American Health Information Community Transcript
January 17, 2006

Male Speaker:
Good morning everyone. Would everyone please take their seats? We're getting ready to start. Would everyone please take their seats? We're getting ready to start. Thank you.

Secretary Michael O. Leavitt:
Good morning. It's a pleasure to have all of you here. Ed, we're glad you're here, you're hear representing Julie. Would you like to introduce yourself briefly?

Ed Sondik:
Hi, I'm Ed Sondik [spelled phonetically]. I'm representing Julie Gerberding, Centers for Disease Control and Prevention. And I'm actually the Direction for the National Center for Health Statistics, and the acting Director of our Center for Public Health Informatics. I'm happy to be here.

Secretary Michael O. Leavitt:
Thank you. We're delighted you are. I guess everyone else has been here before, been introduced. I want to welcome all of those who have joined us today. I might add that last, our last meeting, over 200 people attended in the room and we had over 500 who joined us through our web cast. So it's clear that the deliberations we are undertaking have become of importance to the broader community. We have a lot of ground to cover today, and so I will simply launch us. Toward the end of the day there's -- you've seen the agenda, it's a very aggressive agenda, and it will produce some deliverables that I want to assure are completed by the end of this calendar year. Since our last meeting HHS has made significant progress, and I want to give you a brief report and some announcements in that context. I am very pleased to announce that HHS is funding four projects to test the standards of e-prescribing that will be conducted by CMS and ARC jointly. The programs will be evaluating how the standards work together to enable e-prescribing and to improve safety and quality of care. We will know a lot more about how to make e-prescribing work in individual doctor practices and across the entire system through the important work that these four programs will be undertaking. This is a kind of successful -- this is the kind of successful collaboration that we need to see and I'm delighted and appreciative of the fact that Dr. McLellon [spelled phonetically] and Carolyn Clancy [spelled phonetically] from ARC are leading. I also am aware that many Federal agencies beyond those that are represented here at this table are quite significantly involved in health IT and have quite an impact. Therefore I've asked the national coordinator to pull together a task force whose members will be representative of all of those other Federal agencies. The task force will ensure that the Federal government does its part as we advance this work through the community. The task force will respond to recommendations from the community and it will coordinate decisions across agencies so that the Federal government acts in concert to accelerate the progress of health IT. It's worth re-stating, I think, that much of the implementation power of a group like this comes when we take the recommendations of the community and begin to implement it as a

matter of policy across the Federal government, something that I am committed to, and others who are here from the Department of Defense and Department of Veteran's Affairs and so forth, when we implement it, it will obviously have some impact. But we want to make sure that the broader community than the Federal government's doing it in harmony, and this task force will assist in assuring that. We'll be formalizing the task force in the next couple of days. I've asked Jodie Daniel, the Director of Policy and Research in the Office of the National Coordinator, she will serve as, Jodie will serve as chair. Now I'd like to focus on the work that I expect we'll accomplish today. At the last meeting we talked about forming work groups to deliver, or to create deliverables this year, so that consumers will begin to see direct impact from our work. We'll obviously continue to work toward what we've referred to in this group as the pure vision, but our strategy generally has been to find the immediately available progress, to consolidate it and work toward the pure vision and assure that they connect. We identified the potential to produce early breakthroughs in four areas: bio surveillance, consumer empowerment, chronic care, and electronic records. Today we're going to actually set those work groups in motion. Each work group is comprised of a cross-section of key constituents that are needed to advance individual topics and are led by people who are well known and respected for their work in their particular area. So by the end of today's meeting we should have these groups organized so that they can begin to fulfill the charters that guide each group's work and meet the quarterly goals that will enable them to produce the real outcomes. And again, I want to emphasize this year. So with that brief greeting and laying out an agenda I'd now like to call on Dr. Brailer to take you through each of the work groups in greater detail. Dr. Brailer.

David Brailer:
Ok, thank you, Mr. Secretary. And before I start I'd like to also turn everyone's attention to an announcement that we're making today about the naming of permanent directors in the Office of the National Coordinator. And this should be circulating in the room. Today we're naming Karen Bell as the permanent director of the Office of Health IT Adoption, Kelly Cronan [spelled phonetically] as the director of the Office of Programs and Coordination, Jodie Daniel [spelled phonetically] as the director of the Office of Policy and Research, and John Lunsk [spelled phonetically] as the director of the Office of Interoperability and Standards. Captain Robert Wobb [spelled phonetically] will continue in his roll as the acting deputy national coordinator, and Dana Hass [spelled phonetically] will continue her work as the executive director of the American Health Information Community, which is you. Also Mya Bernstein [spelled phonetically] who is with us today who is the department's senior privacy officer will continue her work liasing in this area. So I'd just like to have the people that I named stand so people can recognize them. You will see much more of these people.

Secretary Michael O. Leavitt:
And may I just add that this is an all-star group who I have had the pleasure and continue to have the pleasure of meeting with regularly. David, you have assembled an extraordinary team, one that I think all of you will find both effective and delightful to work with.

David Brailer:

Thank you. And thank you, Mr. Secretary, for helping with your leadership and providing the context for this team to come together. With that I wanted to turn to this question of how do we conceptualize the different parts of the work that we're doing, because today we will not only complete the efforts of putting breakthroughs in place, but you will hear for the first time today reports from the contractors and partners that we're working with to develop a long-term infrastructure for health IT. And these are somewhat at odds. And so I wanted to try and, to find a way to depict how these pieces could come together. And with that let me try to walk through - and I emphasize try, because this is a Power Point build that relies upon intense coordination between the hand of the person on the computer and my words. And so we'll try to lay out how these pieces fit. So the first piece of this is that we have components of the technology industry represented here, represented in the work that we're doing, obviously represented throughout the health care industry. Spawning from this are a variety of infrastructure components. And you'll be hearing from these today. Efforts to standardize the health information technology and content, and using a harmonization approach. And you'll hear more about why we chose this methodology. Efforts to certify technology for its compliance with respect to standards. Efforts to develop a nationwide health information network to tie together all of these components and infrastructure. Work to advance privacy and security in collaboration with the states in an ongoing effort to monitor in an independent way health IT adoption. These are how we broke the key components of technology into workable areas, and we've engaged in contracts with partners, each of which have a substantial public private process underway to develop their own respective component. You will hear from the first four of those today. These take us across, over time, towards a transformation of the industry. These create the enablers of substantial change in how health care is delivered, how work of physicians and nurses is done, how hospitals operate, etc. But it is quite long-term to set these in place and have them work through the cycle of change as they have in many other industries - banking, manufacturing, global services, transportation, etc. Now working in a perpendicular way we have the more traditional health care industry - the work of doctors, nurses, and hospitals. In this group we have divided into these so-called breakthroughs, which are the areas that the Secretary has already mentioned in bio surveillance, consumer empowerment, chronic care, and electronic health records. These are four value statements of many ways breakthroughs could be articulated. Or value statements made about health care. But these are the ones that through a variety of processes, including what's happened here, we're whittled down to the areas where we're going to focus and organize. As these work through over time much shorter time cycles, they result in value that is realized by the consumer that -- just waiting for the button to be pushed; there we go -- that delivers immediate changes. The breakthroughs that we'll discuss today are very focused on something that American consumers could benefit from in a year. Something that would touch real lives in a very near-term way. Now what you notice in the next step is that these two are somewhat at odds, and they have many intersection points. For example, just to take the example under consumer empowerment, here the focus that we have is on the medication history, for example, or the registration record. And in this we might need, for example, the standards harmonization group to focus on certain standards - some of this is already underway - but the certification commission to determine, for example, when the NCPDP script version 8 should be certified in electronic health record. That's just one example of an intersection

between the long-term work and the short-term work. The NHIN prototypes, for example, may need to determine how to integrate certain technologies into the national infrastructure to allow for secure prescription routing. The health information standards security and privacy collaboration has to examine issues relating to privacy and security of this information, and so on and so on. And there are many, many intersections at play. And this is really where the work of the Office of the National Coordinator and the American Health Information Community come together to be able to coordinate the policies, the resources, and the priorities that allow the inter-play between these groups. There is no perfect answer for these, but they rely upon judgments made by people like yourselves, people like us to be able to say, "How do we focus on achieving short-term goals that are leveraged across time and how do we make sure that long-term goals result in material value up front so that we have the buy in of the public with us and we're able to continue to deliver value on a day-to-day basis." So this conceptualization is very much about how we view, from this point forward, the work of our office and the work of the community going forward. It's managing the polarities of these different axes and being able to make sure that we carry them all forward together. So today will represent a key turning point, besides locking down these breakthroughs, we will also begin the process of learning about the infrastructure that's being laid out. And over time this group and the work groups will begin examining how it is that this can play out over the course of time. So with that as an introduction let me just stop and ask for any questions, or comments, or clarification. I understand this is quite high-level. This is not intended to be a rule book or a set of detail specifications for how this is done, but conceptually, how it is that we view these roles and these relationships happening to accomplish these two somewhat conflicting goals about short-term and long-term benefits.

Male Speaker:
Good morning. I have a question:
in terms of the side of the matrix that represents the activities of the coordinators, how open are you to adding issues and, I guess this will, I don't want to move ahead of later discussions, but we don't have across the top 'measurement reporting medical research or R&D on IT' and I would assume that one could argue that really those issues across each of the areas that we've got will have task forces and breakthroughs in, and I wonder whether we, at least I would argue we need to add boxes going down for measurement reporting medical research and R&D on IT. Because obviously it's a cross-cutting, but from the provider standpoint - hospital standpoint particularly - anything we do is ultimately going to have to relate to reporting it to someone for measurement.

David Brailer:
Ok. Well to the generic question of how does the agenda of the American Health Information Community relate to this, I think that's the over-arching questionship [spelled phonetically], these four breakthroughs that we're talking about today, or these four categories, are a starting point. And over time I would expect the community to continue to evolve and to look at questions and to determine, to some degree, what its own course of inquiry is going to be. We've identified the breakthrough as a particular element of that, which is something where a

charter is given that says there's a specific goal that we're going to back. So that's a particular element, but you could continue to have open meetings on topics that are not a breakthrough, or over time you could convene breakthroughs. To the specific question about R&D and the other components, medical research, to some degree those are embedded in each of the long-term infrastructure components. Each of those pieces are charged with looking at both short-term and long-term issues. But it's not meant to be exhausted. So whether they go across the top or down the side or there's some other component that's on this, that's an example - those are three examples of areas where this has to be evolved. And it continued to, it has to be organic to add things that come that might be those or others.

