than 200 covered lives in the state and utilizing that resource, which is now up to about 3 million dollars a year we're able to help support in addition to the funding that we're getting from ONC and in the hopefully pretty near term also funding from Medicaid, able to support this infrastructure. We do have the long range plan to also have fees for providers utilizing the system, but the policy decision that was made a number of years ago was that it was really better to build out the infrastructure and demonstrate the value on the front end before trying to finance it through sometimes somewhat skeptical participants. So, we've had great experience getting really substantial buy in. We'll have, for instance, all of the hospitals in the state will be fully connected sending, most labs in Vermont

are done by hospitals, labs being transmitted, and at this point we actually have 40% of all Vermonters who are served by our blueprint medical homes also are connected to the exchange.

Paul Eggerman – Businessman/Entrepreneur

That's very helpful. Could you give me an estimate, 2/10 of 1% of the claims, what is the dollars that that generates annually?

Hunt Blair – Deputy Commissioner Division Health Reform Department of Vermont Health Access – Medicaid

This year it will be about 3 million dollars, remember we're a tiny state, 625,000 people.

Paul Eggerman – Businessman/Entrepreneur

Okay. Thank you very much.

Paul Tang – Palo Alto Medical Foundation

David Lansky?

David Lansky – Pacific Business Group on Health – President & CEO

Thanks Hunt and Claudia, its David. My question, I guess for both of you, Claudia you described this very pluralistic environment around the country where different states, whether it's a smaller state like Vermont or a big state like Texas, have different HIE strategies and constraints and needs, but it does seem from Hunt's presentation like Vermont has, because it's a more trackable geography and scope, you're able to do some really wonderful things with integrating across programmatic areas and technology areas, and kind of being a vanguard for the rest of us who have different kinds of environments like California and Texas. I guess I'm wondering should we at this committee be thinking about a way of leveraging the really great leadership efforts of places like Vermont and I'm thinking specifically about the policy side of it, the development of uniform policies. Claudia you mentioned criteria or certification bases for inclusion in these exchanges or federated models, who gets listed in the provider directly and what the criteria are for its data list, data or maintaining ones functional role in that directory, the templates and business agreements among partners in the exchange who are at different levels kind of commitment and closeness or farness from the structure of the distributed model.

Is there, and Claudia can you talk about how ONC sees it, or Hunt can you say how you see your own opportunity to be a teaching site for the rest of us so we can take advantage of what you're doing?

Hunt Blair – Deputy Commissioner Division Health Reform Department of Vermont Health Access – Medicaid

Well, I'll jump in, I mean I think that you put your finger on it David, that, that, there, I think there is an opportunity for the Policy Committee to weigh in on the role of government, probably federal and state, to provide policies that set a framework. I mean it's kind of the same thing as narrowing in on some of the standards and defining those. I think that there's plenty of room for innovation in an environment where some of the boundaries of that environment are defined and I think exactly some of the things that you listed with regard to provider directory and participation, and various elements of governance are appropriately something that government can weigh in on. I realize speaking today in our nation that not everybody agrees with that approach and role of government, but I think that it's at least worth making the case that in order to advance, I think the thing that we can, regardless of political persuasion, the thing that we can all agree on is that in order to get a handle on the rate of growth of costs in healthcare we've got to have data liquidity. We can't move from volume to value based payment without the information infrastructure there, and we can't have a true information infrastructure without some agreement about at least some of the boundaries of how that happens.

So, it's, you know, it's my mission here today in Portland is to talk to folks in Oregon about why we think that health reform and H Policy are absolutely one in the same, and so yeah, I think that I would strongly encourage the Policy Committee to weigh in on that point.

Claudia Williams – Office of the National Coordinator

So, this is Claudia. Just a second, I guess I see at least 3 areas where that might be particularly productive. One, at a policy level to think about how our work intersects with healthcare transformation work, whether the exchanges or whether ACO efforts at the state level, and so I think there could be just asking a question of how the pieces are intersecting and each intersects both in a national policy level and a state level.

I think second though is to actually dig into some of the efforts going at the state level like you said for the vanguard states, in an effort to expose and reveal the kinds of issues and challenges, and opportunities that we're finding from those that are pushing the fastest and the hardest, and you know, here out in Oregon the government, they passed PPO legislation which is like ACO legislation and they're in the process right now of drafting the H. and HIE requirements that would be built into the expectations for every one of these accountable entities. So, I think there's hope.

I think we need to almost step up and say okay how does HITECH both provide a roadmap and interact with these other things that are going on, but secondly, how can we really, at a fairly granular level learn from what's going on at the state level, understanding that not every state is going to use their government powers the same way, but that there's some generalizable opportunities and challenges that I think could be really useful for us to consider.

Paul Tang – Palo Alto Medical Foundation

Thank you and Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you so very much and I'm totally fascinated now, you're going to have a phone call from me when the meeting is over when you get back from Oregon I can guarantee it. Certainly, many of our states, and being a state legislator I can tell you this is a big issue in states and making these decisions and how we move forward and the next year is going to be absolutely critical in the development of HIE. I think that probably the pivotal thing that will happen at the state level or not happen at the state level. There's a whole lot of resistance and there's no money. So, it's going to be very, very challenging and I think if perhaps Vermont and other states who are those bellwether states, who are those beacon communities, and perhaps our committee could come together and pull some of that information for other states to use would be extremely helpful to states to do it.

I'm interested in really 3 basic things and perhaps Claudia or Hunt you could expand a little bit more on what Oregon, I mean what Vermont is doing and perhaps what Oregon is doing since they're just really kicking theirs off, is the funding aspect you've addressed and funding is critical. States do not have money to do this and the grants will run out very soon, you know, the money's there, it's going to be built in infrastructure but then it's gone. So money is key to making this happen.

Governance, the decisions that how you're going to set this up and how it's going to operate. Who are the decision makers, is this a state entity, is this a public/private corporation and who are making the basic governance decisions?

And then, the same thing I keep harping on, privacy and security, and how are those decisions made in the privacy and security framework that you've established in Vermont, are they set by the state, are they set by each individual node, are there clear policies or even requirements on privacy and security? And I'd appreciate your comments on those.

Hunt Blair – Deputy Commissioner Division Health Reform Department of Vermont Health Access – Medicaid

Sure, so the governance is actually very interesting because the original model in Vermont back in 2005 was that the state delegated authority both for policy and infrastructure development to an organization called VITL Vermont Information Technology Leaders, which is a 501(c)(3) organization. After the H. fund was established, the claims assessment that I described earlier, and then sort of, even more amplified by passage of HITECH, there was a decision by the legislator and the administration that delegating policy authority to VITL was perhaps burdening them with more than was really fair and to a

certain extent impeded their ability to function operationally because they were spending so much time on policy. So in 2009 the state passed some new legislation very closely modeled on the HITECH Act placing responsibility for policy governance back inside state government and operational governance with VITL, which is authorized in statute to play the role that it does, and so we have an extremely close partnership in the case of the section 3013 funding program that Claudia operates, we the state are the grantee, we turn around and subgrant most of that funding out to VITL. We work just absolutely hand in hand in terms of ensuring that the kinds of state policy and vision that I described are implemented by VITL.

And in terms of the privacy and security framework, originally back when VITL had the role to develop policy they developed a set of policies, privacy and security policies, which they required all participating providers to adopt so all the nodes to have, if not exactly the same forms, the same general content in their policies. When the legislation in 2009 brought policy authority back to the state we adopted those privacy and security policies that VITL had developed as the state policies. We have subsequently and are currently in the process now of reviewing and revising the consent policy. We're doing that through a process, a governance process where I as the state H. coordinator have convened a workgroup, which is, you know, broadly representative of all the, you know, usual suspects that you would expect to participate in that.

We're making some revisions to the consent policy which will then, once they are formally adopted and approved within the state hierarchy, which is interestingly outside the legislative process, so the legislation gives us the authority, gives the administration the authority to implement and oversee policies without having to go back and codify it in statute, which I think obviously gives us a little bit more, makes the process a little more nimble than it would be otherwise. So, that has proven to be a good structure, a good framework and division of labor if you will, between the state and VITL and a good partnership.

Paul Tang – Palo Alto Medical Foundation

Thank you very much and thanks once again to Claudia and Hunt for your very informative update. I know that you have other things to get to out there in Oregon so we'll move on the agenda and thanks again.

Claudia Williams – Office of the National Coordinator

Thank you.

Hunt Blair – Deputy Commissioner Division Health Reform Department of Vermont Health Access – Medicaid

Thank you.

Paul Tang – Palo Alto Medical Foundation

At this point I'm going to do the review of the agenda and really as far as I had mentioned, I think at the top of the agenda for this meeting is a tribute to Judy Sparrow, she's put in 20 years of dedicated service to this country and all of us who work with her just realize how big a contribution that's been. I've been in public policy for over a couple decades and the pace of things going on, certainly globally and nationally, but the pace of things going on in HHS and the Office of National Coordinator is dizzying and the ability, their ability to keep up with this and to keep the, both the regs and the execution of these things, everything from the grants like we were talking about in HIE to Meaningful Use and the money that's going out already I think is half a billion or something, is just amazing, and it shows how much can be accomplished within the federal government.

It's really been a privilege for me, and I know every person on this committee and the workgroup, to be able to work with Judy. That amount of dedication and expertise, the meetings come off seemingly flawlessly, but it's amazing what it takes to get, it just looks like its smooth operation. We have hearings where we bring people from throughout the country. Sometimes it is brought together, you know, workgroup chairs, whatever, say we need to have this in 3 weeks and the amount of work it takes and really the expertise it takes to just make that happen is awesome, and Judy makes it happen. It just, she makes it happen. It comes every time for the past however many meetings we've had, hundreds, it just

happens because of Judy. So, really when I first heard it was, I guess only a millisecond of happiness for her and her retirement, and then it went into the stages of denial and I'm still, every time I write an email I'm still in denial, because it's just been so incredible and I know that the FACA Committees all recognize we couldn't have done our work without you and the amount of, and her contribution to the office. So, thank you very much, Judy.

Applause.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. Thank you.

Paul Tang – Palo Alto Medical Foundation

The rest of the agenda, we had to squeeze in a couple of our folks from ONC and Farzad out at the beginning of the agenda because they had other commitments in the work in Oregon. So, we're going to continue after this on updates from ONC. A lot of again, dizzying array of activities going on. There's, and so Jodi is going to update us. The strategic plan just got approved earlier this week. The consumer e-Health summit came off on Monday and there's other activities going on in the data, integrity and fraud detection prevention that she is going to update us on. Then privacy and security has yet more challenging subjects that they've been wrestling with and their bringing to us some recommendations to approve. We'll have a brief lunch and then continue on with other activities going on in ONC, in particular Query Health, which is a distributed way of bringing together information into these quality reports. And then finally the CMS is going to update us as they do every month on what is going on in terms of particularly in the Meaningful Use Program as increasing number of providers, hospitals, and eligible professionals report in on and attest to their Meaningful Use.

So before we move on with the agenda I would like to get an approval of the minutes from last meeting.

M

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Paul Tang – Palo Alto Medical Foundation

Okay...okay, any further discussions. There were a couple of missed attributions that have been corrected, but, all right, all in favor?

All

Aye.

Paul Tang – Palo Alto Medical Foundation

And any opposed or abstain? Thank you very much. And so now we'll move on to Jodi and her update on the activities going on in ONC, or some of the activities going on in ONC.

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Good morning. Is this on? Okay. Yes, this is just a very small subset of all the activities going on at ONC, but there were a couple of things that are very timely that I wanted to bring to folks attention and to talk through and just give a little more detail. Some things that you all have been involved with, so I want to kind of close those loops and some things that we may want to hear from you about, so that's sort of the flavor of things that I'd like to talk about. Okay, so the 3 things that I'm going to talk about today are the strategic plan, the Consumer e-Health Program launch and to give a little bit more information, I know Farzad kind of gave people a little bit of the overview and flavor of our Consumer e-Health launch that we had on Monday, but given the timeliness of our meeting after that event I wanted to spend, and the interest of the committee in consumer e-Health issues, as this has come up many, many times, I wanted to give that a little more attention. And then the third is data integrity and fraud detection and prevention, this is an issue that has come up many times when we talk about health IT over the years and we wanted to just talk about what activities we have done in the past and see if there are some areas that we should be prioritizing and to get some feedback from the Policy Committee.

Okay, so starting with our strategic plan. So, this is just a refresher. We released our plan in March, a draft plan in March based on the fabulous input of this committee and we put it out for public comment. So these were the goals that we had set forth, 5 goals, focused first on achieving Adoption and Information Exchange through Meaningful Use of Health IT, Improving care, improving population health, and reducing health care costs for the use of health IT. Three, inspiring confidence and trust in health IT. Goal four, this was the consumer empowerment one, empower individuals with health IT to improve their health and the healthcare system, and then the fifth one is achieving an rapid learning and technology advancement learning healthcare system. So this was the framework. We did just release our final strategic plan on Monday as well. It was a very big day for all of us and I think we have made some friends or enemies even in the department through all the things that we had to put forward at the same time. But, we did get out our final plan on Monday, which basically stayed pretty much intact from where we had it in March, but we did get a lot of really good comments and we did make some changes so, I just want to highlight some of those.

We received 240 comments on the plan, many of them were very detailed and went through a lot of different pieces of the plan, but we still have the same 5 goals and this is now a final plan and I'll talk a little bit about what we're hoping to do with it because we're trying to think about this in an innovative way that leverages technology to keep our plan fresh and up-to-date. So just briefly, I wanted to cover a couple of the things that were changed. I did a blog on our website on this so there's a little bit more detail if folks want to look at this more and point out some of the issues, but I wanted to just highlight them for you all.

Probably one of the areas that we got the most comments on, as usual, is privacy and particularly consent management. So, we highlighted that. We've actually commenced a process in HHS for exploring privacy and security policies to ensure trust in health information exchange. We're still looking at our, using the privacy and security framework for electronic exchange of health information that we released in 2008 as the framework, and we're using the recommendations from this Policy Committee as the basis for those discussions. So this is being led by Joy Pritts, our Chief Privacy Officer, and she has commissioned a principle level interdivision task force in HHS to develop an updated approach to privacy and security which are informed by the recommendations from the Policy Committee, so taking the recommendations and bringing them back to the agency to figure how we incorporate those into policies, what policies we're able to establish, etcetera. So I wanted to close that loop, one because it is very relevant to the work here and that we have established this approach for taking those recommendations, and trying to establish privacy and security policies based on those involving others in HHS.

The second, probably most common comment that we got was about the pace of change and the timing for Stage 2 Meaningful Use. Again, another issue that you all are, that is probably near and dear to all of your hearts, we just re-iterated the point that Farzad made that we understand the challenges with the pace of change and the timing of Stage 2 Meaningful Use and that we got recommendations from the Health IT Policy Committee that suggested that we extend Stage 1 and that we just re-iterated that we support those recommendations and that we will be considering those recommendations as we go through our policy development process.

Third was usability of EHR products. This was another one, there we go, this was another one that we heard a lot about and I mentioned a little bit about this last month during our meeting about what we're doing on usability and we just highlight it again that we're working with NIST on their efforts to do research in the area of EHR usability, that we're committed to transparent processes for exploring ways to improve usability of EHR products, and that we're exploring ways to improve data portability so that we can reduce switching costs for EHR products as well.

Outreach and education to providers and consumers. We just launched our putting the I in Health IT Campaign, which is our communications campaign to reach both providers and consumers in understanding our initiatives and understanding how Health IT can improve health and healthcare, and you can now go to healthit.gov our new website, which we're really excited about that has some really great information targeted to providers and to consumers and I'll talk a little bit more about our outreach

strategies and I want to talk about the consumer launch. But this is new, there is, we're getting some personal stories from both providers and consumers and trying to provide a lot of useful tools that are targeted to particular audiences, so our communications team has been really doing a lot of work in that space.

A couple of other areas that we heard comments about and that we addressed were barriers to adoption in health information exchange, we made some minor changes in the HIE sections, need for further harmonization of standards, addressing providers who are not eligible for incentive payments, these are all issues that, you know, we've all talked about at the Health IT Policy Committee and we heard, again and tried to clarify some of our thinking in these areas. So I do encourage you to look at our final strategic plan.

The one thing I don't have a slide on, because this was just in discussion yesterday, but what we're trying to do, and we'll see how, you know, how it comes out, but we want to come up with a way to make our strategic plan more current and interactive so we're going to have it on our website, but try to figure out how we can get comments on it on a more regular basis and keep it, make it a little bit more iterative and keep it fresh and updated as things change not, you know, every 2 or 3 years, but at a quicker pace than that using our website, using social media, and ability to get input in real time. So stay tuned I'm not sure where that's going to go. We've been talking with a lot of folks about how we can do that and make it a much more open transparent process in light of open government. So, we've looked and nobody has done this as of yet, so we're going to be the guinea pigs. So if anybody has any great ideas we're open to them.

