

AMERICAN HEALTH INFORMATION COMMUNITY MEETING

September 12, 2006

Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 800
Washington, DC 20201

List of Participants:

- Secretary Michael Leavitt, Chair
- David Brailer, M.D., Ph.D., Vice Chair
- Robert Cresanti
- Nancy Davenport-Ennis
- Nada Eissa (*representing Department of Treasury; also represented by Jason Brown*)
- Colin Evans (*representing Craig Barrett*)
- Douglas Henley, M.D.
- Lillie Smith Gelinas, R.N.
- Julie Gerberding, M.D. (*represented by Lynne Steele*)
- Kevin Hutchinson
- Charles Kahn, III
- Robert Kolodner, M.D. (*representing Department of Veterans Affairs*)
- Mark McClellan, M.D., Ph.D. (*also represented by Tony Trenkle*)
- E. Mitch Roob
- Scott Serota (*also represented by Justine Handelman*)
- Linda Springer (*also represented by Daniel Green*)
- William Winkenwerder, Jr., M.D.

Presenters

- Laura Adams
- Ryan Campbell
- Kelly Cronin
- Lynn Dierker, R.N.
- Linda Kloss
- Kala Ladenheim, Ph.D.
- David Blumenthal, M.D.
- Michael Painter, M.D., Ph.D.
- Sara Rosenbaum, J.D.
- Jane Sisk, Ph.D.
- Gregory Downing D.O., Ph.D.

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SECRETARY LEAVITT: Good morning! I want to thank you all for being here. I'd like to take a moment if I could to take a deep breath and acknowledge the heavy lift that all of you have been enduring. I want to thank you for the work that you've been doing. I want to make particular attention to the Office of National Coordinator and fine staff of people that are functioning to make this effort move forward.

I understand that the burden is substantial but the appreciation that we have matches it. And with that, let me just say that today in a very short time we have a lot to cover.

As you know, three weeks ago, the President signed an executive order that will bring the full weight of the federal government behind the work that we're doing here at AHIC. The Community is obviously taking a very important role in the development. Not just development information technology standards but also the vision of a value-based competition. The executive order requires four things of departments and agencies of the federal government who are involved in the procurement of health care.

First is that we adopt health IT standards that will be at the level of interoperability that exists and since we're defining that work, it's a very important part of the President's executive order. And it's important to us that he has now done it.

The second thing that executive order does is it creates an obligation on the part of federal departments to work with common quality measures that will be adopted to engage the care, the quality of the care that's being purchased with our tax dollars.

The third is that the federal health care programs including contracts with those who provide care will start making price and quality information about the care that they purchase and provide transparent to their consumers.

And, fourth, create positive incentives to reward those who offer and those who purchase high quality, competitively priced care. So health IT standards, and quality measures, a transparency of price and quality, and proper incentives, these things all bring us much closer to our vision of value-based competition. And they all depend on systems that can manage vast amounts of information and, of course, it needs to be done seamlessly and securely and that's at the heart of our task.

As I've said before, health IT is the backbone of each of the priorities that we're focusing on here at HSS. The Community's work is critical to moving those priorities forward and allowing them to grow as new demands and opportunities arise. Having mentioned the growing work and new opportunities, I would like to acknowledge a new topic I would like to introduce today: and that's personalized health care. More specifically, the enormous potential of personalized medicine that's based on the human genome.

Today a 100-pound girl, 13 years of age is recommended often the same dose of some medications as a 240-pound man who is age 50. Logic tells you that their bodies are different. Logic tells you that -- and science confirms it. But just as people metabolize foods at different rates, they also metabolize medicines differently. Each of us is biologically unique; each one of us has our own DNA structure. Understanding this structure means that healthcare providers need to be able to consider genomic information in conjunction with the pharmacology of medicines that they prescribe.

Ultimately, personalized health care will mean using our genomic information that will enable us to deliver health care that's unique. Unique to each one of us. In other words, it will enable our healthcare system to be based on treatment of individuals rather than averages. This is an incredibly exciting opportunity in the advancement of medicine. All of us have dealt with it in one way or another.

I introduce it today, because while it sounds a long way off, it's a lot closer than you think and we have already begun to read the human genome and the costs of doing so are falling constantly. Scientists continue to find ways to turn basic science of genes into better health care.

However, doing so on a large scale requires systems that can manage volumes of information about individual patients. As we've each experienced in our own way, this information will have to be managed in a standardized way to be used effectively. I see an opportunity to think ways of going through the information now before we're mired in hundreds or, may I say, thousands of competing standards for it.

Much of our work is devoted to subjects on which many have worked for a decade or a decade and a half and competing standards have emerged and we're now in the process of sorting through those. This is a green field. This is a place where we could start now and incorporate the capacity to store genomic profiles as a part of our electronic health record. And if we start now, we can do it before the standards compete and allow the organization and speed the development of this very important discipline.

I think the Community is a natural place to start pulling those elements together and we -- but we need to be able to ensure that the systems we use to do that are in place and support this as science develops. Dr. Greg Downing of the National Institutes of Health is leading this priority for me. As secretary, I've asked him to give a brief overview today on the potential of personalized health care and gene based medicine and the role of health IT in bringing that about.

You'll see that his briefing is added to our agenda for later today and I look forward to hearing his presentation and getting your reaction to it.

With that, I would like to now turn the floor to Dr. Brailer who will take us to today's agenda. Dr. Brailer.

DR. BRAILER: Thank you, Mr. Secretary and members of the AHIC. First, before I turn to the actual agenda, I do have some housekeeping items, the first of which is actually merit worthy. This is the 8th meeting of the American Health Information Community and this is our one-year anniversary. So, Mr. Secretary, I would like to thank you for your vision and for your efforts to make sure that this has been a great success for not only of those of us in healthcare but for the whole United States and appreciate your time very much.

The AHIC now has seven Workgroups. I'm going to review the two that you have created recently: Confidentiality, Security and Privacy, and also Quality. We now have more than 100 people working actively in our Workgroups. And as some of the Workgroup members know, this is a very daunting task. It's very time-consuming. These workgroups have taken themselves into full operation, and I appreciate very much the very hard work that everyone has put into this.

Let me now turn to the Confidentiality, Security and Privacy Workgroup. You can see we have slides on this. Remember that this was charged by the Community three meetings ago. Confidentiality, security, and privacy is something that came up in every Workgroup, in EHR, in chronic health care, in consumer empowerment, and biosurveillance. And the purpose was to extract all of those items around this topic and put it into one full independent Workgroup that's able to look around common policy and activities around confidentiality, security, and privacy.

This effort is underway. And you can see the broad charge and the specific charge here. And we have 16 Workgroup members and you see these. And I'm really happy to tell you we really have a sampling of some of the nation's best leaders and thinkers in this topic, which is a very a complicated topic and one upon which, as you all know, a lot rotates.

And Paul Feldman, from the Health Privacy Project, and Kirk Nara from Wiley, Rain, and Fielding, are going to be the co-chairs of this. Jodi Daniel and the Office of the National Coordinator is the senior staff support. So you will hear more from this Workgroup, not today, but in subsequent meetings as they being formulating their activities along the specific charge that's been laid out, that have focused on some of the key protections versus accessibility issues in the four immediate breakthroughs that are underway in the other Workgroups.

They have a hearing that's scheduled on identity proofing and user authentication, Friday, September 29th from 10 a.m. to 4:30. And as all hearings and activities of the Community, this

will be live telecast so anyone can join and participate.

Also we have the Quality Workgroup that was discussed at the last meeting. And I'm happy to tell you that this has been formed and just to remind you that the broad charge is relating to having the ability to automate the measurement and reporting of quality information out of the physician work place and the hospital. So that it isn't a manual extraction and we can have significant uptake and increasing breadth of quality measures.

The specific charge being focused very much on we collect this core set of ambulatory and inpatient measures that are already underway. The first meeting of the Quality Workgroup will be September 22nd, 11 a.m. to 2 p.m. This group has 16 members and I'm happy to tell you that Carolyn Clancy, who you all know, is the administrator of AHRQ, and Rick Stevens, who is from Boeing Corporation, will be the co-chairs of this. And again, we have a panel of people, and I won't recite all of their backgrounds who represent not only the key experts in this topic, but the key organizations that are making our quality agenda move forward. So this Workgroup will be very active in helping us bring forward the linkage that the Secretary has described and laid out for us in terms of how health IT and move transparency together.

Now at the next meeting of the -- oh, I've got one other quick item. Based on the recommendations of the American Health Information Community, a letter has been authored from the American Health Information Community for Emergency Responder, EHR recommendations, and so that will be received by the Secretary in the next 48 hours.

Finally, we have a visioning exercise planned for the next meeting. Many of you know that we've had a very active dialogue underway about the strategic plan, building on the framework that was laid out in 2004. You saw three meetings ago a significant dialogue here about different strategic directions that the Office of the National Coordinator and the Department of Health and Human Services could go to be able to accomplish the President's goal and the Secretary's vision. That visioning exercise, that strategic planning is underway and I know that some concerns have been raised about this, and a GAO update. But I think it's safe to say that this process is healthy and doing quite well.

And to that end, at the next meeting of the American Health Information Community, we're scheduling a visioning exercise. Already underway are Workgroup leaders working with facilitators to be able to come back to you with visions for how their charge works into the healthcare system in the future, what it ultimately looks like way out in the future, half way out, and maybe a third of the way out. Key steps that we can use to drive some of the technical planning from. And this will come to you for a substantial debate and discussion at the next meeting, and the recommendations you make will be into the key inputs into the closure of the strategic plan and to the guidance of how we set use-case priorities and other priorities here for the next one to two years at least. So that'll be a key effort that's already underway.

Finally, we need to approve the August 1st, 2006 Community minutes. I'll just ask for a motion to do so. Second? All in favor? They stand approved.

With that, Mr. Secretary, we have a busy meeting today, that is comprised not only of the two

briefings we're about to receive but also the one that you have directed in personalized medicine.

The first is related to state level health information exchange. And we have had underway for about nine months a study led by Linda Kloss and the American Health Information Management Association, one our trusted partners, to go out and assess and talk to state leaders and understand what is happening at the state level with respect to health information exchange.

Where are their priorities? Where is their progress? Where are they facing pitfalls? What do they have in common? What's different? What is it that we at the federal level need to understand to continue to support and nurture these critical grassroots and state level efforts?

And with that I'm going to turn it to Linda to give an overview of this effort and then to introduce her panel. And I encourage you, members of the Community, to really dig deep with this because you have some of the nation's best experts sitting before you today.

MS. KLOSS: Mr. Secretary, Dr. Brailer, and members of the Community, we're happy to have this opportunity to provide an overview of the project to study state level health information exchange initiatives and the practical program guidance that's come out of this effort. I will say that we turned in the two reports that were distributed today, both a development Workgroup and a final report two weeks ago. So, this is very timely in terms of moving this topic forward to you, and I think you will agree when you have heard from our panelists that it's an important topic to engage AHIC in.

I'm going to provide a high-level summary of our research findings and then explain what's in those two work products that were distributed. And then we'll hear from panelists, and I'm very pleased to introduce to you Kelly Cronin, who I think is well-known to you who as Director of Programs and Coordination at the Office of the National Coordinator. She served as our project officer.

Laura Adams from the Rhode Island Organization, Ray Campbell, Massachusetts, Lynn Dierker, Colorado, so you'll actually hear from state level health information exchanges and then Kala Ladenheim from the National Conference of State Legislatures who was a co-convener with us. The bios of our panelists are in your handouts and please do take time to read them.

We're going to move fairly quickly. The project actually was completed in just a little under six months. Quickly, the phases for our project were to select nine state-level health information exchange initiatives for study, particularly focusing on governance, financial and operational characteristics, health information exchange policies, short and long-term priorities. I underscore that we were looking at organizations that were not local or regional RHIOs but were state-wide in their scope or working their way to being state-wide.

We set out initially to identify best practices, but as you all know, benchmarks and best practices are metrics-based and we learned fairly early on that it may not be possible to develop, at this point in time best practices, but we strove then to develop consensus principles based on the most experienced organizations, how they would approach developing a state-level HIE. And that really is the essence of the book called "Workbook." It really is guidance material for developing

HIEs. And that is as you see here, our primary work product.

To get to that consensus we hosted a consensus conference in the middle of July and invited states. We were throwing a party. We weren't sure how many would come. But, in fact, we had 130 attendees and they were from states that were early on in the process and interested in this and they did just what we wanted them to do: they critiqued the guidance, told us where it was helpful, told us where it wasn't helpful, and what additional information was needed. We drafted the dissemination plan and with the help of a very able project team, outlined recommendations for follow-on projects.

I will acknowledge the project staff, all of whom are listed in the first several pages of both volumes. Led by Victoria Prescott, who was our principal investigator, and the team of project staff. Most ably by a steering committee, by technical advisors, by the National Conference of State Legislators, by the Office of the National Coordinator and the Agency for Health Research and Quality and liaisons to other organizations who have been very instrumental in developing guidance material for RHIOs such as HIMs and the e-health initiative.

I do want to acknowledge particularly the steering committee. And if you look at this slide you see bolded the names of nine states. And so the steering committee was really comprised of senior leadership from the nine state health information exchange initiatives that we were working with. And as you know, three of those leaders are here with us today to describe their state and provide some real lessons.

But this was a group chaired by Dr. Molly Coy, who came together in an extraordinary fashion, took very raw insight from what we were learned as we were trying to tease out what the lessons were for developing organizations and I think did a wonderful, wonderful job.

They were guided and aided by several technical advisors who helped us in the area particularly of governance and financial models. So we had a very able project team and I really acknowledge the terrific work of the steering committee and technical advisors.

Now, let me move to -- right to key findings. We learned, not surprisingly, that these organizations today differ significantly in their sponsorship, in their drivers to action, market characteristics, governance, operational approaches, and we learned that through consensus that they really believe that there is no single model today. We couldn't tease out a single model and that we felt and concluded that there shouldn't be at this time. That it's an important time for innovation and learning that's underway. So an important innovation in learning but it needs to be captured. No single model -- and we actually spent a fair amount of time trying to boil down what we were seeing in terms of how these initiatives were organized into two or three models, but concluded that it may be a little bit premature to do that.

Importantly, we learned that -- and documented, I think quite well in the reports -- that states are uniquely positioned to engage stakeholders for the coordination of HIE efforts and that they need to be in that role. Play critical roles also in the nation-wide health information network and that consensus that they must be more fully engaged in partnering with the federal government in this development.

And finally, a key finding: even the most experienced organization, even those that we often cite and are here today to describe their experiences, face significant barriers. So, our -- we really felt that we've documented some -- yeah, and through consensus, determined some important findings.

A very interesting area that we probed was what the potential important roles for state-level initiatives were. And we drew this diagram as a way of depicting them. At the bottom we see state health information exchange initiatives being conveners, educators, facilitators, conveners of the stakeholders. Educators as to the strategies and communication between local and regional efforts and the state. Facilitator in terms of really getting true consumer engagement in this, encouraging HIT adoption and other kinds of facilitation roles.

We saw roles in which states could really help move toward standard -- or adoption of standards, adoption of uniform policies where that's appropriate so the state could be a mechanism for ensuring that that kind of essential uniformity gets in place where it's most needed.

Bringing state governments to the table was an issue that the group spent quite a lot of time on. And we really felt that that was an important area where state health information exchange initiatives were uniquely positioned to move us forward.

And then areas like operations actually doing health information exchange, technical assistance, and being a bridge between the states and the nation-wide efforts. Critical roles for state level health information initiatives. And as you will hear from our panelists they're playing different roles. These are evolving very quickly.

Major barriers that we found: of course, funding for organizations. Even those that are more mature, sustainability is a real issue for them. Lack of consensus on the most effective role for state governments in health information exchange, minimal participation and support from payers, from private payers. And that was a uniform consensus that we were identifying. Not aligned stakeholder interests, obviously. These are new discussions and new dialogues happening. Lack of shared experience about strategies for success. Each of them, kind of too much going their way, although there are sharing opportunities but a feeling from the group that we really need to formalize those.

And finally no road map for how the state-level HIE relates to the federal NHIN programs and vision, including how contiguous states should relate to one another. And some of these barriers we were looking at the effect of making explicit at least the most fundamental role for the states.

Finally, recommendations -- and these are contained in the second document of the reports. These recommendations do represent the consensus of the steering committee and we get much deeper into what these recommendations mean.

But, first of all, mechanisms to promote strategic synergy among states and between state and federal efforts, a recommendation relating to the need for a coordinating body for active, ongoing collaboration and a road map to make that linkage more explicit.

Salient financial models. Understanding that at a deeper level, so we identify what some of the short-term high potential projects are, and how they contribute to the financial sustainability. Engage and leverage the public and private payers. Advancing understanding how state policy makers and governmental agencies should be involved and vehicles to support knowledge sharing.

We also found some barriers that the federal government can explicitly address and help these organizations deal with. And that is to encourage the IRS to expedite tax-exempt status decisions for the not-for-profit organizations. And we do -- you will see in the workbook that it was a consensus that these organizations should be 501c3, tax-exempt organizations.

So that's a high level summary of our recommendations and we hope there will be opportunities to discuss as we go along.

Kelly, I think you're going to help us understand a little bit more fully what the whole landscape is of the state initiative.

MS. CRONIN: Good morning Mr. Secretary, members of the Community. I wanted to touch briefly on the amount of activity that's going on across the country, across states to give you a perspective of the momentum that's being built and actually articulate some of the specific activities that the states are taking on. And also talk about how ONC's responding to the recommendations that Linda just presented.