Male Speaker:
I guess my request would be as we think about probably the, on this coordinate, as we think about those boxes, that we might have explicit boxes, and the reason I'm hung up a little bit on having them be explicit is because it's going to be easy as people are really pushing forward on the top four to get output, for these to sort of be left behind or forgotten. And I'd like it to be sort of, at least from my standpoint, I think the standpoint of hospitals, I think it needs to be integrated and at every point how's this going to be, relate back to measurements we're going to be expected to make, how is this going to relate back to the potential of medical research and collecting information. And whether it's bio surveillance, consumer empowerment, chronic care, or EHR, embedded in each of those needs to be that thinking, and I think it could get forgotten if it's not real explicit.

David Brailer:
I think that's a good way to view how to broaden the charge of these groups. Remember that the community is an advisory group and underneath this the Office of the Coordinator is actually managing Federal contracts and managing a substantial amount of work in the Federal government along the breakthroughs. So we have a variety of other processes underway that are not depicted on this chart, some involving research and looking at the question of quality. And you'll have a chance to discuss the quality metric reporting issue today. So we can continue this and make sure that there's a place for that and any of the work that's been, that does, and it is done from this point forward. Any other questions or comments on this deployment coordination schema? With that, let's turn then to the question of the work groups themselves. We have spent since the last community meeting considerable time looking at how to actually frame the charges and the specific goals to meet the Secretary's expectation that we have something visible to show the American public one year from now. And that certainly means framing these in a way that is specific and narrow, but at the same time is broad enough that it has real impact. In being disciplined about not pursuing things that could be valuable but either have significant other processes underway, or which face great limiting steps that are beyond our control. And through that process you will hear, you will, we will have six discussions today that include two presentations about four areas that we are recommending that we go forward with - a work group and two areas that we believe for now the community should continue to monitor and not go forward with a work group. And these are being passed out to people in the audience, and these documents will be posted on the web within the next 24 hours. Let's turn

first to bio surveillance. And what you see in front of you is a brief two-page document which, of course, is three pages. And the goal of this document is to very succinctly summarize why we are talking about this issue, and this is obvious to many people but we want to document this. And then laying out what we call a broad charge and a specific charge for a work group. The broad charge looking out essentially two to three years, perhaps. Some time that is certainly in the moderate term, but far enough away that we're not measuring accountability for it today. And a specific charge that is essentially one year out. And this, as you remember from the last community meeting, was deliberated these charges and actually words missed [spelled phonetically] as part of the meeting. And so I'll just review these just quickly to refresh our minds. The broad charge is to make recommendations to the community - this is the charge to the work group now - make recommendations to the community to implement the information tools and business operations to support real-time nationwide public health event monitoring and rapid-response management across public health and care delivery communities and other government agencies. Specific charge now focused on a year from now:
make recommendations to the community so that within one year essential ambulatory care and emergency department visit utilization and lab result data from electronically-enabled health care delivery and public health systems can be transmitted and standardized in an anonymized [spelled phonetically] format to authorize public health agencies within 24 hours. So it's setting a breadth of who, it's setting a format of what, and it's setting a time frame, the 24 hours. We then lay out who are our work group members, based on a very large number of nominations that we have received for the American Health Information community for looking at people that have participated in some of their briefing exercises to start with, and also it's laying out that each of these would be co-chaired by two members of the community itself. And here we're recommending Julie Gerberding [spelled phonetically] from the Centers for Disease Control, and Mitch Rube [spelled phonetically], who is here with us today, to be co-chairs of this group. And then we lay out support, which is how this work group would interact with the Office of the National Coordinator and with our contractors. And then some key quarterly milestones, which are relatively generic for these four work groups. They lay out key process milestones to ensure that we're able to integrate the work of this work group into the meetings of the American Health Information Community so we can work in a linear way toward the goals at hand. We actually are working now off of monthly timetables, and soon we'll be down to weekly timetables in our office planning process. But these quarterly milestones give some sense about how we view the process going forward. And the key steps here are identifying what things are available, on the shelf, if you would, to be able to have this near-term specific charge be realized, identifying the key entities that need to be around the table, and then refining the time table. That's Quarter one. Quarter two is to look at the key, very high-level key policies that need to change - at the business level or the policy, the public policy level. Changes that are required to ensure the result can be realized. Consider privacy issues - that'll be a separate discussion and dialogue with the contractors - and also look at the standards: architecture and certification criteria, again with contractors. The third quarter should be making very specific recommendations for how this should be deployed, about education and awareness, about how to transition from the narrow charge to the broad charge, and then looking at how the pilot effort actually begins to take shape. These clearly in the out quarters would be modified by the timeline presented in quarter one by

the work group, but we wanted to lay out a process that worked backwards from something real and tangible that affected the American public in this area. This format was used for all four, but obviously the content is quite particular to the area. So with that, let me just stop and ask for comments on the bio surveillance work group implementation plan. Craig.

Craig:
Just from my understanding, do the words 'can be transmitted' and 'make recommendations' are not bottom-line result-oriented words. What are you expecting out of this? A theoretical paper study, or within a year that you actually do something?

Male Speaker:
Let me respond to that. It is my intention to have this implemented, at whatever level possible, within the year. I have other compelling reasons to have that done. AHIC inherently does not have the legal authority to implement. AHIC advises the Secretary, AHIC advises the Secretaries of the other federal agencies, and that is the reason we have formed this federal task force that you saw formed today. Many of the things that will need to be implemented to make this work will have to happen in various federal agencies, and so while AHIC's operational wording may not connote action, I can assure you that what's going to happen underneath that is [inaudible]-oriented.

David Brailer:
Is that responsive to your --

Craig:
Well, it's directly responsive, but I'm just wondering if there might be a, then, an overall goal that you can put at the top of this before you make the charge to the work group. The overall goal is in fact to have a system implemented in a year that's working. That's quite different than making recommendations. I'm just trying to structure from a hierarchical sense of where we intend to take the system.

David Brailer:
From a documentation perspective there's a parallel document that exists that is charging our office to do work in each area that does not have the words 'make recommendations'. It is quite specific about delivering the result that the Secretary has asked for. So part of this is the legal [inaudible] about how the advisory process works. These would be the actual implementation process.

Craig:
I'm all for results, I'm just trying to get you to stick your neck on the chopping block, that's all [laughter].

David Brailer:
It's there [laughter]. It's there [laughter].

Craig:
So noted.

David Brailer:
Other questions or comments on the bio surveillance work group implementation plan? Lillie.

Lillie Gelinas:
Dr. Brailer, is a year soon enough? When you're on the sharp edge of our health care delivery system, and knowing what we're facing? I think I'm in Craig's camp here, but I saw what you were able to do with katrinahealth.org in a week. So I just want to ask, is a year soon enough?

David Brailer:
Well, you know, it's a question we deal with a lot. And clearly with respect to bio surveillance there's a lot that's already happening. In fact one of the things that we'll come back to with e-prescribing, where we're recommending that we don't form a work group, is because there's so much happening that we don't see a clear role where it can add value to the process. In this area we think it can, because of the necessary coordination between federal, state, and private sector business and policy organizations. But I do think, based on the timeline that we have laid out, to do this result it does take months -- perhaps not a year. Remember that one thing about katrinahealth is that it was a one-time event done under a really unusual circumstance that pulled people together. We suspended strategic thinking, we suspended business models, we suspended all the realities that lead to long-term sustainability to achieve that goal. Doesn't diminish its importance, it just recognizes for us to have a long-term sustainable result we have to work through those. And I think those do become often the rate-limiting step in these. So we have significant urgency, and if we can accomplish these in a faster time line, i.e., if the work group comes back and says, "Why did you give us a year? We can do this in three months," we'll call that victory don and we'll move forward. So we're very much along that line of what can we do right now to get this done.

Secretary Michael O. Leavitt:
One observation I would make, there are two components to this - there's the technology and there's the sociology. I never found technology to be the right limiter - it's always sociology. And given the fact that we're going to require, be required here to coordinate 50 different states, or at least some high number of states and locales, you're dealing with lots of complex sociology. And working it through that process is the rate limiter. I would also want to stress that we're not talking about the pure vision here. We're talking about finding a way to take what's readily available and begin to connect it together faster. This will not be the system we all envision ultimately happening within a year, it just doesn't, it's just, the complexity of the sociology, the politics, the different legal structures, the checks and balances - all of the things that slow us down, I think, is what makes a year a rather ambitious goal. And we do feel, at least I am feeling a need based on bio terrorism needs, based on pandemic flu concerns I have, I will be delighted if at the end of the year we have accomplished what this task represents.

Male speaker:
One other suggestions in terms of being as precise as possible with respect to the goal is that in the charge statement it refers to presenting this information, transmitting information to authorized public health agencies within 24 hours. Of course that's very broad, and maybe understandably so, but it might be worth, you know, to sort of work towards at least the Centers for Disease Control or HHS, you know, something of a national nature. We would be interested, of course, to not only participate, and we are and well, but to be users, being, you know, sort of a designated user. But then, it seems to me, designating some number of states so that it, you know, sort of fixes how many states and how many federal agencies as just sort of we will achieve this. Just a suggestion.

Male speaker:
Thank you. That's a, that's well-received. I believe we will end up at the end of the year not so much measuring our success, or at least the pattern of our data collection by states as much as we do systems. I think we'll be gathering information from systems as opposed to just states. There will be a lot of states involved in it, we'll need to include the states in the dissemination, but it appears to me the fastest progress we'll make here is to be able to go to existing systems who have the capacity and be able to link that data together, and it'll overlap a lot of states, and then we'll begin to work behind it on a state-by-state basis. But my guess is it will be systems. And yours being right at the front of the line, and VA as well.

Kevin D. Hutchinson:
Just a quick comment. By looking at the members of the work group, I would echo first everything about the technology, I know the, I think everyone in this room would agree that the lab industry has spent the last several decades automating its processes and putting systems in place that turn lab results into electronically-enabled and allow them to be delivered electronically. I don't know if the members are locked in, but since lab results are so prevalent with respect to bio surveillance, it might behoove us to actually add a representative from the lab industry who has some experience with this capability from a technology standpoint, and process standpoint.

David Brailer:
It's good advice, Kevin. I, just a comment on the members since I didn't actually line item review these. The names that are listed are people who have agreed to participate. The areas where we have TBDs - to be determined's - laid out by sector is because we identified that slot. And there are still others that we're looking at as well. But we'll take that under advisement, and I think it's good advice. Any other comments on the bio surveillance charge?