Okay, so consumer e-Health. We had a fabulous summit on Monday and this was very exciting. I know there are a couple of folks here who were active participants and some others, who were listening in, but we had an event from, on Monday afternoon and we had a lot of announcements, a lot of activities that went on. The goal was really to try to talk about consumer empowerment. We focused a lot on patients getting access to their information as a tool for empowerment. And the way I think about this is that there is sort of a few different needs and ways we're thinking about the different announcements and activities we have going on is that we need to work with the stakeholders that are actually out there, have the data, have the ability to reach out to people to improve our, to take on our efforts for consumer empowerment and patient access to their data. And so we announced a pledge program to have people pledge to empowering consumers using health information technology and we have a pledge for data holders and a pledge for non-data holders. We've had 40 people, 40 organizations so far pledge and we are going to keep that open for some time and we're looking forward to having other people pledge to empower consumers using health IT. So please go onto our website and I tried to list all the websites and the links for folks. I think it's actually going to be live where you can go in and enter your organizations name and say I want to pledge, pledge now, I think that's going to be up today. So, if you don't see it yet go up there, just wait a couple hours and go back up.

Then, also looking at where there is a barrier to consumer empowerment or patient access that we need to address and that's sort of the spirit of the CLIA and HIPAA changes to enable consumers to get access to their lab tests directly from the lab. So there are some, in some states this was possible and other states this is not currently possible, and so we had some proposed rules to make it so that we remove those regulatory barriers. These are proposed rules; it's open for comment, so folks should comment on those regulations.

And then also where we can develop, then the third piece was protecting the privacy of the information, so for encouraging patient access to their own information, how do we make sure that that information is protected and so we had the, our new director for the Office for Civil Rights, Leon Rodriguez, come up and talk about that in fact, yes patients do have a right to access their information, which we still keep hearing over and over again, that there are providers who don't think that HIPAA actually doesn't allow them to provide the information to patients, so in fact he clarified that yes patients do have a right to access their information and also the importance of privacy and security protections of the information.

We also put out this voluntary PHR model notice with the thinking that as people get access to their data they may want to store it in a personal health record and use the personal health record to manage their information, and that there are personal health records that are not covered by existing HIPPA regulations, some are, some are not. So what we did was put out a PHR model privacy notice that was based on consumer testing and was supposed to just highlight some of the things that folks felt were important to understand before they put their information in a personal health record. So, we did this based on consumer testing and so it's not the, everything that somebody might want to know, but it's sort of some key points, it's modeled on the nutrition facts label which has a consistent format on every can of soup that tells you how much sodium is in the soup but the government doesn't tell the soup manufacturers how sodium they can put in the soup, just that they have to be transparent about it so if somebody cares about that piece of information they can readily and easily find that piece of information. And what was exciting was we had 3 PHR vendors that had agreed to make the pledge, Microsoft Health,...., and NoMoreClip Board and they all agreed to use this PHR model privacy notice to disclose and be transparent about their data practices and security practices.

And then one other exciting thing was just, as far as I've mentioned, that the white house proclaimed this week to be National Health IT Week, which is not an easy task to get the president to actually make a proclamation of a particular week, so that was particularly noteworthy and exciting for us.

So, I mentioned the pledge program and I just wanted to give a little bit of information about this for folks. It's open to any stakeholders, public, private, non-profit entities who want to participate in the pledge campaign, again our goal is to, we are not the, we can provide some messaging and reach out to consumers, but what we would like to do is sort of be the convener and the catalyst for other people who are already doing great work and who have this as something that they have the capability and the interest in doing to, you know, provide tools and to organize the effort, but we're really looking for other people to take the lead on this. So, we have a data holder and a non-data holder pledge. For the data holders we're asking that people pledge to make it easier for individuals to get secure electronic access to their health information. There is a much more detailed pledge on our website, but specifically we identify group under direct as approaches to doing that. For the non-data holders we are asking them to pledge, help spread the word about the importance of getting access to information, to your own health information, and to have tools for using that health information. So that kind of the gist of it, again, I said there were 40 organizations that have pledged so far, and we are hoping to have a lot more join this movement toward consumer empowerment.

This, I think we've talked about this a little bit before, this is just a, when we talk about ONC's strategies to support consumer engagement we're looking at this as three kind of basic strategies, access, action and attitude. So, I just want to touch on what we are doing and how we're looking at ONC's role in consumer empowerment through Health IT. So, with respect to access we have the pledge program, obviously Meaningful Use program, and putting that as one of the measures, as measures within the Meaningful Use program, PHR model notice, and then some state...challenge grants that are focused on consumer mediated exchange.

With respect to action, another announcement we made on Monday, is that we have a challenge grant in the space that we have just made available, but we're looking at how we can challenge others to develop innovative tools and applications to help individuals use that information in a way that helps them manage their health and healthcare, and we have a beacon partnership that is focused on looking at some of these consumer e-health tools as they relate to diabetes, management and diabetes care.

And then the third one is attitude, looking at how we can help shift attitudes on consumer empowerment and the consumer of the patient as a partner in their own care. Don Berwick had some really fabulous quotes if anybody listened to his remarks during the e-Health Summit and we are hoping to get that, those were all of the remarks, up on our website soon, but he talked about, he made a couple of comments about, you know, the provider being the coach as opposed to the expert, which I thought was really powerful and about the consumer as part of the team, and so trying to shift the attitudes toward consumer empowerment and our putting the I in Health IT Campaign, our tools on healthit.gov, and working with consumer groups, as working toward that.

We also have two exciting new projects that we are kicking off, one is an animation that we're going to use to try to explain Health IT in a way that is understandable more to the general public as opposed to the insiders, and then an opportunity to do crowd source video where we're going to do video challenges to get folks to tell their stories and make those available up on our website.

Okay, so now the part where we are looking for some input from you all. This is data integrity and fraud detection and prevention. So, as a goal, so we are not the office that deals with fraud or anti-fraud, or data, you know, data integrity obviously is an important part of our work, but we are not the central point for this work, that said, if there are implications that Health IT has on data, integrity and fraud detection and prevention, or if there are areas where Health IT activities can help address these concerns, we would like to consider this. So, we don't think that we are the focus of this topic, but to the extent that our work has any impact or can have a positive impact in anti-fraud or data integrity, we want to think about that and explore those options.

So, what I would love feedback on, and we can talk about this after I go through what we've done so far, is where there are any areas that we should think about prioritizing with respect to ONC activity or where ONC already is taking some steps and we should be considering the fraud, you know, the areas where we can have a positive impact in this space.

So, just by way of background, we've done a lot of work in this space already and some folks may be aware of some of the reports that we've done already on data integrity and anti-fraud. In 2005 we had 2 reports, one called automated coding software development and use to enhance anti-fraud activities and there're some recommendations to software developers about automated coding systems that can have a potential to detect improper coding and minimize improper coding. So there's one report on that and the second, the report on use of health information technology to enhance and expand health care anti-fraud activities, was a study on how health IT can enhance or expand on fraud management. It was a fairly broad overview report, but again, worth taking a look at.

In 2007 there was a more specific report that had recommendations for requirements that should be built into an EHR, certification requirements, to help enhance data protections, looking at data validity, access and integrity. And we have, that was presented to the AHIC back when we had the American Health Information Community before this committee was formed, and there was some sense that it was, there were some things that were controversial, there were some things that folks were concerned about, particularly in light of where we were with respect to certification programs and EHR adoption, etcetera. So, this was back in 2007, obviously the world has changed a lot in the space of Health IT and EHR certification, now with the Meaningful Use Program, with our certification program and so we wanted to raise this again to see if there were some areas where there might be opportunities that we should be considering with respect to the programs that we have in place.

So, we are open to your input on this and I talked with Paul who was suggesting that it might be good to have a workgroup actually just look at this and see if there are areas that we should be prioritizing or if this is again, you know, something that is not within our scope, that we should kind of keep on the back burner. But, in looking at some of the recommendations that came out of the 2007 report there are some things that we have done already and there are some things that we haven't done in our certification program. So, you know, for instance, we have developed certification criteria regarding audit logs, which was something that was recommended and we've developed the standards for the information that we captured in the audit log. We have, you know, authentication regarding healthcare providers but we don't have identity proofing standards or criteria for patients, which was something that was recommended.

So there is, some of these things were actually already built into our certification criteria and standards, some are not, some were controversial when we brought them up at the AHIC, some were less controversial, some of them are things that can be built into the technology, some of the recommendations were things that seemed to me to be more of processor administrative requirements that we wouldn't build into a certification criteria. So, what I was suggesting when Paul and I talked before was that it might be good to have the certification adoption workgroup look at some of these

recommendations, we can provide some staff support to help identify some of the activities that are currently going on or that have already occurred, and then think through whether or not they're recommendations that we should be considering or following up on or sending to the Standards Committee or if there are particular areas that we should be looking at that weren't in the recommendations, but to just take a look and give us some thoughts about any areas for priority, any low hanging fruit, and that sort of thing. So that's it. Thank you.

Paul Tang – Palo Alto Medical Foundation

Thank you Jodi. Comments, questions, or reactions from certification adoption workgroup? Marc?

Marc Probst – Intermountain Healthcare

Jodi, thanks. On the areas open for prioritization, that list, that was from the AHIC report, I mean couldn't that be a broader list if the certification.

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Absolutely.

Marc Probst – Intermountain Healthcare

Adoption looked at that.

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Absolutely. This is one I just adjusted some of the areas, this is not a complete list, and yes, if there was something, I was suggesting that folks may want to look at that report, but again it's, you know, it's 4 years old, and there also may be some other great ideas of things that we should be considering, so it's not an exclusive list by any means nor is it, you know, am I suggesting that those are the right things for you all to focus on.

Marc Probst – Intermountain Healthcare

Thanks.

Paul Tang – Palo Alto Medical Foundation

Other comments or questions? Paul?

Paul Egerman – Businessman/Entrepreneur

This is Paul Egerman. This is a great presentation on the issue of the data integrity and anti-fraud. I do think there are some things, to pick up on Marc's comment, beyond that list that could be done. You know, one of the issues you have is your involved with a very large group. You have hundreds of clinicians and you may have 1 or 2 players who don't get the word, you know, who, you know, who are over coding, over billing, and so we've got these vehicles to help organizations detect that.

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Absolutely.

Paul Egerman – Businessman/Entrepreneur

Internally, because it's an interesting issue, I mean you think that it's just one organization that's doing something wrong, but you know, we've got a very labor intensive process here and it's very hard for organizations some times to really know what is going on within their own so called 4 walls. So, I think it's a great comment, a great area. The other comment I give you is it's actually inter-related, in my opinion, with the consumer access to the data too, because if consumers have access to their clinical data they can be an additional watchdog if it were to find out, is, you know, did I really have this test done, did I really, you know, is this diagnosis, was it really that severe in terms of what I had.

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Absolutely and that was actually one of the reasons, one thing they did recommend was about patient access information for that very reason. We do have, just briefly to mention, a project that we're working on looking at, we call it the dispute resolution, it's not quite, it's basically how patients who recognize that there's something wrong with their data or something incorrect or something they think is false to raise those issues to the healthcare provider or the provider organization and we have a project looking at how we might facilitate those queries and amendments or additions to the record that is ongoing right now. So, I agree with you, I think it's actually an area that is very ripe and we can give you some more information about the project we're currently doing and see if there is anything else that we may want to be considering for that.

Paul Eggerman – Businessman/Entrepreneur

Thanks.

Paul Tang – Palo Alto Medical Foundation

Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you very much. Terrific report Jodi and I just wanted to add the importance of the fraud component. This is a huge issue in Medicaid, it's a huge issue in Medicare, we estimate that there's at least 10% of the 23 billion dollars we spend a year in Florida on Medicaid that can be attributed to fraud, a lot of that can be duplications or actually things that were not necessary, or perhaps a coding, and things of that sort. So, this is a tremendous tool that is available and I think in the long run this is going to part of what will help reduce the cost of healthcare, so the fraud aspects and the ability to really make sure that the data integrity and the fraud, the ability to use this information is tremendously important, so the certification workgroup should certainly, certainly look at how you make sure that those items are built, the ability to detect things is built within the records. So thank you for this and adding it to the agenda.

Paul Tang – Palo Alto Medical Foundation

Neil and then Marc?

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

This is a non-lawyer question, so I'm reading about the CLIA business and lab access so I'm always trying to figure out what the federal government has authority over and what the states have authority over, so if New York State has a law that already says that labs can't give direct access would this supersede that and what kinds of rules are going to come out of the federal government that are going to try to sort of tells states what to do in these kinds of areas, because you know, access is really clear, but on the other hand there's all these other laws that sort of can be on the books in various places and I just don't understand how that takes place.

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

So, I'll start by saying I'm not a CLIA expert and I don't work for CMS, so I'm just telling you my understanding of how this all works, but I'm not, this is not the official word from the folks that actually regulate in this space. The way CLIA, CLIA is a, there's a federal regulation and the federal law defers to the states on certain things including who is authorized to receive a lab report, and so what this would do would say that, it would say from the federal law perspective that an individual, the subject on record is a person who is authorized to receive that information. So, if the state said, you know, prohibited that, it would in fact, my understanding is it would supersede a prohibition at the state level.

The HIPPA rules, this was a HIPPA and CLIA regulation, proposed rule that went out, the HIPPA rules talk about a patient's right to access their information and there is something that was in the current existing final rule, HIPPA rules, that has a carve out for CLIA and so that's why the HIPPA rules were proposed to be modified as well to eliminate that carve out.

So, you know, as far as your other question about, you know, we're they're states and federal, where the state laws may prohibit certain activities, you know, I can't really speak to any federal government rule in addressing other state laws, I mean this is the one thing that we have.

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

Right, I mean I guess my question is that you know, this is sort of a proactive move to give people access to something so that's different than sort of, you know, the rules that restrict access and things like that, so you're giving people access, and I guess if the federal government decides they want to give people access to their lab data and that's, you know, a federal law, you know, is that really going to change the way things are done across the country and that's, or is it allowing states to do that, you know, is it allowing states to say that labs can directly, can give direct access or is it commanding states to say that labs have to give direct access to patients.

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

So, currently some states allow patients to get direct access to their lab data from labs. The proposed rule would make it so that patients can get access to their lab data in any state, again, it's a proposed rule, I just want to highlight that this is a proposed rule and at worst you can comment on it, so, but that would be the effect if that became the final rule.

Paul Tang – Palo Alto Medical Foundation

And Joy do you want to.

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Oh good Joy's here, thank you. Please.

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

If I could just jump in her a minute. When you read the notice of proposed rulemaking there is a section on how it is anticipated that this would interact with state law which may be helpful. Okay. And I know nobody likes to read the legal documents, including us, but they are helpful in that respect. The regulation here is somewhat complicated because as Jodi was saying there was a carve out in HIPPA that gave people right of access to their health information from all healthcare providers, except for directly from laboratories, right? And it did that in a kind of, it wasn't that direct, it said if prohibited by CLIA and CLIA used to have some limitations in it. So, what CLIA does now is they have removed those limitations and the privacy rule itself includes that right of access. Does that help any? Okay.

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Thank you Joy.

Deven McGraw – Center for Democracy & Technology – Director

Neil it's also the case that congress had declared that HIPPA would preempt any state law that was deemed to be less protective and so, you know, in terms of sort of the legal issue it's, I think it's really uncertain and arguably not permitted for a regulation by itself to be able to preempt a state law and make it go away, like one in New York for example that says patients can't get their lab data directly, but since congress already said that HIPPA was preemptive of any state law that provided less protection, and since HIPPA provides patients with a greater degree of access the sort of boot strapping effect of saying of eliminating the limitations in CLIA which used to be sort of wrapped into HIPPA you end up with a preemption, you end up tying into the congressional preemption piece of this. So it's not just HHS saying we can rid of any state law we don't like right?

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Right.

Deven McGraw – Center for Democracy & Technology – Director

Congress has already spoken on this issue and HHS is building on that, but there, you know, again it's an open comment, public comment period and I suspect they'll get a lot of comments on this.

Paul Tang – Palo Alto Medical Foundation

Marc?

Marc Probst – Intermountain Healthcare

Well now that we've cleared that up. We could talk about, just on the fraud piece and there's just so many moving parts right now in healthcare, and this is just a question. Is there anyone looking at, it seems to me the new payment mechanisms that are being looked at for healthcare could have a tremendous impact on fraud, the way they're doing it. Is there any group, is ONC looking at that, is there someone else that is looking at it that might provide reference to the adoption and certification committee as we go through this

Jodi Daniel – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

That's a good question. The Office of Inspector General and CMS have, you know, are the points on anti-fraud activities. I can, so there, you know, that's in their bailiwick, but we could see if there might be somebody who would be available to provide some guidance and insight to the committee. I can talk with our IG and CMS colleagues and see if we can get some folks and experts to talk with you all.

Paul Tang – Palo Alto Medical Foundation

Okay, well that was wonderful Jodi and clearly you've stimulated some interest in this particular area. Because actually there are laws that, including in California, that get in the way of the intent for this and so thank you very much for the work, the tremendous work that is going on at ONC and for this specific update. Okay, now we're going to move onto the Privacy and Security Tiger Team again, and boy this is fast work, because I think the ANPRM just came out a matter of weeks ago, but now we already have some information and deliberations from the Tiger Team and recommendations.

Deven McGraw – Center for Democracy & Technology – Director

Nice to see you all on the other side of the die.