So right now in 38 states, 121 bills have been introduced. And in 2005 and 2006, 36 bills have been passed in 24 of those states. So there's an enormous amount of activity throughout the legislative process across states. Governors in 10 states have also created executive orders that have been intended to enable improvements in healthcare through the use of health IT. And on top of that we have approximately 35 states that are already engaged in some level of state-level health information exchange. So, you can see the progress around the country is quite impressive, and while there's varying stages of progress, there's certainly a huge level of enthusiasm and commitment to using health IT, to really see improvements across the states.

More specifically, most states are actually participating in either a state-wide or regional collaborative. So they're convening stakeholders. Twenty-one, specifically, are actually trying to organize multi-stakeholder organizations for planning, communicating, and coordination of health IT activities. Sixteen states are actually providing some staff support to manage these activities. Seventeen states are providing funds to support regional efforts in the way of a loan program or grants. So there's an enormous amount that's going on.

We're not -- going into this project, we weren't entirely clear, what is the federal role, how do we relate to these efforts and how do we try to coordinate with states and these entities that are acting across states to support their activities.

So, based on the steering committee recommendations, ONC is supporting additional work, working with this existing steering committee and their technical advisors to more specifically

identify the barriers to health information exchange. And those that have federal solutions and articulate them carefully so that we can act on them.

We want to analyze and look carefully at the health information exchange cost models that exist today in regions and states that are actually generating revenue. What are the evaluated services they can be implementing more broadly among the states to be operating in the red and get them over this initial period where they're at risk for not having a financially sustainable business model.

We're also wanting to determine more carefully the involvement of state and Medicaid programs; we know that it's variable across the country, there's some Medicaid directors that are quite interested and engaged, there's others that don't have the time and are very caught up day to day in managing their programs. But we would like to specifically examine the flexibility that exists under Medicaid and understand what opportunities they have at a state level to facilitate health information exchange.

We also want to explore how and when to engage, for states to engage CMS and other public payers in their planning and implementation process. We also want to examine more carefully the role of Veterans Administration, Department of Defense and Federal Employee Health Benefit Program so that again, these states know how explicitly they should be coordinating with these programs and agencies.

And again, following up to Linda's point for the need for explicit coordination mechanism, we recognize that we need to be working, ONC, but more broadly the federal government with these state-level initiatives in some kind of a coordinated fashion with real explicit links between organizations.

So with that in mind, ONC is also forming a state collaborative that will mirror the role of AHIC and will take on a variety of issues including long-term solutions to ensure privacy and security as we create an interoperable infrastructure for health information exchange across states.

They'll look at state law practice of medicine barriers to health information exchange, look more carefully at governance models that will work across a variety different types of states. And again, look at the longer term issues with sustainable business models for health information exchange, the role of private payers, both from a governance perspective but also their role in facilitating a viable financial model.

And then also the integration of state public health and health care programs since they will be directly impacted by a new, emerging infrastructure for health information exchange and stand to benefit considerably from an operational health information exchange at a state level.

So with that I will pass it to Laura Adams, our first state representative, who will give you an overview of the activities going on in Rhode Island.

MS. ADAMS: Thank you, Kelly, Secretary, members of the Community. We're very, very pleased to have participated in this program and I can tell you it was untold value for Rhode

Island to be a participant in this project. And we would like to thank the Office of the National Coordinator for initiating it.

A couple of bits of background about Rhode Island that will help put our information in context. We are a small market. We're really 1.1 million people; we have 16 hospitals, 3,000 doctors. And our sense is that if we can't do it in Rhode Island, can it really be done anywhere? We do have cost pressures on all fronts, we're no different than anyone else from that standpoint.

We certainly have our digital divides. While we have hospitals among the most wired every year in a row, we have those that have yet to leave the starting gate. We have some digital divides of course developing in physicians, our larger physician groups stampeding ahead in many ways and putting together extraordinary collaboratives that will enable them. We have other solo practitioners that, of course, are falling behind. The same is true with our community health centers. Some are setting national pace, and others, once again, not having left the starting gate.

We have very strong leadership from our governor, which we're very pleased and fortunate to have. And that has been no small feat in terms of the work that's been done on government side that has to do with our Health and Human Services leadership there. Our department of health leadership, and our health insurance commissioner's leadership, all founding members of the quality institute five years ago.

We have some new developments in Rhode Island that have enabled our work. The first is the healthcare quality and cost transparency law that's been enacted, some legislation that once again in some ways mirrors the national legislation that Rhode Island has in public reporting outcomes from our hospitals and nursing homes for quite some time. That's now extended to the community-based care and will also be in linking the cost and quality reporting in the state. Our health insurance commissioner has until March of 2007 to develop a plan to make this usable and accessible to the consumers.

And we also have a RHIO designation and a funding potential law that's been enacted through legislation and I will be saying more about that in just a moment.

The Quality Institute -- it's helpful to have just a little bit of background about what we're trying to accomplish. We were not formed to do information technology; this is a larger umbrella to improve quality, safety, and value, we're really here to redesign the system of care in the state. We have amassed the CEOs and highest ranking leaders from every one of those organizations, insurance, academia, and government, physicians, providers, consumers across the state, because our goal really is to redesign the system and our first step is to put information technology as the platform to enable all other activities that we're trying to do in the state, but we really are there to enable a wide breadth of quality activities.

I'd also say that we do have a strong, strong focus on the consumer and you'll note that if you look at the first phase of our website that we just launched, it's a public basing website. It will be a few months before you can find our documents, before you can find internal documents of the institute. Not because we don't have them or they're not ready, but because we posted the consumer site first on that.

To give you a sense of the information exchange activities going on: we were one of the fortunate recipients of the \$5 million AHRQ contract award to the Rhode Island Department of Health. A unique example of our public/private partnership there is that that award went to the state under that contract, but the quality institute as a private entity has assumed governance for that project. Probably unheard of, at least in the state of Rhode Island.

We're also involved in the HISPC work. We're part of the governor's healthcare agenda. The governor has aligned very strongly with the work of the quality institute which I can once again tell you has an interesting history because we were started by a very strong Democrat in the state and our Governor is Republican. Truly a demonstration of the bipartisan nature of the work going on there. We're very proud of that.

Promoting EHR adoption state-wide. We are creating partnerships to lower the barriers. If we had time, I'd tell you about an achievement that we've got five competing physician organizations that not only agreed to come together, they ended up selecting the same EHR and they eventually went into business together; they represent half of all physicians in the state of Rhode Island, so they lowered the barriers around adopting this.

We are informing pay for performance programs through this as well, making sure that our pay for performance programs include a pay for adoption, and that's been accomplished through Blue Cross in the states.

We are promoting electronic health record adoption. We're a proud partner of workplace SureScript [spelled phonetically] and just long, long record of a strong partnership there.

Now we have an aggressive goal. You can take a look at that. And we take a sharp and take a breath every time we see it. 75% of all prescriptions sent electronically by 2007. We think that that's an invitation to innovate because we know we can't do it with our current system but we don't want our current system.

We'll be enabling administrative data exchange, promoting standards, developing business case and sustainability plan, and planning for coordination of PHR efforts.

I have some slides in here about our governance. Market-wide activity here. Our hospitals are connecting with their partners. We're beginning to see -- I know that one of the strategies of the government was to make sure that this was not a top-down, that there was a lot of development of market-based activity. We certainly see that. Now our job as the RHIO is to make darn sure that that doesn't grow up as a hard-wired fragmentation into the system, that we pull that together through the RHIO.

We have a budget article that was produced in Rhode Island, \$20 million revenue bond that the state is stepping up to pay their fair share of the health information exchange, and you can see that that includes Medicaid state employees. It does not include the uninsured.

You can see some information there about who makes decisions and how. Largely it's a board

that meets monthly; this is a very -- it's a workhorse board, even though it's CEOs and highest-ranking leaders, they are a workhorse.

Issues are identified by our committee of chairs. Workgroups are put together. Our board meets publicly, openly. Every decision we make is in front of our community. It certainly has an effect on people's behavior. Once our behavior is public, it makes it much easier for all of us to do the right thing.

Our state role, our governor is personally engaged, and deeply engaged in this. We have some pioneering work going on with Kids Net and our Health and Human Services Secretary, our Director of Health and our Health Insurance Commissioner are providing strong leadership in all the ways that you see listed there.

Our recommendations for a federal role: we feel very strongly about the work of the [unintelligible] prototype, and those cost estimates, and how valuable they will be to us as we formulate our sustainability plan. Now we consider six strategies in Rhode Island for sustainability.

We are arriving at a modified public good model and a who benefits model. We're going to be developing that over the next few months and that bond initiative, if we have matching funds from the other payers, there will be about \$6 to 7 million from the state to support their share of that.

We'd like to see that federal health initiatives support state and regional initiatives, and we can't thank you enough for this dialogue today, and we hope that this will be the start of an ongoing dialogue about how the federal agenda is playing out in the states.

I'd like to assist the states in aggregating their market power. Employers, we need much, much more understanding and engagement from employers. We have Medicaid at the table in Rhode Island, but not deeply enough engaged. And regulators all working together.

It's a delicate dance with the state, that their role as regulators in some ways is helpful and some ways not in enabling this because they are a stakeholder that has to come to the table and hold hands as well. So this is going to be a new role that we'd like to see perhaps based more on an economic development model, than maybe some of the more heavily regulated models in the past.

We'd like to also have help from the government to answer the who benefits question based on real world experience. We've got some great models; we need some evidence.

And then the last one, rapidly advancing, a national prescription drug history. We just think of it as one thing we could do that would be an enormous breakthrough, it would be that.

Thank you very much.

MR. CAMPBELL: Good morning, Secretary Leavitt, Dr. Brailer, members of the Community, and members of the audience, my name is Ray Campbell. I'm the executive director of the

Massachusetts Health Data Consortium. And I appreciate the opportunity to come here today and tell you about health information exchange activities in Massachusetts.

In terms of the Massachusetts environment, just some quick data points to sketch out. There is six million people in Massachusetts; it's a fairly compact geography. That's a bit of an advantage when you're talking about health information exchange.

Another advantage, of course, is that we have a dense cluster of world-class health care organizations in Massachusetts: medical schools, hospitals, even health plans, we have some really excellent health plans. We have a sophisticated technology economy, and that of course also makes it easier to do health information exchange projects, because there's deep reservoirs of technical expertise so we can draw on expertise in these activities.

Another unique -- or not entirely unique, but a salient feature of the Massachusetts landscape is that local, nonprofit organizations dominate the provider and payer communities. So virtually all of the major providers and payers are Massachusetts based non-profits.

Another feature that I think is quite unique in Massachusetts is that there is a very long, and very well-established tradition of collaborative activity around health information technology projects, and I'll talk about that a little bit more.

And then finally, there's the health reform law that was passed this spring, chapter 58 of the Acts of 2006, that should bring us close to 100% coverage with health insurance in the Commonwealth. Somewhere probably north of 95% of the citizens of the state will be covered by health insurance.

In terms of the health information exchange activities that occur in Massachusetts, we have what we call a virtual RHIO. And it's virtual not in the sense that there's nothing concrete and actual happening, that it's all just in cyberspace. There's real activities going on on the ground, but it's a series of five organizations that are working together to make things happen. And so rather than a single RHIO we have a virtual RHIO.

The component organizations are first the Massachusetts Health Data Consortium, we're the convener. We do education, facilitation, incubation of projects, and we're also responsible for policy development activities relating to health information exchange and health information technology.

Secondly is NEHEN, the New England Healthcare EDI Network, this is an organization that was established in 1998. This is doing administrative health information exchange between provider and payer organizations. It is a free-standing, self-supporting corporation owned by its members. It processes approximately 50 million administrative transactions per year, and it's completely self-sustaining.

The third organization is Mass-Share, that's a subsidiary of my organization, and it is charged with creating community utility for clinical data exchange, so creating common technologies and tools that can be used by any organization in Massachusetts that wants to avail themselves of

them. Mass-Share has been involved in a number of significant activities. It created a project to share realtime medication history information with emergency departments in Massachusetts. That was just a pilot; it was not put into production phase, so it has since ceased, but we learned a tremendous amount about health information exchange at the real operational level from that project.

Mass-Share is also the organization that created with the record locator service with the Markel Foundation and they're connecting for a health common framework. We developed that with Markel's assistance and Markel funding. We're also participating in the national -- or nationwide health information network projects that being run out of ONC, and we were also doing some e-prescribing and other -- we are looking at push technologies now as the latest thing that we're starting to pilot and roll out for Massachusetts healthcare organizations.

The fourth organization is the Massachusetts e-health collaborative. For my money, this is one of the most interesting and innovative projects going on in the healthcare IT in the country. Blue Cross Blue Shield of Massachusetts put up \$50 million and instead of the approach that you often see of being a mile wide and an inch deep, this is a real drill down on what would happen if you took three communities and provided every single provider in those communities with electronic medical records.

So the project is rolling out. I think about half of the providers -- I think it's 450 providers and 200 practice sites across three communities are being provided with electronic health records, and they're not just being thrown over the wall, there's a substantial readiness assessment, training, and technical support component. So we're expecting failure rates will be close to zero. So you'll actually see three communities where essentially every provider is using electronic medical records. I think that'll go a long way towards providing some of the concrete information about who benefits from the deployment of electronic health records that Laura was mentioning in her comments.

And then lastly, our QIO organization Mass-pro, was one of the original docket program organizations, and so there's a substantial amount of experience and history there.

In terms of governance and operation, the consortium, my organization has been convening Massachusetts healthcare entities for the past 28 years. And that's what really contributes to this culture of collaboration that I mentioned. There's been -- long predating the current focus on health information technology and health information exchange, the consortium has been convening the Massachusetts healthcare community. That's created this deeply ingrained culture of collaboration.

The other unique future of Massachusetts, as I pointed out, we have a virtual RHIO composed of multiple organizations. Having multiple organizations allows for tailored governance. Instead of one governance model that is appropriate for every type of activity, we have different organizations with different governance structures, and that allows for some tailoring of how we approach governance issues in Massachusetts.

I should mention that each of the boards, though, tends to be large, very inclusive, and

overlapping, so that there's not any sense of separation or competition, but rather it has an interlocking feel in terms of how we approach governance issues.

As far as the state role, the state has been at the table and supportive every step of the way but the state has not been leading our efforts. So they're neither leading nor lagging. They've provided encouragement and support, and thought leadership. They participate on the Board of Directors of every one of the organizations that I mentioned. They provided financial support for certain initiatives but not a disproportionate financial support. They have been providing funding, ongoing support for my organization and also for the Mass-Share clinical data exchange projects. But the level of their funding is about what you would see from a large provider organization or a large payer organization. It's not, you know, in any sense, you know, a leading role in funding.

And lastly, I would point out that so far we have not had nor have we perceived a need for any legislation or executive orders in order to move projects along.

Last slide in terms of the federal role, I think it's important that groups like the Community and other activities that are going on through ONC continue. I think thought leadership is really important. I think using the bully pulpit to drive change and to get buy in and to keep people focused on this and emphasizing the criticality of health information exchange projects is important. Obviously removing barriers to health information exchange and helping to align incentives so that we can bring market forces to bear to promote health information exchange activities.

I would caution -- I guess offer two cautionary notes: one would be to avoid proscriptive mandates. I think sometimes it's very easy when you see something that you want to have happen soon that you want to tell people how get to the finish line. I think that we need to realize that this is going to take some time, there's going to be some iterative learning that's required. We're going to make some mistakes and we'll learn from the mistakes. We'll learn from what other states are doing. And through that process I think we'll get to the finish line faster than if there's simply a mandate saying, you know, it shall be done, and it'll be done this way.

So anyway, thank you very much for your attention and look forward to any questions you have.

MS. DIERKER: Secretary Leavitt, Dr. Brailer, and members of the Community, I'm very pleased to be here today and bring you a story in contrast coming from the west in Colorado, and to give you a sense of how this state level HIE environment is emerging there. We are a really different story from the two states that you've just learned about.

We're a classically-western state. We have a distinct preference for the market over government solution so won't hear me say a lot about how the government and state has really been leading us so far. But we are a state that while we have a diverse geography and some classic elements that everyone thinks of as a western state in terms of vast spaces, mountain ranges, agriculture, ranching, we have an interesting, changing demographic happening in Colorado, both economically and in terms of the people in the populations.

We have certain communities where we range from having immigrant populations being brought

in by resort communities, where we have populations of the wealthiest of over 400% of the national average income.

And yet we have a lot of troubling demographics. We have a rising uninsurance rate. We've come out of a decade of really severe budget restraints, and we have an environment, a market environment that's characterized, especially in healthcare, as highly competitive. But unlike the states that you've heard, very diverse.

We have non-domiciles for profits that dominate largely our locally grown plans and providers are of the smaller ones in our state. And you know, as I say, worrisome health statistics in terms of how we're really doing are drivers for some of the emerging health exchange activity.

We have a gubernatorial election coming up that's going to bring some change to our environment. But right now it is really meant we are in somewhat of a holding pattern in terms of what the policy-makers have done in our state about leading health information exchange.

All that said, there is emerging, in our state, clear goal, and this has come out of a really organic kind of coalition of people who've come together and like many across the country, see the promise of health information exchange, sort of the mandate of this being a fundamental driver to improving health and healthcare.

We have many things happening in terms of technical development and health information exchange. We're one of the six state demonstration sites and we're building a point of care clinical data exchange.

We are a recipient of the Privacy and Security -- previously known as HISPC contract -- to work on privacy and security analysis. We've got a couple of different grants in the state through the information links project, the Robert Wood Johnson Foundation to explore population based health exchange.