Secretary Michael O. Leavitt:
Hearing no other comments, I'm going to declare a consensus on this point and move forward as outlined.

Male Speaker:
Thank you. Let me turn you now to the consumer empowerment work group. Again, this was discussed at the last meeting and laid out in particular detail with respect to the charges, but if you'll turn to page two, I will recite the charges again. The broad charge to this work group is to make recommendations, and again the caveat applies here that there's a parallelism in terms of the actual internal accountability for how this gets done - make recommendations to the community to gain widespread adoption of a personal health record that is easy to use, portable, longitudinal, affordable, and consumer-centered. Specific charge:
make recommendations to the community so that within one year a pre-populated, consumer-directed, and secure electronic registration summary is available to targeted populations. Make additional recommendations to the community so that within one year a widely available, pre-populated medication history linked to the registration summary is available. This was modified slightly after the last community discussion for just parallelism, but largely speaking this is what we discussed at the last meeting. Two work group co-chairs from the community, Nancy Davenport Ennis [spelled phonetically] and Linda Springer [spelled phonetically] from the Office of Personnel Management. And again, members representing various Federal agencies and other agencies and public organizations. Support and milestones are quite similar to the last, somewhat adapted to the particular relationships and overlaps that are unique to this topic. So with that, let me stop and ask for comments and discussion on the consumer empowerment work group implementation plan.

Secretary Michael O. Leavitt:
Other comments on this? If you need a chance to review it we'll give you that time. Do you see holes in the membership that we ought to be, in terms of categories? Craig.

Craig:
Just to interject my bottom-line results issue again, what do you expect in this area by the end of the year? I see 'available', and I see 'likely available', but if we guestimated how many people might be involved in using this in 12 months time, what would an acceptable answer be?

David Brailer:
The, this is as close to katrinahealth on a long-term basis as we can get. In fact, the second part of the charge is quite particular. And because of the high degree of concentration of the existing electronic information in this area, again this is an area where the technology barrier is probably quite narrow, so the question becomes which populations can be targeted and accessed and we can work through the education and awareness process and support them? And so I don't know the answer today, Craig, of how big that population would be. But that should be a population in the hundreds of thousands or low millions at the minimum to be able to accomplish a meaningful test of this.

Secretary Michael O. Leavitt:
I think that you may well be in a position to answer that question better than anyone. My judgment, this is going to be answered by how well it's embraced by a handful of - I shouldn't

call it a handful - by some number of private sector vendors. It may be and anyone from the major search engine organizations who would see this as a good market. I've euphemistically used the post office as another, utility companies, there could be any number of people who view this as an appealing thing to offer their members or their subscribers. And so I'd be curious to get your reaction to that question, to your own question.

Craig:
Well, if the answer came back as David just mentioned, which was a hundred thousand to a million, I'd say this is relatively incidental to what's going on in the marketplace already. So I would have to engage a number substantially larger than that to really achieve some degree of success here.

Secretary Michael O. Leavitt:
We already know that there are lots of insurers, Scott, who view this as an appealing opportunity to offer their policy holders, or their beneficiaries. We, a lot of health plans already have electronic medical records that they use internal to their system. I think our purpose here is to create a sense of commonality and harmonization that allows that information to be used on a more broadly focused basis. So I guess I would harbor both the aspiration and the suspicion that it will be a substantially larger number once they have the, just converting what already exists into a more universal format will begin to drive those numbers much, much larger. Scott, do you want to comment?

Scott Young:
I guess I come from where Craig is that particularly when we're, excuse me, focusing on registration information and things of that nature, which we're not going to run into privacy, significant privacy issues about, that the number should be in the - I mean, if we only got one hundred thousand to a million in the blue system we would consider it a failure. I mean, I think we need to look at numbers significantly larger than that, and as we move into medication records I just think the numbers are going to be very big very quick. And I don't think we're going to run into the same sociologic or barriers for this kind of information. Usage will be a different issue. I think people will have them; whether they'll be accepted and whether providers will say, "Oh, because you said it it's true" kind of thing is a different issue. But I think that they will be available and in much bigger numbers than that.

Secretary Michael O. Leavitt:
Nancy, I know you'd like to comment. As we go to you let me just say that one of the reasons I felt so strongly about having this as part of our early breakthroughs is because what we, one of the things we've lacked is a consumer driver. Something that consumers demanded that moved the market in a viral way. I believe this is the item that will ultimately drive a viral market. Nancy and then Doug.

Nancy Davenport-Ennis:

Thank you, Secretary, but I would like to add that I think we have the opportunity through this breakthrough to engage the employment community. And to launch a national education process for consumers so they understand the benefit to having this tool in the marketplace. Scott I would concur that certainly with the blues the enrollment would be, I think, much larger than the hundred thousands or the millions. I think within our government programs where we know we have so much of this data already collected. I think the major hurdle that we're going to have in making this a successful breakthrough is in direct proportion to the time we spend reaching out to consumers to engage them on this issue. Consumers being defined not only as the patient community, but also the medical care giver, provider community to get them to embrace this process moving forward.

Doug:
Well, amen to Nancy's recent comments. Not only could this be hugely valuable to be pushed by the employer community, but the physician and provider community as well in the context of their interactions with patients, with consumers, in everyday health care could be a huge way to promote this and educate a lot of the people of this country in meaningful ways about this imported technology. My real reason for raising my hand is the question, is this group focused on a personal health record or, as we've kind of alluded to in the last two meetings, focusing on a medication history or a registration history? I would propose that we should be focusing on the personal health record, and I hope that's the direction we're going. Because, in my view at least, representing the provider community, that there needs to be a technology that provides all of that data at the time that a patient or a consumer interacts with any part of the health care system. So yes, the registration data needs to be there, yes the medication data needs to be there, yes the allergy history needs to be there, yes the past, pertinent past history needs to be there, but it all needs to be there, not just, you know, parse it out to different technologies. So I hope that's the direction that we're going, in a more inclusive technology rather than parses of it.

Secretary Michael O. Leavitt:
I think it's very clear the idea is to have a growing and expansive record that begins with some component parts and grows as we have the capacity to do it, but we ought not to wait until we have it all before we begin to build the epic and opportunity. Let's go to Chip and then back to Kevin.

Charles N. Khan III:
What occurs to me in looking at the list on page one, and we didn't talk about this last time when we talked about the clipboard per se, but it says name, address, insurance, medications, allergies, etc. It seems to me that, and this sort of addresses the last point, too, that we might want to add one other basic, sort of building block before we get to et cetera, and that's hospitalizations. And that one of the groups, and one of the ways that diffusion might be undertaken here, other than through the employment sector or through insurance sector, would be through hospitalizations. I mean, first, they need to be there, because you can have all this other information and if there's not the information this person was hospitalized, even if he isn't hospitalized and diagnosis, you could miss something. But second, I don't know, I'd have to think about what your authority is,

but there, and obviously we're reticent about mandates, but it seems to me that at each hospitalization there's a lot of information collected and there's some kind of electronic notation made, even if it's just name and address, and that could possibly be one of the crossover points. Because you've got millions of people going to the hospital in a given year, and that could be an incident where there's enough infrastructure and you're only dealing with 4,500 institutions. You could create at least a record for those people who were hospitalized. I mean the, whatever the clipboard is. And ask hospitals to do it. I mean hospitals do a whole number of things now whether it's information regarding living wills or whatever, and if it were part of the hospital orientation at the beginning when you go in the hospital, either for emergency or otherwise, maybe that would be a good angle. And so I guess I suggest that. And I guess if you did want to go down that path I suggest you might want to consider having a hospital person as the membership, because it's sort of the one area that's sort of missing and it might be one of the best crossover places.

Secretary Michael O. Leavitt:
I'm, I might say, thrilled by the pushing of the envelope that's happening this morning. I mean that's the right posture. And it's the place I would like to be as well. I mentioned earlier that there's technology and there's sociology, and that's, I think again, the rate limiter here isn't the technology, it's the, it's working through the privacy issues, it's working through all of the things that we need to be very careful in pushing through. I also I want to emphasize that I am resolved to using the authority provided me as Secretary of Health and Human Services to use the, the government paid health care mechanisms as a means of driving this. And we have to move with some deliberation on how we use those. So I don't think, again, that this is a function of technology limiting, it's a function of how fast can we reasonably move the market in a way that's not going to ultimately create counter reactions that slow us down. Kevin.

Kevin D. Hutchinson:
There, in looking at the list of the individuals on the group, I would make a recommendation for three additional areas to consider. Since we are talking about getting rid of the clipboard, or the registration information initially, and I do see this as ultimately being a source of information to personal health records as we move down that path. I think a glaring one that's missing to me is the office manager, who actually deals a lot with the process of registration in the physician's office. And they understand that a level of data, one of the things that will have to come out of this, obviously, is a standard data set for the types of information that you gather that would be stored in some type of registry. And I think that having some office manager representation, whether it's from the MGMA or some other type of organizations would be helpful. We've always said that security and authentication is going to be a major issue in this particular process. I think there are companies out there, organizations out there that have spent a great deal of time focused on authentication and security in this particular space, and it might be helpful to have them at the table talking about the possibilities and things that are available. And lastly, also individuals that have some working experience with the deployment of personal health records, since that ultimately is where we're would be going with this, understanding that maybe initially

we're focused on getting rid of the clipboard, but as we start feeding this with medication history this does become a feeder to these personal health record systems. That was my only comment.

David Brailer:
Thanks. We'll take that under advisement.

Secretary Michael O. Leavitt:
Any other comments? These are very good and thoughtful. Yes, excuse me, Ed?

Ed:
I had a thought as a member of at least the first work group, I know these quarterly milestones are going to be very important to these groups, and I wonder if it makes sense, given what we'd like to achieve at the end of the year, if the first recommendation under the fourth quarter, which is to implement a pilot effort. And this also relates to the first. We're actually in the third quarter as well, and the fourth quarter milestone focused on at least a preliminary evaluation of a pilot effort, and then looking to the future. I'm a little concerned that it's late in this in order for us to really achieve the charge for the first year.

Secretary Michael O. Leavitt:
That's, I think, a quite valid thought. David, do you want to respond to that?

David Brailer:
Sure. As I said these are relatively generic quarterly time lines. We tried to compress them as much as possible, and so we certainly could look at that again. I would remind you that the first task for this group is to come back to you for your March meeting with a real time line exactly what they're going to do. Because ultimately it's your work group that you're going to charge to go off and make these recommendations on a timetable. So we'll certainly pass on that advice to them that they not bring back a pilot plan for the fourth quarter.