Paul Egerman – Businessman/Entrepreneur

Thanks, good morning, I'm Paul Egerman here with Deven McGraw and we're going to tell you about what we've been doing in the last month other than the hurricane and the earthquake. And so these are the members of the Tiger Team that are listed here and these people have really done excellent work including a couple of the members are here at this meeting, Neil Calman and Judy Faulkner, but the entire group has been terrific. For this most recent deliberation we added, and Gayle Harrell of course also a member of the team, and for this topic we added to what we called contributing experts, Richard Platt from Harvard and Shaun Grannis from Regenstrief also helped us, and from ONC we have of course, Joy Pritts and the incomparable Judy Sparrow, we leave Judy the last because we leave the best to the last. She is the absolute foundation so this may be our very last presentation ever without her.

So, the topic, the topic, it's interesting we just had this terrific discussion about HIPPA and CLIA, this topic relates to an ANPRM an Advanced Notice of Proposed Rulemaking that deals with this issue of research on human subjects, and the set of regulations that deal with that are called the Common Rule, which is what is sort of like underlined on the screen and it's sort of like a separate set of regulations, separate from HIPPA that need to be discussed, and so this Advanced Notice of Proposed Rulemaking was published where it is really a request for comments. It says that the comment period ends Wednesday, October 26th. Initially when it was published the comment period ended September 26th or roughly September 26th which is why we sort of went into overdrive to complete our deliberations on this topic. It does mean that this is a slightly different approach, we will be, in this discussion, be making some recommendations which I'm going to talk about in a minute.

The recommendations are really to be submitted as a recommendation or as a letter from the Policy Committee I guess to the secretary as opposed to a recommendation to the National Coordinator for something that we are, some action that we're suggesting for ONC as a suggestion for HHS. So here's what we're going to do in terms of explaining our recommendations. First, Deven is going to give a summary of the Common Rule itself. Then she will give a summary of HIPPA and research, in other words how research is handled currently under HIPPA. Then we will do a summary of the ANPRM, which is a great document, again it's asking for feedback and input, and then after that we will describe our recommendations and ask for your approval.

Deven McGraw – Center for Democracy & Technology – Director

Thanks very much Paul. So, we're asking you really to bear with us, we, there's a tremendous amount of background information that we think it's important for you to have that will allow our recommendations to make sense to you. We actually spent the very first call that we did with the Tiger Team really going through all of this background so that everybody would be on the same page. So, again, you know, bear with us. There are a lot of slides here that are really just background before we get to recommendations, but hopefully it will set the stage for you to understand the approach that we took, what we focused on and why we came out the way that we did.

So, as Paul mentioned, you know, the Common Rule are regulations that govern really most federally funded research on human subjects and it was really primarily designed to address clinical trials and so it focuses on the risks, the physical risks to human subjects from research as opposed to focusing more on the informational risks associated with data, the use of data in a research context. Nevertheless, the Common Rule does cover research that is using data and not research on people, its research on data, when that data is identifiable. It doesn't cover research on data that is not identifiable. And the framework of the Common Rule is based on sort of 2 foundational requirements. One, is the requirement for independent review of research by what's called an institutional review board and then the second prong is really informed consent of the research subject when there is more than minimal risk to the research, minimal risk to the subject from the research.

So, I'm going to talk a little bit about the role that IRBs play. We, as you'll see as we get closer to setting the stage for our recommendations, we do not opine specifically on IRB constitution, their processes, we don't really have the expertise for that, but I think it's important to sort of set the stage for the sort of tiers of review that typically take place when IRB review is required for research and particularly to understand when IRB review is not required by the rule.

So, in general IRBs have to be comprised of members of various backgrounds. They review and approve all research activity generally they have to, they require documentation of any informed consent that might be required, they also can waive it as we'll see in a minute, and then they do ongoing reviews of research, so in addition to sort of approving the research protocol at the front end they also will do these check in's on a yearly basis on research. However, if the research falls into a list of categories that involve no more than minimal risk then it can be reviewed by a single IRB member as opposed to the entire IRB and that's generally called expedited review.

And then, more importantly, for our purposes today, there are categories of research that are exempt from required IRB review and in particular one of the categories is research that involves a study of what's called pre-existing data that's initially collected for purposes other than research. For example, treatment data from EHRs. As long as the investigator is receiving the information in a way that doesn't directly or indirectly identify the subjects. When those conditions are met the research is exempt from required IRB review, it doesn't necessarily mean that the institution might review it, have its IRB review it just as a matter of their own policy but in terms of whether or not it's required, it is not when these conditions are met.

When the research is not exempt from IRB review for the most part it also requires the informed consent of the subjects. However, an IRB can waive requirements for consent that might otherwise apply and these are the conditions under which the waiver can take place, probably most important is the second one, when the research involves minimal risk a waiver would not adversely affects the rights of the

subjects. The research really couldn't practicably be done without the waiver and the subjects will be provided with additional pertinent information after their participation. So, I think the other thing to note here is that the Common Rule currently does not require researchers to adopt any security measures. However, we know, and as we'll note again when we start to talk about HIPPA, there are some researchers that are covered entities or business associates and therefore would be covered by the HIPPA security rule, and of course if HIPPA coverage is implicated then if they're using what's called a limited data set, which is frequently used in a research context, that requires a data use agreement which does require the commitment of the researcher who is receiving the data for research purposes to commit to adopt appropriate safeguards for the data.

So now we shift gears a little bit and talk about what does HIPPA say about research and again, HIPPA doesn't apply to research across the board but applies to certain covered entities and business associates of covered entities when they conduct research and for our purposes, since, you know, ONCs programs really are aimed at providers and hospitals that is typically the entities that are covered under HIPPA. So HIPPA coverage is going to be relevant for much of the population that we typically speak to as a Policy Committee in terms of our recommendations.

Again, HIPPA also only covers protected health information so the information needs to be identifiable. As a result, some entities may actually be subject to both HIPPA and the common rule, and for those of you who are sort of steeped in these issues and know that the IOM did a report on this, there is some considerable angst in the research community about perceived conflicts and lack of clarity between how those rules sort of can be read together to create a sort of consistent set of obligations.

Most important to note on this slide, because it's very relevant to the recommendations that we're bringing to you today, is that research is distinguished from healthcare operations in the following way. So healthcare operations include quality, assessment and improvement activities that a provider or provider entity might engage in, but it's only considered to be operations, meaning the research rules don't apply to it, its operations, it's not research, it's only operations as long as one of the primary purposes of the activity is not to obtain generalizable knowledge. So a lot of times this gets sort of characterized as if it's internal its operations, if it's internal but you plan on reporting the results of what you're doing so that people can learn from it then is arguably contributing to generalizable knowledge and arguably does not fit into the operations bucket and fits into research.

So, how does HIPPA regulate research? Well, it requires authorization from the individual who is the subject of the data that's being used, in most cases if fully identifiable data is being used, in other words, not a limited data set, and not data that meets the de-identification standards under HIPPA, and the authorization has to be fairly specific, it's not people are allow to do research on my data, it has to be much more specific than that although there is a pending rule from the Office of Civil Rights to try to create an easier pathway to achieving this consent. Nevertheless, the rule as it stands today requires authorization, which is much more specific than a general consent.

Now a covered entity can release PHIs, Protected Health Information, that's identifiable health data for research purposes if it receives documentation that an IRB or privacy board, you can have one or the other, has approved a waiver of that requirement and then there are some circumstances where the authorization that would normally be required is not required and that includes if your examining data in preparation for research, you're looking to see what is the possible question that you might want to address and the data physically remains at the provider entity and doesn't leave. Research on decedents, in non-legal terms that means dead people, or releasing again a limited data set which has certain identifiers stripped out of it and requires a data use agreement as we said. We actually have some more information on this limited data set, again it's stripped of the name and other identifiers, but it is still considered potentially re-identifiable because it has information on it like dates of service, which are often quite relevant for research purposes but make the data much more susceptible to being re-identified, and again it has a data use agreement requirement.

If the data does qualify as de-identified data under HIPPA it is largely not subject to regulation by HIPPA and the de-identification standard is no reasonable basis to believe that the data can be used to identify

an individual, data use agreement is not required in that circumstance, although sometimes institutions do use them just as a matter of their own policy, does also require a commitment not to re-identify the data, although if you're already covered by HIPPA and you're a recipient of de-identified data, if you inappropriately re-identify it's possible that you could be held accountable for that because as a covered entity you're already accountable under HIPPA there's already that sort of chain of accountability that where the authorities have an ability to hold you responsible if you do do that.

So, now we're going to move to what the proposed changes are that are in the ANPRM and as Paul mentioned an ANPRM is an Advanced Notice of Proposed Rulemaking, which is really an early look at what HHS is thinking about in terms of making some helpful changes to the research rules to make it easier for research to be conducted while still protecting the individuals who are involved in it. There will need to be a proposed rule that comes out of this process and then a final rule. So there are lots of processes built into this. So in many respects our comments, any comments that we would submit at this stage would still be subject to further consideration both by the agency and subject to yet another public comment period if the department and the agencies involved in the research enterprise thought that what we had to say was worth proposing as part of the proposed rule.

So I think, I underscore that only because I think it's important for us to acknowledge that we don't have to get it all perfectly right down to the tee in terms of the recommendations that we're putting before you because there will be opportunities for this to be further vetted through the process, which you know, it provides me with some comfort that we can throw an idea out there that we think is worth doing but acknowledge that it needs further deliberation and should be further deliberated and we'll get to some of the details of that in a minute, but I just wanted lay that foundation.

So, what is in the ANPRM? The focus is absolutely on changes to the Common Rule, although they do express a desire to harmonize and streamline the research rules in HIPPA with the Common Rule and there are many instances in the ANPRM where they borrow specifically from concepts in HIPPA in order to try to make those rules more consistent. There are a number of changes proposed that's like the understatement of the century. There is a lot in this rule, much of it we determined that we would not take on, in part because of timing, but probably more importantly we recognized that, you know, rules about IRBs and IRB process are really not in our sort of traditional scope of expertise and what we have done as a Policy Committee in the past, and so we decided right from the start that we would focus on those provisions that had a direct impact on ONC programs, specifically the rules surrounding secondary uses of health information initially collected for another purpose, treatment, because that really does get to the heart of secondary use of data that is being collected in EHRs per the Meaningful Use requirements that we have helped to establish.

They also have proposed to expand the scope of the Common Rule to any institution that receives federal research funds, even if the particular research project in question is not supported with federal funding and so that's an interesting expansion. We don't have a specific recommendation on that but I thought it would be interesting for you all to know that. Again, they expressed a desire to harmonize HIPPA and other relevant rules governing research such as the Privacy Act which governs federal entities that conduct research on the government side.

There is no change in the definition of research; it still covers investigative activities that are intended to contribute to generalizable knowledge, that's an excerpt from the definition of research under the Common Rule. You'll see that it dovetails very well with how operations and research are distinguished in HIPPA, which is if it's intended to contribute to generalizable knowledge then it's research and if it's not then it's potentially operations if it falls into the quality improvement bucket. It does continue to exempt research on this EHR data on existing data from IRB review, potentially even if that data is still identifiable. However, it recommends that such a study, again it's still considered to be research, be registered by the filing of a brief form with an institutional office, like a 1 page or a 1-2 page summary. It does still require informed consent for the use of data that is identifiable for research purposes. So, if you've collected it for treatment purposes but you want to secondarily use it, you've collected for treatment but then you want to secondarily use it for research purposes you're going to need to get the consent of the subject if that is identifiable. Now if it's a limited data set you do not need to get that

consent and if it's de-identified data you would not need to get that consent and they specifically ask in the ANPRM whether consent should be required here and if so what type.

The ANPRM also proposes, really for the first time, that researchers be required to adopt security measures that vary with the identifiability of the data and this is one of those places where they borrow from HIPPA and say that essentially the HIPPA standards ought to apply where you've got individually identifiable information being used. In the case of a limited data set or de-identified information the security requirements are lessened a bit, they focus in particular on commitments not to re-identify, really in both of those cases. But this was a very interesting development, the application of security protection for the first time to the research enterprise. Again, covered entities have always had the obligations to adopt security measures. And so I want to turn it over to Paul to introduce what we are in fact going to make recommendations on.

Paul Eggerman – Businessman/Entrepreneur

Thanks, Deven. So, what Deven has done so far is she has summarized the Common Rule and her best to summarize HIPPA and research, and summarize the ANPRM, that was really excellent, and that's covering a lot, that's covering a lot of material in a very short period of time, and as she said a lot of these regulations are really set up for more physical kinds of concerns or risks for patients. I have to say when I was in college I was actually a human subject in a couple of these studies, which I did because I got paid to do it, and so I did like a sensory deprivation experiment where I got paid 25 dollars to do something really bizarre for 3 hours and you know, but that was good money at the time. So, but we are focused on the EHR data and providers.

So, we made recommendations in two different areas, what you see up on your screen. The first is what secondary uses of EHR data should be considered to be "research." In other words, what secondary uses of EHR data should be considered to be research that qualifies for this IRB and consent situation? The second is just a discussion of the application of the full complement of Fair Information Practices and not just consent and not just security. So those are two different issues that we raised and we made recommendations on, and so in terms of making sure that I do my best to frame our discussion, again our recommendation is based, is confined, at least on the first question to provider entities only because a lot of reasons for that, but we feel we do our best work when we sort of narrow ourselves to like specific questions.

Again, the ANPRM, as Deven said, does retain the exemption from IRB approval for the secondary uses of clinical data for research but does require general consent when the data is identifiable and certainly when you see the word consent that was something that would wake up the Tiger Team because that's what we did last summer was have a great discussion about consent, so this was an issue we addressed. And then as Jodi pointed out when she talked about the strategic plan this morning, earlier this morning, the goals, one of the goals of HITECH, one of the goals of ONC strategic plan is the creation of this learning healthcare system. So the concept of the learning healthcare system one would assume is you do things you get some evidence and then you do something perhaps different or better as a result and so you have this constant evolving healthcare system. So the question is well how does that relate to what's in the ANPRM? And the final comment here, in terms of background and framing, I guess it's not the final comment, there is one more slide, but the use of the EHR systems do create new technological opportunities to improve treatment of patients and we were concerned that if you considered those activities as research it might limit those activities in some ways.

And, also as we look at these new technical opportunities to evaluate quality, safety and effectiveness, sometimes we think about quality in issues like they are like reports and so you produce this report and there is just like a number and it says, you know, X percent of patients have an infection or something, but technology changes all of that. You could have, you know, you could have dashboards, you could have alerts, you could have drilldown capabilities, which the, you know, you got a certain percentage of patients that have something adverse happening and you like click on that cell and you can get a list of the names because maybe those patients are still inpatients and you can try to see what's going on with those patients. And so this is also a comment that the technology is changing. So it's really a very

interesting issue of the learning healthcare system and how does it interrelate with these regulations relating to the research.

To continue to clarify this the current rules, both the Common Rule and HIPPA, define this research as we put in quotes as activities designed to develop or contribute to “generalizable knowledge.” And then we made this other comment, characterizing research as “any evaluation, activity that is intended to contribute to generalizable knowledge might no longer serve the interest of either patients or providers.” So, those were the sort of like series of concerns we had that brought us finally to a description of the recommendations.

Deven McGraw – Center for Democracy & Technology – Director

So, I’m going to go through what we have is essentially two recommendations with some sub-parts that go to the question of what secondary uses of EHR data should be considered to be research and then Paul’s going to take us through the recommendation with respect to researchers and adoption of a full complement of Fair Information Practices.

So, essentially what we say here is that the use of a provider entities EHR data for treatment purposes or to evaluate the safety, quality and effectiveness of prevention and treatment activities should not require consent or IRB approval or registration. Such activities should not be considered research but instead should qualify as treatment and operations if conducted by or on behalf of, such as by a business associate, a provider entity, and we think this exemption should apply even if the results are intended to or end up being publicized or more widely shared, in other words contribute to the generalizable knowledge. So, we are really taking on that line that says if you want other people to know about it and learn from it, it’s research, and if you don’t it’s not, and saying in a learning healthcare system that doesn’t make sense.

We expect that provider entities are to maintain proper oversight over and be accountable for the conduct of these activities. So, even though we might arguably be clarifying or removing a potential obstacle to the conduct of these activities it’s not as though we’re saying they shouldn’t be regulated at all, in fact provider entities will always be responsible for things that happen with data over which they have stewardship over and that, you know, bears repeating given that, you know, we’ve made a recommendation that boldly says this shouldn’t really be considered to be research and that also goes to consent as well, it shouldn’t be required to access EHR data for these purposes even in circumstances when the data does not qualify as either a limited data set or de-identified data, in other words it’s identifiable data.

However, we acknowledge that in these cases that an entity should always be using the minimum necessary amount of data to accomplish these purposes that’s already, if you’re covered by HIPPA, that’s already a standard you need to be abiding by, which in some cases could mean removing some identifiers prior to analysis when it’s not necessary to identify individual patients. Now acknowledging that we’re not suggesting that a provider entity can’t open up a record and look at it until all the identifiers are stripped off of it, that’s not what we’re saying here, we’re simply stating that and recognizing that in some cases these kind of evaluation activities will take place with identifiable data, sometimes they will not, that shouldn’t be the trigger for consent. Instead, we really ought to rely, as a requirement, we really ought to rely on the institutions to have oversight and be accountable for how they use this data and obviously as a Fair Information Practice using the least amount that you need in order to accomplish the purpose is what we’re aiming at here.