And on an informal basis, we have some state HIE leaders who are working along with some of the NHIN projects to really benefit by and contribute to those developing models.

Now, one of the big drivers for health information exchange in our state is really at the local level. We have some early adopters and some leaders in different parts of our state. On the western slope, which is on the western side of the state, and in different pockets of the communities that are really developing local RHIOs, we call them, and we have various sectors and providers who are putting in various levels of clinical messaging and other kinds of health information exchange.

Of course we have concerns about levels of adoption, about providers. We have a lot of rural single solo small practices, and we have safety net providers who are interested and working on how to really get into the game. But at this point are sort of watching and waiting and trying to find points of leverage for how to really increase their capacity.

We are an example of what you would call an emerging state level health information exchange. There's been, as I mentioned, an organic movement, a coalition of people who now number about

40 who come from all sectors that are supporting the development of what we call CORHIO, the Colorado Regional Health Information Organization. We've sort of used that acronym to build upon.

And as you look in the workbook, you'll see that there's sort of a couple of prevailing models of what states are doing. And you've heard about the Massachusetts and Rhode Island, both convening, being virtual, pulling other entities together. But then also playing a role in operations.

Colorado faces the challenge of really needing an organization that will do both. In order for us to really bring up health information exchange, especially through our ARC contract and our point of care exchange, we need to have an independent entity that can actually provide services. We need to be able to have web enabled record locator service master patient index that will serve the state-wide exchange. We also need an entity that will convene this divergent group of stakeholders and keep them together in doing a new way of business relative to health information exchange.

Now who has really led this in our state has been the Colorado Health Institute and my organization. We are relatively new, independent, not for profit information policy analysis center, created by three foundations in our state and we stepped into the void to provide facilitation and are really the incubator for our RHIO.

We have a lot of consensus on principles and where we want to go and we have that real distinct challenge in this moving environment of how to really put a stake in the ground and get started. So unlike some of the other stories that you've heard in these other states, we are sort of designing and building, and we're looking and watching what's happening and trying to really get some consensus around the starting business case and the resources that are going to enable us to really put an operational model in place, hopefully by the end of the year.

So our challenges are relatively obvious in terms of how we really, without a major government leadership role, without any one entity, organization from our market, saying, yes, we must do this. How we actually are going to get leverage to move forward and get this done and take advantage of current momentum.

In terms of our state, as I mentioned, we really have had a low level of participation to date and yet they remain key leverage for us. We've had conversations with our Medicaid agency. There's interest and participation in the CORHIO steering committee, but it's pretty low level. Public health has been the most active in our state and are interested in developing some pilots. And while we've had the governor's support for our HISPC participation, as I mentioned, given the upcoming election and change in leadership, there's really been not much else that's been able to be done there.

Now our legislature really has been most aware of telemedicine and has acted somewhat on that. They are becoming increasingly aware of the activity across the country in terms of states and legislatures and we expect that there will be growing interest during this next session.

So when you think about a state like Colorado and some of the points that have been made already about the importance of the federal role in really achieving some type of synergy with states to really provide points of leverage, we offer an interesting case study in how to think about the different types of state stories and needs that are out there in terms of what to do. I'm sort of reminded of that commercial on television where, you know, the big company has just lost its long-time client and the CEO goes around and gives people plane tickets and says go visit. And I think about that often and I'm excited about this project and this opportunity to really stay in dialogue during this formative time. Because we really are in search of, like I said, points of leverage and ways in which we can take a payer in our state like Medicaid or the market to respond to certain incentives and to actually move forward and put a new piece of infrastructure in place in our state.

So with that, I think I'll stop and thank you so much for the opportunity to be here today.

DR. LADENHEIM: Good morning Mr. Secretary and the Health Information Community. I'm Kala Ladenheim from the National Conference of State Legislatures. And I do want to do the typical caveat: my comments reflect the research in this project and do not reflect NCSL official policy.

My charge was a little bit at a tangent and it really speaks to what Linda referred to as seeking mechanisms to promote strategic synergy. I was tasked to identify ways that states collaborate, work together in ways that are both within and outside of states. Perhaps less than national but perhaps as much as nation-wide. And I think the idea is to provide a lot of models that may be useful in thinking through the nature of collaborations that you can do to build a process beyond individual states. We certainly heard in the previous presentations the diversity even in these three states. And I have to say, if you looked further you would find even greater, not less diversity among the states. There is an enormous amount of variation in this, as in almost anything else you wanted to point to.

Going on within states now, as you would expect, you see a variety of coordinations among state health programs. And I think the places where you're likeliest to see these starting typically -- and we heard a comment again from one of the other states already, that states as funders look to how you can coordinate the state's total financing burden. So you'll often see joint purchasing beginning to emerge, efforts to do that with public employees and Medicaid programs, efforts around quality, again, around those programs because the state has a highest level of control.

Although we have found -- I actually took part in a project evaluating some state efforts to combine quality efforts in Medicaid and public employees. And one of the challenges is that legal requirements will differ among the programs. There are often conflicting federal requirements on vis-à-vis private employees and Medicaid recipients that reflect different nature of the fiduciary responsibilities. So as states try to do coordination among the programs, they're often faced with the challenge of these conflicting frameworks.

At the same time there are positive existing models of joint public policy settings. For instance, in the area such as juvenile justice, or substance abuse, where there's coordination across [unintelligible] and funding streams and different sorts of programs to deal more holistically with

individuals. So there are models that do exist within state government of collaboration that are quite fruitful to build from.

Coordinations across government and public/private, again, often center around employee purchasing, so that we do see, for example, states' public employee programs participating with private employers in projects related to transparency. Purchasing programs around things such as Leapfrog project in Wisconsin where the state public employees are participants. And in actually in Massachusetts, Medicaid was one of the earliest participants with one of the public employer purchasing coalitions that was centered around quality and purchasing.

Among the states you see a lot of basis for collaboration. Obviously you have regionally-based collaborations which often relate to environmental and economic development issues. You have regional compacts and authorities such as, for instance, New Jersey and New York with the Port Authority. Issue-driven collaborations often come around -- can be carried out in a number of ways that range from developing standards and model language, legislative language, which we often get a lot of requests for. Through explicitly developed compacts where states will join compacts and compacts assure that states have laws in the process that are uniform.

It's a voluntary process. In some cases there's an effort to create a mandatory process, in which case you'll see federal overlay on state compacts.

From the point of view of states, what's desirable about a compact is you have more voice and exit. If a state does not wish to take part of a compact any longer, it simply leaves the compact or as compacts develop new legislation, do not adopt the legislation. And compacts are often a very interesting transitional progress that you see. For instance, we're seeing a longstanding adoption compact amongst states that now has a federal overlay and that's a very typical progress that we see between state and federal rulemaking that goes on.

Intergovernmental associations such as my own, such as National Conference of State Legislatures, Association of State and Territorial Health Officers, are important mechanisms for disseminating information and sharing effective models among the states. And, actually, encouraging the kinds of experimentation that this process we're seeing provides us.

We have best practices, comparative evaluations. And the federal government is really key in our ability to do that kind of evaluation. You know, within a state you'll often have evaluation of your own program. It's very difficult to get the funding within one state to evaluate across other programs. So, this is a place, the federal government and private philanthropies are really, really key.

And if you want to have that kind of learning across states, you have to have that kind of knowledge. States are the labs of democracy. You have to be having a lab; you have to be writing up the results of your experimentation.

Next slide? Thank you.

States are eager -- states vary, I'm sorry. I skipped two slides. States vary in their capacities, in

their resources and in their preferences. You're a frontier state, you're very anti-tax, low participation of government. Massachusetts is probably pretty far on the other end of the continuum.

And it's a challenge when you're developing strategies to do ones that encompass them both. And that's where states come in. Because states can provide a buffer between national policies and national decision making that takes into account those real regional differences in preferences for the roles of government terms of vis-à-vis the private sector and also for differences in the infrastructure in the capacity of government, in the tendency for government versus the private sector to take on roles, you know, your state philanthropy, that in another state may be taken on primarily by government.

History matters. And I want to talk about that. There's an interesting way -- really, two different ways that history matters in states, and especially in something like this where we're looking at very rapid dissemination, very rapid evolution of the field. It's important to distinguish between these. One way is path dependence. Experience that has taken place that may be unique to a state, sunk costs, relationships, I'm thinking for example, right now, of an experience in Maine that took place recently, where they had a real problem in the implementation of Medicaid information systems. That has shut off a path relative to the relationship of Medicaid and health medication exchange in a way that would not be shut off in another state. And if you went into a state without knowing those historical particulars, you can run into a lot of frustration.

The alternative way that history matters is the one we're all familiar with, developmental models, stages of adoption. And it's important to be looking at both at the same time, taking into account when we're looking at stages of development where there's some really important sharing roles. There are ways that the models and the transitions are really key versus the ones where, you know, you're really kind of stuck.

So I'm going to flip on to the next slide. We really touched on a lot of those.

Clearly the states looked at the federal government. When we're talking about standards, we're talking about looking for models; the states are absolutely looking to the federal government for this. They're anxious about the health information technology initiatives, particularly because Medicaid dominates state budgets. They're particularly anxious to know what's coming out of the CMS, what rules of reimbursement are going to be in relationship to Medicaid and health information. Because that is going to be a real basis of anything that states can do. It's the financial cornerstone.

I think in this, as in any policy, there is no strictly state or strictly federal role. And I think I want to leave you with that final message. Whatever policies are adopted, there is a partnership at all times and attention to how that partnership is defined at the time the policies are developed will help shape the direction as they grow.

MS. KLOSS: We are open for discussion and questions. I would say that there are brief summaries of all nine states that participated in the appendix to the workbook. And you will identify the further variation.

I would also say that for the project findings as part of dissemination, there is a staterio.org that has been set up and we ask for your help in disseminating these findings.

DR. BRAILER: Thank you, Linda, for a great report and to members of the panel. We will now open it up for questions, and I think Mr. Secretary, you were going to make some comments.

SECRETARY LEAVITT: Yes, I would be interested to know what the relationship, in your observation, with the health information exchanges and the quality collaborations that are going on in most states. Are they the same organization or are they working together? Is there -- that'd be my first question.

MS. ADAMS: For Rhode Island, it is one in the same. Our RHIO is a subset of our quality and safety initiative. It was one of the first projects, in essence of -- granted it's a very large one, but we see that being able to be maximized only under an umbrella of a larger intent for extracting everything we can from it in terms of quality, safety, and value. So, for us, it's the same, and we will, probably over the course of the next few months, be developing a parallel strategy to continue.

We've got a lot of fire-power around the table and we know that we've got things rolling well in terms of the health information technology. And we now need to turn to some of the things that we've been doing, such as our state-wide ICU collaborative. We have every ICU in the state working on reduction of ventilator associated pneumonias and central line infections, and enabling some of these things alongside the development of our information health technology which we know will take a while to produce some fruit.

MR. CAMPBELL: In Massachusetts there's certainly points of connection between the health information exchange organizations and the quality improvement organizations. I mentioned that our QIO is part of the virtual RHIO in Massachusetts, and in addition, the Mass e-health collaborative, the \$50 million project to deploy electronic medical records in three communities has a very extensive quality warehouse component to that. And they're going to be using actual clinical data to populate that warehouse. So in everything we do we're certainly thinking about the quality improvement aspect of it. But there a cluster of different organizations that we're mentioned on my slides that are active in the quality space. And so we're always looking for opportunities to work together but the two agendas are not explicitly linked.

MS. DIERKER: And I would say that quality really has a lot of appeal. It's a big driver about why we need to do this. But getting data from health information exchanges down the road. And in the meantime, what is a real challenge is how to really pull people together. There are people working on quality and quality agendas in different silos and pockets, and so pulling in docket and pulling in all of these efforts together is really an emerging role. There's a lot of energy that goes in to creating the new piece of infrastructure. And I think the appeal of bringing it all together is something that's really felt on the ground.

MS. ADAMS: I can I add that my sense is that some of the challenges that we face in the rest of these arenas all has to do with standardization, getting us going in the same direction, whether it's

public reporting, whether it's pay for performance. All these kinds of things benefit from public agreement and community agreement on how to benefit with things.

One of the other examples -- I would be remiss if I didn't also recognize our TYO, quality partners of Rhode Island, how strongly they contribute to this, and they have quality initiatives in their own right that are not part of the quality institute, but are linked.

And I just would say that when you think about things like -- one of the projects we will consider would be like potentially setting up a state-level standard for the board's role in quality in organizations, provider organizations. We have such a varied, varied understanding of the board's role in quality. We think we can do things -- high leverage things in that regard as well, that won't take an enormous amount of time and money but will be high leveraged.

DR. LADENHEIM: Quality and safety tend to be the ticket in for legislation in states that are trying to wet their feet in it. Whether that -- which institutions that engage this I think varies a lot with how active as that goes through the legislative process in a state the existing quality organizations are. There is a challenge because in some cases you end up with sort of parallel and perhaps potentially competing organizations.

However with that said, this is the ticket. This is -- if the state is just starting, you can point to specific outcomes, specific possible improvements that are quantified, that are defined, and that makes the case.

SECRETARY LEAVITT: You mentioned the phrase "competing organizations." To what extent, in your states, and in the states generally, are their competing organizations? And to what extent, in Massachusetts, you've basically established yourself as the north-bound train in Massachusetts, and in Rhode Island, it sounds like the same thing.

But in states where they're just starting, these things tend to grow as entrepreneurial ventures that are -- I'm interested to find out in Colorado, for example, and generally, are there competing organizations?

MS. DIERKER: Well, we have organizations who are doing pieces of things. And while right now perhaps they're not competing there's really the big possibility for competing. And I'll use an example of the patient safety organization recently became enabled through federal legislation and a group of folks got together and started to think about, gee, we should create one of the those. And meanwhile, as we sit looking at creating a RHIO, a state-level exchange with all of the pieces of governance and all that you go, well.

And then we are fortunate to be -- we in North Carolina have an under grant project and it involves a lot of the national certifying boards, the physician boards, to look at improving primary care and practice and using informatics and many of the techniques that Donald Berwick and IHI have put into place.

But comes the issue of data and registries and information and start to think oh, we need to create this whole -- and we have to go no, wait, wait, wait. And the hospital association who's really

had a revenue source of producing quality reporting information about hospitals and that's sort of ramping up in our state.

The question becomes: who reports, who does all this, where do we set the standards for what quality reporting looks like? And that's the point about this piece of infrastructure that we're talking about at the state level, is a standard setter, is a convener, it's getting everyone to play and those functions are what's needed across a lot of these.

SECRETARY LEAVITT: A number of you mentioned standard setting. What do you mean by that? What are you setting standards for?

MS. KLOSS: I could comment on that. The sense of the group, the technical advisory committee is that the state health information exchange initiative can be the group that kind of insists that national standards be followed. There's a concern that we will have 1,000 flowers blooming in regional health information organization initiatives and that this could be one role of the states: to convene the organizations to follow at least a set of minimum exchange standards.

MS. ADAMS: One example in Rhode Island is for the pay for performance program for Blue Cross, our largest insurer, they worked hand to hand with us to develop their quality counts program, started some time ago. And part of that has to do with making sure that the EHRs that they support under that program are only [unintelligible] certified EHRs. That's an example of not just any EHR but we've made sure that that standard is written into the pay for performance program.

MR. CAMPBELL: I think another important consideration is that there's technical interoperability or technical standards, but there is also policy interoperability. And I think that in some ways that's the more challenging issue.

And so while there's technical standards that need to be defined and followed, we think that it's an important part of our role as the convener in the Massachusetts e-health community to make sure there's a focus on the policy framework, that it will support health information exchange, so that we don't have organizations, one pursuing opt in, one pursuing opt out, one having this approach to privacy, another having a different approach. We want to make sure that to the extent possible, we harmonize our activities at a policy level so that those barriers to interoperability don't rise up and don't create problems further down the road.

MS. DIERKER: And that's really perceived quite strongly at the ground level. I mean people really don't want to have to build twice. They don't want to have to do something that doesn't pay off. I mean they just really want to understand.

And then you have some of the issues about the -- where sectors and those who just want to do it will go off and start to put things into place and people realize that should that happen we will end up with electronic silos and we won't really accomplish the end use.

SECRETARY LEAVITT: There will be other questions, but why don't we go around and let others ask questions and I will have some comments at the end.

DR. BRAILER: Bill Winkenwerder.

DR. WINKENWERDER: Great discussion. You spoke about the need for the federal government to be more active in setting standards, but you also talked about the state setting standards at the state level. And so I'm interested if you're able to describe what kinds of things ought to be best done at the federal level in terms of standard setting and what kind of things might best be done at the state level.

MR. CAMPBELL: I mean, I think the technical standards need to be nation-wide in order for there to be national interoperability. I think that from a policy perspective as Kala was saying earlier, different states approach these issues in a different way. And I think that it's probably on the policy level where you can have more flexibility.

One of the projects my organization is about to undertake is try to do a deep drill down on specifically the policy issues relating to health information exchange. The Markel Foundation has their common framework that they put out that includes a policy component but they explicitly only address the things that they felt had to be harmonized on a national basis for there to be a national health information exchange. What we want to do is try understand what is it that can and should vary at the state level, but furthermore what should vary even at the local level because not every community is the same.

We're also not sure that health information exchange is purely a -- occurs at -- that the geographic -- that the best way of thinking about the different levels is not purely geographic. So for instance, behavioral health facilities might have a very set of different policy issues around health information exchange or public sector, Medicaid providers might have a different take on it. So we want to understand where we need harmony and where we can recognize the unique aspect of the organizations that provide healthcare in the community. So that's something we're about to tackle.