Secretary Michael O. Leavitt:
Why don't we ask Craig and Mark who would be the co-chair of this group, whether those milestones are unrealistically long? Can we shorten them? Are you prepared to accept the charge?

Male Speaker:
I think you've got the wrong group.

Secretary Michael O. Leavitt:
Ok, I'm sorry, you're right. I'm looking ahead to chronic cares. Nancy.

Nancy Davenport-Ennis:
I would certainly concur with Ed. The ideal would be if we could move the demo to the third quarter, and then when you go to the evaluation process that comes in the fourth quarter. And

obviously if we're going to really have something to evaluate we need to try to move it early into the third quarter rather than later into the third quarter.

Male Speaker:
I would just like to echo that with the caveat that I think we need to circle back to the work group and confirm that with the whole group.

Male Speaker:
I'm sure Dr. Gerberding [spelled phonetically] would echo that as well, for the first one.

Secretary Michael O. Leavitt:
Good. I'm heartened by that. Any other comments on the electronic health record? Am I hearing any dissent with…

Male speaker:
This is really a question for Mark, I guess. I know a number of states are looking forward to using this electronic health record for their risk-based managed care product - we are in Indiana. January first we go. So your ability to connect this process here into the CMS, into the Medicaid piece of it will facilitate our moving 600,000 folks in Indiana to using this on January first of 2007. But I do need eleven fifteen B waiver to do that.

Mark:
Yeah. Well we're obviously working on that waiver in a number of states are now paying close attention to the opportunities for health IT to lead to better coordination of care and lower overall costs. Also, in the Medicare program we've set up a Medicare beneficiary portal that now focuses on allowing individual beneficiaries to get access to all of their Medicare-related information. And that includes a lot of administrative data that's probably not best used by individual consumers in its raw form, but could be if linked to a consumer personal health record product. It's an extremely useful edition. And we're looking at pilot programs this year that we can use to expand that, and that might be another way to build on the efforts that you want to undertake in the waiver.

Secretary Michael O. Leavitt:
Hearing no dissent, the chair will declare a consensus and move forward.

David Brailer:
Ok. Thank you. I'll turn your attention now to the chronic care work group implementation plan. As you recall at the last American Health Information Community meeting we had a quite authoritative and complete presentation and discussion about chronic care. This is obviously a broad area involving more than seventy percent of health care expenditures and a large share of the American public that consumes health care services. And there were a few themes that came out of that presentation, but no specific or broad charges. We weren't able to come to that level of specificity. Therefore after that meeting, in dialogue with a number of you, and following

with the briefers [spelled phonetically] who were here with us, we tried to ferret what it is that we could bring back to you that gave a degree of specificity to this that would allow this to move forward, given the very strong sense in this group that something in chronic care should be moving forward aggressively. The core question we identified came down to is should this be process-focused or disease-focused? Should it be narrowly focused, say for example, on diabetes, or asthma? Or should it look at something that is cross-cutting that affects many? And the sense we had from those dialogues is that something that's cross-cutting, that could leverage across many different constituencies, many different populations, many different change agents, like yourselves and others, would be the key focus. For that reason, we're bringing back to you a broad and a specific charge for a work group that are as follows; broad:
make recommendations to the community to deploy widely available secure technology solutions for remote monitoring and assessment of patients and form communication between clinicians about patients. This is introducing very broadly the theme of remote monitoring and tele-medicine. Because of the recognition that so many issues in chronic care involve early detection and prevention, before a patient comes to see a physician, or before other issues begun to transpire that caused them to deteriorate in their health status. The specific charge, again, drawn from that to give it a point of focus for the first year:
make recommendations to the community so that within one year, widespread use of secure messaging as appropriate is fostered as a means of communication between clinicians and patients about care delivered. Again recognizing that this need both for the clinician to have the capacity to communicate with patients and in a synchronous way that reduces returned phone calls, missed telephone calls, visits that could end up in turning the patient, et cetera. And on the flip side, the ability of the patient to have easy access and to be able to have the capacity for communication that sets up these forms of monitoring that could be useful downstream. The two co-chairs we have identified would be Craig Barrett [spelled phonetically] and Mark McLellon [spelled phonetically]. And again, milestones and support are quite similar to the others. This, again, I want to emphasize involved a substantial amount of deliberation and further investigation by our contractors after that discussion to be able to bring this back. And this focus that we brought back is one where we think we can set up a quite pervasive change that is able to support many of the issues that were discussed in that presentation at the last meeting.

Doug:
Well, David I applaud very much the taking the more, the broader approach, the cross-cutting approach. Again, most patients who have chronic disease have more than one chronic disease. So it's not just about one disease process, it's about a process of care over a continuum of time. In terms of looking at additional members of the work group, I would make the following observations. I would think that you might want to get someone from the home health care community that represents the perspective of that group from the standpoint of actually being involved in care at that level. But also this may be an area where you may want to expand and have more than one physician group representative, and perhaps other health care provider representative as well. Because really if you look at Ed Wagner's chronic care model it's very much a team approach, and the multiplicity of providers need to be represented there.

David Brailer:
Very good advice. You can tell by the proposed membership that this one is still being worked on. We spent so much time framing the charge we had a lapse of time to get membership together, so those are very timely, Doug. I appreciate that very much. [inaudible].

Female Speaker:
Just tagging on to what Doug said, home health nursing. You know one of the groups here that seems missing on this particular work group would be nursing representation. Because there are so many nurses that provide chronic care long-term as well as monitoring at home.

David Brailer:
We've actually started some screening process around that, so if you have some suggestions we'd appreciate that.

Secretary Michael O. Leavitt:
Mitch.

Mitchell E. Roob:
If I may, do you specifically include, or exclude, or have you not reflected on the developmental, on those suffering with developmental delays and disabilities, and the mentally ill, which are sub sets, but very expensive sub sets, very difficult sub sets, of this patient population. And I think that if you do choose to include them, having people from NAMI or ARC involved in this would be appropriate. And if not, I would, and I would frankly recommend not, because they are very difficult patient populations, that you subsequently agree that you'll deal with them separately. That's your choice, obviously, but I think that on overt decision, otherwise they'll just be out there in the gray, which is the worst place to be.

David Brailer:
Well, Mitch, we had not expressly excluded any population segments from this, and so I think it's really a question to the community, if you want to pass further instructions to the work group before they come back to you in March. Because they will come back and start targeting populations and potential low-hanging fruit, if you would, where we can get significant progress here. So if the community has expectations one way or the other, I think it should be transmitted earlier rather than later.

Secretary Michael O. Leavitt:
Chip.

Charles N. Khan III:
You know I wonder, looking at the membership list, and obviously this might be self-serving for them, but we have a whole disease management industry that has developed and it sort of stands behind and contracts with insurance companies primarily. But obviously they're deeply into this, and I wonder whether someone from that sector or, I don't see an insurance person on here,

or an insurance person who deals with that sector ought to be on here, since you've already got, am I missing something?

Male Speaker:
Yeah, regents [spelled phonetically] group is-

Charles N. Khan III:
I didn't know what regents [spelled phonetically] group was, I…

Male Speaker:
That's Blue Cross Blue Shield in the Pacific Northwest.

Charles N. Khan III:
Oh, I'm sorry. Well I still think someone, you may want someone from the disease management sector. I mean, because those are really usually independent entities from the insurers and there are number of companies that are doing it.

Male Speaker:
Nancy, did you -

Nancy Davenport-Ennis:
Just two considerations perhaps. One that we have representatives from specific chronic disease organizations that could serve on this working group, because we are dealing with such specific needs in chronic care. And number two that we consider having representatives from the social worker community that serves both the pediatric and adult populations in the area of chronic care, and they are so familiar with dealing with both the integration of medical and social service needs of that chronic patient. So both of those areas may bring diversity and depth to your representative working group.

Secretary Michael O. Leavitt:
Nancy, your comments remind me that many of these have unlimited categories that could, in fact, be included properly. That it will be impossible for us to include everyone, but it is not impossible for us to hear from everyone. And so one of the, one of the characteristics of these groups, I think, has to be a small enough sub set that they are able to manage, but large enough that they have a broad representation, and that they're able to reach out to a broad community. These are very helpful suggestions. But we do have -- I think we do ultimately have to recognize the need for outreach as opposed to an unending list. Particularly when you get in disease categories. I've learned in my dealings with the National Institute of Health that every disease has an advocacy. And they're strong, powerful advocacies. And they need to be heard.

Male Speaker:
If I could just comment, sir. We chose expressly to not limit populations in these charges, but clearly for the work group who will be coming back to you and accountable to the public, if you

would, to assure that the recommendations are made, one early thing they need to do is to look at population targeting. Because these are public work groups, i.e., they're extensions of the Federal Advisory Committee rules that you follow, they can have, they will have open meetings, and they can have hearings or listen to populations that come to talk to them. So membership is not the only vehicle for getting the input that is necessary here. But I think early on we do expect all of them to start focusing on which populations would accelerate the realization of this goal. And I think therein lies the question of how big the first year population goal would be.

Secretary Michael O. Leavitt:
Rob, and then Ed.

Rob:
If it would be helpful, certainly VA is not listed here, but with 10,000 patients that we monitor every day at home in their growing number we'd be glad to be of assistance if that would be helpful.

Secretary Michael O. Leavitt:
Thanks. Ed.

Ed:
I just want to underscore, I think it's very important to have one patient group, if you will, population group represented. And you do on this with AARP. And I think that really is crucial. It kind of fits with Nancy's comments as well. I think without that it's more on the, on one side of the communications channel here, and we really want to be sure that we're listening to both, that both are involved in the deliberations of the work group.

Secretary Michael O. Leavitt:
Thank you. Mark and Craig, your reflections on this?

Craig:
Well, very simply I think there's an exact parallel of an industry which is way ahead of the health care industry, which is the financial industry today, which is involved with secure transmission of information and confidentiality. When I was writing down suggestions for other members, or other areas to come in I noted that in my own direction. I would hope that we can draw heavily on the experience in that field, and not re-invent the wheel and go forward. I do also appreciate the comments of everybody that I think you need to get all of the constituencies involved, and that's from patients to different practitioners who are involved in delivering health care. But I suspect the bulk of the framework from a communications and secure transmission capability are already heavily in use today.