And then I wanted to just note we have some examples here, did you want to go through these or do you want me to?

Paul Eggerman – Businessman/Entrepreneur

I think I can do it.

Deven McGraw – Center for Democracy & Technology – Director

Yeah.

Paul Eggerman – Businessman/Entrepreneur

So, we wrote up some general examples of what we're talking about and to sort of walk you through a little bit of this, you see the first couple that says, starts by using EHR data to improve care provided to patients and it says identifying patterns of adverse events to detect issues. One example that we talked a little bit about was an example, I tried to, to give you an example use identifiable data where an acute care institution discharges a patient to an extended care facility. The extended care facility might not be a member of the hospital's OHCA, of its organized Healthcare Arrangement, these are 2 separate entities, perhaps located several miles apart, but they may decide that they want to collaborate on issues related to reducing the re-admission rate and in order to do that collaboration they probably have to look at when re-admissions do occur, the patient's identifiable data to examine that to examine data beyond what was necessary in the discharge summary, maybe want to do comparisons against patients who had similar circumstances that were not re-admitted to try to understand why that occurred, maybe develop some hypothesis of something that could be done to reduce the re-admissions rate and then do some statistical analysis as they implement that hypothesis whether or not that results in a reduction of the re-admissions rates. So you go through all that process, you know, you're using identifiable data, if you come up with some conclusion it would be nice to publish it, because that might be information that would be helpful to other people to know, but, and so that would be sort of an example that I think would also be consistent with the things that we try to do with the learning healthcare system.

You see this bullet, evaluation of interventions, desire to improve compliance with existing standards of care and outcomes, actually Neil gave a great example of that in one of your emails. I might not be describing this correctly, but it was a project involving the evaluation of treatment of patients with diabetes and determining well gee if you send them to a nutritionist, you know, does that cause them to have a change in their behavior or diet in such a way that you can measure that with a blood test, and if so that's valuable information and that's information that one might want to publish, and so that would be contributing to generalizable knowledge. I don't know if I did describe that well enough. And so you see some of these examples.

The next bullet is monitoring individual clinicians and professional staff, so we talked a little bit about that on the stand-point of, you know, comparative analysis when we were talking about fraud detection, but there are major variations within individual organizations of how clinicians do things and so simply comparing that information can be a learning process, and this is sort of written like it's talking about individuals but of course a fair amount of healthcare is given by teams, so this could be comparison of care units or locations in terms of various criteria, and then the outreach efforts.

And when you talk about outreach efforts and you think about identifiable data, you know, you could be doing an outreach effort to try to figure out gee why do certain patients not comply with suggested follow up for say mammograms, and you may want to do an evaluation to say what is the problem that these people are poor people and they live in an area where there is no public transportation, and so you could do an analysis based on age and based on the address or the location where these people live, which starts to get into identifiable data, but then you might say okay well I am going to try provide transportation to see if changes my compliance level, so it's you know it's sort of an outreach effort, and again if you can conclude that that has an impact that maybe worth also publishing.

So the idea here is to try to list a whole series of analysis, of concepts, and I go through this again the other point I'm trying to make is it's not necessarily all just reports, you know, these are iterative processes where people are analyzing data, trying to come to conclusions, actually coming up with some theories, testing it, looking actually at individual patients records, and doing the kinds of things that one would think one would do in the learning healthcare system.

Deven McGraw – Center for Democracy & Technology – Director

Thank you Paul. So then the second part of the recommendation and this is consistent with the statement that we made earlier, which is the provider entities really are the ones who are accountable for activities that occur with the data over which they have stewardship, and that is to say that consistent with a previous recommendations, which we've labeled as the Tiger Team's recommendations, but actually

they were recommendations that were endorsed by all of you last summer in the Policy Committee. This exemption, from the definition of research, of these types of activities should apply only when the provider entity or the organized healthcare arrangement, and we've got a definition for that in the text materials, it's the same one from HIPPA, retains oversight and control over decisions regarding when their identifiable EHR data is used for quality, safety and effectiveness evaluations, and again this is really based on some of the work that we had done previously that recognized expressly that patients place trust in their healthcare providers with respect to stewardship of their health information.

So that when the provider entity or the OHCA in which they might be participating no longer has control over decisions regarding access to patient identifiable data, such as for example, in certain centralized HIO arrangements, which we called out in our previous recommendations as well, the patient really ought to have some meaningful choices, and we've outlined what meaningful choice looks like as well, regarding whether or not his or her identifiable information would be part of such an arrangement. So, again this is all consistent with the idea that the responsibility and accountability lies with the entity and shouldn't necessarily be pushed onto the patient through a consent requirement.

Now we wanted to make sure that this exemption would be interpreted to allow provider entities or their OHCA's to collaborate and share identifiable information for treatment purposes or to conduct quality, safety and effectiveness assessments, as long as those entities are still remaining in control over decisions regarding how that data is to be accessed, used and disclosed, and I think this pulls up the example that Paul gave about two collaborating organizations just a moment ago in the presentation. And as always, again consistent with our letter of last August, which you all endorsed, entities should follow the full complement of Fair Information Practices in using identifiable data for these purposes including, but certainly not limited to, because this list would otherwise be very long, being transparent with patients about how their data is used for treatment, quality, safety and effectiveness evaluation purposes using the minimum amount of data needed to accomplish the particular activity and protecting the data with security measures that are commensurate with the privacy risks associated with the data.

So, I just want to create a summary here because I think it's important to understand how our Tiger Team recommendations are a bit different from what the ANPRM is already proposing. The ANPRM already seeks to reduce obstacles to the use of clinical data for evaluation purposes by continuing to exempt it from IRB approval, but under the ANPRM such activities are still considered to be research, it is still required to be registered with the institution or IRB even though their approval isn't required, a general consent, i.e., research yes/no would be required if the data involved is identifiable, i.e., not a limited data set or de-identified, and no other institutional obligations will be put in place beyond compliance with appropriate provisions of the security rule.

In our view we think we have clarified and strengthened what the ANPRM began to do and this is what we are proposing to put before them, because we're recommending not creating real or perceived obstacles to doing this work, these types of evaluations that really contribute to a learning healthcare system, by calling such activities research and subjecting them to additional regulation as long as you've got the provider entity still in control of decisions regarding that data and they, as always, are ultimately accountable for the activities that occur with data over which they have stewardship, that means that the consent should not be required even if data are identifiable, and again, there is that accountability with the provider entity which is typically, again, remember our core value, the locus of trust for patients with respect to their data.

I wanted to make one more note before turning over to Paul to take us through our last recommendation. You know, again we sort of harped on this enough, the current line that gets drawn is, does it contribute to generalizable knowledge and if it does then it's research and if it doesn't then it's not and I think we've already established that we don't think that distinction holds, and instead we're recommending relying on provider entities to be accountable for what they do, which means that they sort of decide how to regulate the activities that take place with data over which they have stewardship. But, we did talk about whether just having the provider entity be accountable is this enough to protect individuals from inappropriate uses of their health information and one could sort of paraphrase this as are all quality, safety and effectiveness evaluations good, is there a better way to draw the line than generalizable knowledge

versus not, we played around with some different distinctions, none of them worked very well quite frankly. And so rather than attempt to figure out where the line is drawn we instead said rely on the provider entities to do the right thing, hold them accountable when they don't, but by the way, since this is just an ANPRM you really ought to spend some more time exploring whether in fact there is a line out there that people will understand that if you draw it won't create obstacles to doing these evaluation activities and having that contribute to a learning healthcare system.

Paul Eggerman – Businessman/Entrepreneur

And thanks Deven. So this is actually, you know, it's a lot of words and a lot of discussion, but an extremely important recommendation and this relates to what we're trying to accomplish. It's interesting that we didn't know this when we put this together. But this afternoon we'll have a discussion from Rich Elmore that discusses something called query health that's in some sense interrelated, it almost creates an expectation that healthcare organizations will be doing these things and he has some other examples of things like comparing statin usage and ways to do vaccinations in his presentation. So, if you remember I said that there was like two issues. So all of that was on issue number one. Actually, the next one only has 2 slides, so basically this is the second area, which is the application of information fair practices. So the first issue was all about the EHR, usage of EHR data, and this is sort of like a broader view, and to give you the background on it, again as Deven said the ANPRM primarily focuses on when consent should apply to secondary use of EHR data, and we make the observation that consent is but one element of Fair Information Practices, you know, and also an observation that over reliance on consent can inappropriately shift the burden for protections to the patients.

The second bullet we say here is ONC has adopted a good articulation of Fair Information Practices for its programs and then you see something written in like blue and really small font, that's not supposed to be an example of encryption, that is actually a link, that is actually a link to the ONCs Fair Information Practices description. But, you know, we thought this was also an area that the Tiger Team and hopefully the Policy Committee should provide a perspective on in terms of private and secure uses of EHR data, especially when you look at what's written as the last bullet on the screen, which is from a patient perspective most patients, probably the vast majority of patients will not understand the difference between what's called a covered entity and a research entity, so they sort of would expect that however their data is protected when the provider gathers it, it will continue to be protected that way, if the provider, you know, sends that data to some other entity or organization. So, that's basically the framing of what we were trying to do.

So, I'd say our second recommendation, that's number three, we made two recommendations on the first sort of like questions, so this is a third recommendation on the second issue, is that researcher entities should be required to adopt policies that follow a full complement of Fair Information Practices regardless of whether or not a patients consent is required to be obtained. So this is actually a very simple statement. And then there's some examples like limiting the amount of information collected to what is necessary, limiting the people who have access to those who have like a, who are performing research and who have a legitimate reason to access the data not listed here, but transparency also would be likely a Fair Information Practice that needs to be included, and then we also make a comment here, also another example is of Fair Information Practices, is of course security protections for the data, and we say the Tiger Team applauds the ANPRM for recommending researches be required to adopt security protections and that's correct. I mean, we think we do a service also for, to realize the ANPRM, if we say not only what we disagree with but the places where we agree, and so we think that this part is very good of what the ANPRM is and so we wanted to state that also.

So that in a, I know we talked for a long time, but we actually did our best to cover a lot of very complicated material and interesting material in a short period. Those are our recommendations and they're actually very important recommendations that we are submitting for your consideration and asking for approval.

Paul Tang – Palo Alto Medical Foundation

Well, thanks again, another terrific job by the Privacy and Security Tiger Team of digesting and presenting in a concise, and clear way difficult issues, and the background for them and the rationale.

So, I, that's already a contribution. So let me open it up for discussion or comments, or questions. David?

David Lansky – Pacific Business Group on Health – President & CEO

I really want to commend and applaud, thank you, this is really important. I think we maybe even underestimate how important it is. This one piece of fairly technical language I think affects thousands of providers in the way they behave and what they do with their data, and I think all of the goals that we have here are really teetering on getting this set of regulations right, because we don't, I mean none of us really care that much about just collecting data in a digital format, the question is what can we do with it and how can we use it to improve the healthcare system. So, I'm really interested in the work you've done I think it's just fantastic. I have a couple, sort of contextual, issues that I think, because we are early in the process of the rulemaking process this is a good time for us to add some perspective and context to the rulemaking that is underway that reflects the things that we particularly care about here. So, I hope, as we think about the letter we ultimately decide to send we add some language around that context that we talked about earlier this morning.

So, the one thing is the idea, the alignment with the larger goals of health reform, meaning that the kinds of information being generated through treatment has the opportunity to improve the healthcare system and we can shorthand that with learning healthcare system, but I think that underestimates or doesn't flag a couple of critical additional challenges one of which is how the data will be used for public recognition and payment programs. So quality measurement is our shorthand for that, which is taking the data that is captured in the EHR and generating quality measures from it, which is then in turn pushed out for whether it's the EHR incentive program or other payment and incentive programs that are yet to be developed, that is going to be a major pipeline of how this data gets used and it's very sensitive, it's considered high stakes. Not only is the information in the EHR going to be used to generate that and therefore subject to some of these secondary uses we're talking about, but many of the newer measures we're interested in require linkages between systems. So, even something as simple as re-admission rates pretty much requires us to capture data not only from the primary institution but from some other attachment system whether it's claims data or an HIO, or some other vehicle.

So, the multi-institutional data aggregation question comes up fairly quickly and I think what we can do is open the aperture of the discussion for the regulators that it's not enough to sort of fix whatever Common Rule and HIPPA issues may be on the table today, but we need to look forward to the applications of data that are very much on the horizon with ACOs and other structures coming right down the pike. So, I think there's, so one question I'd like us to try to address in the letter, besides laying that out, is whether or not use of data for public reporting and quality measurement is in the research bucket or in the operations bucket, and part of that has to do obviously with the issue of patient consent, and particularly if the calculation requires linkage between institutions which therefore implies some kind of identifiable data to permit that linkage to happen, that's one issue.

The second issue I hope we can talk about are what I'd broadly call clinical registries and the issue there, I know there was just a meeting at the white house last month on the number of the registries talking about these exact questions, and there was a letter they sent that I hope you'll look that recommended some changes aligned with much of what we're saying here, although more narrowly focused, and the issue there, the one example they gave is the one registry right now has had to get 19 different IRBs to approve each hospital's participation in the registry, because each hospital has this idea that they need to run it through their own IRB process. So, one solution in that context was could a single IRB issue a blanket authorization that all participating institutions would accept and not reinvent the process. But, that only applies, as a solution, if we decide this is in fact research to capture and use this data in a clinical registry for typical registry purposes, is that research at all, going back to your point Deven, and I think it will be helpful, the advocates I'm referring to from some of the registry world have said let's clarify if registries are operations or research, ideally they would advocate this is really operations and it's for the purpose of the learning healthcare system and improvement, even though it's multi-institutional, but, if the regulatory process deems that the registries are "research" then let's at least simplify the IRB approval mechanism that would apply to address the patient consent issues as well. So those are the two things,

besides the contextual thing, I hope as we develop our letter we could address those two specific implementation questions. Thanks.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. I think we intended to say that those activities, again, would not be considered to be research as long as you sort of have the entities still in decision making control over their data which is distinct from physical control, it means it's allowing for data sharing but under their purview, under their stewardship, you know, with all due accountability and oversight and attention to Fair Information Practices. And so, you know, the struggle with examples and we went back and forth on this and it's one of the reasons why the snapshot of examples that we have is relatively short, is then suddenly the conversation evolves into whether we all agree that this example is in or it's out right, and so we sort of erred on the side of not getting too specific on the examples because we were concerned that we would end up spending all of our time, you know, discussing, arguing, not really, discussing civilly whether something was or wasn't, you know, was in or was out, when you know, conceptually we wanted to get everybody sort of on the same page and acknowledge to the regulators that, you know, they needed to do some additional work here to sort of further define that.

Maybe that's the area where we suggest that there are these circumstances where making clear statements about whether they're in or out would be enormously helpful and to provide those as some of our examples, some other ones that Judy helped find for us, Paul eluded to an email that Neil sent around, I mean we've a plethora of examples, but wanted to avoid having this conversation be about is this in or is this out, but I do think there is an opportunity in the letter to say, as you move this forward you need to provide clarity on these items.

Paul Eggerman – Businessman/Entrepreneur

I also want to make a point that our recommendations do allow for collaboration among institutions, you know, so there are a lot of examples of why that would be needed, one was for example a children's hospital might just not have enough data to do some quality initiative and may need to collaborate with other institutions in the region or other children's hospitals in order to get the data that they need. The registry issue is an interesting one, but we did our best to stay focused on the provider entities because it seems like there might be a lot of other issues with registries that we're not familiar with.

Paul Tang – Palo Alto Medical Foundation

And I have my card up as well to get in line. I have two questions. One is a simple clarification; one is a maybe more challenging question. One is, when you say that the use of clinical data, secondary use of clinical data for research should be exempt from IRB approval, let me just check, it doesn't mean that anybody can decide it's exempt they need to get exemption, it's the ability of the IRB to exempt it from their approval process. Is that correct or no?

Deven McGraw – Center for Democracy & Technology – Director

No. So, there are requirements in the Common Rule on IRBs and then there are institutional policies with respect to the role that the IRB plays in managing data use within their institution. If something is exempt from IRB approval it's not that the IRB is given the authority to exempt it, it's that the rule does not require IRB approval for that to take place, and keep in mind that already under the Common Rule secondary uses of EHR clinical treatment data would be exempt from IRB approval. What the ANPRM is saying in certain circumstances you still need consent and we want you to register it, we won't require it. We are well aware that there are institutions who whether IRB approval is required or not will still, as a matter of their own sort of professional, their own liability and risk management, ask for an IRB to bless or affirmatively waive the need for approval on certain types of protocols and we're not trying to tell provider entities how to manage their own, their activities. We are leaving it up to them. What we're saying is from a perspective of what the rule requires we're saying that it should not require approval, not that the IRB would be given authority to exempt it, but that it would not be required as a matter of law.