MS. ADAMS: We need help significantly at the national level with helping to help states understand their role and how to energize and engage the states, and some of those policies I think, come down from the national level better than they do than being developed state by state in terms of describing that role and perhaps standardizing that role in some way.

Certainly some local flexibility is needed. We specifically feel that local flexibility will be an absolute requirement for things like how these data will be used. We all understand this is way too expensive to build to simply move data from point A to point B, as valuable as that is for the immediacy of clinical care. We're all thinking broadly about this in terms of using it for biosurveillance, using it for a variety of other things. But as soon as you raise that issue locally, it's a hot local issue. And I think that that one is so difficult to resolve locally; I can't imagine it being done nationally.

MS. DIERKER: I would like to make a comment about Medicaid, because Medicaid is both a state and a federal issue together. I mean obviously at the federal level it's an example of how you can really use the leverage of a big payer and to bring Medicaid to the table and to really

advance infrastructure and demonstrating through Medicaid how to really integrate quality and health information exchange, and build it. And you need the state in that too and we need federal leadership that will help states and especially a state like ours, where we're really not in a strong leadership position in our Medicaid program at all to really understand they need to do it. And then we need our state policy makers to really understand how to use a program like Medicaid as a source of leverage. So it's a really important example where a lot can be done.

DR. BRAILER: Mark, did you want to respond to that?

DR. MCCLELLAN: Sure. I think this would be a good time to make some comments about where we are with Medicaid and Medicaid reform. And it's a very important time in the Medicaid program thanks to Deficit Reduction Act, thanks to many steps that states have taken over the last few years to find better ways to pay for needed services in the Medicaid program. There really are a lot of good models that states are starting to adopt that focus on improving quality, getting care out of the costly institutions, costly emergency room care, and into more basic coordination. We're working with the state of Louisiana on the gulf coast, redevelopment for this purpose.

There is a process that we're undertaking with the state of New York that's actually investing, planning to invest a significant part of Medicaid funds that have been going to poorly coordinated institutional care into supporting the IT infrastructure that can promote prevention and smooth use of services across different settings.

I guess the big comment I would make is that under current law and with the approach that we've taken at the agency, there is a lot of flexibility for states to redirect their Medicaid dollars. They have to meet, as always, a budget neutrality test overall. But we have been working with a number of states to implement reforms that rely on supporting interoperable health IT. And we expect to continue to do so.

And I think this is a good opportunity for CMS to continue to work with groups like yours and examples like yours to get the word out to other states. What we find in a lot of desirable Medicaid reforms is that like us and like everyone, states have tight budgets, their staffs are stretched in lots of different directions and having some good examples and models to adopt can make it much easier for more states to go down the same road that we have seen elsewhere.

Mitch and Indiana have also been looking at some similar steps. There are a lot of good examples out there, and I think it's the right time for us to highlight the approaches that states can take under the new flexibility and Medicaid financing to redirect the dollars to promote quality, prevention-oriented care as opposed to costly and duplicated services that we see too often in the Medicaid programs today.

DR. BRAILER: Doug Henley?

DR. HENLEY: A comment and then two questions. I really liked the term that you introduced, Ray, of policy interoperability. Thank you for doing that, both you and Lynn. That is a huge issue at the grassroots level as you have indicated, and perhaps that's something we can learn from, Mr. Secretary, as we address the global issue of interoperability and policy can certainly be

a part of it because it can get in the way.

The two questions: one is with all the great stuff that's going on at the state level that you've identified, how are patients and consumers involved in this, from the standpoint of getting the word out as to what this really means for their improved health care? That's question number one.

And number two: much of what you have outlined, it sounded to me like is occurring primarily at an institutional level and at a very large practice level. But at the end of the day, most care in this country is occurring in small and medium-sized practices. And so, where are those physicians and other healthcare providers, at that level, how are they being brought into this equation at the state level?

MS. ADAMS: In terms of the consumer engagement, we decided that we were going to pick some of, in essence, our most feared consumer activists and put them on the board. We wanted them to hold their feet to the fire until they blistered on these privacy and security issues. So we decided to take the ones that are on the news whenever the consumer issue come up, not fear them but embrace that sector of our society and bring them in and talk to them -- and have them. We knew if they were able to champion this idea, if they were able to co-design with us, that we would make a system that consumers could trust and then the message could be brought to them by the people that they trust. They don't know us in some ways, in terms of speaking directly to consumers. So we built our consumer advisory committee fairly early on last year with -- and comprised of both people who are advocacy groups and people who are also off the street consumers and we got them from asking our physicians to give us some examples of names of people they would approach as physicians and ask if they were interested in serving our committee. They did. And now we have a robust and well functioning committee that I'll tell you, speaks up on the issues.

And so we know that they helped us develop our website and said we don't want one of these websites that tells all your other colleagues about what it is that you're doing. They have ways of finding that out. You need one that speaks to us. So you will see our website looks different than the others. And so we have that going on.

That consumer group now has led us through several consumer focus groups where we've learned lots of things, about we thought that the idea of reduction of errors would sell. No, they don't believe that.

They don't believe this is going an accuracy of data entry. They have data entry errors all the time. There are issues that really resonated with them with the idea of seeing the whole of me, the whole patient, treating the whole patient. So we now know that we have to deliver this in a different language to our consumers.

We knew who they didn't want to have possession of their data. They were very clear about the three groups. No question about it, they did not want to have that, leading that.

So we have, we've really taken that on. Has it taken us longer? Yes, there is no question about it. We have gone around and around the horn on some issues around consent, on what kinds of data.

So we know that this is a little bit longer route, but we think that's a temporarily longer route. We do think that we'll have stronger consumer buy-in over the long term for that.

To answer your second question, or should we stay on consumers until we're finished with the consumer question? Let me respond to the practice.

Our five physician groups that came together and decided on the single EHR did so not only for their own benefit but because they thought that if they were able to come together, group purchase, be able to help with Blue Cross's quality counts program that what they could do for the small 1, 2 physician, was be able to offer them the benefit of about a year and a half of their own research to find one of the most flexible excellent EHRs that they could bring to the state. That if they were join this co-op that they would be able to get a lower price on that, that they'd be able to benefit from quality counts program, that they'd be able to benefit from local implementation support, people who live right next door to them supporting them, their own physician groups leading it. So that over time, when that EHR implementation has now happened and they're passed, every implementation learns from the last one. So they're beginning to share their stories about how to write their templates, how to do all the things that result in a successful implementation. And then once all of those EHRs are implemented, they're going to be starting a learning community on how to get the best quality out of those EHRs.

So that program was not directed for the large practice groups. In fact, one of them involved in that five groups is a local community health center. And it is directly interested in making this available to people outside themselves, most specifically those single doctors that can't afford an IT person on staff, why not join the co-op?

MR. CAMPBELL: I think you're certainly right to emphasize the criticality of consumer involvement. I think that if we design these systems without the consumers' viewpoint in mind, that we'll be -- it will take more time rather than less time. We'll run into further difficulties down the road. In Massachusetts we've made a number of decisions about how we implement health information exchange that's designed to preempt some of those objections, so for instance, we don't believe in centralized databases of medical records, we're following a very decentralized architecture.

And secondly, in all the projects we've done so far, we've followed a very strong opt in approach as opposed to an opt out. So unless a patient affirmatively consents to the sharing of their information at every point of care so you can consent to having the record at your primary care physician shared, but not at your psychiatrist. So unless the patient opts in at every single point of care, the records don't get shared. They get to opt in or opt out at every point of care.

But it's something we are struggling with; we want to involve more consumer advocates. That's something we've identified as something that needs to be done. There's a tendency to just have the large organizations and the people that are kind ready to run with the ball to drive the agenda. And you really need to consciously include people other than the people that are most ready to move the ball forward. You really need to look far and wide for the right types of representatives to include.

In terms of the issue with small providers, I guess there's a couple ways we're getting at that. One is that we're trying to develop community utilities that can be used by any organization, so the development costs are spread by the larger organizations and government organizations in the state. But once developed, those tools are available for anyone to use. It's essentially an open-source model.

But the truth is, small doctor practices, I mean, whether it's open source or whatever, they just don't have the technical capability. We don't have a statewide project on that front, but I do think that the Massachusetts e-health collaborative, the \$50 million project that I referenced, is learning an incredibly large amount of really interesting things about doing technology at the retail level in the healthcare space. And one of the things that they've discovered is that they've driven the failure rate down to essentially zero. From what I've understood from some reports you can have failure rates as high as 30% in very small practices and it's because there's extensive spending on readiness assessment, training, support, transition assistance, and that that's one of the ways of driving some costs out of the system is by not shortcutting on those types of expenditures and just thinking that it's a matter of hardware and software. It's as much about the readiness and the change management and all the technical support that you need.

MS. DIERKER: Yeah, I wanted to -- on the consumer issue, this is a lot about communication. And we -- like Ray -- are really looking at a decentralized approach so that, you know, we benefit by something that's the most consumer friendly and the perception of consumers right now about this opt in and opt out issue and how data is protected and who really gets to own it and all that, although I think we're sort of leaning more towards an opt out.

But in any case, I think the big challenge is how to really describe to people what we're doing and to take this whole technology, HIT, HIE, arena and talk about it. Even people supposedly doing it and in the business of it aren't really on the same page. So the messaging, the talking about it, the getting out to people, we have consumer representatives on our steering committee and all that. But we're now about the process of just going out and talking to people and finding opportunities. The privacy and security project is giving us the opportunity to now go out and talk about it and describe it to people and to just spread the word.

Things frankly like Katrina and others, have made this opportunity of electronic health information much more understandable and palatable to people, so we find that folks are pretty receptive to understanding the benefits to themselves from streamlined, non-duplicated, you know, and they want to understand about specific aspects like privacy and security.

So that's sort of what we're using as a hook and we're, like I say, in the process of really trying to do some strategic communications about messaging and how we're going to talk about it.

On the small provider issue we have that issue big-time, because we have a lot of small providers spread over vast areas. And while I would say there's a really -- a growing awareness of the fact that it would be nice to do, the burdens on the primary care community are so immense that many, of course, are sitting back, going, yeah, we'll -- I invest but who gets the benefit? So I think that while our CORHIA model is really looking like Ray indicated at open source, and making a lot of advantages, low cost of entry to providers once they can do exchange, I think

there's a real challenge for us to piece together resources, largely from our philanthropy community. Some creative financing options about how to drive adoption, and that's where perhaps there's a real interesting role for state government, even in a market-based approach to really think about how to do that. And I think that's what's upcoming for our state.

DR. LADENHEIM: I was going finish with it, but I'm going to start by agreeing with you, because I think one of the roles that we've seen states already starting to look at is what their roles may be both in initial graduate education and continuing education in helping to take part in that, in addition to some of the states do have small grants programs that are designed, but the cost of entry is not just the cost of the hardware and software. It's really the wet-ware, getting the people up to speed on it.

On consumers, from the policy maker point of view, consumers constituent, and this is a huge issue. This is probably the driving issue from a policy maker's point of view, is the level of consumer acceptance on this, and there is a lot of nervousness out there. I think some places where we see states sort of start towards doing something and backing away had to do with consumer concerns around issues like privacy and security.

That said, one of the areas -- and I'm sorry that Mark McClellan's left, because I think CMS has really pushed on this, one of the areas where all these pieces converge is people with complex care that need a lot of coordination. They're often the people who have the largest interaction with the health system and really see the opportunities, really see the advantages of that the continuity of care can provide. And some of the recent Medicaid waivers we've seen in states have tried to develop programs that institutionalize, that use electronic exchange as an important piece, specifically for people who need disease or care management in complex ways. I'm really eager to the results of those experiments.

DR. BRAILER: Kevin Hutchinson.

MR. HUTCHINSON: One of the things that we've learned in the deployment of Katrina Health was this issue around privacy and security and across state lines. And we know that there's been a contract let by the government to do research in this particular area, but we have a unique opportunity here in having Rhode Island and Massachusetts sitting side by side, where there is a lot of your own people crossing your own state lines for both work as well as residential. And one of the items we discovered was the differences in the privacy rules with respect to access to, in this case, medication history information.

I'd love to hear the comments about the states' opinion on how we resolve some of those conflicting patient and privacy rules or legislation across state lines to allow consumers who are crossing those state lines for both either work or residence to still have equal access to medical information.

MR. CAMPBELL: That's an important and difficult issue. Because particularly in the east where the states are relatively small you do get an awful lot of interstate traffic, and especially for Massachusetts, which has some leading healthcare institutions, we do tend to attract people from a relatively far distance that come for medical care.

I think that the HISPC project is going to be a very important step forward in this. It's helping us inventory -- the projects we did on medication histories, allowed us to inventory all of the state laws that relate to that. And one of the things we discovered that was very problematic was that payers, the health plans, are forbidden by law from sharing information, even with the patient's consent, for medications relating to HIV, behavioral health issues, sexually transmitted diseases, substance abuse, and so even if the doctors in the emergency room had a conscious and competent patient in front of them saying I consent for you to pull down my entire medication history, they were not allowed to do so. But interestingly, if the data had been coming from pharmacies, they could have. Because the law was specific to health plans.

So in doing this project, MedsInfo, we learned about the very specific and granular barriers that existed and there's a bill that has been drafted and filed with the Massachusetts' legislature to eliminate that particular provision, at least as it relates to the provision of emergency care, with the patient's consent.

But through the privacy and security collaboration project, we'll learn even more about barriers to health information exchange, and some of them -- I think barriers is a blunt term, because some of them are appropriate protections, but some of them are barriers that ought to be removed. There is a plan to have some regional gatherings as part of the privacy and security collaboration, and I know that Massachusetts and Rhode Island will be at the same one. So I think this will be a way for us to start getting traction on that issue, but it's a difficult one, and frankly one that I think, we've been just so focused on issues within our own borders that we haven't done, probably, as good a job as we could of working with other states in our area to try to tackle that.

MS. ADAMS: [unintelligible] In New England, the New England Health Initiative -- Health Institute, and they are pulling the groups together, RHIO groups. We've met on occasion, just as lovely locations, and we've gotten together, but we really haven't had a serious agenda for sharing, and I think that their next set of strategies for us is to start thinking about these critical issues that we need to set for our agenda as a region now, instead of states that may be sharing that information most likely will be. So I expect that we'll have that enabler.

MS. KLOSS: I would just also add that that was -- that kind of sharing was behind the recommendation that there needs to be mechanism to promote strategic synergy among states and between states and federal, because we saw that most people live on borders.

DR. BRAILER: Just to follow up on that question and perhaps expand it: is there dialogue going on in the states or did you surface it, Linda, in the project relating to state licensure and how that's affects telemedicine either across states that could be contiguous or on a more broad national basis. Is this on the radar screen or not?

DR. LADENHEIM: It shows up in states very much around telehealth and delivery of care. You see it primarily -- well, you see it first of all in the rural states. You also get into offshoring issues around that -- states developed some protective legislation around that. This gets very tied into interest group protectionism. So, it's a very much political issue when it gets down to making the decisions at a state level.

MS. KLOSS: We spent no time looking at that but we did acknowledge that that was one of the areas where there was opportunity.

MS. DIERKER: I would like to highlight the challenge, too, because this is something that policymakers are able to sort grab on to at a local level and start the work on. But we need to really bring people up to speed about how to really think about these connection issues, and it would be very helpful to tie it to licensure, to discussion with the licensure boards about that, standards of practice.

DR. BRAILER: Mitch.

MR. ROOB: First of all, as a state official we will miss Mark enormously. He will be a tremendous loss to your agency and to ours.

But specifically, about what the federal government can do to incent states more effectively. And I think I've raised it -- I know I raised the issue with CMS officials. But this week or perhaps next week in Rhode Island is the Medicaid Management Information Systems Conference annually. It happens to be occurring -- you may or may not know this -- in Rhode Island this year. I'm sure that's a complete coincidence.

But that -- the architecture and what CMS chooses to pay for and not pay for, in terms of how it integrates that infrastructure with the personal health record and with the electronic health record and how it standardizes that architecture with what it does in terms of Medicare will really define, I think, much more, or as much as the standard setting, what you choose to pay for. As, you know Mr. Secretary, we will, in the states do. And what you choose not to pay for, we are unlikely to do.

So it is a terrific opportunity, I think, that you have to define what that interoperability will look like, and particularly from a cross state perspective it's probably the most effective way of assuring state interoperability prospectively.

SECRETARY LEAVITT: Could I reflect for a moment on how unique I think this is as a public policy question? We are truly exploring the new frontier of federalism here. For centuries federalism has worked and continues to work and will continue to work. But we are having to reinvent it for our generation in a way that -- and this is classic! We've got big state, little state. We've got a state that tends to be heavily oriented toward the use of government, state that isn't. And -- I mean, the founding fathers may have been brilliant in that they created the perfect form of government for the information age.

But we're having to invent something entirely different. I mean, our form of government is federalism and we're sort of inventing net-eralism. I mean it's the sociology of a network and how we create the capacity to coordinate but not dominate -- how we create -- how we have central coordination but local control. In a way, a network is a perfect metaphor.

I mean, the federal government -- the states and local communities have to be PCs. They have to

have the ability to operate independently and to capture their own sense of agenda and do what they think is best so they innervate and continue to be the laboratories of democracy that they were referred to earlier. But there has to be an operating system. You can't have a network without an operating system. And the federal government very clearly has to lead in an aggressive way. And I think our capacity to pay and our capacity to lead has to be evident here.