Mark:
I'd agree with Craig. As you know, we're announcing some new pilot programs on electronic prescribing that are intended to build in exactly this sort of reliance on prior information and

assistance in helping people with chronic diseases prevent complications. So I think the aggressive agenda laid out here is achievable, especially if we draw in experiences from other industries and existing programs and pilots that are steps in the right direction.

Secretary Michael O. Leavitt:
Good. Well what we have on the table, then, is this document modified by the suggestion on the accelerating the pilots by the, in the third and fourth quarter. And with recommendations on an expanded level of participation in a couple of categories that we'll explore and, but there, would there be any objection or any comment on the need for us to deploy immediately and get started? Hearing none then I would declare a consensus to empower the group, move them forward, subject to additions that will be made along the way.

David Brailer:
Ok. Let me turn your attention now to the electronic health record work group implementation plan. As you recall at the first meeting of the community there was considerable discussion about the electronic health record, and several of you noted at the time that that was one of the obvious key goals that we had across the board of the efforts that were here. Our sense after considering that and looking at the process by which the work groups were being formed was that if we did not memorialize electronic health record in one of those mechanisms, we might not have a mechanism for carrying it forward on a specific basis. For that reason we brought back to you a recommendation that the electronic health record work group be formed with the following broad and specific charges. Broad charge:
make recommendations to the community on ways to achieve widespread adoption of certified electronic health records minimizing gaps in adoption among providers. The specific charge, again, a specific point within a year to empower this:
make recommendations to the community so that within one year, excuse me, standardize widely available and secure solutions for accessing current and historical laboratory results and interpretations is deployed for clinical care by authorized parties. This laboratory issue was a reflection of information we had gathered on where various interface standards were in the industry and consultation with our partners. We're recommending that Lillie Gelinas: Golenas [spelled phonetically] and Jonathan Purlan [spelled phonetically] be the co-chairs of this group. Again, you can see the proposed membership. So this is a work group that we're bringing back, again with the hope that we can begin having a mechanism to explore what issues are particularly relevant to the electronic health record and the physician or other care provider office setting.

Secretary Michael O. Leavitt:
Comments. Doug.

Doug:
Mr. Secretary, where I come from in North Carolina we have a saying that called 'bless your heart'. And it can be very complimentary; sometimes it can be a little cutting. But on this one it's very complimentary - bless your heart. At the end of the day whether it's chronic disease

monitoring or bio surveillance, etc., the meat and guts of all that is going to be the electronic health record, implemented throughout the health care system. And as I've said at previous meetings, this is extremely important. There is a significant movement certainly in the physician community and elsewhere to move strongly in this direction. It's a wave that we want to continue to push, and this emphasis I think will further enhance that.

Secretary Michael O. Leavitt:
Comments, further. Nancy, was that a comment? Kevin?

Kevin D. Hutchinson:
On the specific charge it talks about the historical lab results. I was just curious if, why we, because of all the work that's been going on with medication history why we wouldn't also include med history, especially in the electronic health record, as a specific charge to get integrated into the EHR systems. I know it's in the other areas.

David Brailer:
I can't give you a reason other than parsimony. The effort to try to stay very narrowly focused and to recognize that to some degree that under the guise of electronic health records we're doing work that's complimentary to medication history, and under medication history doing work that can be leveraged over here. So, you know, hopefully across all of the work groups which come back here, this community will be looking at how does it leverage the infrastructural changes that are being made across all of the different efforts. But we didn't lay it out as a specific charge in the sense of we create, to some degree, dual accountability.

Secretary Michael O. Leavitt:
I think it's worth realizing that, what a powerful combination we will have created if you just take the medical clipboard, chronic care, and the work group on electronic medical records, and then you add in to it bio surveillance. If at the end of the year we have created a vehicle for that to move forward on a broad and ubiquitous basis we've changed the world in a fairly significant way. So while it may not seem as though we are, this may seem in component pieces to be narrowly focused. The aggregate of those narrow pieces begins to move this whole thing forward rapidly and in a bold way, in my assessment. Any other comments on the electronic medical record work group? We should probably hear from the chairs, do you feel comfortable in undertaking the time frames as they've been outlined?

Female Speaker:
Yes. Yeah. Dana and I have had some really good conversations related to this one, and you know for the most part when you think of the electronic health record we have islands of excellence breaking out all over the place. But islands of excellence are also silos. And so the silo issue is one I think that this work group is going to have to be dealing with very, very early. You know, because there are outstanding free-standing, piece meal components of electronic health record that are already in the public health sector.

Secretary Michael O. Leavitt:
Any other thoughts?

Make Speaker:
Mr. Secretary, I might suggest that there be a payer representative in some form. There's a lot of data that resides in the claims databases that could be used to pre-populate.

Secretary Michael O. Leavitt:
That's a worthwhile suggestion. Hearing no other comments, the chair declares a consensus on the electronic medical record work group. That gives us four work groups that we have empowered today, a schedule upon which they will report, milestones on which they will, for which they will be responsible, and a plan of integration as represented earlier along the major lines. I want to acknowledge Chip's point that we undoubtedly will add to the horizontal lists. I think it's quite possible we'll discover other boxes that need to be placed on the vertical list. But I think the graphic demonstrates the way this network will be developed, and I think this is an important step forward in the development of our long-term vision. Any other comments on the work groups? Thank you. And now let's go then to the next part of our agenda, which is the quality management discussion. David, would you like to introduce this?

David Brailer:
Sure. There were two issues, as you all know, that were of substantial interest to the community. And you're going to hear again from both of these:
quality management and then e-prescribing. And the reason we brought these back to you was because we found substantial interest, but at the same time could not determine a specific mechanism to bring a work group together. For quite different reasons. So we're bringing it back to you so there can be a further discussion about how does the community want to engage on these topics in the absence of the ability to form a specific work group. So with that, let me turn it to Karen Bell, director of the Office of Health Information Technology Adoption in the National Coordinator's office. Karen.

Karen:
Good morning, Mr. Secretary and members of the community. Thank you very much for the opportunity to provide you this morning with an update on quality monitoring. In the next few minutes I will provide you with some concerns and considerations with respect to this topic for your subsequent discussion. As I draw your attention to the fact that quality in health care continues to be a major, heavily publicized concern, I would also like to remind us of the time-honored approach to assessing clinical care. Donabedian's [spelled phonetically] model, which examines the structures, processes, and related outcomes of care, provides a foundation not only for assessment, but for improvement as well. Well, my topic today is quality monitoring; the tracking and reporting of clinical measures. These measures are the outcomes of quality management structures, and quality improvement processes. Quality management is the organizational infrastructure that supports information flow and use, prioritizes areas of concern, sets goals and in sense reaching targets, and provides the resources necessary to allow quality

improvement through care process change at the delivery system level. Together they drive demonstrably better outcomes. The next slide outlines a number of real world examples of this. Over the past five years, the main Health Management Coalition has been assessing primary care offices quality management infrastructures, such as electronic health records, staff plans which attend to issues of quality, etc., and quality improvement processes, i.e., the use of care plans, recall systems, reminders. Throughout the state office performance on heates [spelled phonetically] process measures that are robust enough to demonstrate statistically significant differences are also measured. These results, along with each office's ability to track its own outcome measures, are reported on the coalition's website, which is available to the public and represents every primary care practice in the state. Bridges to Excellence has created a pay for performance model that also assesses office infrastructures and care processes through its physician office link program. Clinical outcomes are assessed and rewarded in its diabetes and cardiac care programs. These are but two of many multi-stakeholder efforts designed to improve health care using the structure process outcome model. There are also striking examples which have emerged from collaboration among delivery systems. The governance and management structure of the Northern New England Cardiovascular Collaborative was formed 10 years ago when risk-adjusted mortality data for cardiac surgical procedures demonstrated marked variation among seven northern New England hospitals. Today, after working closely together on care process improvements, these hospitals have the lowest risk-adjusted mortality for cardiac bypass surgery in the country. The Institute for Healthcare Improvement has provided support for over 140 different such collaborate efforts across multiple settings and disease processes, both within delivery systems and stakeholder groups. And I would add that the California Foundation for Healthcare Improvement is probably among the best known of these. The Federal government has made similar strides in this arena. The Agency for Healthcare Research and Quality is one of the founding members, along with the American Academy of Family Practice, the American - I'm sorry, the Association of Health Insurance Plans, and the American College of Physicians of the Ambulatory Quality Alliance, a coalition of nationwide provider organizations, payers, and employers which has developed a core set of measures for assessing care, initially in the primary care setting. However, its multi-year plan includes developing measures of efficiency and quality that is applicable to multiple specialties. The Centers for Medicare and Medicaid, which also participates in the AQA, reports publicly on hospital, nursing home, and home health quality metrics at its compare web sites. In addition, the current scope of work that Medicare has contracted with its quality improvement organizations focuses on supporting adoption of electronic clinical information systems, care process improvement, and reporting specific quality metrics. The Federally Qualified Community Health Centers must also report specific quality metrics to HERSA [spelled phonetically], through the Bureau of Primary Care. Most impressive are the delivery systems that the Federal government manages directly. Both the VA and the Department of Defense have strong, centralized quality management structures which support the various networks and care delivery sites throughout the nation and the world. Clinicians at the Veteran's Administration have had access to a robust electronic health record with decision support features in it since 1999, and the Department of Defense is completing its roll out of similar electronic health record support across all branches of the military over the next few years. Electronic health records and support for quality improvement processes are also