Paul Tang – Palo Alto Medical Foundation

Second question, the principals that you've developed over time are wonderful ones and it's easy to go back to them like control over the decision making of how that information is being used whether anybody

else gets control along the way, those kinds of things, and one of the values of making sure that we maintain the trust to providers is that's how you're going to facilitate all these other good things by maintaining that trust. So you're clearly on solid basis when it comes to let's say the provider covered entities in terms of all the good and learning things that you're proposing happened, essentially automatically. We need to also test whether some bad things can inadvertently slip in so that we try to prevent those because it would just hurt the trust.

So one question is having to do with repurposing of data and involves the business associate. So, if a business associate gets access to identifiable information through a legitimate means did you talk about or did you comment on whether that business associate after having obtained the information in a legitimate means can then go on and repurpose it even if it goes ahead, it uses the identifiable information, creates de-identified aggregate information and then uses it for other purposes, where that for me, the test I try to use in my own mind is would the patient expect such a thing to happen? They expect you to.

Deven McGraw – Center for Democracy & Technology – Director

That's a Paul Tang test.

Paul Tang – Palo Alto Medical Foundation

They expect the provider to share information with other people coordinating the care. They expect them to do quality management so on and so forth. Would they expect them to lose control even if it then becomes de-identified in the business associates hand and go on to be used for other purposes? Here are some examples of where the consumer might not like, creating, aggregate information that would cause underwriting rules to exclude populations that that consumer or patient is a member of, or looked at the other way, have that consumer be targeted for marketing. So, these are things that they did not expect as their provider goes and maximizes the health and well-being of that individual, their data can get out of their control, but through a loop hole get converted into aggregate data that's no longer covered by HIPPA. So, it's sort of a long argument, but it is one of those things where if we aren't careful in the ways we let data be used without consent or authorization and some bad things happen we could deteriorate the trust that people have in their provider.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, undoubtedly, and by the way requiring consent would probably not keep any of that from happening.

Paul Tang – Palo Alto Medical Foundation

I totally understand that.

Deven McGraw – Center for Democracy & Technology – Director

But, having said that, so we have some, what we did about business associates in this particular round of discussions was to assume that the business associates are acting only pursuant to strict, you know, some confining authority from covered entities with respect to identifiable data. You'll recall that in the August, I call it the August letter, I think the actual date is September 1, but we approved it in our August meeting of a year ago, we put actually some very strong language on the table for ONC that said, you know, intermediaries including business associates that receive data need to be using that data only to the extent necessary to perform the service, oh and by the way, if they're going to use de-identified data they ought to at least disclose it to their customers, right, to the covered entity that they are getting the data from, so that the entity can then decide, well I don't know whether I want to give the data for that purpose. So, we could make specific reference to those recommendations because we've already made them and I happen to think that's a very good idea.

On the issue of uses of de-identified data there's a lot in the ANPRM that could be fodder for comment. We ultimately decided that that set of issues we didn't have time to fully mine in time to be able to submit a comment, get it through the Tiger Team, get it through the Policy Committee, feel like we were operating on firm ground with respect to having investigated all of the different issues and the ramifications that we just stuck to what we'd said previously, what could be applied to the set of

circumstances rather than taking that issue on. I personally think it's an important one. We've had discussions about this, but I don't think we have the time to go into it in this particular letter.

Paul Tang – Palo Alto Medical Foundation

It really does test your principal of maintaining control over the decisions that are made.

Deven McGraw – Center for Democracy & Technology – Director

Well, it tests the principal of the provider entity and decision making control, it tests the Paul Tang principals, patients should not be surprised about what happens with their data, but I think I've done personally enough work on the de-identification issue that it's not a simple one to resolve and I wouldn't shy away from us taking it on but I think we'd need some more time to do it.

Paul Tang – Palo Alto Medical Foundation

And your compromise at least of requiring the business associate to be transparent to the covered entity.

Deven McGraw – Center for Democracy & Technology – Director

Right.

Paul Tang – Palo Alto Medical Foundation

The source of the data at least gives them ability to exercise some of their decision authority correct?

Deven McGraw – Center for Democracy & Technology – Director

Yes. Yes.

Paul Tang – Palo Alto Medical Foundation

Art?

Arthur Davidson – Denver Public Health Department

This was excellent. Thank you. I've been dealing with these issues for several decades and as a public health person and trying to deal with population health perspectives it's extremely difficult to get many of the things that you're talking about to happen without going through the hoops of an IRB to get exempted. So I'm, and as David pointed out earlier about ACOs and registries, and I think Paul you have addressed some of that in the multi-institutional sort of collaboration, you're addressing those issues as well. I'd like to go back to one of the final points that you made about this provider entity accountability. So, the FDA and the federal government in general have set up these institutions that have driven the process of performing quality assurance in many instances, their calling it research because it was generalizable, even though that wasn't necessarily the case, and I love the fact that you want to contest that, but how, since there is this structure that's been established for us to operate under these IRBs, do you think that just saying that the provider accountability is enough? Do we need to provide some structure to that to allow my organization or other organizations to work with me at a level where we can do this quality improvement or population perspective, is it enough for us to just say it's a covered entity their going to act responsibly?

Paul Eggerman – Businessman/Entrepreneur

Great question.

Deven McGraw – Center for Democracy & Technology – Director

I think it's a really good question and it's one of the reasons why we have some specific language that we've drafted in the letter that says, we may need something more here, it may be a different line than generalizable knowledge, and it may be, and we don't expressly acknowledge this, and it may be worth acknowledging it, it may be some other process of oversight over the organizations themselves to make sure that, you know, the public is wholly comfortable with all of the activities that are going on. There's a role, there's a greater role, I personally think that transparency can play with respect to these activities, much of them patients are not aware of. I think if they understood more about what was going on they would be largely supportive because they want improved healthcare too. So, you know, I think we're reluctant to go down, and we acknowledge that in some cases that, you know, for an individual institution

who has the responsibility for oversight over any activity that goes on with data over which they have stewardship responsibility that we didn't want to tell them exactly how to do it, but we acknowledged on the call that many of them would probably use their IRBs in some role to get this done and the IRBs would want to have that role, they have traditionally had that role, but I think we were hoping that eliminating it as a requirement might actually at least begin a conversation about, you know, how we can remove real or perceived obstacles to get this going, but without removing the institutional accountability that we seek.

If you have any other suggestions it's the very sort of crux of why we said "thank God this is an ANPRM" right. Like we don't to have all the answers we can actually throw some things out for HHS to further consider and we might get another bite at this apple and we hope we will, not necessarily we the Policy Committee, but we the public who care about this so.

Paul Tang – Palo Alto Medical Foundation

Ms. Agarwal?

Madhulika Agarwal – Department of Veterans Affairs

I also just wanted to say, you know, you have done an incredible work for a large group of clinicians who have been using the data to improve the quality of care and I say that because, you know, this does have basically a certain value in learning organizations it's just not enough to just collect it's data, but unless someone is looking, especially the clinicians themselves, it has such potential to continue to do what I think why this was intended, and I think, unlike my colleague here, I would rather leave it more broadly open, and I realize that, you know, there are certain downsides to it, but by and large for those entities that have been using this information for over a period of time, we also then begin to use the IRBs for a certain purpose or not, and that becomes more, I know it places the burden back on the providers and the institutions, but I think that's probably where the focus may need to be as opposed to defining it much more concretely, because if you put more barriers it becomes a challenge and that's one thing that we just don't need more of. Thank you.

Paul Tang – Palo Alto Medical Foundation

Judy and Rob and David?

Judy Faulkner – EPIC Systems Corporation

I also think this is a really exciting area and the phrase that keeps going through my head is the soul of medicine that's what we're discussing right now. One of the things I wanted to mention is I think that with technology and the way it's going we're not going to see research in the same way that we did before and I'm thinking now of all the folks who when they ask a question they pull out their smart phone, they type some stuff in, they get back a result and they've found the answer themselves, and I think we're going to see that being more and more of the case in the future where the physician who has a patient with a strange rash and high fever and knows that it's caused some really bad illnesses is going to say let me look, or the physician with the bungee cord injury in front of him is going to say what else, who else has had that and how do I treat it. I think we're going to see that which falls under this definition of research perhaps, looking at that data, and if we don't allow that we're going to really not take care of both the individual patient who is in front of that physician as well as things like Lyme disease and AIDs, and Legionnaires' disease, and thalidomide problems, all of those, if we had had those tools there might have saved a lot of lives by finding this stuff out right away and I think if we put obstacles to that individual physician, who will be the researcher of the future, and I think that's what you were eluding to, that's going to be a difficult obstacle.

The question that I have is about re-identification and I'm not sure what, if I understood that properly. I'm thinking now of suppose you've got patients with various implants, heart implants or joint implants and they find out, and I think there was, I think this is sort of a real situation, that 4-6 months later some of these people are suddenly dying and you want to look to see, uh oh, do we have a problem here. My question is if a physician is saying I've just had a patient die I want to see if there seems to be a problem, finds out that there is can you not re-identify those patients to say you better do something, you're going to have a problem? That worries me.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, that would be called treatment Judy and you always have to use identifiable data when you do that.

Judy Faulkner – EPIC Systems Corporation

Okay, yeah. All right that's okay.

Deven McGraw – Center for Democracy & Technology – Director

The point is, is that if you as a researcher are getting data from an institution that is de-identified, you know, typically you want to, and your basis for being allowed to have that data is that it's de-identified, you want at a minimum a commitment not to re-identify that. Now, certainly if the researchers see something in the data they ought to come back to the covered entity and say "hey I saw something in your data and we need to identify your patients" and then that entities should in fact do that.

Judy Faulkner – EPIC Systems Corporation

I'm okay with that. I'm wondering if there's some, as we look through this we should be real careful when we use the word researcher that in many cases it's a physician taking care of the patient.

Deven McGraw – Center for Democracy & Technology – Director

Right absolutely. Well when a physician is taking care of a patient they call that treatment and under any circumstance.

Judy Faulkner – EPIC Systems Corporation

That's okay.

Deven McGraw – Center for Democracy & Technology – Director

There's no obstacle to the use of identifiable data for that purpose.

Judy Faulkner – EPIC Systems Corporation

Okay.

Paul Tang – Palo Alto Medical Foundation

Okay, Robert?

Robert Tagalicod – Centers for Medicare and Medicaid Services

I again want to reiterate what everyone has already said you did a great job and actually I'm thinking of pulling some of slides in order to talk about the Advanced Notice of Rulemaking. I also want to punctuate or highlight a couple of things that you've already mentioned and I'd like, whether it's actually in the rulemaking process or in some other process, is about the oversight piece and the other side of the coin is compliance and I think this is something that we've been struggling at CMS and certainly other federal agencies, so what is the bite if there is noncompliance and how far do we go and whether that's really more of an operational rule versus the actual regulation, that's a kind of struggle, and hopefully that'll be borne out in the rulemaking or the Advanced Rulemaking process.

I think the other thing too is to also be aware of, and again it's an operational thing that we're also struggling with, where, about identifiable data or re-identifiable data, because there are a lot of data sets out there and we have encountered where we may give de-identified data but if it's about a practice or several practices that might be in a rural area and there are discrete number of providers with discrete number of patients that could be used in taking other data sets in order to do that. So, again, but where do we do that and what kind of principal do we put out there.

The third thing that I wanted to kind of punctuate is harmonization, the harmonization between covered entities and non-covered entities, but I think the challenge for us in terms of federal agencies in particular, I think we kind of need to look at, because each agency and then HRSA as well, is that we do have equivalence of data governance boards and people come to us asking to do research, and I think part of it is, my question is, and it's really a question to be kind of answered again in this process, is so what rule

is there at HRSA versus CDC or other places so that they're harmonized, because what we want to avoid is, oh I can go to agency A because I can get the data easier and therefore I'm going to go there and then that has an operational effect which is they're going to go all over to one group of another, so I think, and then it confuses the message that we want to say, so we have two values, we want transparency, but at the same time we want to protect certain data. So, I think those are the kind of things and those are more of comments.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. They're good ones I mean the ANPRM does call for harmonization but I think they probably don't spend as much time on it as they could, so, yeah, of course.

Paul Eggerman – Businessman/Entrepreneur

Excellent comments. Partly in response, this afternoon Richard Elmore and I think Doug Fridsma are going to be presenting a, what they call query health which is about distributed analysis, which helps a little bit with some of these issues of de-identified data. And Deven has told me and I may not still get this right, that when we talk about de-identified data there is like de-identified raw data which is about a patient, but there's also de-identified data that says, you know, you've got, you know, three people with central line infections or 3% or something like that, and so they're going to be talking about situations where you don't have to have the what I'm calling the de-identified raw data transferred all over the place which helps a lot, but it's also an interesting issue because those institutions who perhaps are the ones that are most helpful, in terms of trying to provide data when requested, could have this sort of like unfortunate cyclical thing where they're get asked more and more, which, you know, is possibly both an expense factor for ones that are trying to be helpful, but also could be in some ways skewing the data, right, because only certain institutions perhaps because of the financial capability will be providing some of the data. So, the whole area is extremely challenging.

Paul Tang – Palo Alto Medical Foundation

David, Neil and then I'll have a final question.

David Lansky – Pacific Business Group on Health – President & CEO

So one of the reasons I didn't flag earlier is we are now in Meaningful Use proposing that providers be capturing data from patients, sending data to patients and gradually capturing data from patients, and I don't know that we have fully thought through in the context of this, how that data, I mean know it will be treated de facto as EHR data once it's acquired by the, but in reality it'll probably end up existing, a little bit as Judy said, in a variety of other platforms and media and by other partners, and I would like it if our letter again would open the aperture a little bit for the rule makers. In our registry work we have about 60% of the cases, patient cases, not capturing the patient reported data because the institution feels it's too much trouble to go through the permission, the consent process, to get the data from the patient because of the distal relationship to the patient at home and getting follow up data is hard, and I think they often cite the requirements for consent as one of the barriers to gathering data from the patient in the course of everything else in the registry they will capture from internal systems, this piece, which we all think is very valuable for patient reported outcomes and so on, is considered harder because of the consent issues.

So to the extent we can, in the course of this next cycle, bring that process into the fold, it may be helpful to do, and again that raises the IRB question and whether there are mechanisms that are easier than the hospitals particularly perceive the current situation so that they will be, that won't be a barrier to getting patient reported data.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I think they're working on, notwithstanding the extension of the time, I think we probably, we really don't have bandwidth for a sort of full consideration of specific issues in terms of what we fold into the letter, but what the additional time does give us is a chance to flush the letter out in some more detail and you'll have another chance to read it and react to it and make sure we got it right before we can submit it. Nevertheless, I do think that as the Meaningful Use Workgroup continues in discussions about patient reported data that we ought to be keeping this set of issues in mind, you know, previously because the

Tiger Team had only talked about, you know, treatment and primary uses of data we didn't stray into the secondary use category, now we clearly have. So, we have really a richer plate upon which to weigh some of these considerations which will be good.

David Lansky – Pacific Business Group on Health – President & CEO

The only problem with that is from the Policy Committee side of it, in a way the Tiger Team was convened early on with the idea of taking on kind of quick wins in a variety of areas that needed very thoughtful but quick responses, technical in a sense, and I think what we're seeing in this particular instance is this rulemaking triggers some of the most strategic questions in front of us around care coordination and patient involvement and so on. So this is a very important moment for us as a policy body to almost go sort of beyond the Tiger Team's charge and say we see these important areas of data, acquisition and use, which raise important privacy and security questions, and we don't want the rulemaking, we're not going to get many, you know, bites at this apple, and I think this is chance for us to say, before you put in place another set of rules like HIPPA that are many years to revisit, and very inflexible ultimately, make sure you anticipate the needs that we're going to be having in the next 5 or 10 years to support these larger programs.

Paul Tang – Palo Alto Medical Foundation

It's a polar effect. It's a good thought. So, real quick one, Neil, I mean, yeah.

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

So, I would just support that because I think that as Judy and others have pointed out that we're sort of in a real transformational point where it's not just that some research is going to emanate from quality improvement studies, but the way that the entire medical care community is focusing on quality improvement could become the dominant way in which people asking the questions of data and start to do this. So this is critical and our own organization is deeply involved in this and I just, there's one piece that we haven't talked about yet and I know it's beyond our purview, but we need to concentrate on how we're going to deal with it and that is something that came up at our research meeting yesterday, which was somebody raised the issue that journals all require IRB approval and I actually just went on-line to look at a study and actually it's gone from 51% of journals to now 76% of all medical journals require IRB approval before they'll publish an article. So, again, if you're thinking about sort of reducing obstacles we might be able to reduce the obstacles on our side, but if people are all, sort of feel like they have to go through this process in order to eventually publish something there's going to be a blockade a little farther down the road that is going to keep us from generalizing knowledge and I think maybe a good thing will come out of that and medical journals will become obsolete and we can get the information, we can get the information on-line in a peered review way and in a way that doesn't take 4 years for it to see the light of day. But, it is another thing that we should deal with.

Paul Eggerman – Businessman/Entrepreneur

Yeah it's an interesting comment but when I was looking, talking about publishing I did not necessarily mean just medical journals there's lots of ways you can publish your information and publishing information just might be making it available on a website and once you've done that, that by itself could contribute to generalizable knowledge, it's a very interesting thing, you don't need a medical journal anymore to publish

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

We're hoping.