So one of the things that we've been working with on the other side of this with the quality initiatives. I've been in 27 cities in the last couple of months, meeting with quality initiatives. And it's clear to me that the connection between the quality issue -- the quality collaborations and the health information exchanges isn't what it needs to be. It's clear to me from your comments, or I guess I should ask this in the form of a question. I sense that there's a fairly heavy appetite among the states for the federal government to have a strong role in being able to bring sense of -- some sense of order to this. And yet we don't want this to be a government-dominated kind of proposition.

In the quality initiatives, we had a meeting on the 24th of August with the six -- we have six pilots that we have selected to nurture in quite specific terms, Massachusetts being one of the them, there's one in Minnesota, one in Wisconsin, one in Boston, one in Phoenix, one in California, one in Indianapolis, and we have now begun to bring them together into a network. And the network will be working with the AQA and HQA, which are the quality adopting organizations for hospitals and ambulatory care.

This network would have three functions. The first is the cross-pollination. The second would be the harmonization, and the third would be to charter many more like them and to nurture them. And it sounds to me like a similar kind of effort which ONCHIT has begun that is going to be vital with the health information exchanges.

We've got to cross-pollinate now among them. We've got to begin to harmonize what they're doing, because having different people out inventing different parts of this that are competing will not be productive. And we've got to get a lot more of them, because I'm persuaded that while the standards have to be national, the effort has to be local. Because it's all about trust, and you can't develop trust at a -- from afar.

So, Dr. Brailer, I think our time is close to concluded on this point. But here's what I'm learning from this: one, there's a lot of activity and a lot of smart people doing things.

Two, there's a hunger and a desire for coordination. Three, the federal government needs to play a strong role in being able to provide that coordination. Four, that it will largely be defined by what we can pay for and not just the federal government but also the private payers. I want to remind you that the strength of what the president did recently by having the federal government and the executive order say as a condition of doing business with us, we're going to be defining these issues as having paramount importance in our procurement, begins to create this north-bound train that I think is going to be necessary. And we're working with the private payers to accomplish the same thing and the insurers and so forth.

So this has been a very helpful conversation and I will follow on it, and the pieces of this are

starting to come together in my mind. But it becomes clear to me we've got to determine how to organize the chartering of these that begin to give them harmony. We've got to figure out how we harmonize the health information exchanges with the quality because they have to go together. We've got to then figure out exactly what the federal role will be, how we will knit this together. And your efforts today have certainly clarified many of the issues in my mind. Unless there's others I think we might be ready for a break.

Any other comments?

DR. BRAILER: And I would say, Mr. Secretary, that I think the second phase of the project, which this report now sets up is the appropriate forum for that steering committee to come back to the American Health Information Community with those recommendations on how these actions can go forward. So I certainly encourage you to back to us, Linda, with your group, whenever it's ready, when you're ready to have those recommendations.

SECRETARY LEAVITT: Let me just underscore the word "urgency."

[laughter]

We don't have enough time to get this done so we just need to move this on and we'll look for your report soon.

Thank you.

MR. CAMPBELL: Just to follow up on what you said: in terms of the federal government taking a leadership role, I think that in my mind probably the most important thing that can be done is the transparency agenda you have been talking about.

The hardest thing, from my observation, of making things happen in this space is the inability of having market mechanisms work effectively. And so in Massachusetts, where there's been -- when you can go to a CFO of either a payer or a provider and say that this will take your transaction costs from being \$4, you know doing it in paper, down to 15 cents electronically, they gladly sign up, they write the checks, and you have a self-sustaining activity.

But when the incentives and the payment flows are so unrelated to the provision of services, and there are benefits that flow from the initiatives, then it becomes -- the sustainability model becomes, essentially intractable, because you can't -- you can do pilots, you can do demonstrations, but you can't create sustainability without the market mechanisms. I mean unless somebody wants to just step up and write a check. But in terms of getting the market participants to create sustainable activities, there need to be market forces that will support that. So I really think the transparency initiative is really important.

SECRETARY LEAVITT: It's very clear to me what's ultimately going to drive this is a need to have pay for performance functioning and working. There's a pay for performance. We've been dabbling in it. And it's a true and profoundly important concept that I believe will ultimately be adopted in the statute at some point. And we're all going to have the responsibility both in terms

of the market driving it and legislation driving it to make this work.

And as it stands today, quality measurement in this country is a nurse who comes in on a Saturday morning and goes through a two-foot stack of files to try to figure out who got their aspirin when. And whether or not people had a blood check. And to fix that, we've got to get through adoption which we will talk about in just a few minutes. We've got to have standards. And the level of urgency that I'm feeling to get this into place is profound and I appreciate the effort that you have gone to, and we'll look forward to your next report.

MS. KLOSS: November 15th.

SECRETARY LEAVITT: Good for you. Thank you.

DR. BRAILER: We'll take a 15-minute break and adjourn promptly at 10:45, thank you.

[break]

SECRETARY LEAVITT: We'd like to begin again. And, I will ask Dr. Brailer to introduce the next panel.

DR. BRAILER: Thank you, Mr. Secretary.

We now have a panel that I think you will find very interesting and very important to the Community's deliberations. And this panel is asking the fundamental question of where are we in this process and how do we go about scientifically understanding how we go forward. What is the basis of adoption analysis that feeds not only the Community's discussions but policy instruments, the work that's being done in the private sector and in the states?

And to this purpose we ask Sara Rosenbaum and David Blumenthal, who are very respected health services researchers, to put together a blue ribbon panel of experts and thought leaders, to help digest what we do know and to lay out thoughts about how we go about measuring adoption and the disparities and variations in adoption across time.

And with that, let me turn it to Sara and David to start the panel and then to introduce the other participants. Thank you.

DR. ROSENBAUM: Thank you, Dr. Brailer. Mr. Secretary, Dr. Brailer, Community members, it is a pleasure to serve as the home for the HIT adoption initiative and to appear before you today to talk about that initiative.

This is a collaboration between The George Washington University and the Massachusetts General Hospital. And I know that I speak for both institutions when we note the added value brought to this work by the joint endeavor between the department and the Robert Wood Johnson Foundation.

The purpose of the adoption project is to create a definitive, public baseline for measuring the rate

of HIT adoption. This panel is going to discuss measurement, the standards for measurement, why we need standards for measurement and how to establish and implement an appropriate adoption measurement system.

We hope to discuss with you the topical domains of measurement. Not only the methods used to measure adoption, but also the choices that inevitably must be made regarding what to measure. In selecting these topical domains, the AHIC and other policy-makers will make critical decisions, not only about what to measure, but really in the end about what matters most in HIT adoption.

Some of those critical decisions are which practice settings command the most attention, which types of actual or perceived barriers will be examined, the extent to which adoption is reaching the communities and populations that stand most to benefit from improved health care quality.

With that, I'm going to turn to my colleague, David Blumenthal, to start us off on the presentation on adoption.

DR. BLUMENTHAL: Mr. Secretary, Dr. Brailer, and members of the AHIC, it's been a privilege to be able to work with the Office of the National Coordinator on helping to understanding where we are, where we're going, and what the agenda for learning should be about HIT adoption and dissemination and its impacts.

I want to commend the Department, Secretary of AHIC, for their leadership on this vital area of policy.

We have been working to understand, based on existing evidence, where we are with HIT adoption up to this point, and I'd like to share with you some estimates that our expert consensus panel has vetted, looking at the existing literature on the adoption of HIT up to this point. This focuses actually on electronic health records, on electronic health records in three sites. Individual physician practices, groups of physicians, and hospitals.

And what I want to particularly focus you on is the column on the right, which is entitled "Best Estimates from High Quality Surveys." These are data through 2004. And you will be hearing from Jane -- Dr. Sisk, who's to my left, some more recent data that may slightly modify these estimates based on one particular federal survey.

But based on our best estimates and the process of review that the expert consensus panel has gone through, we believe that overall, physicians -- about 17% of American physicians have access to an electronic health record. That would be about 13% of solo practitioners, and nearly 40% of physicians in groups larger than 20 physicians.

We didn't find any credible information on electronic health record adoption in hospitals. I would be glad to expand on that in further discussions, but we do think that CPOE is present in a minimum of about 5% of American hospitals.

Based on the trends that we observed from early surveys of about 2001 to later surveys of about

2004, we saw about a 3% annual increase in physician office adoption in electronic health records. And we projected in a very simple, and I would say simplistic way, what that would mean if we went through to the president's 2014 goalpost for overall adoption, if we just extended that rate. And it would get us to about the 45-50% range. If that rate were increased to 6%, it would get us to the 70-75% range.

We see major problems in the existing data that I have just reported, and there's no question that it could be improved. And to improve it and to track the adoption of electronic health records over time, we need to accomplish these tasks.

First of all, we need to define what an electronic health record is, so we know what we're measuring when we measure it. Our expert consensus panel has agreed that the Institute of Medicine's definition, laying out eight key functionalities is probably the most desirable definition. And we actually, for survey and data collection purposes, modified that to four key functionalities that we think constitutes the core of an electronic health record.

Next one is, it's essential to define what you mean by adoption, because adoption really has three parts to it. The acquisition of HIT or EHR, its installation. And then ultimately the most important part, its use. And one needs to know what you're talking about when you ask people whether they've adopted.

And then it's necessary to have data collection methods that are reliable and objective and reproducible. And we have some such data collection methods in place through some excellent data collection processes that are undertaken by the federal government through a survey called the AMSS [spelled phonetically], through the American Hospital Association and others, but we believe these could be complemented by other data collection activities to give us even a fuller picture.

We also -- if we want to understand more than just adoption, but to also understand value, barriers, and incentives, we need to define measures of value, what aspects of quality might be influenced by HIT, what should we look for, how would we define efficiency for the purpose of understanding impact.

We would need to find ways to compare the value and efficiency of care with and without operating electronic health records. That's a major experimental challenge. We need to be clear conceptually on what the barriers and incentives are so we can go look for them and how they operate, and then we would need to define measures of barriers and incentives in regular data collection activities.

These are some of the issues that the HIT adoption initiative and the expert consensus panel are continuing to grapple with.

That concludes my formal comments, Mr. Secretary. And I think I will turn the podium over to Jane Sisk.

DR. SISK: Good morning, Secretary Leavitt, Dr. Brailer, and other member of the committee.

We're delighted to be here to share with you some of the data that we've been collecting in our routine surveys by the National Center for Health Statistics, which as you know, is part of the Centers for Disease Control and Prevention.

I'm going to share with you data from two surveys. Mostly the top one, the National Ambulatory Medical Care Survey but also the National Hospital Ambulatory Medical Care Survey. These are both annual surveys, with samples of office-based physicians on the one hand or hospitals on the other that are selected to generate estimates that are nationally representative of those providers across the country. The scope is that the physician one covers nonfederal office-based physicians. It excludes radiologists, anesthesiologists and pathologists, and the hospital one covers non-federal, general and short stay hospitals that have emergency departments or outpatient clinics.

The process of data collection is that a representative goes to the provider. For example, the physician in his or her office, and conducts a face-to-face induction interview and then takes a sample of visits that are going to occur in the coming days and abstracts those medical records to get information about the patient and the clinical management of the patient once those visits have occurred. So it's a combination of data and information about the clinician, the physician, the organization, whether it's the hospital or the physician's practice. And then the patient and the clinical management of that patient's condition.

Response rates have been quite high, as David alluded to. The physician one on the order of 65% or even higher in some years, and the hospital one on the order of about 90%.

These data go back to 2001 when we first started to put questions about use of electronic medical records on these two surveys. The measure for the physician one for example was whether the practice uses electronic medical records not including billing records. And in the pretest for this, all of the respondents said that they understood that electronic medical records meant keeping documentation in computerized files rather than paper files.

The question -- these questions were on the hospital survey only in 2001 and 2002. And the lines there are flat as they can be. 31% at that point for emergency departments, and 29% for outpatient departments. The physician one started and has remained lower, about 18-17% through 2003. But then as you can see, there was an up tick in 2004 to 21% and in 2005 to just about 24%. We also calculated what the situation was for physicians in groups of three or more physicians. And those groups had reported use of electronic medical records a couple or so percentage points higher through this entire period. So flat through 2003 and then up to 23% in 2004 and almost 28% in 2005.

A few more details from what the situation was in 2005: it's notable here that characteristics of the practice, in the sense of the numbers of physicians in the practice, the ownership of the practice, the region where practice is taking place, have a significant association with whether or not the practice has electronic medical records -- medical record systems. But not the characteristics of the physician.

So, the age, gender, specialty of the physician, for example, does not have a significant relationship with whether or not the practice has -- reports electronic medical record use.

You can also see that in the context of about 24% of physicians reporting use, solo physicians in practices are way lower than the rest and that the percentage increases with the size of the practice, the number of physicians in the practice, to almost 50% by the time you get up to 11 or more physicians. This is related to, but different from ownership where if a physician or physician group owns the practice, the rates are significantly lower than, for example, if an HMO owns the practice. If an HMO owns the practice, two thirds of them have electronic medical records use.

Note also that those categories where they're most likely to have electronic medical records are also the categories where there are the fewest physicians. The large practices and HMOs. HMOs being a tad less than 3% of all physicians. Also note that the northeast has about half the percent of the other parts of the United States in use.

We also were interested in looking at the characteristics whose primary care providers used electronic medical records. Of the patients who saw primary care providers in 2003 and 2004, about one-sixth had physicians that reported using electronic medical records. It's notable that this percentage did not vary by the characteristics of the patients that I've listed there: age, gender, race, which is black, non-black, ethnicity, language ability, region of the country, urbanicity, source of payment, income, and education. The latter two we took based on the average for the patient zip code.

And finally I wanted to share with you some of features that the physicians reported that their systems had or didn't have. So, again, this in the context of about 24% overall on average reporting that they used electronic medical records at all. Quite a bit of room for growth there in the percentage of practices, percentage of physicians that report having these different features. Especially notable at the low end, only a little less than 11% reported having clinical reminders as part of their systems. Only about 5% having the capacity for public health reporting. And the clinical reminders, of course, are particularly important because of the potential there to improve quality of care.

I also want to mention that the 2006 surveys -- both these two that I've been describing to you as well as one newly in the field this year on ambulatory surgery facilities -- have more detail about the features of the systems and whether or not they are turned on or off. That all thanks to the advice of Richard Singerman in ONC.

So, the overall -- these data have picked up an up tick in the percent of practices in the last couple of years that the percent of physicians in practices who report having these systems, and show where we're doing well, where there are short falls and there's room for improvement. Thank you.

SECRETARY LEAVITT: Can I ask you, Jane, does this mean 21.4% of the physicians who have them have the demographics portion turned on or is that 21.4% of total physicians?

DR. SISK: The latter. 21.4% of total physicians.

SECRETARY LEAVITT: Okay. I was going to say 5.4% of 17%.

DR. SISK: It's even smaller. It's small enough anyway. That would be even smaller.

DR. BRAILER: [unintelligible]

[laughter]

DR. PAINTER: Thank you. Good morning, Mr. Secretary, Dr. Brailer, members of the Community. I am Michael Painter from the Robert Wood Johnson Foundation. And I'm very happy to be invited here, along with the rest of the panelists to speak with you today.

We at the foundation are very excited to help co-fund this measurement assessment project. And we're eager to talk about it. I'm going to take a little bit different tact here, I'm going to take us out of the findings and the data just a little bit. And if you will indulge me just for a moment, a number of us at the foundation have used a narrative device, a fictional story about a family in a purely fictional town in, say, 10 years, and to sort of describe why we're interested in things like this, this measurement assessment project and other pieces of this kind of effort.

The patient is Mr. Romero, Richard Romero. And he lives in a purely fictional town of Liberty. It can be anywhere in the United States. Mr. Romero, with family origins in the Dominican Republic, has a strong family history of diabetes, but Mr. Romero is very happy with his decision to move his family to the town of Liberty because it lives up to its motto to be the best place to live to be a high quality, healthy life.

Mr. Romero, like most Americans, still remembers a time when American healthcare was getting more and more expensive. The quality was variable and downright poor for many. And access to even that care was out of reach for many others. For instance, the national healthcare disparities report in 2005 noted that nation-wide, Hispanics had poor quality care for 20 of 38 important core reported measurements of quality. Again, Hispanics had poorer quality of care than other racial and ethnic groups and worse than other Americans on average.

For instance, the median difference was 16%. That means that Hispanics were 16% more likely than non-Hispanic whites to receive poor quality care. They were less likely than non-Hispanic whites to get preventive services like mammograms and pneumococcal vaccines. If they had diabetes, they were less likely to receive strongly recommended services for diabetes than non-Hispanic whites.

Also research, like the Dartmouth Atlas Project, which the Foundation also funds, that project revealed that Liberty, to their surprise, had one of the highest amputation rates among diabetic patients of any city in the nation.

And as Liberty's healthcare community gathered and reported more and more information, patients and providers, unfortunately learned the very worst about healthcare in Liberty. It was somewhat worse than the national average, both overall, and for some racial and ethnic groups, particularly Hispanics. All this information was very concerning, obviously to Mr. Romero and his family, and to the leaders of Liberty. And they did something about it.

The town of Liberty is a very different place than it was 10 years ago. And the citizens of Liberty can prove it. Liberty has evidence that it's living up to its commitment to high quality, affordable care for its citizens. For instance, I'm just going to run you through a couple of things that have changed now.

The quality of Liberty's care has dramatically improved, all aspects of the quality, including the equity dimension of that care. Liberty's average hemoglobin 81C is now 7.5% community-wide, and again there are no disparities in this measure of Liberty's diabetes care. Liberty now has the lowest amputation rate for its diabetic patients of any other municipality in the country, and importantly, past disparities are closed. There are no differences in the amputation rate by racial or ethnic group. And Mr. Romero knows this fact because he follows these and other rates for Hispanics closely, he can follow these rates because Liberty made it ease to see and understand this kind of information.