available at the care delivery site of the Indian Health Service. All of these delivery systems have performance incentives at the delivery network level to improve healthcare quality. The fact that quality has improved in the VA was reported a little over a year ago, in the December 2004 issues of the Annals of Internal Medicine, where Steven Ash [spelled phonetically] and others demonstrated significantly better performance compared to a national sample on the quality measures over which it had control. But perhaps most important is that I'd like to emphasize the collaboration that is underway among the Federal systems of care. Quality management personnel from all departments meet regularly to share information, and strategies, and to align metrics. What efforts are then underway in the private sector to move the quality agenda, and the quality monitoring agenda forward? Health plans use administrative data sets or claims on which pay for performance is based. On the physician level, the quality metrics are focused on primary care, and within HMO products. However, many plans are now including PPO products, using algorithms of care to assign numbers to physicians. And in some parts of the country, multiple plans are sharing data among themselves or with a third-party entity in order to develop more consistent measures. As I indicated earlier, the AQA will be coordinating measures of both quality and efficiency with multiple stakeholders across a range of ambulatory care providers. But providers too are moving forward. Integrated delivery systems such as Inter Mountain Health, Kaiser Permanente, Partners Health Care will continue to generate and use electronic clinical information to identify opportunities for care process improvement and better health outcomes among their multiple settings. Standardized quality information is now available among the academic medical centers in a confidential format similar to the model used by the Northern New England Cardiovascular Collaborative. Would like to point out that the Leap Frog Group continues to actively promote hospital systems, which have been associated with safer, better quality care and continues to report on these results. And lastly, the National Specialty Societies are creating dynamic guidelines for care specific to their specialty, as well as ways of assessing their use. With such a rich array of effort and commitment, what opportunities exist for real breakthroughs in demonstrating quality improvement, particularly at the ambulatory care level? I believe the answer likely lies in the barriers. Lack of harmony among measures is problematic. One cannot truly compare rates of procedures among patients with diabetes unless there is a consistent way of defining a patient with diabetes. While, the AQA has come to consensus on a starter set of ambulatory physician measures, these are primarily applicable to primary care clinicians, as I mentioned earlier at the present time. Previous comments made here, both today and at previous meetings, underline the need for more patient-focused measures which address multiple [inaudible] morbidities, or patients with special needs. And care obtained from multiple providers. Difficulty in identifying the accountable clinical entity for a given measure is still problematic, particularly in a fee-for-service system with patients with multiple problems and care providers. And lastly, the infrastructure for collecting and reporting of quality measures is still fragmented. And a cohesive secure system is yet to be established. There are, then, opportunities for moving forward. The widespread adoption of interoperable, certified electronic health records will clearly move the quality improvement and quality monitoring agendas in the direction that's necessary. This effort was emphasized earlier and will be emphasized again. However, the direction of Dr. Caroline Clancy [spelled phonetically], recognized the need for the following:

first, national consensus on a set of evidence-based quality measures which are applicable to all types of clinician providers. Second, the need for standardized measurement methodologies. Third, the need for a secure infrastructure for collecting, processing, and reporting quality metrics that is acceptable to the public. Dr. Clancy [spelled phonetically] is at present overseeing the roll out of the AQA pilots which are testing the ability of physicians to report out on the starter set of metrics. She will be available to brief this community on a regular basis on the progress that will be made in this area as well as the ones listed on the slide. Once we have consistent and standardized metrics, the broader health IT community can move forward with facilitating electronic reporting. Thank you very much. I open this now to your comments.

David Brailer:
Thank you, Karen.

Secretary Michael O. Leavitt:
Dr. Brailer, do you want to lead this conversation?

David Brailer:
Sure. So this synopsis again just both refreshes you about the issues we discussed some time ago, and secondly begins to really bring a much more focused point to this question about how does this group representing health information technology progress intersect with this issue that has a significant breadth of areas and other rate limiting steps. So with that lets turn it to discussion and start with Chip.

Charles N. Khan III:
Yeah, I guess there was one thing missing with the -- the Hospital Quality Alliance was missing from the presentation, and you have the Hospital Quality Alliance, and it will be mandated if [inaudible] passes. Actually basically on hospitals, because you're going to have to, you lose two percent if you don't report. And that's going to be reporting up to 22 measures fairly soon - we're almost there now. And those measures will all be National Quality Forum approved, and then you've got the Ambulatory Quality Alliance here, which was described in the presentation. And I guess the question over time, which is not the question for this group is sort of how will the process that AQA has that is still in its formative stage, the process that HQA has, which is already reporting, but I would argue is not really settled onto one platform. And sort of how is it all going to be squeezed together so all the information will be available on individuals and then, I mean individual providers, in a meaningful way that can be reported. But at least in terms of hospitals, we're fairly far along in terms of how to report on hospital compare. The issue though is that we've got sort of multiple platforms there, and then how to integrate the AQA, I think, is going to be quite complicated. And the HQA and the AQA have actually met together and had some preliminary discussions. But I think eventually, and as I said it's not necessarily an issue for this group, there has to be sort of a single platform developed, whether it's public private partnership or CMS, for all this information for reporting on providers, the question I guess for this group is what's the interaction going to be between the development of the record and that

process of putting all reporting on sort of a single platform so it will be meaningful and comparable across providers.

Male Speaker:
That is an important issue for this group. HQA and the AQA are making a lot of rapid progress, but without those kinds of electronic standards in place, much of it is happening, especially in the ambulatory setting, off existing data systems, and in some cases we're working off administrative claims record reporting in the short term. So from the CMF standpoint we very much like to support the efforts of the AQA and HQA to get to this more integrated kind of reporting structure that relies on electronic records rather than on existing systems.

Secretary Michael O. Leavitt:
Rather than what?

Male Speaker:
Existing systems which, as Chip said, are not going to standardize and in many cases are not electronic.

Secretary Michael O. Leavitt:
So are they actually have to take the information manually to draw?

Male Speaker:
Right now hospitals, depending on their systems, are either taking it manually, or if they're lucky enough to have electronic systems, but then they feed it in electronically, and I guess the QIO in Iowa takes the information on these particular measures and then ultimately from that is produced the information for the three conditions that are now being looked at:
heart attack, heart failure, and pneumonia, reported on hospital compare. So you've got something going on right now, but I should say even from the hospital level right now, it can be pretty labor-intensive, because they could have paper records that they're taking information on for these measures, and making them electronic so they can go into the process to be reported on hospital compare.

Male Speaker:
Well I would echo Chip's comments, Mr. Secretary. It's a very challenging issue that we face, but a very important opportunity that we face as well. I have been very proud to be involved with the development of the ambulatory care quality alliance, and Mr. Secretary the support of Caroline Clancy [spelled phonetically] and Mark McLellon [spelled phonetically] for that effort has been tremendous to moving that effort forward. And just last week, as Karen Bell alluded to, the AQA agreed to broaden its scope to include the entire physician community, not just those related to primary care, which I think will bring a degree of uniformity to the whole process of, at least as it applies to the physician community and other health care providers in a very important way. To me, the intersection here from the HIT standpoint, I think, hopefully will be alluded to in perhaps our last presentation today, and that's the certification commission for

health information technology. Clearly as the HQA and the AQA do their work, and performance measures are considered, agreed upon, sub sets are developed for certain specialties, and so forth, and implementation begins, pilot testing validates the process which we're moving forward with - the background certification process for electronic health records - which is in process now with the CCHIT. And then their next effort, which will be a huge one, is the certification process for inpatient EHRs, if you will. Should allow this interface to occur so that as hospitals and physicians are collecting this data electronically at the point of care, the information is collected, stored, and easily reportable to whomever at the proper time in an electronic fashion without hands having to type things in and so forth. So it seems to me that's the important intersection that we have and the opportunity that we have. And Mark Levitt [spelled phonetically] will speak to that, I'm sure, later on when he gives his presentation about the CCHIT.

Secretary Michael O. Leavitt:
Scott.

Scott Young:
The only comment that I would make in this regard is what we hear from the marketplace very strongly from our customers is a need for transparency. And as we develop these systems we can't develop them so inside the system that they're not of any utility to anybody who, outside the system. You know, our customers, consumers, and others, employers are demanding information about quality, and if we are going to invest the energy in developing good, solid, accurate measures of quality, which we have to do, we have to develop in such a fashion that the average consumer can use them. So I just want to emphasize the fact that transparency is a critical issue in this and we need to make certain that we're considering that piece.

Male Speaker:
What's the process for determining the priorities in terms of, you mentioned three diseases: heart, what were the three?

Charles N. Khan III:
Heart attack, heart failure, and pneumonia.

Male Speaker:
What was the process used to determine those three?

Charles N. Khan III:
I guess two. One was obviously those are very heavy hitter conditions in the hospital area, and two, the measure, the process measures were there and approved by the National Quality Forum. So it's sort of a problem of what can you, what measures make sense and are practicable, and what things aren't you to be looking at? And there was an intersection there. The next measures hopefully will be infection measures, which probably will be the most useful of all. And they'll be -

Male Speaker:
And also patient satisfaction.

Charles N. Khan III:
Well, that's, I was going to get to that. And then also there will be some mortality measures.

Secretary Michael O. Leavitt:
Chip, what was the name?

Charles N. Khan III:
There'll be some mortality measures next for those conditions, then there'll be infection measures. Then we're also, the HQA is going to also include in our agenda the consumer expectation survey. And I guess we're about 12 months away, or eight months away from that.

Male Speaker:
Yeah, that's been finalized and been through O&B approval and so forth, and we're actually going to be starting pilot testing of that in some sample hospitals next months.

Charles N. Khan III:
And we're trying to collapse that process to that can happen. Be reported generally before '06 is over. So we have a lot sort of being, sort of brewing up, but we're a bit dependant on the National Quality Forum approving measures that, because they're sort of the gold standard, that we can then put in place.

Secretary Michael O. Leavitt:
So the answer to the question how do they come about, you've told me what the priorities are, but who set them?

Charles N. Khan III:
Well, the Hospital Quality Alliance is a public-private combine, and the group did focus groups, and did sort of town home meetings, and had a process and made a recommendation, and then ultimately CMS was the final arbiter, but basically our recommendations were accepted.

Secretary Michael O. Leavitt:
And you were the final arbiter because you're the big payer, or?

Male Speaker:
Well, we really wanted to push this effort along, but the actual content, as Chip said, was not determined by us; it was determined by a broad stakeholder collaboration that included a lot of leadership from the hospital associations, but also involved a health professional group, groups, payers, consumer organizations, a very broad spectrum of health care stakeholders. That kind of consensus approach driven forward by a push from the Federal government, because we really

need these kinds of measures for our patients, or for our beneficiaries getting better care. I think it's a very good model.

Male Speaker:
Just looking at the lists that would be in efforts underway in the government sector, and in the private sector, I don't see the FEHBP listed, and I'm curious as to whether we know whether there are any barriers to that significant Federal entity in participating with these efforts? Or perhaps there are efforts underway there?

Male Speaker:
That's a timely point. Just next week we're meeting with some key stakeholders. As you know we already - well, you may not know - we already require reporting of NCQA results for all HMOs that participate in the FEHB. I mean we are focused at this point at the insurance company level. We need to expand that where 75% of our enrollees are in PPOs. So we are working with CMS and following their lead and will be meeting to discuss ways of rolling out a set of measures for the PPO plans that are in the program. And that will be our primary focus on quality over the next year.

Secretary Michael O. Leavitt:
Kevin.