M

I have a quick one, the, we're talking about moments in time and transformation. Part of our problem is that HIPPA only covers the covered entities and that was good at the time and what could pass at the time. Are we ready for comprehensive legislation that says everyone who touches data is accountable and wouldn't that solve a lot of our problems?

Paul Eggerman – Businessman/Entrepreneur

What you're suggesting there is pretty close to what we put into our last recommendation, which is we said the research entities must follow Fair Information Practices.

M

Well, I mean.

Paul Eggerman – Businessman/Entrepreneur

We are getting very close to saying what you're saying.

M

In a sense if you go all the way to everyone who touches information has by law, by federal law accountabilities, enforceability, then that could actually raise the bar for everybody and actually reduce all these loop holes and chasing after the loop holes.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. I mean undoubtedly, it's not something to take on in this letter, but keep in mind in our September letter we said "all entities who handle health data should be subject to."

Paul Eggerman – Businessman/Entrepreneur

Yes.

Paul Tang – Palo Alto Medical Foundation

Yes, Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Yeah, I wanted to, in fact I'm tagging onto what Paul originally said and also what he's just brought up again, and this is since we have an additional month to respond to this ANPRM I think we need to really discuss, at our next Tiger Team Meeting, the question of this secondary use of this information, especially when you get into business entities who have a relationship and where we're going, business associates who have that relationship, and especially for commercial purposes, and the accountability for that, when you talk about what patients expect to happen to their information. So, we are, because the information is there and it's being used we want to make sure that it's used appropriately and patients are not surprised at the end of the day as to what happens to it.

Deven McGraw – Center for Democracy & Technology – Director

You're not suggesting that we try to tackle that in time to put it in this letter, but just.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

I think.

Deven McGraw – Center for Democracy & Technology – Director

Suggesting a future topic?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

I think it needs to be raised in this letter.

Deven McGraw – Center for Democracy & Technology – Director

I think what we will be able to do in the time that we have is to reference the recommendations that we made previously with respect to business associates. We probably have one meeting between now and the next Policy Committee Meeting in October, they're 2 hours long, that's a big issue, and we have been asked by ONC, as you'll soon learn Tiger Team members, to take on some issues related to query health that are going need to get resolved relatively quickly so that they can move onto the work that they want to do to get that up and running. So, I'm not trying to shy away from that work I think we said some very good things about business associates that are not currently reflected in this letter that we can easily put in because we've already come to agreement on it. And then do some thinking off-line about a schedule that will enable us to take on some of the issues that have been raised today with respect to de-identified

data use either by covered entities or their business associates when we have some more time to tackle it.

Paul Tang – Palo Alto Medical Foundation

Okay.

Deven McGraw – Center for Democracy & Technology – Director

Is that okay Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Yeah.

Deven McGraw – Center for Democracy & Technology – Director

I'm just thinking of our timing.

Paul Tang – Palo Alto Medical Foundation

Extraordinary summary and extraordinary work. Thank you so much. It's so much clearer. You've got the full engagement of the committee back in. It sounds like what you'd like to do, especially given the extra month that...gave you is to sort of revise the letter, incorporate a little bit more your thoughts, refer back to some of the previous things, which I think are very germane to the topic here and circulate that or how do you, or do you even want to bring this.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. Yeah.

Paul Tang – Palo Alto Medical Foundation

Back next month.

Deven McGraw – Center for Democracy & Technology – Director

So here's what I'm proposing to do and I'm sort of going off the top of my head so, I don't even know if Paul's okay with this, he'll tell me if he's not, and other Tiger Team members who are around the table. So, I think what we heard today was some suggestions for how to improve the letter, but not necessarily a need to modify the recommendations and that's terrific, thank you all very much. So, we could work on the letter and have a draft circulated prior to the next Policy Committee meeting and then we'd ask for a shorter, we could do one of two things, ask for a short amount of time at the meeting to deal with any lingering wordsmithing or other issues, or just ask for folks to respond by email and work it through that way, however you think is best.

Paul Tang – Palo Alto Medical Foundation

So, I think this topic always warrants a discussion even if it's for information, just getting everybody on the same page.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Tang – Palo Alto Medical Foundation

So a short presentation next month would be wonderful.

Deven McGraw – Center for Democracy & Technology – Director

Okay we have time to do that thankfully.

Paul Eggerman – Businessman/Entrepreneur

And, just to be safe.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, you okay with that Paul?

Paul Eggerman – Businessman/Entrepreneur

Yeah, we didn't do a vote on everything, but is it correct that the Policy Committee accepts the recommendations, at least in principal as we've described them?

Paul Tang – Palo Alto Medical Foundation

Okay, so let's have a vote for that. So this accepting their recommendations and then we'll revisit sort of the revised letter that helps embellish some of the points. Any movement for that? Motions, yes? And second. And any, Okay all in favor?

All

Aye.

Paul Tang – Palo Alto Medical Foundation

Any opposed? And abstain? Thank you very much.

Paul Eggerman – Businessman/Entrepreneur

Thank you.

Applause.

Paul Tang – Palo Alto Medical Foundation

All right so I don't know that there's any possible way to have lunch in a half hour anywhere so let's try 1:35 to reconvene. Thank you. Well, in order to get done, we're supposed to, 1:35, yeah thank you.

Deven McGraw – Center for Democracy & Technology – Director

Places in the general vicinity in theory.

Paul Tang – Palo Alto Medical Foundation

In theory.

Lunch

Judy Sparrow – Office of the National Coordinator – Executive Director

I think we're ready to begin if everybody could please take their seats and let me check, Rich Elmore are you on the telephone?

Richard Elmore – Office of the National Coordinator – Query Health

Yes I am.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay. Thank you. Dr. Tang.

Paul Tang – Palo Alto Medical Foundation

All right for the folks on the phone and over the web the reason we're a little bit late and why's it's still a little bit noisy here is we're having a celebration for Judy Sparrow's retirement and like to acknowledge and thank Judy Faulkner for providing the cake and ice cream and to which the committee members contributed, so thank you. Thank you, Judy. We're trying to drown our sorrow I think. We're just totally, incredulous that it's just like the Privacy and Security Tiger Team and this may be our last meeting for all we know. Yes the members of the audience can also, there's plenty of cake.

Judy Faulkner – EPIC Systems Corporation

Yeah everybody should go help yourself.

Paul Tang – Palo Alto Medical Foundation

Yeah, please help yourself. All right, getting onto other business, we're going to hear an update on a very interesting project called Query Health it was eluded to earlier this morning, and we have two members joining us by phone, Richard Elmore and Doug Fridsma, you both there?

Richard Elmore – Office of the National Coordinator – Query Health

This is Rich I'm here.

Paul Tang – Palo Alto Medical Foundation

Okay. And Anand Basu representing ONC here in the room. So who is going to go first?

Richard Elmore – Office of the National Coordinator – Query Health

So, thanks Paul, this is Rich Elmore I'll be presenting on behalf of all 3 of us and Doug will be joining the call...today. So.

Paul Tang – Palo Alto Medical Foundation

Wonderful, thanks Rich.

Doug Fridsma, MD, Ph.D – Office of the National Coordinator Director, Office of Standards & Interoperability

Paul and Rich, this is Doug Fridsma.

Richard Elmore – Office of the National Coordinator – Query Health

Hey, Doug. Okay, so should I go ahead?

Paul Tang – Palo Alto Medical Foundation

Yes please.

Richard Elmore – Office of the National Coordinator – Query Health

Do we have the presentation can that be brought up. Thanks very much. So, the discussion today is about Query Health, which is an initiative that Doug and Farzad...and myself just launched just a week ago, and the goal here is to be able to come up with standards and services for distributed population queries and so the timing for this conversation with the H. Policy Committee couldn't be better. We think that guidance and linkage with H. Policy Committee is crucial to the success of this initiative and thank you very much for making some time. Next slide please.

We are going to cover two items here, one is just some background in which I'm just going to drive through quickly, a lot of it, for anyone who participated in the launch event it'll be familiar to you but I just wanted to make sure everyone was level set on the project itself and then really wanted to talk a little bit about how we work with the Policy Committee, some initial thoughts we have on a policy sandbox to guide the work of the initial pilot implementation and that's the agenda. So next slide please.

The position here really is to enable a learning health system to be able to understand the population measures of health and various other aggregate measures such as those related to performance measures or measures of disease outbreak, or quality measures, and in a way that'll be respectful with patient privacy and consent I might add, to be able to improve patient and population health and to reduce costs. So that's the idea of really enabling that learning health systems. Next slide please.

A context you all know as we're reaching critical mass of deployed electronic health records and with more and more clinical records like the health information exchanges also coming on-line we're at a time perhaps like never before where we're able to ask these kinds of questions in a way that is thinking about standards that can be applied, you know, across the country, and the opportunity here really is to be able to enable proactive patient care in a community and generally to be able to improve community understanding of population health and performance and quality in order to be able to deliver insights for local and regional quality improvement and to facilitate consistently applied performance measures and payment strategies. And also to be able to think about identifying treatments that are most effective, you know, comparing effectiveness considerations for the community as well. A community could be, it could

be a health system, it could be an out region, it could be the nation, so that's in the broader sense what we're shooting for, but really focusing on the local and what we can do to be able to be impactful in that regard. Next slide please.

The challenge is obviously that there are pretty high transaction and plumbing costs today in terms of folks that have been working on distributed queries and there's some really great work going on, we'll talk about that in a minute. But there are some challenges, you know, clearly there's variation in clinical concept coding even within organizations using the same system. There's a lack of any distributed population query standards, and there is isn't necessarily good appreciation of what are the best business practices. I really appreciated the work earlier today of the Privacy and Security Tiger Team, some of their work on secondary use, you can imagine the applicability to a project like this, and some of the challenges that we'll obviously face in this regard. There's also a centralizing tendency that moves data further away from the source as a way of trying to get at data across organizations, but it comes with, you know, a risk of increased PHI exposure and to a certain extent limits our ability to be actionable in response to patient consent preferences. So, you know, if there are ways to be able to distribute the queries as opposed to bringing the data together to be able to ask the questions that will do more in terms of being able to reduce some of those risks and exposures. And the work that has been done so far really has been limited to larger health systems, those that have the budgets either in research or in IT, and there are a few notable exceptions to that, some really impressive work that's gone on in New York City and some other places. So, that's the challenge. Next slide please.

Our goal is really to improve the community understanding of patient population health to be able to ask the question, whether it's to, you know, a small physician office or whether it's to a larger hospital and to be able to get an aggregate result back, and those questions might be about disease outbreaks, they might be about prevention activities, or research, or quality measures and some of the others that I mentioned earlier. Next slide please.

So the scope and approach is for those of you who are familiar with the direct project it's somewhat similar in the way that it's being structured. It's a public private partnership project. It is focusing on the standards and services related to distributed population queries and we think that there's applicability both to EHRs and to other clinical records. I mentioned possibly health information exchanges. It is also possible that there may be applicability to a personal health record. And the idea is to have an open democratic community driven consensus based process to get us to that goal and the idea the way this works is basically to try to get some rough consensus quickly, and to get to running code and pilot is a way of, you know, using the practice to be able to drive our understanding of what works and to be able to use that to try and get to recommendations around final specifications and standards. And we think that there is a critical linkage here from the H. Policy Committee and I should add the Privacy and Security Tiger Team to provide the guidance that we need, the policy guidepost that we need to be able to drive this project. There are two words that will not appear in the project. One is policy, one is governance as things that are part of our scope, we expect that those are things where we'll taking directions from the Policy Committee, but we do think that it's an important area where our working together can ensure that we're doing some good work for the country. Next slide please.

Just very, very quickly I'm going to run through a couple of user stories. This one is a case controlled vaccine efficacy story, really it's looking at, firstly looking at quality compliance here, the number of patients over the age of 50 who have received a flu vaccine so, you know, sending out a question about that. The second part is about surveillance, determining what patients have actually contracted the flu, and then the third part is kind of the effectiveness or efficacy part is this 2 x 2 vaccine yes/no and flu diagnosis yes/no, and then we suggested, you know, that you could refine this query, for example response to H1N1 to add GI as a symptom in the query and to be able to test by H1N1 vaccine. So, the idea here is, is that we get a better understanding of a particular situation that we're aware of we need to make some adjustments to queries. The idea of this initiative is that we would be able to do that in near time. Next slide please.

So, here's another example, this one is more of a comparative effectiveness example where the other one was a little bit more of a public health example if you will, but the structure is very similar. So, here

you have the number of patients over 18 who have been diagnosed with, are potentially hyperlipidemic, the surveillance is determining, oh sorry, number one is that their taking a statin, number two is that they are potentially hyperlipidemic, and then there's the 2 x 2 the comparative effectiveness of those who are taking statins and the incidents of hyperlipidemia, and then the refining part of this particular user's story is the, you know, select 2 statins and compare the efficacy of those. Now, we had our second meeting of the clinical workgroup today. They're coming up with a number of other user's stories, some really terrific ones both generalized and ones that are more consumer oriented, so there is a number that will go into...how we need to determine the architecture and the standards and so on, but eventually we'll probably boil it down to a couple that we'll probably put into trial or onto a pilot. Next slide please.

So, again the goal here is to be able to use this one, you know, kind of simple secure use case to be able to establish the standards and protocols for, you know, the patient data that's going to be queried against, the query and case definition, suggesting here that that might be done in some sort of a published subscribed model, but in any event under the disclosing entities control, and then thirdly the results out and back to the requestor of the information. So that's the basic model that we're using to be able to establish the standards and protocol. Next slide please.

The organization itself has a voting group of committed members called the query health implementation group. There are three workgroups, the clinical workgroup, which is focusing on the meat and potatoes of what's the data, you know, what's the question, what are the results. The technical workgroup, which is focusing on more specific standards beyond vocabulary and the architecture and the actual then reference implementation of that, and a business workgroup, which will I think have probably the closest linkage to the work of the Policy Committee and the Privacy and Security Tiger Team, we'll describe that in a little bit more detail in a minute based on some of the challenges, but the little yellow arrow says where we are in the project timeline, we're just into the requirements and specification stage. We just completed an environmental scan of the number of folks that have been doing kind of work on the distributed population queries and provided us a good foundation for the work we're going to be doing. Next slide please.

So, here's the community participation, the various groups that are coming up, this is just more for your information. Next slide please.

There is goals alignment here both with the S&I framework of which this project is an S&I framework project. It's an open government initiative. We're trying to engage a wide variety of stakeholders and we're also trying to make sure that we're well aligned with Meaningful Use and various standards as you can see here, and we'll certainly have more on that as the project progresses. Next slide please.

We're also going to be aligning with one of the major strategies of ONC, which is, you know, the digital infrastructure for a learning health system and as we look at some of the work that came out of the IOM report recently on this that has been sponsored by ONC we saw a good deal of alignment between query health and a number of the attributes for a learning health system. Next slide please.

The summer concert series was the presentation by the practitioners that have been doing work on distributor queries, there were a number of them that presented, terrific work, amazing results, and just great value propositions, and kind of indicates the importance of this project and what it can offer to the country. It also came with it a set of challenges. Next slide please.

And, you can see the list here, both, you know, just how you handle data use and data sharing, sustainability to what we're calling organization management and coordination and so on. One of the things we've heard from a number of folks was, you know, the hardest part of distributed query isn't the technology it's the policy and governance and here's where you all come in and trying to deal with that, help us, you know, kind of bring this project through. So, we have these challenges, we think that, you know, we're going to have to put some focus on them as well as on the clinical and the technology, and we want to make sure that we've got the right kind of coordination and follow up and guidance from the Policy Committee and the Privacy and Security Tiger Team. Next slide please.

So, we want to get your input. We think that both of you are able, both the committee and the Tiger Team will be able to provide policy guidance, and our intention would be to make sure that you're receiving updates and able to monitor our progress, and probably the first place that we'll need some help is in the policy sandbox for the initial pilot and the idea here is to put up the guardrails for that initial pilot to make sure that we're within the right bounds, you know, I think that there is other work we'll want to do in terms of trying to reduce costs and make the work of query requestors easier, but the purpose of this is to make sure that we have something that's safe, cautious, and conservative for the purposes of starting that initial pilot work. And that reference implementation work won't start until later in 2011, so there is certainly time for a needed review. Next slide please.

So, the initial set of policy sandbox ideas has been modeled after previous S&I framework initiatives, it's been done in consultation with the ONC policy and privacy and S&I framework leaders and their staff. It's not new. It's not foreign. And the applicability here is really to the initial query health pilot, you know, we really hear it on the side of abundance of caution to this. Next slide please.

So, basically the idea is that query request, we focused, I should also mention focused on the privacy side, certainly there are security considerations and they will be part of our work as we go into a reference implementation. But, from the point-of-view of privacy in particular, the idea is that query requests and responses shall be implemented in the pilot to use the least identifiable form of self-data necessary in the aggregate within the following guidelines. So there are three principals. First is that a disclosing entity should have its queries and results under their control and that could be manual or automated, you know, publish/subscribe model or maybe other means of doing that, but basically under the control of the person, of the entity that's responsible for the data.