And perhaps most importantly, Liberty physicians report information about the results and outcomes of the care they provide publicly. This public reporting means that Mr. Romero, and all of Liberty's healthcare consumers, as well as the town's physicians and other providers can see which providers or groups are providing the overall best results for, say, diabetes.

This information is incredibly valuable as you can imagine, to Mr. Romero, as he decides where to get his care. He combines this information about results with the price information that Liberty's providers also report. With that information, Mr. Romero and his family can really zero in on the highest value for their healthcare dollar. This information -- this healthcare information works well for the Romeros because Liberty did not just look to the medical community to develop its community healthcare information; they also took the somewhat radical step of getting consumers, including consumers from every racial and ethnic group to help design the public reporting system. That assured that reported performance data was much more useful to patients, and since more patients understand the data, it's helping them think more about their own role in their healthcare.

And, the Romeros, of course, shop for everything. The Romeros have become adept at using the publicly reported information to help them make their healthcare decisions and choices. Incidentally their employers, and even their church provided a lot of help teaching them how to use this new health information.

But it's very different, obviously, now, back here in 2006. Now it would be impossible to know which doctors and hospitals were providing high quality care and which were not. And almost as disturbing to the citizens of a town like Liberty where the folks could measure disparities, the disparities between racial groups were huge. So what changed?

Well, health information technology is front and center, it's a critical piece, a critical ingredient. Liberty came together to implement and adopt electronic health records and push for interoperability so information, health information, flowed privately and securely but efficiently to serve Liberty's patients. Interestingly, a standardized approach to national measurement of electronic health record adoption identified early on potential gaps and disparities in this EHR

adoption. Liberty was able to use that information and make sure that all providers in Liberty got the help they needed to implement, adopt, and connect their health information systems.

Liberty came together under strong leadership with projects like some of the things going on in the department here, or maybe the Robert Wood Johnson Foundation's Aligning Forces for Quality. All to align market forces to drive and sustain quality.

Liberty came together to develop a system of public reporting. Reporting that is, on performance, outcomes, patient experience, and price. The community's efforts resulted in dramatically increased healthcare value, which is obviously higher quality at lower costs. The efforts also helped to align incentives, not necessarily paying more for performance, but rewarding results, since higher quality care with better results usually costs less.

Liberty providers embraced the goal of quality improvement. Further they also recognized that in many ways they were ultimately going to compete on outcomes and results, so they all needed to understand know how to redesign their practices to deliver these results. Thus they built sustainable mechanisms, capacity, and capability, that allowed them to improve the care they provide, to meet the interests and the demands of the Liberty consumers. And they have the ability to compete with each other, based on the actual value they deliver, results and outcome per unit price.

And Liberty also came together to engage its consumers, all of its consumers, including those of every racial and ethnic group, helping them understand the publicly reported information, and helping them think about their own role in health care.

So what does that have to do with this EHR adoption measurement project? The implications for EHR adoption measurement are critical. As we noted, the health information technology and the EHR adoption piece are critical ingredients to almost all aspects of this vision. As Doctors Blumenthal and Sisk noted in their presentations, we know from this sort of this gold standard assessment now, that the rates of adoption are still very low, probably too low.

We need a standard, consistent, regular report card to monitor the adoption trajectory. And to do that we need a standard definition of what we mean by the electronic health record. We need to make sure that we include important vulnerable groups, that we don't leave behind the usual suspects. Like certain groups, communities, areas of the country, certain types of practices, for instance the small and medium-sized practices that are so hard to reach, with all of this quality improvement and the EHR adoption, so that folks like Mr. Romero can really enjoy the vision of healthcare in 2016.

And we need to understand and devise ways around potential barriers to adoption. The medical, cultural, financial, and technical barriers, and we to think more about the demand side, engaging in activating consumers to help us really drive a great deal of this change, including the automation piece.

Thank you.

DR. BRAILER: Thank you. At this point we'll open the discussion for questions, comments,

from the members of the Community. As we do that, I actually do have just one, maybe, factual statement that, David, on your part, and Sara, you're producing a report from this panel. And I just thought maybe if you could describe that, when it's going to happen, how it's going to be framed. Certainly you're not prepared to fill me in on what you've said today about what it's going to say, but help us to understand what to expect from that.

DR. BLUMENTHAL: The Robert Johnson Foundation, as you know, has generously complemented the support that the ONC has provided to produce a report on the state of HIT adoption. We think that that report will be released probably in the early to mid part of October. It will summarize our findings across the set of questions that we have addressed which include how to define an EHR, how to define the adoption of an EHR, optimal methods for measuring rates of EHR adoption, optimal methods for measuring impact of EHRs as well as summarizing the expert consensus panel's view of quantitatively, the current levels of adoption using two alternative definitions. The one that is sort of -- the imprecise definition that's used in most data collectivities as well as a more precise one that the ECP has evolved itself.

There will also be a heavy focus on disparities in adoption and what the best information is up to this point, and then some recommendations going forward for how to continue the measurement process.

As I said, we expect that that will occur in mid October. We are hoping that at the same time there will -- we can arrange publication of some of this material in a peer-reviewed form that will increase its availability and dissemination to the community at large.

DR. BRAILER: Nancy?

MS. DAVENPORT-ENNIS: Yes, I'd like to thank the panel and certainly thank you, Dr. Brailer, and Secretary Leavitt, for the opportunity to have the presentation.

I do have two questions: Mr. Painter, thank you for your focus on the consumer and the role of the consumer within the adoption of personal health records, electronic, medical records, as we're moving the nation forward.

The question is: as part of the survey work that is being done and reported out, are consumers being surveyed with regard to their attitudes of how important is it to them that the medical provider treating them, indeed, is using an EMR? And within that survey work to also survey the consumer to determine what they see as barriers to the adoption, implementation and utilization of the EMRs.

Ultimately I think that our adoption in the country may be to some degree influenced by the role of the consumer in defining its importance and their demand for that level of service. So the more we have consumers that are saying I only want to be treated within a facility or a practice group that has an EMR, the more we're going to see these practice settings move to the EMRs. Thank you.

DR. BLUMENTHAL: My response is that consumers are surveyed much less frequently than

other groups. We didn't -- the ECP wasn't charged with looking at the consumer side at this point. It would be very desirable to have the kind of data that we're developing about providers also on the consumer side. And hopefully that will be forthcoming over time. And I do agree with you that if people come into doctors' offices with the expectation that an electronic health record will be used, that it will have a major influence on both institutions and on physicians.

SECRETARY LEAVITT: Could you elaborate on barriers? I know it's not right inside the sweet spot of your research, but I think you all must have formed instincts about that and I would like to see an inventory, if you could, today.

DR. BLUMENTHAL: Sure. We actually did introduce a report for Dr. Brailer's office on barriers. And I think they come in -- and by the way, barriers and incentives are the reverse side of the coin. They really are the same categories. I think they come in four flavors.

The first is economic. And that's referred to often as the lack of a business case for adoption. And the second is legal or regulatory. And Sara Rosenbaum has been extremely helpful in helping us to identify those barriers. But examples are the Stark and anti-fraud, anti-kickback laws, as well as potential legal liability that might be associated with how EHRs are used or not used.

Technological. Uncertainty about which forms of electronic health record work and how well whether they'll be compatible with other forms.

And then finally organizational. This is, I think an extremely important type of barrier. As witnessed -- or incentive -- as witnessed by the fact that groups tend to be much more frequent adopters than individual practices. You can unpack, Mr. Secretary, each of those categories into specific manifestations of the category, which I'd be happy to do. But I think that's a useful heuristic for thinking about the kind of baskets in which they come. One can identify specific policy interventions for each of those barriers, and they've been circulating in the discussion here today already. And I think some of them can be assessed through data collection in terms of both their importance and whether they were mediated through policy.

DR. ROSENBAUM: If I could just add, there are some interesting synergies that go on between these baskets and some of the most pressing issues. For example, going back to the Ms. Davenport-Ennis' question about consumer preferences. Another way of thinking about the same question you asked is, is it more important to the liability of physicians for downstream conduct that they be totally open and transparent and on top of information with their patients, versus liabilities that would flow by being open and transparent.

And one of the constant discussions among the research group is that it is much better, actually, given the legal framework in the world to be quite transparent because the law actually, in ways that I think are not well understood, favors greater transparency. And so then going back and tying consumer expectations to issues that comport with what is an appropriate response from medicine in terms of its own liabilities, you begin to see that quite -- in contrast to moving in opposite directions, in fact, the interests begin to align. Which is why understanding how to categorize the barriers and tying consumer expectations with physician expectations or hospital

expectations and concerns begins to uncover important insights that I think are going unnoticed at this point.

SECRETARY LEAVITT: I had a conversation that I think I reported to this group before but it's become a symbol to me.

Young pathologist, by the way, I guess was excluded from your report. But nevertheless, he was just ready to leave the university and go out and set up a practice. I think he set up in Tennessee, but he said, "I heard your speech and I believe that stuff. We need to have electronic medical records and I'm going to have them in my practice. I just need to know which system to buy." And then he said, "I can't do this more than one time; I have to be right. And so what's your advice?"

And, you know, I wasn't at the point where I could give him advice. Although I did say to him, "If you're going to be a sole practitioner, it seems to me it'd be very important that you're aligned closely with the hospital and hospital system that you're going to be practicing in for the most part and you might want to talk to them." And I told him a little bit about Stark and about the leaf that we hoped to provide and have now provided.

Obviously there's this problem with economic equation where people who pay for it don't necessarily get the benefit. And we've got to work heavily on that. But we can't afford to wait for a 3% or a 6% gradual -- this has got to be exponential, and it's got to happen in a 3 or 4-year period or we're not going to get critical mass. And I would be interested to hear you to reflect on my friend the pathologist and how many of those sole practitioners in your graph -- it looks like that's the group under 11 where there's 54% of the practice.

If we were able to -- if it becomes evident that there will be compatibility, that you can resolve this issue, that you can work with your hospital, what's possible? How fast could adoption move in your -- I recognize you have not done serious research in this. I'm asking for your instincts.

DR. SISK: I'll try it and then defer to you.

By my back of the envelope jottings here, it seems as if the last couple years the rate of increase has been a lot higher than the 6%, which was the highest. So I think it's somewhere a little shy of 15% a year. So, these are fairly small numbers and a small period of time but at least that's what's been achieved the last couple years.

In general, if we pay people and organizations to do something or pay them more, they're more likely to do it or do it more rapidly. And we've talked earlier today, and I know in lots of your other deliberations about the policy leverage that the Medicare program, the Medicaid program, can exert in that role.

DR. ROSENBAUM: I would just add that the greatest single story I can think of about the speed at which adoption can happen when this department stands behind speed is how quickly every hospital in the United States came into compliance with Title 6 of the 1964 Civil Rights Act. After Medicare was enacted, HEW at the time indicated that as a condition of participation in the

program, hospitals would have to be in compliance with Title 6. And it took six months for every hospital in the country to come into compliance with Title 6. I agree with Jane --

SECRETARY LEAVITT: What's Title 6?

DR. ROSENBAUM: I'm sorry. The 1964 Civil Rights Act is the federal law that prohibits discrimination on the basis of race or national origin.

And HEW said we have a wonderful incentive here, it's Medicare, it's a federal program. If a hospital wants to participate in Medicare it will be in compliance with -- it will agree not to discriminate. The financial incentive for Medicare participation was so enormous that absolutely every hospital came into compliance.

And I think that in that sense I agree completely with Jane: the most single powerful tool you have for incentivizing compliance or adherence adoption of this technology and then essentially moving it out to all other payers is the use of federal authority over both conditions of participation in federal programs and federal authority to clarify the conditions under which that participation and the adoption and financial support for the ongoing operation of the system is a recognized federal allowed expenditure. That is -- I think it would transform the country rapidly from the supply side.

DR. PAINTER: Maybe I will jump in a little here too, Mr. Secretary.

From our perspective, all that is true and very important, but we're also sort of interested in this definition of the electronic health record and I know there have been other presentations to the Community along these lines. But it's just really critically important, as you see in the story that I wove, that the electronic health record sort of fits in and drives the public reporting and the performance collection, all of the stuff to sort of help pay for itself as it's going.

And the way we measured it even with this, we didn't really include that functionality because it we had, the rate would drop substantially -- of adoption, would drop substantially.

And that gets me to the other point that we're interested in, in our shop, which is this demand side that I ended with is looking at the consumer side. Because we're concerned and think there needs to be something to kick the adoption rate up a little bit.

SECRETARY LEAVITT: Any idea? I would assume that if you take that population of small practitioners -- that's the one I'm focused on right now -- and most have internet access, wouldn't they? So there's been adoption of technology to some extent. It's not...

DR. BLUMENTHAL: Ninety percent of them will be using the internet for personal purposes.

SECRETARY LEAVITT: We're not moving them from zero technologically? This is about adoption of software and practices in their -- you know, one of the things that I find -- one of the adoption models I find quite interesting is the internet. If 15 years ago we had said to the world: internet is the future and everybody needs to have it and, you know, I'm sure there would have

been -- we need a government program to pay for everybody to have it.

Everybody's got to have a pc, so let's have a government program. And somehow the internet has ubiquitously found its way into the way we operate and we couldn't do business without it. It seems to me that what made that possible was the existence of standards and the marketplace finding its way, finding a level of efficiency. And there are some barriers to the adoption of electronic medical, or health records that has not made that possible.

But ultimately this question of how we finance this, there's got to be some macro changes in health financing that will accommodate this -- and I'm not just talking about Medicare and Medicaid. I'm talking about the whole equation is going to have to shift a little bit in order to -- but if we really believe, as I think everyone at these tables would, that there are substantial efficiencies to be gathered, then that shift in macroeconomics ought not to be an unhappy event. It ought to be a very happy one.

What I'm hearing you say is that the barrier -- that's one barrier. But the real barriers right now to me are the legal and regulatory and the compatibility and the organizational. If we can get those -- it looks like to me 3 or 6, or 6 or 15, whatever it is, ramps up fairly quickly. Because my friend at the pathology bench is saying to himself right now, I know the system, and I can't do business outside of this. Just -- I'd like to get your reaction to that line of thinking.

DR. BLUMENTHAL: I think the -- every doctor's office that practices medicine has an examining table and telephone, and it's fitted out, and that's probably a capital expenditure that way exceeds the \$10 to \$50,000 that are estimate for HIT. So it can be built into the economic model of practice if there's a case for it.

The problem is that they don't -- physicians right now don't see it essential to practicing the way they see the examining table, and the tuning fork and the reflex hammer, or the X-ray machine. And that -- getting past that will be important; it's by no means insuperable, if the federal government puts its mind to it and if payers put their minds to it.

The other barriers are in some ways more important because they -- especially the technological and organizational, because they reduce the efficiency of use of the record once it's in place. And I think supporting physicians -- if you've lived through, as I have, as a practicing physician, the implementation of electronic health record, it's very helpful to have your hand held for a considerable period of time afterwards. And having that handholding gets more out of the record than if you don't have it. So, I think that's another ongoing cost that needs to be built in.

I just want to add that the CDC, Dr. Sisk's group with our -- has helped us a lot in looking at different ways of defining "adoption." If we use a stringent, a more stringent view of the electronic health record, that is looking at whether it incorporates four key functionalities, the overall rate of adoption in the country comes out at 9% rather than 23%.

So I think that emphasizes the importance of being clear on what you mean by electronic health record, and that 9% doesn't include connectivity.

SECRETARY LEAVITT: What were the four you used?

DR. BLUMENTHAL: The four were: having health information and data in the record. Pretty basic. Having the ability to display that data in a manipulatable form. So results management. Having order entry capability. So, prescribing or ordering diagnostic tests, and having clinical decision support. So, reminders, for example. Those were the four that we said were the minimal. Didn't include the four others that the IOM has defined as core functionality of an electronic health record.

SECRETARY LEAVITT: Do you have the second list?

DR. BLUMENTHAL: The other functionalities were connectivity, patient support, so the ability to educate, produce patient educational materials and also to interact with patients. Administrative processes, so billing and administrative support. And then population reporting and public health reporting.

DR. BRAILER: Mr. Secretary, perhaps a comment on this and I'll turn it to a question for, I presume David, but perhaps others on the panel.

One of the reasons early on we identified interoperability as being one of the key essences of our effort, were not only that it lowered the cost to make these tools more plug and play, and it raised the value, as you've heard, for reporting or consumer portability, but to this third issue we're talking about, that it had the potential to create a network effect in adoption, not unlike the internet or a fax machine.

That the more people begin to adopt, the more it becomes easier and required for other people in the economy to do so and essentially creating its own imperative.

My question is, I think David, but again, anyone, to what extent did the panel discuss, or do you have feelings about the network effect that's created by interoperable EHRs -- and how much can that give us a kicker in adoption towards this kind of exponential curve?

DR. BLUMENTHAL: Well, I suspect there are people sitting around this table and in the audience who are even better at answering this question than I am. I've no -- we didn't explicitly discuss that. It wasn't part of our mandate, if you will, to sort of look ahead and think about what policies or changes might affect the rate of adoption.

It's very likely that you're correct, I would think. And I think that that's one of the things that operates within organizations: that when your peers in an organization are using an electronic record and in order to gain access to them you yourself have to, for specialty consultations or for sharing of patient information, I think that that magnifies the willingness, and overcomes some of these barriers to investing personal time and effort in making it work.