Kevin D. Hutchinson:
Just a comment on, I recognize and I preface my comments by stating I understand you have to gather the data, and this topic is about quality monitoring, but in the years that I've spent focused on hospitals, my VHA days and now physician offices focused on trying to get electronic health records and e-prescribing going, the number one issue that keeps coming up when we talk about quality is reimbursement. And I know that this isn't parallel, but we need to, there's a lot of pilot programs going on, and different discussions around pay for performance and issues like that. But there's a lot of confusion out there about ultimately how are physicians and hospitals and other entities going to be reimbursed based on quality measures? And I think if we were able to lay out a longer term vision or strategy for our transition from the quantity of care to the quality of care, you would see a lot more interaction. And maybe this falls in Karen's other hat of health IT adoption, because it definitely is an item in that particular category of if I knew where this was going, I may be more likely to invest in this technology.

Secretary Michael O. Leavitt:
Mark, do you want to elaborate a little bit on what's happening at CMS currently? How the pieces we've talked about fit into that agenda, and I'd be interested to hear a little bit of your thought as to how this, the community can build on what we've heard about today. What should our agenda with the community be?

Mark:

Well, first of all, with respect to these efforts that are already underway we absolutely want to keep supporting them. The more there is adoption of electronic systems, the easier it is to get reporting on quality of care, also efficiency and costs of care, which are very important to consumers and healthcare purchasers today. So we'll continue those efforts. Many of our current activities, both in legislation that now applies nationally, and in our pilot programs, our focus on exactly the issue that Kevin raised of how can we support better quality reporting and quality improvement through our payment systems. Right now, as you know, hospital payments and Medicare are adjusted based on whether or not the kinds of quality measures that Chip talked about are being reported under the deficit-reduction act that's pending before Congress, that set of measures would be expanded substantially to include the kinds of categories of outcome measures for surgery, and patient satisfaction, and other measures developed through a consensus process that we've already been discussing. Beyond moving to paying more for quality reporting, which clearly has value and clearly can work, the Medicare program is supporting a number of demonstration programs that take a next step towards paying based on quality of care actually delivered. These variations of performance-based payment models come in different forms for different kinds of providers. But in all the cases, we're working to support not only the consistent reporting of quality measures developed by consensus, but also the use of electronic record systems like Karen has described to help providers get to better quality to lower cost and lower cost reporting at the same time. For example our physician group practice quality demonstration program, which has been underway since last February, includes a number of large physician groups, many of which had already adopted some electronic records capabilities because in the demonstration program we pay more for reporting on quality, demonstrating improvements in both chronic care and preventative care quality, and reductions in overall costs of care; for example, by preventing costly complications, we're seeing more investment by the groups involved in support for personal health records, early intervention programs based on what's in their existing electronic record, other kinds of electronic interactions with patients, and we're seeing more investment in the electronic reporting of these quality measures. We're in the final stages of developing a similar demonstration program for small physician practices, and we're looking at other opportunities to implement the same kinds of steps - to pay more for better quality rather than pay more for more visits, more utilization, and more complications. So I think these do go hand in hand, and I'm hoping is that as AHIC process goes forward we can make sure we're communicating closely and using these demonstration programs where we pay for better results and pay for quality reporting to help encourage more rapid adoption of the electronic record systems.

Secretary Michael O. Leavitt:
It seems to me that the question that we're examining here is what is a reasoned agenda for the community to undertake, to drive what's already happening forward at a faster, more efficient pace. What I've heard Chip say is there are, all that have been listed and other important ones that are moving forward on disease-specific areas and have an agenda that will drive forward. I'm hearing Doug and others say this is the right thing to be doing and it needs to be accelerated. I'm hearing Karen say, and all of others saying that the thing that limits us is the ability to have electronically compatible data that's rolled up into one place at one time, but what's happening

lots of different places and the, that appears to be the, what, that appears to be what's creating most of the friction. Given the fact that our responsibility, or our opportunity in the community is to find ways of creating that sense of, in breaking those barriers down and being able to find harmony, to harmonize the standards, I think the purpose of this briefing today was to say what's the best role for us to play? What can we reasonably take on in the next period of time that will advance that process? And I'm not yet hearing the answer to that question. Dr. Winkenworth [spelled phonetically].

DR. WINKENWORTH [spelled phonetically]:
Mr. Secretary, just a thought about, and I don't know how well constituted and led the infrastructure of these two organizations, HQA and AQA. But maybe AHIC could formally ask those organizations what do you think AHIC ought to do to support your agenda, and what do you think you ought to do to support our agenda? And in a very precise way, you know, list some things, maybe press them to accelerate their work.

Secretary Michael O. Leavitt:
Thank you. Chip, and then -

Charles N. Khan III:
I guess my argument would be furthering of the agenda that's already been outlined, including the interoperability, obviously, and all the work that's being done by the various groups that are helping with that. In some ways getting the record as far along as possible as fast as possible and diffusion of it then making that possible, and then in the process and probably in the guts of a lot of the development of the interoperability, respecting the issue of you're going to have to, reporting is going to be expected, and physicians and hospitals and other providers are going to be looking to, to be judged on certain measures, and somebody is going have to go mind those measures - I mean mind those records - whether it's at the hospital level or the physician office level or some other level. And there are a lot of technical issues that that raises, and it seems to me those issues in a sense ought to be sort of in the guts of development of what the consultants and the standard setting groups are doing. But it seems to me that that is really our, I would say our role is to get us to a point where all of these other entities that are creating standards, measures that are then having providers report and trying to bring some confluence of that activity so that those measures are not just measures of a hospital, whether or not a hospital gave somebody an Aspirin, but the whole process of that care. That can be done. I think one other point, though, is that the problem we've got in pay for performance is that DEPRA [spelled phonetically], if it's passed by the House, sort of sets out railroad tracks for hospitals by FY09, which is October 1, 2008 if I got my dates right, you would have the power and I think the actual word is Shell. Shell have a pay for performance for hospitals. And there's a lot of modeling going on now. There's really not the same, even though you're developing the process is not the same for doctors, and this issue of confluence, because a lot of what goes on in hospitals if it's going to be meaningfully judged, is ordered by doctors. That confluence has got to take place. But I think that's outside this body if you get all the infrastructure there then some of these questions are easier to answer.

Secretary Michael O. Leavitt:
Doug, before we go to your point, let me just comment that it's clear from what was said earlier and also statutory responsibilities that are likely to fall upon CMS, that CMS clearly has the attention of all of these groups for reasons that we all understand. Likewise I'm guessing that the Veteran's Administration and DOD are deeply involved, and I know that the Office of Personnel Management, as a significant enough player, is probably there or involved in those existing processes because they control that much data. It seems to me that a logical next step for us would be to invite those that are broadly involved in this list that we've already talked about to meet with the Office of the National Coordinator with the idea that we're going to invite them at our next meeting to come and to talk about the ways that we can use this process of driving the standards process faster and in a more coordinated way. What sits at this table, the reason we call it The Community is because it is the, in large measure, the payer community represented in large measure. And we've got to have a way of deciding and moving forward, and I would think they would find that quite appealing. So I'm going to at least pose that as an idea, and then go to Doug and come back to that.

Doug:
Well, I would build upon that, Mr. Secretary, and what Bill said earlier, speaking I think carefully on behalf of the AQA I think we would welcome the challenge to answer that question about what the community can do from a technology perspective to push forward the whole issue of performance measurement as it relates to the ambulatory environment. It just so happens that last week we considered and decided to create a working group, well, a sub-committee on our work group on data sharing and aggregation that specifically deals with the issue of health information technology and its role in this important environment. So I'm sure the AQA would be very happy to respond to that request and do that. Secondly, as I said earlier and I will state my bias, because I used to be a commissioner for the Certification Commission on the HIT before I got this job. So I bring that bias to this table. But I see the CCHIT is doing exemplary work in the certification area, currently focused on the ambulatory EHR, but soon to be focused on the inpatient EHR, and that, the convergence of that, I think, presents a very important opportunity for the reporting of performance data at any level - certainly to the public and to consumers as it should be, but also to the providers of care for the process of quality improvement. And the electronic technology background can do that.

Secretary Michael O. Leavitt:
It has been my aspiration as Secretary to create a community - this one - to become the process by which conclusions could be arrived at and moved forward. And it seems to me until we get that part of the community involved here where we're able to coordinate along those axis lines what's happening, we'll continue to see them make progress, but in a separate way than we are, and we'll ultimately end up with a giant reconciliation that may have to be made later that's unnecessary if we start now. Craig.

Craig:

Just an observation. It's interesting that, again, this is the only industry in the world that needs more IT infrastructure and capability to report on its own quality. Couldn't, wouldn't it be cheaper to hire J.D. Power and Associates to come in? Ultimately what you're really interested, as Scott mentioned, is providing the consumer with information. And most of the discussion I've heard today is providing the system with capability, and it leaves the consumer totally out of the loop. And all of the systems we're talking about putting in place, and pay for performance, etc., etc., it's system oriented. It's not consumer oriented.

Secretary Michael O. Leavitt:
Well, that assumes that J.D. Power could receive all of the information in a way that they could make sense of, and that people would subject themselves to providing that information. And while, and I think that's the, it may well be that some J.D. Power-like organization will ultimately be the certifier of that data at some point in the future. But what appears to me to be lacking is the capacity to bring the data together in a way that people both have confidence in and are willing to let it be used.

Charles N. Khan III:
I understand the extremely complex nature of the transaction that we're talking about. And there's an immense amount of data that goes with it. But there seems to be two ways to look at it. One is you can hide behind the complexity and say that I can't do anything until I get more and more information analysis capability to smooth out the complexity. Or you could just say, I'm going to report the data." And it's, just as an outsider listening to the conversation it's much more of an insider -

Secretary Michael O. Leavitt:
Speaking in whose voice? I guess that's the question - whose voice are you speaking in?

Charles N. Khan III:
I'm speaking in the voice of the consumer.

Secretary Michael O. Leavitt:
When you say, "I'm going to report the data," who are you speaking - whose voice there are you speaking?

Charles N. Khan III:
In that case I'm obviously speaking of the practitioner, and whether it's the doctor or the hospital or the health clinic or whatever it is. And I applaud the fact that we are going to report of heart attacks, and heart deaths, and pneumonia, and I don't know what fraction of the medical transactions those cover, but I suspect it's relatively small in terms of quality. But if I wanted to go in and have an operation of X, Y, and Z, I'd like to be able to, as I can, looking at all of the elementary schools in the rural, in the United States today, go online and see what is the grade each elementary school has for the sixth grade in terms of its capability? Somehow our

education system is able to do that, but I don't think I can get the same information on an appendectomy or bypass surgery, etc. for my local hospital. Maybe I can, I don't know.