The second is that in terms of data exchange the data being exchanged, again for the initial pilot will either be test data or it may be aggregated de-identified data sets, or aggregated limited data, in the sense think of them as the data columns from which the aggregation will occur each with data use agreements, and just a note there that we understand that not necessarily is de-identified data sets required, data use agreements, but in the abundance of caution category we will expect to apply them for either one.

And then the third is the public health permitted use which could involve exchange of identifiable information that is permitted under state or federal law regulation.

And the last principal is this notion of small cells that other than for regulated or permitted use purposes that cells of less than 5 observations shall be blurred by methods that reduce the accuracy of the information provided, and that's not, it's based on some good statistical science and it in and of itself it's just really designed to provide a bright line for the project that allows it to proceed forward. So, next slide please.

So, that in a nutshell is the project, again, you know, it's this notion of aggregated distributed population queries and, you know, we're looking forward to working with both the committee and the Tiger Team and appreciate the opportunity here to be able to present and would like to open it up for questions if that is appropriate at this time.

Paul Tang – Palo Alto Medical Foundation

Thanks, Rich. Any other comments from Doug or Anand? So that's it. Go ahead.

Doug Fridsma, MD, Ph.D – Office of the National Coordinator Director, Office of Standards & Interoperability

This is Doug, I just want to appreciate and sort of applaud Richard for all the work that's he's done to date. There's a tremendous amount of work that has gone on over the summer sort of to understand the problem a little bit better and, you know, the goal here is aligned with many of the principals that we have within ONC and provide the little guy, provide the folks with the boots on the ground that are the ones that will be the enablers of change to have the same kinds of analytic resources that a larger organization might have as well and being able to provide that kind of distributed query and functionality I think is just

so important to the larger goal of improving the healthcare system and the way in which we deliver high quality care. So, thank you, Richard that was a really nice summary of the work that has gone on so far.

Paul Tang – Palo Alto Medical Foundation

Okay, comments, questions? Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, this is pretty exciting work and I'm glad to see it happening. I was happy to see it up on the S&I framework website whenever it was a week or two ago, time flies in this committees experience. And I noticed that you had a slide packed with people who are already experts in the space, so it sounds like there has been pre-existing work that's been done, at least at some kind of pilot level. So, the question I had was really how this relates to some other things that we're doing, which is around the quality measure initiatives where eMeasures have a specification that's in theory machinable for actually running the measure against the dataset and then a standard for returning the results of that quality measure. So, has there been any discussion yet on how that track of thinking ties in with these queries?

Richard Elmore – Office of the National Coordinator – Query Health

Yes there has. This came up in the, what we call the summer concert series, where we heard from all of the practitioners and it's also come up in the technical workgroup and we expect that over the course of the next couple of months we'll be making decisions on which standards will be applied and certainly HQMF is one of the ones that is being looked at. Some of the initial feedback we got was a question about, you know, whether or not it works, it has the flexibility to work for a query approach given that it's declarative as opposed to a procedural approach to defining the measures, but it's very early days and, you know, we're going, we'll let the technical team and the clinical team weigh in and provide their guidance. We have a really terrific, dedicated, smart, experienced group of folks that have signed up for this project across a variety of stakeholders, so I think that we'll have, you know, really good input that will guide those decisions, but we are absolutely intent on leveraging other initiatives that are underway and trying to make sure we're as much as possible leveraging the work of, you know, for standards committee work and leading on vocabulary standardization and so on as we move forward with this project.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

It seems to me this is a place where we'll get some feedback on how well some of those things work and we really should keep our eyes on looking to minimize the diversity of requirements we're going to be generating for systems to be able to handle queries and result sets. So, we actually can get code efficiencies and organizational efficiencies as people do what we talked about this morning, start to make more use of the data they have for various ways to learn and improve care. So, glad to see that it's going out there to see what's actually doable in the world. I hope some of the feedback is not just limited to the scope of research as it exists today, but we're using it in a more generalized way.

M

Thanks Paul. Rich, as you know I think it's really an important area and I'm really glad to see this work proceeding under ONC auspices. I had three questions, one is a short question I think, on your next to last slide you talked about data exchange with mock or test data and so on and it surprised me because the earlier use cases, at least that you illustrated, talk about sending aggregate results not primary patient data and I'm wondering what the term data exchange really means as you look at the scope of the project, that's my, then I'll come back to my other comment.

Richard Elmore – Office of the National Coordinator – Query Health

Yeah, thanks, so that's where we may need to do some improvement on this description, but the idea of this is, so the information that's behind the organization's firewall we're assuming is identifiable. The organization that would be, the information that would be sent out to a request for information was the point of the data exchange and that was really to be able to say, well first of all, this is mock or test data so it's really not an issue, or we will use aggregated information that would come from either de-identified data columns let's call them or aggregated limited data sets as what would be included in an initial pilot. And then the third case is a public health permitted use where it would actually potentially include identifiable information.

M

Okay. As long as you laid out the use cases it would be good to understand in each case whether identifiable data might be outside the firewall that is what I was curious about.

Richard Elmore – Office of the National Coordinator – Query Health

The only one that would be would be in the case of a public health permitted use.

M

The second thing I wanted to say is maybe close to Larry's point. I think this whole strategy has big architectural and certification implications down the road, not now, but soon, and getting in front of those and thinking about them early will be really important. As we look at, I look at sitting next to Judy, you know, whatever the vendors will need to do over time to have releases which have the APIs or other kinds of capabilities to except and respond to queries will be, I think it's a really potentially very important capability that would address a lot of the concerns we have including the privacy and security concerns, but I'm suspecting that there's a pretty long production time-line once we figure out how that would ultimately work and feel confident about it and certify it and then, you know, to have vendors begin to build to it and all that, it's very elaborate, I'm guessing that's 4 or 5 years or some fairly extended timeframe, and we should at some point get a clarity about what the potential timeframe looks like so that it effects the rest of our thinking and work in the areas like quality measurement.

And then the third thing, and I guess the other architectural is just we have a growing concern about the availability of intermediate layers of data aggregation in the ecosystem as a whole, whether those are HIEs or registries, and this is one of the important tools that might help shape the way that intermediate ecosystem gets built, so it would be good to have that discussion be part of what you guys work on.

And the last thing is really you mentioned an implementation committee on one of your slides, implementation group, and I was also kind of puzzling over the quote you have, which I like, about the hardest part of queries is technology, it's not technology it's policy and governance, because I would think that the business case is probably the critical question and because this is potentially exposing data that is sensitive or proprietary, or results that are sensitive or proprietary, there is a challenge in how willing enterprises will be to let an externally generated query come in and then they decide whether or not to run it and report on it, that business case question is pretty fundamental and the good news is there are a lot of programs, incentive programs, payment programs, licensing, certification, MOC, all kinds of things where reporting aggregate data will be a business advantage to the reporting entity and this technology could have high business value for creating a secure, and economical, and standardized way to report to those outside parties which trigger some economic reward. So potentially there is a business case there, and I would hope that as you do your use case development, even in this initial round, you think about including a couple of those so that we begin to elaborate the requirements for reporting to CMS or reporting for a specialty board or whatever it might be that would build the business case and the business values so that all the different pieces of it, all the dominoes in the chain will ultimately want to do the hard work of making this capability part of our system.

Richard Elmore – Office of the National Coordinator – Query Health

Those are just terrific comments and thank you very much for them. Just a, so in general, I mean I would just start by saying that I would agree with your comments. I think it's very important architecturally in terms of how we are thinking about this. That's a major focus for our technical workgroup and, you know, I think that the business case question that you raised is absolutely fundamental. One of the reasons that we're talking about, in the policy sandbox, is the information stays under the disclosing entities control, is that, you know, with the possible exception of, you know, regulated kinds of questions, you know, it's one of the areas that has been a challenge, right, and so we need to find ways to make it, you know, easier and less expensive for folks to be able to work together on being able to, you know, ask questions that are important not just from a, you know, provider to government point-of-view, but from a, you know, a payer to provider point-of-view or, you know, any one of a number of other use cases, I mean there may be consumer use cases, there may be others that involve, you know, kind of what's happened to other patients like me, you know, that can be addressed. So, all of these kinds of considerations need to go

into the way in which we address the support for the project but we're going to make sure it stays under the disclosing entities control.

Paul Tang – Palo Alto Medical Foundation

Good. Thank you. Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you very much and I find this absolutely fascinating and also a little scary and the potential abuse of something of this magnitude is very significant, and I think, I want to have a clear understanding of the direction where going right now, is this a pilot project that is envisioned by ONC under ONC's auspices? Do we have, where are we going with it, it has tremendous potential, but also very frightening to the public in potential abuses for it. The governance and who's going to control who asks the questions, can anybody just go in and ask a question? What's, when you talk about the business case for things are you going to, you know, if I'm an insurance company and I want to know everyone's, you know, I want to do some evaluation of, you know, some particular illness or medication, how many people are on x-y-z medication, or what genetics are there involved in some particular disease and you know, can identify everybody who has that DNA, or whatever. Huge questions on where we go with this and there's a very significant upside. There's a very significant potential for abuse and I think this is going to engender a whole lot of conversation and, Paul can you give me some direction as to what input we as a Policy Committee are going to have as this moves forward as a pilot. Is it, you know, what is the vision for how this is going to proceed.

Paul Tang – Palo Alto Medical Foundation

Those are good questions. I'm not sure I'm the person to ask, maybe Doug, maybe in a better position, sir, what's the current date.

Deven McGraw – Center for Democracy & Technology – Director

Paul.

Paul Tang – Palo Alto Medical Foundation

The future and Gayle's question about is this a pilot and what's it's.

Deven McGraw – Center for Democracy & Technology – Director

Yeah and Paul this is Deven I have some response. I mean, I don't know if you want to let Doug answer it too. I alluded to this in Paul and I's presentation on the Tiger Team side. We are actually having Rich at our next Tiger Team meeting to dive in a bit more on what's going on with query health and these sort of initial policies that they have internally developed at ONC that they want us to vet and give them feedback on, so you can look forward to exploring this in some more detail at our next Tiger Team meeting, which of course we don't do anything as Tiger Team that doesn't ultimately come to the Policy Committee. So, that may help.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

In way to follow up on that I'd like to, with your permission of course Mr. Chairman, you know, this security of the privacy implications and I'm glad it's coming to the Tiger Team is huge, absolutely huge, and who controls this mechanism and where that governance is placed and the rules and regulations beyond the use of the knowledge and the stuff that comes out of this is huge. So, I think this may be an ongoing very long conversation from many, many levels.

Paul Tang – Palo Alto Medical Foundation

So Doug or Rich you want to respond in terms of how either we can help or what influence we have on the policies there.

Richard Elmore – Office of the National Coordinator – Query Health

Yeah, so first of all I think that the Policy Committee and the Privacy and Security Tiger Team have, you know, tremendous and important input and we are looking forward to engaging with you to make sure we're staying on the, you know, on the right side of all of the issues that Gayle talked about. You know,

the very much the framing of this project was designed to be very sensitive to those variants from a number of perspectives. Number one, we're talking about, with exception of public health where it's already allowed by law today to send some identifiable information we're talking about aggregated information which won't be exposing individual's information. Secondly, the idea here is that the project itself will be trying to drive towards enabling, kind of, on non-centrally planned use of technology that is under the control of the people that are responsible for the data. So the idea is that however we implement this that the, let's say it's a provider organization, the provider organization who has responsibility for their data will be deciding what kinds of queries it's interested and being able to process, it will have the opportunity to be able to decide whether or not that's information that is appropriate to disclose.

We saw in the summer concert series that there were some particular use cases, particularly in connection with the FDA and the...work, or sorry the HMO Research Network work where payers may want to ask a question of an organization and the organization may want to be de-identified so they were willing to share information but they wanted to be able to have a trusted intermediary who not only de- identified the patients information but also de-identified the organizations information. So, you know, a number of these considerations are going into the user stories that are being worked on now, and, you know, we're very, very sensitive to making sure that we don't create exposures for patient information. So we look forward to the conversation and the guidance as we move forward.

Paul Tang – Palo Alto Medical Foundation

Good. Art.

Arthur Davidson – Denver Public Health Department

Yes. Thank you. This is Art Davidson. Thanks Rich and Doug for the presentation. I'm going to also look at the summer concert series slides and make a few comments about that. You can see on that slide, as I know some of the people who have made the presentations that there are multiple approaches to the same domain, there are people who are on different boxes on this slide, who more than once have they appeared on this slide, and there are multiple funding streams that federal agencies are now pursuing to develop these models, and since I work in at least two of these boxes, if not three, I want to talk a little bit about what it's like to be on that side of the fence and the burden it creates for an organization that is trying to participate in these very important population based efforts to analyze and allow us to proceed to the learning healthcare system. And I wondered if during, I know it was a concert series so people got up and did their band one at a time, but has there been a discussion at ONC about the leadership role that either ONC or the Policy Committee might play in harmonizing these various data models, because we all know how difficult it is even to put a box on this slide no less to ask the same question of multiple boxes at the same time and get a response from each one of them. So, the question is about whether there has been discussion yet within ONC or even from these participants in the summer concert series about how to harmonize the data models that have proliferated because of funding streams or because of significant efforts by various institutions.

Richard Elmore – Office of the National Coordinator – Query Health

So, that's a great question, you know, and the discussion about, you know, what data and kind of how do we think about different data sources or extensibility of data are very challenging in connection with this kind of an effort so I really do appreciate your question. A couple of thoughts, one is that the technical workgroup, which met this morning, had some of its members present on the patterns that were seen as part of the summer concert series and there's additional work that was indicated at that discussion on exactly this topic which is the data models and taking a look at them. We are not trying to, you know, take a best of approach from each possible implementation of distributed queries, but we are going to try to come up with something that we think is workable, practical based on, you know, what's computable in standardized today, and so to that extent we expect that there will be some harmonization of standards looking forward toward in particular, you know, phase 2 Meaningful Use vocabularies. But even still, we've heard from a number of participants that I talked to in starting up this project that there are some challenges around, you know, kind of mapping concepts to codes and you know, and just a very kind of meat and potatoes kinds of things like what's a computable definition of angina, or what's a computable

definition of acute hepatitis B, are things that are lacking today in our systems and so we have some hard work to do, and it's a very important area.

We've also heard that, you know, it's not enough just to be thinking about, you know, clinical data or EHR data that we should be thinking about claims data and so on. So, I think architecturally we think that that is important to allow for that kind of extensibility. We also think that, from the point of view of keeping it simple for an initial pilot implementation that we'll probably create a focus around the clinical record whether that be an EHR or whether that be more of a health information exchange.

Paul Tang – Palo Alto Medical Foundation

Okay, we're over time, but Marc if you have a short comment, please.

Marc Probst – Intermountain Healthcare

Sure, I promise it would be short. It's more of a comment. And as I've been listening to this it's more of a sequence issue. I mean this is a great example that if standards were in place this would be, at least technically, relatively easy to do. Governance would be difficult. And what concerns me, well it doesn't concern me, it's just something to keep in mind, is what we don't want is a harmonization of standards that creates a whole another standard. There's a lot of work out there and hopefully all the right groups are being brought to the table because, you know, there's just a lot of effort on standards right now whether it's data map models or vocabularies or communication protocols, or whatever, so it's more of a sequence issue as we look at query health.

Paul Tang – Palo Alto Medical Foundation

Comment, So I think there's a lot of excitement about the concept and I think there's a lot of devil and details that we need to work out and we'll need to work out together and glad to hear that you're plugged in with the Privacy and Security Tiger Team for sure. All right. Thank you very much Rich and Doug, and Anand. And we'll move onto the update from CMS about how the attestations are going with Robert Tagalicod and I guess Robert Anthony.

Robert Tagalicod – Centers for Medicare & Medicaid Services

And I want to thank you and I'm glad that Robert Anthony from our H group in CMS and OESS is here who can actually help answer some of the more detailed questions you might have. But, before we launch into the data and the reports I'd like to make a few points and one, the number since our last meeting is quite a bit encouraging and as you will see there's an uptake that Rob Anthony again will shortly discuss with you. Secondly, CMS and OSC are working much more closely together to ensure our activities around the RECs and the beacon communities, as well as CMSs regional offices are just even much more coordinated. We get that it's important to continue that upward trend and we will do everything that we need to do very operationally, if you will, in order to continue that trend. I think through an integrated communication planning between ONC and CMS that includes outreach and education to our various partners and we may be actually sharing the same audience and so we'll just do, we're heartened to work even more closely together.

I think the other too is, and this in response to a comment that was made at the last meeting, about the myriad things that the federal government is doing in terms of healthcare reform and how that impacts one thing or another and it might be potentially confusing and so we're actually working together, not only between us and CMS, but with HRSA and other folks, in order to get a better sense of what effects other things, what are some of the things that are being asked of both industry and of our stakeholders in order to, and how that impacts the actually up tick, if you will, or the trend, in Meaningful Use. And I think some of you may have seen, it's either this morning or yesterdays in government health IT magazine about how ICD-10 and 5010, which we're also responsible for at CMS, and Meaningful Use are interrelated and how they may affect each other, sometimes maybe negatively. So, I think we need to take a better look at what those are and how can we mitigate any kind of issues that might be related to it.