So, that's my personal opinion. And I think there's probably evidence from the adoption literature in general, if that's the case. And that's why you get that signaling curve for adoptions. When you get that interactivity that you begin to get it --

DR. BRAILER: Unlike a stand-alone EHR?

DR. BLUMENTAL: Right.

DR. SISK: Just to build on that, David mentioned the typical "s" shaped curve that we see looking back on the adoption of technologies in the past, not just health, but in general. And what that literature has found over the decades -- Dr. Brailer, I know you know -- is the very important role of opinion leaders, of respected peers in the community. In this case it would be the medical community. And what their take is, what their evaluation is of whatever the new thing is.

Often times in the medical community that happens around the hospital. There are a number of reasons why -- of the categories that Dr. Blumenthal mentioned that go into why the rate is -- the level is so much lower among solo practitioners and partnerships, and I would think that that -- at the very least it's consistent.

Secretary Leavitt, as you alluded to, solo practitioners make up a bit more than a third of the physicians in the country -- across the country. They make up two-thirds of the practices. They are, as you saw, at a level of about only one-sixth who have use of electronic medical record systems.

This also dovetails with a survey of physicians that the Commonwealth Fund undertook in 2003 where they asked about barriers to adoption. And the solo practitioners were more likely to note a range of problems that fit in the categories that Dr. Blumenthal outlined. The first one as I recall, was the perceived effectiveness of these systems. So, all of this sort of dovetails for me that typically we can spur people and organizations to do things if we pay them more.

Also, very important, perhaps even before that, is the perception from colleagues, from these opinion leaders, for example, that it's worth it. That whatever it is -- in this case, these systems -- are effective in helping the physician do whatever it is that he or she wants to do.

SECRETARY LEAVITT: Could you drill down a little on the solo practitioner for me? A solo practitioner is not unaffiliated. A solo practitioner has to be affiliated with a hospital, has to -- and therefore is part of a system but what does it mean to be a solo practitioner by definition?

DR. SISK: In our data it simply means when we asked how many other physicians were in the practice, there were none.

DR. BRAILER: Perhaps we should turn that question to Doug Henley, who I think was next up for comment anyway.

DR. HENLEY: I know a little bit about small and medium practices and solo practitioners. It's a good question, Mr. Secretary.

Whether it's the individual physician or other practitioner in solo practice or in a very small practice, they represent the small business community in this country. They're fiercely independent, they're very much like the folks you heard about in Colorado earlier. And -- but

they're passionate about taking care of their patients. But they want to do the right thing.

And so as Jane said -- forgive this analogy, I'm a Randy Travis fan. And Jane, everything you said recently, "forever and ever, amen."

There's a huge opportunity here, while we talk about barriers, and barriers are important to understand, the ability of this group, the small and medium practitioner group to respond to their peers, who have already gone through this process, and can know and understand what the challenges are up front but how those challenges can be overcome even in their environment is huge. And we certainly have learned that in the surveys with our members.

I agree with the -- our survey data agrees very much with the NAMCS data. Something has happened between 2003 and the end of 2005 as we go into this year. Based on our data we've gone with our 60,000 active members, we've gone from 9% adoption to 25-30% adoption. And most of those are --

SECRETARY LEAVITT: That's the total -- not the growth -- the total.

DR. HENLEY: Yes. Now, we need to parse that out more and learn more about that, particularly with some of the key ingredients of the EHR that David has illuminated for us and we anticipate doing that. But the point is, is something has happened to stimulate that group. I think it's the early adopters, and the early adopters often represent the respected peers in communities because they take the first step, whether it's a new clinical process such as EHR or a new clinical treatment, whatever the case may be.

And they take it to their peers and it presents a very important opportunity, I think, to stimulate this group. My concern is that we may be getting to the end of the early adopter community, and what about the next 30% which represents, perhaps, a bit of a greater challenge.

SECRETARY LEAVITT: Let me ask a question: I have been through a number of adoption experiences where we were working to transition a culture. And, I mean, many of these issues are legitimate. There are times when you really have to be a pioneer to adopt and gratefully people did, but there gets to be a point where it's just more expensive to do business with the people who are hold-outs.

An example, when we first -- while I was governor we started trying to get people to do their automobile registration online. First it was just a convenience to the people who were doing it. But it soon became evident it was a lot cheaper for us to have them do that. Not only did they get it faster and more convenient, but it cost us a lot less money, and it was quite a debate at some point where we said in the past we were charging people \$7.50 for the privilege of doing it online because it was better for them. And soon we wanted to say we will do it for you for less if you'll do it online.

Is there a point at which -- and where are we on that curve -- where we start to say, the world expects you to be connected electronically. And those of us who are payers are now at the point where, you know, it's not a matter of us paying you. But, well -- paying you more, maybe it's a

matter of you getting less if you don't do it. Now, I recognize there are some -- but at what point do you cross that barrier?

DR. HENLEY: Challenge accepted.

[laughter]

DR. HENLEY: I would suggest that we are better off creating a culture of improvement rather than a culture of blame. A culture of positive incentives as you have alluded to earlier with issues of pay for performance and so forth. But with that in mind and knowing that that's down the road, I believe the physician provider community will accept that challenge.

But, again, as I continue my conversation here, it's important to understand that this is no less than culture change and practice redesign change. And we are challenging our members to understand that and know what those challenges and barriers are. But also to appeal to their sincere professionalism in the sense that, regardless of specialty, what the Rand data shows, regardless of specialty, is that we're only doing it right about 54% of the time, okay?

So let's fess up to that, and say we have to do better. And by appealing to that level of professionalism, as well as understanding the need and challenges of redesign and culture change at the practice level, let's get on with it. And I think that increase from 2003 to 2005, I think, is the tip of the wave. It is the tipping point. Let's build on that. And as Jane says, let's understand the power of peer pressure and build on that.

SECRETARY LEAVITT: Mitch has a comment. I don't know --

DR. BRAILER: Yeah, Bill Winkenwerder and then Rob.

DR. WINKENWERDER: I wanted to sort of hone in on one area. And that is the perception that -- from the investor's point of view whether it's the hospital or the practice, or the return on investment. I think we have heard a lot about that. And those of us who, for example, the DoD, we sort of asked that question but we didn't tarry on it for very long at all. We just believed and went forward. And, of course, we had the capital to do that.

But not everybody is in that position and they have to really make that hard trade-off. And as you go to look at where is the return, whether it's reduction of duplicate tests or reduction of errors, or improved decision-making, I'm concerned about the level of evidence-base out there. I think it's emerging, and in our own experience we're surveying our providers about every 90 days, and looking at their perceptions of the system as we've rolled it out over the last three years. And it continues to improve.

But one of the things we ask about is, do you perceive reduction in duplicate tests and ordering it. And that one's probably the highest-rated one. It's interesting. So the access to information reduction, those tests, is very important. Other things are not as good, you know? The learning and so forth takes time.

But where are we in terms of building that evidence base and who's got the data and how do we get that out there as sort of fuel for accelerating the adoption? I say that, recognizing that I think your point, Mr. Secretary, is maybe a more critical one in terms of policy change -- that may drive it more quickly. But I think everybody wants to have some level of reassurance out there in the medical community. What's your perception about that, where we are.

DR. BLUMENTHAL: As is always the case, wearing my academic hat, I find the evidence less than I like it to be. But I would say if I had to put the evidence in kind of regulatory terms, that are familiar to the federal government. If IT were a drug it would be approved for marketing. You might do some post marketing surveillance. But there's good enough data to me to demonstrate its efficacy.

The data about cost-saving, I think is not as firm as the data on perhaps its ability to improve quality. But -- and part of the problem is that most of it comes from a couple of places that have developed their own in-house IT systems and it's not clear that that's generalizable, so you've got the same problem as you have with clinical trials. You know, it's not clear the clinical trials are representative of what's going to happen when it gets out into the population as a whole. But it's a good bet, I guess that's what I would say.

There is a Rand study that estimated savings -- and I'm sure it's familiar to this group as well as a couple others -- which are as good as that existing data, which is far from perfect.

DR. BRAILER: Kevin Hutchinson.

MR. HUTCHINSON: On the discussion, actually I have a comment and a question for the panel as well. I did not hear originally, one of the obstacles being interoperability, originally. And now we've had a long discussion about why that is and this second phase. I can tell you without any hesitation, with a lot of experience in this space, those physicians today that are using electronic health record systems, once they reach a first phase of interoperability, their value and their own estimations of the ROI, the use of EHR goes tremendously up.

As an example, just taking the prescribing process as part of an EHR, being able to send prescriptions, not by fax, but electronically. Receive refill requests electronically, not by fax. To be able to get access to medication history. And each month, we have thousands of physicians registering on the network that are existing users of EHR systems because they now see this value of the first stage. It's not a complete stage but the first stage of interoperability.

I would submit, based upon my past experience as an EHR vendor and now my experience as running a pharmacy network, that if you're going to get to the next tipping point of adoption for physicians, those early adopters would put up with the lack of interoperability for better documentation and for better workloads in their practice. But if we're going to move this ball over to the next phase it's not adoption. We have to start with interoperability.

I know I'm preaching to the choir; that's why we're here, talking about interoperability, but the standards that we need to begin to implement and require, need not to be something that looks like we're going to Mars. It needs to be something that says let's start this in phases of

interoperability and let's start with things of value. And I can tell you, talking to physicians that went from faxing prescriptions through a prescription order to sending them electronically, getting med history and getting refills, those physicians become the biggest champions to those other doctors of why you need to implement an EHR now. And it's a very simple, easy thing, available, ready to go today.

And one of the things I would encourage us to do as a group, and as an organization, as a government, is get rid of the exception within the Medicare Modernization Act for faxes, that allow faxes to be an exception to the rule of standards, because it goes directly against our desire to drive interoperability. And we have an exception in there under the regulations that allow for faxes. If you can't support the standard we'll still allow fax. We need to get off of that and move to the standard. It's ready to go today, and the physicians are ready to adopt it.

The question, the comment I would make, and the question really to the panel is around the definition of an EHR system. Is it closely linked to how we're defining an EHR system with CCHIT? Because I want to make sure as we're evaluating the use of EHR systems and those percentages, if we're requiring certain certifications of the EHR systems based upon certain feature function elements. Are we using that as a definition or are we creating a separate definition?

DR. BLUMENTHAL: I don't remember the count exactly of the number of attributes that a record had to have to be certified but there are many, many. There are over 100, as I recall.

DR. BRAILER: It's 280.

DR. BLUMENTHAL: 280, yeah. It's very hard to measure the adoption of all those standards, especially in the current states. So we will at a certain point, be able to ask people: do you have a certified EHR? And I'm sure that will then meet everyone's definition.

There are a lot of EHRs out there purchased and put in place prior to certification. And for those, it's important to have a subset of functionalities that puts you in or out of the category.

DR. ROSENBAUM: Well, and I think also again it again brings back this distinction between adoption and use. So if -- what certification absolutely will do -- it's a brilliant step, because it allows, over time, really zeroing in on sort of the status, the characteristics of practice.

But to answer the questions that we need to answer to be able to get to the point that Michael outlined, I think then it becomes a question of which of the functionalities are so intrinsic to a different way of practice that you really want to know. And that was, of course, the point at the beginning, that what the specifics are that you will all ask us to measure will drive how this unfolds.

I think that it's like a lot of things where the great news and certification is you now have shorthand for what it means to have adopted. The bad news is you have to get specific again on what you really want to emphasize and use.

DR. BRAILER: We have a number of other comments, and we're running short on time. So I'm just going to quickly go and ask for comments or questions. And first is Lillee.

MS. GELINAS: Just real quick. I think this area, that says EHR in hospitals, it looks like a big black hole when you just see the word "none" there.

And, you know, in my mind, making rounds at the Veteran's Administration Medical Center here and seeing 100% EHR adoption and then making rounds in my hospitals, it is a huge gap. So, I just wanted to make sure that this "none" word, this is really a "none" word.

And I was so glad that Doug brought up the different cultures, but at the end of the day it would seem we need a culture of quality. Because the Rand study I hope is getting reported as a part of your study in some way. But the 45% defect rate in healthcare in America is astounding.

If airplanes plane fell out of the sky 45% of the time, if cars didn't start 45% of the time, would our public tolerate that? And so -- I just want to make sure the "none" word is accurate.

DR. BLUMENTHAL: The "none" word refers to the studies, not to the rate of adoption. So, and we put a very high barrier, a high threshold in front of the studies that we reported in that right hand column. And we had survey experts and look at them and we wanted to be able to verify the information; that was our charge.

There are other surveys that we didn't think of as being of sufficient quality to necessarily trust -- take to the bank that showed rates of adoption in the 10, 20, 30% range for hospitals. But we either couldn't get access to the surveys, we couldn't verify their methods. One of the problems you have with HIT in particular is that if you don't do your survey carefully, you get responses from people who use HIT, because they want to tell you how much they use it. And the people that don't use it aren't so ready to respond so you get an unrepresentative number.

The data number that we reported we thought were representative and, therefore, you could trust. It is -- I'm glad you brought up the hospital side because there's a real challenge in hospitals. Hospitals vary in size; some are pretty big. You can get an EHR functioning on the outpatient department, but have nothing in the inpatient side. Does that mean that you've got adoption? I don't think it does. I don't think that's our goal, to have it -- you know, in two or three places in a huge institution. So you've got to be doubly careful when you start asking hospitals whether they've adopted.

The American Hospital Association is working on this and we are working with them. They do a terrific annual survey. And I think they're going to start including some questions in the near future on this topic and so we should have better data going forward.

DR. PAINTER: In terms of reviewing the Rand quality report card into this work, we were the funder for the Rand study, so that's again why we're -- one of the reasons we're at the table here as well.

DR. BRAILER: Rob?

DR. KOLODNER: Thanks, David. This is an excellent panel and I think your point about getting your definitions right is critical. Even in group practice saying that they have the record doesn't mean that everybody in the group practices [unintelligible] talking to colleagues in that practice and understanding some of the differences would be important.

I think given some of the data that we've seen and that Doug also was talking about. The question is whether we're already on the upswing in the Sig [unintelligible] curve and whether we have crossed the tipping point. Obviously early in that curve you don't know whether it's real or whether it's just -- something we're going to plateau on. But that would be important, because the levers that you pull at that point, may be different than what you would pull if you really have to push pushing something that doesn't already have momentum.

I think the comment, David, that you made, about the exam table and stethoscope -- one of the things that we found in VA is that having now crossed that curve and coming fairly highly up on it, is that, in fact, IT as an enabler, is knitted in to how we deliver care. And we actually use it more than the exam table and more than a stethoscope. It is used in every encounter and that's a different way of thinking, but it's a process change that takes time. And so there's a -- one might think in phases of adoption, and the problem with the snapshot is that you don't necessarily see that while you've done these three things and these others will follow along. It would be important to understand what that adoption curve looks like or what the common ones are in the private sector. We can talk about what it is in the public sector, but it may or may not be the same in the private sector.

And at least what we've found, Mr. Secretary, was that when we had to get it to about 40%. If early adopters are about 15%, we needed to get it well into the early majority adopting it. And then leadership could take a firm role and say let's set an aggressive but realistic date. And at that point you knew that enough were using it to get forward.

So my question to the panel then is: given this adoption process, was there any evidence in any of the surveys about a process that you could look at so that you could see that early on you would expect certain features to be used and that later you'd expect more so that you could say that there was a progress even though in the snapshot it didn't look like you were as far along.

DR. SISK: I don't know. We haven't looked at that. That would be an interesting pattern to look at. And, of course, when we get the 2006 data, it will be so much the better. We'll have another data point but that's an interesting idea that I will take back to the ranch.

DR. BRAILER: Thanks. Mitch?

MR. ROOB: [unintelligible] Sole practitioner goes home, and he goes -- and he or she says to his spouse: honey, great news. You know that pool we were going to buy, let's get an EMR instead.

[laughter]

DR. BRAILER: Another barrier.

MR. ROOB: Right, it is a barrier. It is a serious barrier, but if you look at -- I mean to the point that we've raised on a number of occasions here, if you look at the slide that says EMR use, it's not numbered. NAMCS 2005. You got physician groups, 20%, other 37%. HMOs, 66.5%. That suggests when there's alignment of incentives, that there's adoption of an EMR, right?

And I think that that piece of data is probably the clearest about the misalignment of incentives that you will find out of this data here today, and so I would just suggest that you've got to align those incentives and you'll get the behavior you wish. If you don't align those incentives, then we won't.

MR. KAHN: I think this notion of positive is extremely important. I just was in a city in the west recently and was visiting a hospital that's part of a large ALTAC system, long-term care hospital system. And as you know, CMS is taking a hard view, and OMB is taking a hard view at ALTAC payment.

They have a great EMR system. The problem is they have had it for a long time, it's DOS-based, it will not be interoperable and it's a legacy system that -- but it's \$160 million to move to the next layer and they're looking down the guns of cutbacks from CMS.

And the physicians are sort of, you know, in the same position right now, you know, on the individual level. So, I think this issue of -- and I was sort of taken aback -- by Sara. I mean it's one thing for Medicare to require something when it's simply a social policy. It's another thing when it's a major funding of a mandate that's unfunded.

And so I think we have to be very careful here about tipping point. Because in a sense that what we've looking for, is the tipping point. And I think one of the problems is that there are negative things going on out there on the payment side for some that in a sense counter forces to the tipping points we're looking for on the adoption side. So I think we've got to be very careful about what we mandate and require, which is negative versus what we incent, the trouble is on the incent side, we're sort of moving the other way.

And I'm not arguing for not having a hard Medicare policy in terms of paying for only what we need. But, you know, we're heading into next year and all of the discussion about next year is, you know, black cloud stuff on the payment side. And that could have a negative, sort of, effect on everything we're talking about.

DR. ROSENBAUM: Let me just note that the analogy is not perfect. But put a different way: what hospitals were essentially told, or what was said to them was, if you will desegregate your facilities, which was a very costly proposition you will get the financial advantage of the Medicare program. So looking at it that way it became, in fact, not a negative club. It became a very positive olive branch.

Because most of the hospitals were private and therefore beyond the reach of the federal laws that in fact compelled certain conduct. This was truly an incentivization of conduct. And the reason that the story is so interesting because it shows you when the financial incentive is powerful

enough, the cultural, financial, business of healthcare can turn on a dime, actually.

Now, whether you can recreate a financial incentive as enormous as literally the implementation of the Medicare program is not known. But the notion that you would want a change in behavior to follow on because it's such a seminal and important step, I think is really the lesson of the story. And I think that for patient safety and quality and for the value of the transparency of the information to the public at large, this is every bit in its own way as seminal as that was.

MR. KAHN: One presumes that having this will make the information transparent, which we know from the problems of measurement that it won't. And, two, with all due respect, I'm sure it was extremely expensive to desegregate, and obviously had cultural effects, but I would bet if you lined up the cost of mandating -- literally mandating this and all doctors and hospitals to meet the standards that we're going to set forth, and the cost of desegregation, I will take the desegregation. I don't think -- I can't imagine that it compares.

SECRETARY LEAVITT: I want to try a thought on you. It seems to me that you use -- I like positive incentives, and nobody likes negative incentives. Let's just put that on the table.

But it seems to me there's a point where you use -- this is not now economics, this is sociology. You use incentives to get to a critical mass and to create a norm. And once you have crossed the norm, there is a tipping point. And this seems to me like a setting where we want to use a lot of positive incentives, but then we get to the point that is sort of getting around to it factor. Where, you know, people have -- we're now just talking about -- like, there's really no barrier and the incentive is now gone, or, you know, I could do it when I get ready to do it. But there's a point where you cross the -- it's now become the norm and I just haven't been able to get around to it. And it begins to become an impediment to the rest of the system.

So what I'm seeing in my mind over time is a bunch of positive incentives that get us to a substantial critical mass and then at some point people have to get on board or they become a drag to the system. And that's when negative implications make some sense to me. Does that make sense to anybody else?

GROUP: Yes.

SECRETARY LEAVITT: Everybody but Doug and Chip are saying --

[laughter]

DR. HENLEY: When is the right time, and at -- are you talking about the last 10% at that point, you know, in those things.

MR. KAHN: I think the surveys show we're a long way. And maybe it might just be three or four years if it really speeds up. But we're not anywhere near a tipping point, one.

Two, I mean, I've experienced when I worked on the Hill, there was a point where there was a decision, we were going to require physicians to send in the bills for people on Medigap for

everybody, and they were just required to do it. And there's electronic billing that was required at some point. And all of those things happened. But this is a little bit more complicated than that and it has to do with the workflow and the culture of what you do rather than just billing. But the precedents are there; I just think we got to be -- we still are looking at the mountain. We haven't climbed half way up, I think.

SECRETARY LEAVITT: I agree we're right at the bottom of the mountain looking up. Again, I'm just thinking sociology and not necessarily technology or even economics at this point. But this sort of getting around to it factor is a big deal in adoption. And I worry that if you think about where the tipping point is as a function of percentage as opposed to time, that you will have a much bigger percentage on the stub than you will if you say -- look, there's a point out there where you've had plenty of time to get around to this. And Patton said the government's got its schedule and I've got mine.

[laughter]

SECRETARY LEAVITT: There's a point out there where if you've had plenty of time to get on board and it really ought to be a function of -- as long as you have critical mass it ought not to be a function of percentage, but it ought to be a matter of how much time enough. We're all speaking quite conceptually here, and there's no policy being made. This is just a functional discussion.

DR. BRAILER: I'd like to make a comment and question before I turn on to the next commenter. One thing that has been noted in many regulatory exercises, not just healthcare, is that after certain rate adoption, of adoption of a certain practice or behavior, that it's actually those parties who have already done it that call for regulation or an intervention in the market to create an -- to take away the unfair advantage that those who lag may have.

Which might be the case here, given the question about what does the EHR do to the stand-alone hospital or doctor's bottom line, which is, I know is a point of debate when they're on a stand-alone basis.

I just had a quick question for you, Chip. Would you classify the incentive in the market basket update for voluntary hospital reporting of quality measures as a positive incentive or negative?

MR. KAHN: Oh, it's a negative.

DR. BRAILER: Since it was voluntary.

MR. KAHN: It was a negative incentive, I mean, and it worked, but I mean, it was a negative incentive, I think.

DR. BRAILER: That was a very small amount of money compared to --

MR. KAHN: You know, the law says you're going to get "x" and the Congress came back and said you're going to get "y" unless you do something. I think that's a negative incentive, but I'm

not necessarily saying all of the negative incentives are bad. In that case, you know, it had a good effect and it's not that -- it's not a -- it's a significant amount of money. It's not an overwhelming amount of money. It's not you're in or out.

But I think generally, I'm with the Secretary, I'd much rather, until you get to that point, be positive rather than negative. And we were making a lot of progress on the voluntary front. Frankly, in terms of getting hospitals to report, and I think we were sort of -- and there too, you could get to a tipping point. If we had continued the voluntary approach we had taken with the Hospital Quality Alliance, we were, you know, getting 50 or 60% of the hospitals, there would have been a point where they would have had a market response and people would have asked well, why aren't you reporting -- the newspapers would have asked why isn't hospital X reporting if hospital Z and Y are reporting. So -- but it was rushed up by the government's you know, heavy hammer. And you can do that, and it'll have a response. I'm just saying, you got to be real careful with that power.

DR. BRAILER: Nancy?

MS. DAVENPORT-ENNIS: And I certainly agree with the Secretary, that as long as we can have a momentum moving forward with positive incentive, that's what we want to do. I think because every one of us in the United States is, indeed, a patient. We may not have lived that journey yet but we will at some point.

But there's an incentive that we've talked about in this committee before. And the incentive is a realization that in moving to EHRs, we reduce medical errors. And I think, as I think of the solo practitioners particularly, Doug, I'm very sensitive to the benefit that can accrue to them when we begin to talk to them about the value of reducing medical errors. And I'm hoping this indeed will be an area of attention that will be used to incent, to promote return on investment because it clearly does.

And to also dovetail into the public health reporting, because our nation is now engaged in looking globally at the issue of medical errors and reporting that information out to the public. So, I think it can be a tool that can be used very favorably moving us forward.

DR. BRAILER: Colin, final comment.

MR. EVANS: Wow, that's a responsibility.

I was just building on both patient empowerment and the sort of, what drives technology adoption, picking up on Secretary Leavitt's comment about internet adoption. If you look at the history of the internet as a model here, you know, we went from one website in 19 -- you know -- 91 or something to tens of millions of websites by the end of that decade. And nobody at the time was arguing much about standards or interoperability or that kind of stuff. It was really hundreds of individuals, organizations, and companies clamoring to provide information to the consumer, the individual person, whether it be shipping service, or book buying, or public information or whatever they were -- just piling information out.

So the individual became the agent of change, then. I think there's a lesson to be learned here in

terms of adoption. Those organizations that can find ways of getting information to doctors or to patients in the system, in a clear and crisp way, I think will end up being advantaged as we go forward. And I think we think about what it took for the internet to be adopted. There's no money -- I mean people spent money to build the infrastructure -- FedEx built lots of systems to ship packages, but nobody -- they didn't ask for the government to provide money to do that. It was the best way for them to run their business. And I think the more organizations can get into that frame of mind, that we can incentivize those kinds of things, the more we will spear adoption.

DR. BRAILER: Okay, thank you very much Sara, and David, and Jane and Michael. I appreciate your work and we certainly hope that you'll report back as you continue your progress both on adoption levels, but also on standards and things that we can look at for measuring not only the level of adoption but the policies that are aimed at those. I appreciate it very much. Thank you.

We have one other item of business, which the Secretary announced earlier today, which is a brief overview of personalized medicine, its relationship to health IT, from Greg Downing, who is at the National Institutes of Health, but also, as the Secretary said, his senior advisor on this project. I would note that this will be an exceedingly brief presentation, but will be followed by a full panel discussion at a subsequent meeting, perhaps at the next meeting. So this will be something to help you to get current with this topic, and help any of your feedback shape what we'll bring back to you at a subsequent meeting.

SECRETARY LEAVITT: Let me just add, as has been pointed out, this was put on at my request. This is a project of mine. And my interest is in -- I can see a barrier. There are people who are storing genomic profiles all over the country and they're beginning to do it in different forms and without any standard. And we are -- it's a green field opportunity.

And when we get to the proactive positive quality benefit of EHRs, this is an area that I sense can't happen without EHRs and will be dramatically driven forward faster by an existence of a standard.

So, I have put together a team that is working across HHS. People from FDA, people from NIH, people from CDC, people from lots of different operating divisions in HSS. And we're quite highly focused on this.

So I wanted to just have Greg introduce the subject with the idea that when we get down to organizing our next batch of standards that we're going to undertake -- I should mention that CMS is deeply involved in this, too, for obvious reasons.

I'm interested to have this be -- that we consider this as one of them and to get it started I ask Greg to come and give you a 5 or 10 minute overview.

DR. DOWNING: Thank you Mr. Secretary, Dr. Brailer, and members of the Community. And I am here today representing the personalized healthcare team across the department, and as was mentioned, this has been a journey across a number of the agencies that are doing very important work around this area. And probably this will connect well with the panels that were here this

morning, and Mr. Painter presented a future for Mr. Romero, and we did a very similar vision exercise, several months ago, across the agency and came up with a similar future for that particular individual.

And an additional aspect of it is that the contributions of modern medicine and science and technology, that not only would we have the ability to deliver better healthcare, but new opportunities for prevention and preemption and prediction, if you will, of the risks, perhaps for his diabetes and the ability to modulate that in an individual format that currently doesn't exist throughout much of the healthcare system today.

And so what I'd like to briefly touch base with you today on some of the discoveries that we've had across the frontiers of medicine and science. And some of what we see as the framework for enabling medicine to be tailored to individuals' needs based on biology and many aspects of their healthcare.

So, we see the confluence, if you will, of this rapid advancements in science and understanding, in a large part driven by fundamental discoveries in molecular biology and the human genome project that really has set the stage for new understandings about disease. Disease, risk, and many aspects in terms of how molecular therapies are being developed today are -- share that fundamental.

Another key component to that, that we think is an enabling component to patient-centric care is the health IT aspects. And much has been going on in the Community here in the last year is really setting the pipeline, if you will, for the integration of health IT and genetic information that we believe will be transformative in this same time frame that Mr. Romero's health future was being forecast.

So we believe that this is a critical opportunity to begin to anticipate, if you will, and plan for some of that future. Some of you today have probably noticed in the New York Times' article, by Andrew Pollack, "The Wide Wild World of Genetic Testing." And I think that what we're trying to do here is show that this is a contemporary aspect of what healthcare is being presented to the public, and understanding how to best utilize this new capabilities is really based on how we integrate this into the healthcare system.

This is our pyramid of personalized healthcare. And what is at the base of this, the foundation, is the really the fundamental elements of understanding the basis of disease, and the human genome project has been a major contributor towards that. And as an equal partner in that foundation is the health information technology capabilities, and building towards personalized healthcare, these capabilities will be viewed in product development in a review, of the critical path process that the FDA has underway, is developing enabling tools, many of them based on these technologies that will have an impact on clinical management.

The next steps in terms of disseminating these technologies and capabilities in the healthcare system will also be quite critically dependant upon health IT. And ultimately at the pinnacle of this is the achievement of personalized healthcare.

So what are some of the emerging opportunities that we see for the Community? Many healthcare systems and public resources are now beginning to incorporate genetic tests into their framework in which their primary missions are about.

Some of the practical applications that we are seeing about genetic tests and healthcare are the identification of risk for disease, a confirmatory diagnostic tests and the selection of appropriate therapies as was mentioned at the outset of today's session, a field that we now recognize as pharmacogenomics.

The technology costs for genomic tests are also, as referred to earlier, decreasing rapidly similar to what we have seen in the computer industry. And some of these technologies are already in place at the bedside or in the clinic.

As was pointed out earlier, this was an opportunity because there are multiple standards emerging in the R&D field. And the process for enabling these to become either regulated or part of clinical care requires some elements of standardization of the platforms themselves and this is already underway.

I would like to point out a few examples, just so that we can sort of orient future discussions, if you will, about some of these that are already existent in medical management today. And, for example, risk factor determination for ovarian and breast cancer in the use of BRCA1 genetic testing has been in the healthcare setting for a number of years now, and it has opened the door for selective estrogen receptor modulation as a means of delaying the onset, or preventing, in some cases, the occurrence of these diseases.

The selection of the appropriate therapy for managing particular diseases is also becoming quite common in oncology now. Many of the molecular pharmacotherapies for the various types of cancer are based on the appropriate test to know whether a patient has a specific type of cancer. And these are known as her-2/neu and the oncotype DX chip is now moving from just one simple gene, that genetic defect, to now multiple genes, as many diseases are the focus for this.

And then the selection of drugs based on whether a person's metabolic pathways will enable them to take certain drugs and avoid adverse events is also being enabled by some genetic tests, and there's one commercial product that I've listed here that has that capability of determining who are rapid and who are slow metabolizers, to enable pharmacokinetics, enabling better treatment for patients.

And in regard to other disease areas, there is new pathways underway, enabling us to look at eight genetic markers for patients that are at risk for macular degeneration and other forms of eye disease. And a more common one that the discussions at the state level today reminded me of is that all states have a form of newborn genetic testing, metabolic testing, that is standardized in many of the laboratories and reported in a very efficient fashion across the healthcare setting.

So there is a common pathway for enabling these to be entered into the healthcare system.

And finally I would like to comment a few aspects of what's unique about building this interface

of Health IT, genomics, and the healthcare enterprise, and one commonality is that the health IT system is really built on a digital framework, and so is the genetic basis of biology, actually. In that we're all dealing with four nucleotides in terms of the makeup of our DNA, and that provides a great deal of utility and power.

And building on that, the scientific enterprise has been moving quite quickly in developing a common and harmonized way of categorizing a nomenclature system for genes and disease as well. So this is evolving. But the impact thus far in terms of the healthcare of these has not been fully manifest, and as these technologies enable us to do more testing and capabilities for this, some framework for introducing these into the electronic healthcare record will need to be -- need to evolve.

So overall, we believe that there are communities that are existing that are already developing standards that understand the principles and the pull, if you will, that the capabilities of integrating this data and information into the electronic healthcare and the healthcare systems overall, will help facilitate some of the synergies and harmonization efforts that they are wishing for.

So we believe that this, as a part of the PHC team, that the stage is being set for an integrated genetic testing capabilities, the results of these will benefit patients, and ultimately be able to have impact on the quality and effectiveness of how their healthcare is delivered in the future.

Thank you.

DR. BRAILER: Any comments, questions, or feedback for us as we plan the next steps of this in the Community or feedback you have for Greg, or the Secretary as this starts in the department?

MS. GELINAS: Dr. Brailer, is there any Workgroup that's going to consider this to drive it forward? In other words, when Secretary Leavitt announced the first responder work, that went to the appropriate Workgroup, is there a Workgroup that will help support this?

DR. BRAILER: We are currently considering how to organize the Community's part of that, whether it's an independent Workgroup or part of another as we're even looking how it is to frame this issue in a much deeper way.

I think Greg's sampling to you is to give you a very, very small snippet of an inordinately complicated area of medicine, so we can bring back something that's more sensible in the sense of how does it fit here. But that's part of the recommendations that come with that, Lilliee.

DR. WINKENWERDER: Mr. Secretary, I commend you for putting this together -- this very important area. As I understand the way you have organized it, it's an HHS enterprise, but we would offer to join you and support at DoD for a couple of reasons.

One, our IT system on the clinical side, but also we maintain a very large DNA repository and a tissue repository that goes back, like, 80 years. And we would really -- I mean, we need help on this too. And I think we could also offer some technical support, and we'd just like to join you on

this.

SECRETARY LEAVITT: Offer accepted.

DR. WINKENWERDER: Great.

DR. KOLODNER: VA would like to be at the table too.

SECRETARY LEAVITT: Good. I think that's -- we ought to be proceeding on this. As respect to the Workgroup, there will be a Workgroup. Whether -- I think its relationship with AHIC is the question. I'm going to have the offer of help from VA and DoD, and we're going to be proceeding on this.

And so, the question is: do we manage it inside AHIC, or do we just instruct them to say, keep a very close eye of what's going on at AHIC, because victory is defined as standards that can be harmonized with everything else that AHIC is doing. And I think that's the -- the question is a matter of workload here at AHIC in terms of being able to manage Workgroups.

DR. BRAILER: Any other thoughts? Thank you, Greg.

DR. DOWNING: Thank you.

DR. BRAILER: With that we now have an opportunity for public input. There are microphones in the center hallway. If anyone has public input, please come forward. I would ask again that you refrain from any commercial endorsements or commercial messages, but otherwise we're open to any input or thoughts that you have.

Seeing no one in the queue, thank you. Mr. Secretary, we're done today.

SECRETARY LEAVITT: Thank you.

DR. BRAILER: Our next meeting is October 31st.

SECRETARY LEAVITT: Come back ready to work! Urgent.

DR. BRAILER: That's right. Thank you very much.

(Whereupon, the meeting was adjourned at 12:30 pm)