So, we, I'm not saying that we're late in the game but I think we need to, the one thing that Don Berwick had said before I came to this meeting was we really wanted to hear your input and we wanted to invite more proactively this particular committee in order to help us think those things through. And, of course,

you know, again, not being a lawyer but also being told by the lawyers that we need to kind of follow the rulemaking process, but within that rubric or within that process is a bit more that we can do in terms of both conversation, and I mean a true dialogue, that maybe not, that's not allowed in the rulemaking process, but we can certainly do it in other forms. So, without further adieu I would like to talk about more and Rob Anthony will talk about the incentive program.

Robert Anthony – Centers for Medicare & Medicaid

Good afternoon everybody. So last month we did a presentation about attestation information that we had, this month we're going to cover registration and payment, we are for the October meeting going to do an update of where we are with attestation and look at those numbers again and see how we've progressed, but for right now we're going to cover sort of where we are overall with the program at a higher level. So, all of this information is as of August and I'm sorry we're not able to get this information out in everybody's packet ahead of time, we, it will be I'm assuming available afterwards, but we literally were able to pull this together sort of last minute. But, we had for the month of August a little over 13,000 active registrations happen during the month, that's about a 30% increase over what we had in July, which in itself was an increase over what we had in June, so we're seeing sort of a progression as we go along and I'm going to point out as we go through a couple of different places where we're seeing some very promising progression of people taking part in the program. We now have about, this is all as of the end August, a little over 90,000 people actively registered for the program, this is including all eligible professionals and hospitals both Medicare and Medicaid.

So, the number that I want to pay attention here, this is the Medicare incentive payments that were made as of August, we paid a little over 1000 eligible professionals in the month of August, so these are people who have actively attested, they've gone through the registration, the attestation process, they have been paid, that is nearly double the number of people that we paid for Medicare in July, which in itself was nearly double the number of people that we paid in June, and in fact about half of all of the people who have been paid for Medicare from the EP side happened during the month of August. So, I think we're really starting to realize the number of people that are coming in, you know, in April when we first launched we had a slow trickle and that trickle is turning into the faucet opening up a little bit more and if this trend kind of holds we'll have the faucet fully going hopefully by the end of the year.

I did want to kind of draw some attention to where we were specialty-wise; this is my nice colorful pie chart that breaks down the eligible professionals by specialty. It's not terribly surprising internal medicine and family practice are the first, are the largest pieces of this pie. The third largest piece of the pie with the 20% in the upper left corner there that is really another category and it's sort of a catch all, it's, we break down by specialty according to how they are designated in CMSs provider enrollment chain and ownership system, we call it the PECO system, and there's a designation by specialty that gets pulled in for that, either those people didn't have a designation by specialty and we would have no way of pulling that information in, or they fell well below these percentage numbers, so there's, it's sort of a blanket of a lot of different specialties. But, what I find interesting here and what I wanted to pay attention to is the people who fall under the 22 and 20%, so cardiology, podiatry, we've got a number of different specialties that are represented here and a couple that I can say that at least anecdotally we had been hearing early questions about in regard to Meaningful Use, where they were asking well how are we going to achieve it within our particular specialty, how are we going to achieve it within our practice, and yet we're seeing people like a gastroenterologist and urologist who are successfully being able to apply Meaningful Use within their practices and getting paid.

So, moving onto Medicaid we at this point have 23 states that are currently open for the Medicaid incentive program. I won't go through the entire list but it is included here. We have about close to 1300 eligible professionals that were paid in the month of August, which is an increase of 23 point something percent over July and again it's an increase over what we've seen in June, so we really are seeing this pick up steam as well. The encouraging part here is 150 million, almost 150 million in payments were made for Medicaid incentives within the month of August and that is a little less than half of the total year to date payment. So, we're really starting to see more people coming in in the months.

And again, my pretty pie chart. This really should say Medicaid EPs by provider type because we are not able to break down by specialty for Medicaid, we don't have that information, it's kept at the state level, but we are able to see the type of provider, not surprisingly what we're seeing here is the overwhelming majority of these are physicians and of course nurse practitioners right behind it. But, again, what I wanted to call attention to here is looking at certain areas like dentists where we had initially heard very early on from people in this specialty that they thought that there might be some significant barriers to their Meaningful Use and yet here we are at a very early stage of Meaningful Use and we've already got a fairly decent portion of dentists who are in and able to successfully meet Meaningful Use and attest, so it's a very encouraging sign for the beginning here.

And then finally, just to sum up a total of a little over 264 million in payments made in August. I really like to call it a quarter billion dollars because that sounds so much more impressive. August was the first month where the program as a whole surpassed the 500 billion dollar or half billion dollar, 500 billion would be very impressive, but half a billion dollar mark of incentive payments paid out, this is, again, twice as much as we paid out in July and we're seeing this month over month increase. So, it's not unreasonable to think that we're going to hit the billion dollar mark fairly soon and we're going to see a lot more providers coming in. And that's sort of the extent of things. I know everybody didn't have a chance to look at this ahead of time so if there are any questions specifically on this I'm more than happy to answer those.

Paul Tang – Palo Alto Medical Foundation

Well, thank you for a very encouraging report and we knew some of, one it was early before, and then this little timing glitch which hopefully the message has gone out and maybe we've opened up the faucet a bit, but I already have cards up and Paul Egerman.

Paul Egerman – Businessman/Entrepreneur

Yes, first thank you. This is very helpful to get this information and it does seem encouraging to see the numbers and what appears to be the growth. My question is is do you have any projections for fiscal 12 based on the numbers you have so far as to what will be distributed?

Robert Anthony – Centers for Medicare & Medicaid

So, there really aren't any hard projections a lot of it is sort of dependent on what we're going to see through the rest of 2011. We know that there are a number of factors that are in affect here, the availability of people to be able to get a system on board and running, there were some considerations by folks as to if they delayed in 2011 and implemented in 2012 that they could still collect an ePrescribing incentive. There are a number of factors that may incent people or affect people to not necessarily attest for 2011 but come in in 2012 and I really think until we get further along in this year we're really not going to have a firm idea of where people have really come down on those choices.

Paul Egerman – Businessman/Entrepreneur

But when you say this year, I mean, doesn't your fiscal year end September 30th?

Robert Tagalicod – Centers for Medicare & Medicaid Services

Yes, we're talking about the calendar year. So, we'll look at the rest of the calendar year, I mean 2011 and then we certainly can do trend projections based on those, but those may not be, I think that Rob was kind of getting at, may not be indicative of what we may actually see in fiscal year 12 or calendar year 12 I should say, so, in terms of comparability. So, we certainly, at the end of the year, can advise this particular committee of what we see, what are the trend lines and do whatever kind of analysis that we need to do in order to protect that out, but again, the caveat is, we may see a lot more in 12, so that might not be indicative, our projections may not be indicative of what that might be. So, actually that could be positively we can see a lot more, but again I think we need to be, and this is my more cautious side, this is where I think we will need to kind of look at over time in the next month and so forth what that trend is going to look like, and if we get other information that indicates what 12 may look like we'll incorporate that and advise the committee as well.

Paul Egerman – Businessman/Entrepreneur

It would be helpful to have some sense. I mean what's hard for me is to look at these numbers and on the one hand they seem encouraging but I don't know how to judge it. Does it mean that we're on track where we should be, if we're far behind, if we're ahead, it's really very hard to tell just based on the small number of data points. It does seem to me you could do some projections base, simply on knowing who has qualified for the incentives, because then it gets paid out once you qualify basically in future Medicare and Medicaid payments so you can sort of project out a little bit for those to try to figure out what fiscal 12 will look like.

Robert Tagalicod – Centers for Medicare & Medicaid Services

Right and your point is well taken, I mean it's too early to judge, it's good to look at the uptick and it causes us to be hopeful, but I think, again I would like to wait until the end of the year so that we can advise you.

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

So, I'm curious what variables you're collecting in terms of the various people that are qualifying and getting paid. I mean what do we know about those people, the size of their practices, the products they're on, the, you know, you reported on specialty, whether they're rural providers or inner city providers, I mean what are the variables that we could get information on?

Robert Anthony – Centers for Medicare & Medicaid

At this point in time the type of information that we have is primarily what we've got in our provider enrollment system. So we have some indications of specialty in some cases we have indications of subspecialty. We don't breakdown according to practice, so it's hard for us to say anything about practice size because that's not a measurement that we take, we reimburse individual EPs, although it may be paid out to a group's NPI it's actually done according to the eligible professional. So we're not able to look at it and say oh your part of a 500 EP practice. We do have, because we are through ONCs certified health product list, they're actually getting a certification number, we are able to say what products people are actually using, so we're going to be looking at that information and then I think, although we haven't done this yet, we wanted to get more of a critical mass I think of people, because we don't have enough people attesting at this point for I think the data to be really meaningful yet. We wanted to start breaking down and looking according to zip code and that will give us some sense about rural or other types of providers.

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

I just make the point that I think even now that the numbers are small it would be critically important to figure out whether there's additional information that we need in order to identify gaps and whose qualifying by either, you know, practice size or any other kind of variables and now would be the time to try to work that out. And also, the possibility of matching this database against other available databases to get some other information so there's the AMA master file and lots of other sort of sources of information, state licensing databases, that could be used to try to garner more information about the people that are successfully attesting.

Robert Anthony – Centers for Medicare & Medicaid

No, those are great ideas and we are actually doing some survey ourselves to help identify some of those areas where we can put some additional education out there. We do know that, you know, there are ongoing challenges for smaller practices sizes for rural providers and we know, we've sort of identified a gap at the, I'm not exactly sure what you would call it, the very beginning level, a very basic level, people who really don't know a whole lot about EHRs in general, trying to get them up to speed on both EHRs and the program and what it can mean to them. So, we're making some forays into getting some educational resources together on that area.

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

People are making comments about the age of the providers and the fact that younger providers are more adept at computers and it would be interesting to know whether those kinds of things are holding true and whether or not we're actually sort of putting a whole, leaving a whole group of people out, you know, who are going to retire with their pen and paper in hand.

Robert Anthony – Centers for Medicare & Medicaid

And we do have.

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

Maybe prematurely.

Robert Anthony – Centers for Medicare & Medicaid

We do have some information on that. Again, it's selective because it's been based primarily on survey and it's some work that we've done with some outside organizations like WebMD, Medscape, and actually what we're discovering so far is that while the sentiment is being voiced widely that, you know, older physicians won't be interested in this and they will, the penalties will likely kick in close to or after they retire, so they're not going to bother with this, we at least have some evidence that points to the fact that it seems to straddle across age groups, that we're getting a large number of people from all across the spectrum who are willing to do it. Now, again, that's not necessarily definitive because it's a small sampling, but yeah.

Robert Tagalicod – Centers for Medicare & Medicaid Services

So one of the things that's happening now is that we now have, CMS and ONC are sharing data and so we have, in terms of those providers that are participating with the regional extension centers, we have a lot of that data already collected and so as we match up the provider numbers to the data that we've collected on, you know, everything from geography to practice size, to vendor, to everything we can start to look at some of that. Now, it won't be for all providers but certainly, you know, we now have about, very close to 100,000 providers signed up with the extension centers.

Paul Tang – Palo Alto Medical Foundation

Another interesting data point would be how long they've been up on the EHR, because, to know.

Robert Tagalicod – Centers for Medicare & Medicaid Services

We have that data as well.

Paul Tang – Palo Alto Medical Foundation

Okay. Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Yeah, I think this is absolutely essential that we get this detailed information and if you can make sure we get at least this preliminary information that you have, but Neil's questions are right on, he stole most of my thunder, but I do want to make sure that we do that evaluation. How effective are our RECs? What percentage of these folks are members of RECs? And then, you know, so we have some analysis, not just numbers, but analysis of the data. If people are attesting and getting payments and presumably you're asking, there must be a form they're filling out, and you may want to expand some of those questions on the form to include some information that might be beneficial to us in evaluating as we move forward in making sure that things are working properly for them, especially for our RECs since we've made such a significant investment in our RECs. And then also, if you could provide for us as well the numbers of eligible providers or professionals out there nationwide so we have a percentage, are we, you know, like 0.002%, you know, how many hospitals are there that would be eligible for this, so we have an evaluation tool to say where are we in the whole big scheme of things.

Robert Anthony – Centers for Medicare & Medicaid

Actually, I can give you those numbers off the top of my head.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Okay.

Robert Anthony – Centers for Medicare & Medicaid

The total number of eligible professionals is roughly about 500,000, so we have a little less than 20% of them at this point registered. The total number of hospitals would be, again it's a rough estimate, but about 5,000, so we have a little less than half of hospitals registered at this point in time. We do know, however, in talking to a number of eligible professionals and hospitals that there is a perception that they have to do their 90 days of Meaningful Use and then register and then attest, so there may be a number of people who are already participating who have not even broached the registration point at this point because it does seem to be a fairly pervasive idea. The suggestions that you make are excellent ones and they're actually timely because we are putting together some survey details right now to ask questions and actually identify for some of the providers have you started participating in the program but you haven't registered yet, why or why not? But, we could certainly add some of the very questions you're asking about.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Can you also do it by state? Collect the information by state?

Robert Anthony – Centers for Medicare & Medicaid

Yeah. I think we can.

Paul Tang – Palo Alto Medical Foundation

You mean like Florida?

Robert Tagalicod – Centers for Medicare & Medicaid Services

To some of the barriers that Rob Anthony was referring to about, in terms of trying to make projections some of it also relates to, on the Medicaid side the variation in states, so obviously, about half of the states now have their programs up and running, but certainly some of the big, there are a number of big states that don't and so you would expect that the Medicaid AIU payments would, you know, spike pretty quickly after some of those states go live.

Robert Anthony – Centers for Medicare & Medicaid

Yeah, absolutely, no, no and that's, we're definitely sort of at CMS and in the office looking at some of these larger states come on to see some fairly significant increases, because we know anecdotally, again talking to people from those various states that there are folks sort of waiting in the wings.

M

And I think it's important, again to emphasize what Josh had also said is that ONCs and CMSs data groups are working very much more closely together and it would be helpful actually to kind of formalize some of the questions that you might as a counsel have of us so that we can take a look at that, so that we can frame those, because, you know, it's, sometimes the data is the data, but it really the question that is really important, so we would like be able to answer some of the questions that you have for us.

M

Very helpful, but, you know, when we sort of come to CMS with specific data questions and sort of put those into a process to get them, to help get them answered, and to the extent that the Policy Committee or the Meaningful Use Workgroup wants to formulate some questions we would be happy to take them to our working group on your behalf.

Paul Tang – Palo Alto Medical Foundation

Well, I want to thank you. You can tell that we hang on your every word. We are very. I mean we got to be careful not, as you've been cautioning, not to over interpret the early data, but we really, I mean everyone is heavily invested in the success of the program and achieving its goals. So thank you so much for keeping us updated and thanks for all the good work.

Robert Anthony – Centers for Medicare & Medicaid

Thank you.

Paul Tang – Palo Alto Medical Foundation

So, I think we're ready for public comment now please.

Judy Sparrow – Office of the National Coordinator – Executive Director

We have reached that time. If anybody in the room wishes to make a public comment please step up to the microphone at the table and if you're on the telephone just press *1 to speak and if you're on the computer you need to dial 1-877-705-6006, that's 1-877-705-6006. Anybody in the room wishes to make a comment? Shall we wait one second to see if anybody dials in? And let me just take this opportunity to thank all of you for your well wishes and certainly for the cake it was delicious and it's really just been an honor and a pleasure to work with each and every one of you. I've really enjoyed it, so thank you. Nobody? Nobody on the phone? No questions? So, Dr. Tang.

Paul Tang – Palo Alto Medical Foundation

My last word is thank you Judy and well wishes on your retirement and I don't know how we're going to survive at any rate. Thank you. Congratulations and.

W

We will make sure that everything continues running smoothly and we will, we've got great contactors, we've got great staff, and while we'll, Judy has huge shoes to fill, we will do our best to meet the expectations that she has created for this work.

Paul Tang – Palo Alto Medical Foundation

We're just expressing our appreciation and gratitude. Thank you so much and see you all next month.

Public Comment Received During the Meeting

1. PSTT slide 20, please consider adding "government agencies" to "provider entity", unless you think they already have the exemption for investigating adverse events, patient safety, and quality of care.
2. I agree that research needs to be better defined, and I agree that EHR analysis maybe a good example of what has been called research is really quality improvement.
3. However, I am concerned that it is clear what IS research and that the individual's information is protected when it is being used for quality improvement efforts.
4. I am concerned, if research is not clearly defined, then there will be abuse of the use of these recommendations.
5. Or rulings as they may eventually become.
6. I applaud the effort of ONC to pursue the Query Health Initiative. I hope to see coordination of this work with the efforts of the Patient-Centered Outcomes Research Institute (PCORI) and their efforts to build Comparative Effectiveness Research infrastructure.
7. I think that individuals should be able to consent to have their deidentified information stored in a secure centralized repository that could be used for the purposes of research. Cloud technology provides a perfect opportunity for this effort, and this repository could also implement many of the recommendations of the PCAST Health IT Report.
8. Can CMS breakup the data of successful attestations by zip code, and also by EHR vendors?
9. Are there any efforts being made to mitigate providers who retire after receiving AIU moneys?