Secretary Michael O. Leavitt:
But isn't that essentially, Mark, what you want to provide?

Mark:
The next set of measures are going to include infection complications and outcomes of surgeries performed by hospital. And the measures that the AQA is investigating would probably extend that same kind of measurement system to the…

Secretary Michael O. Leavitt:
Right. The largest payer for those services in the world, what are the barriers to you of being able to do what Craig would also like to have happen?

Mark:
Well, it's been exactly the issues you've been discussing. Some of the complexity of the data, the fact that there aren't standards for straightforward electronic reporting of this information. Also there are a lot of significant clinical issues in that different patients have different risk factors for having complications after surgery, for example, and many patient characteristics as well as the characteristics of the provider, and the action of the provider influence the patient's outcomes. And it's exactly those sorts of issues I think are best worked out through this collaborative public process that the HQA and the AQA have underway. Chip's been involved in this from the beginning, too, so he's -

Charles N. Khan III:
Yeah, I was one of the starters of the HQA. But I think the most important thing here is that a lot of the measures of institutions that have been done in the past really don't work real well. I mean let's sort of, I don't have, you know, the powers thing. But *U.S. News and World Report* has been rating hospitals for years. And Wenberg [spelled phonetically] and others recently did an article in, did research that was in an article in *Health Affairs* that, you know, blew the hell out of the kind of metrics they used. And basically showed there was not much relationship between how well a hospital did and how many nurses it had, or a few other metrics. I mean we are still developing, unfortunately, the metrics, I mean, to actually measure how good a job a hospital does. And, at least from my view, I think this is partly insider, but it really is very public, too, because hospital compare is a website that is up right now. You know, you can go into HHS's website and find hospital compare, and it's only three conditions, it is still sixteen percent of what hospitals do - those three measures, I mean those three conditions. And so I wish we were at a point at which I could say I could trust J.D. Powers, who actually does assess hospitals, to give you the short and skinny, but I don't think we're there yet. But also at the end of the day, the consumer needs to know more. I agree with Scott, and I agree with Craig. But also, hospitals need to know where to improve so they can meet the expectations of consumers. And I

think at least at this stage this process is important for hospital and physician improvement of care, as it is to tell you what's going on in those, in particular places.

Secretary Michael O. Leavitt:
Nancy, and then Lillie Gelinas:
[spelled phonetically], and then I'm going to wrap up this part of the discussion.

Nancy Davenport-Ennis:
Mr. Secretary, I think the points that are being shared are certainly valid from every perspective. Let me go to Dr. Bell's remarks in terms of what are the barriers, and go back to a comment you made earlier today - that there is always the sociology of the issue that has to be addressed. I do agree that consumers need to know more. Patients desperately need to know more. But there needs to be a universal standard of what it is that we're measuring, so that when we read a report, and we read what a rating is, or a ranking is, we understand what the universal tools of measurement are to get us there. And the first barrier pointed out is that right now we have a lack of harmony among the measurement tools that are being used. I think a second sociological issue that perhaps if we could just address this one item would be beneficial to the process that Dr. McLellon [spelled phonetically] is initiating through so much of what he's doing, is that certainly there has to be an answer to defining who the primary care physician is for the chronically ill patient receiving multiple services in a fee for service system. And if we know who that physician is and we can capture the data from them it is going to give us a different insight into what those measurements are.

Secretary Michael O. Leavitt:
Thank you, Nancy. Lillie Gelinas:.

Lillie Gelinas:
Just two final comments respecting to draw this to a conclusion. When we talk about the deficit reduction act it would seem in this space that we need the data collection burden act to reduce data collection burden. Because at the end of the day we have lots of data and healthcare in the United States - we just don't have information. We, I think at our last meeting we talked about, we don't have a failure of medical evidence, we have a failure of execution. It's not about creating more systems and more processes and more, more, more, more. It's about getting on with it. But there's one key thing that we haven't mentioned in all of this, and I would add it to the barriers list, perhaps, is analysis and benchmarking. Because we can have a lot of data, but how do you know it's a quality piece that you're looking for? For instance, one of the most common questions we'll get is what's the benchmark for medication errors? Well that would be zero. We're tolerating a little of insanity here, because we're so used to what's the benchmark? What's the benchmark? What are we driving towards? Is it zero medical errors? Is it five percent? Is it zero heart attacks? Is it zero failure to rescue by nurses in inpatient med surge units? You know, I don't know. But this whole analysis and recommendation piece can also be a barrier, because where is the benchmark and what's the quality platform we're trying to get towards? So just wanted to add that little piece because I hadn't heard that yet.

Secretary Michael O. Leavitt:
Thank you. Let me…

[end of transcript]

Male speaker:
Let me wrap this up with this point. The capacity, the power, if you will, of the community, this organization, rests in our ability to drive conclusions to implementation. And we gain that power by virtue of the fact that large payers sit at this table in a way that they can collaboratively develop solutions and then implement them. This conversation points out the fact that many people at this table and in the broader community are dependent upon -- are moving rapidly toward pay-for-performance standards. For many good reasons. People have different reasons, but they're all good. What I believe we have concluded here today, and I would propose as a statement of consensus, is that we need to bring the larger quality movements into this discussion, with the idea of engaging the community, this organization to reach conclusions about both priorities, standards, and agenda to move it forward on a more rapid basis. And so what my instinct is, as a chairman, is to direct the Office of National Coordinator to make contact with those listed, and others, to indicate to them our desire to engage their efforts into our conclusion process, with the belief that we can accelerate their movement forward by reaching conclusions that will be broadly and widely deployed. Could we gain consensus around that statement and sentiment?

Various speakers:
Yes. Yes. Yes.

Male speaker:
Would there be those who ultimately would find that needed to be improved? If not, I'm going to declare a consensus around that point and direct the Office of National Coordinator to prepare for, if not our next meeting, a future meeting, a discussion with the idea that you will have worked with them to bring back to us specific ideas on how we can integrate their work into our conclusion process. With that, I believe we're scheduled to take a short break, and I'm going to ask whoever's in charge of the room temperature, to raise it.

[end of transcript]

Secretary Michael O. Leavitt:
We will begin now. Could I indicate in advance that Dr. McClellan and I have a news conference at 11:30 that we need to attend to. We're working to get the prescriptions of 24 million people filled today. Having a little trouble getting all of those filled in the right fashion. But we'll continue and I'll return as possible. In the meantime, why don't we move forward with the e-prescribing discussion?

Male Speaker:
Thank you, Mr. Secretary. Again, we had a significant discussion in the last meeting about e-prescribing that was characterized by Craig Barrett's, "Let's just do it." And so we took that to heart and went back and are now having a second presentation to you by two of the new permanent directors in the Office of the National Coordinator, Kelly Cronan, and Jody Daniel about e-prescribing with a very, very sharp focus on who is doing what leaving open the discussion about how do we frame this, how do we put this together and what role does the community play in the acceleration of e-prescribing. Kelly and Jody.

Kelly Cronan:
Good morning, Mr. Secretary, members of the community. As David had mentioned in the last meeting, there was a great deal of interest in this topic, so we thought we'd come back today and give you some more background on the variety of public sector activities, particularly focused on HHS activities and talk about some of the private sector initiatives as well -- talk a little bit about some of the timing of some of these initiatives as well as some of the potential accelerators in this area. The importance of this issue is clear. There are drug errors and adverse drug events that occur daily. They are serious and often life threatening and they cost the healthcare system billions of dollars. The most incredible part of these statistics is that many of these adverse events are avoidable with e-prescribing with clinical decision support which led to the "Just do it" discussion at the last meeting. The -- this is clearly an area that is ripe for action, and in fact, it has been and continues to be a priority for HHS, particularly as CMS expands to its prescription drug coverage under the Medicare Part D benefit. I'm going to talk primarly about HHS activities in this area. HHS has used its statutory authority to drive adoption and interoperability of e-prescribing in a variety of ways. There are six --

[end

Jodi Daniel:

… here that I wanted to talk about but I wanted to … they're really grouped into three different categories. The first two activities focus on Interoperability and Standards. The second two are about some FDA related regulations in the area of e-Prescribing, and the third two are really about Adoption of e-Prescribing. Starting with Standards, the Medicare Modernization Act, or MMA, provided for e-Prescribing for Medicare Part D and required HHFs to adopt Standards for e-Prescribing for that program. The Standards are not only for the prescription itself, but also for related activities and transactions that support prescribing to improve quality and to lower costs. The statute also included a timetable for doing this activity for … and which would've set forth standards that would be effective in April 2009. What CMS did is to take the statutory authority it had, and try to accelerate those standards where there was already adequate industry experience. These are called the Foundation e-Prescribing Standards. CMS adopted rules to -- for these Foundation standards this fall and they became effective January 1st of this year timed to the beginning of the Part D benefit. The way this … the e-Prescribing Standards work is that

Part D sponsors are required to support the e-Prescibing Standards, and prescribers and dispensers are required to use those standards only when they electronically prescribe. The decision to prescribe electronically is a voluntary one. As Secretary Leavitt and Dr. McClellan had mentioned, there are -- the Department is engaging in an e-Prescribing pilot project to test the standards that do not have adequate industry experience. Again, this is something that was set forth in the MMA Statute. This pilot project will be conducted in 2006 and is a collaborative project with CMS and with the Agency for Healthcare Research and Quality. There will cooperative agreements with four awardees in seven states. The fifth one is still pending. And these pilot project … this pilot project will not only test the standards themselves, but will also look at what workflow changes come about by implementing these standard transactions. The process from then will be for the department to evaluate the results of that pilot project and use those to inform the regulatory process for adopting future standards along the statutory time table. The next category of activities are the FDA related regulations. In February 2004, FDA published a Prescription Bar Coding Regulation that set standards and requirements for bar codes for most prescription drugs and biologics and for some over the counter prescriptions. This regulation will help reduce medication errors by allowing scanners to read the codes that are on the prescription to make sure that the right drug is being given to the right patient in the right dosage amount. For the institutions that have already implemented this type of activity, they provide a patient with a bracelet that has an individual bar code on it, so when the clinician is giving the drugs to the patient, they can check and scan the bar code of the patient, scan the bar code on the drug, and make sure that the right drug is being given to the right patient. The FDA estimates that this rule, when fully implemented, will help prevent nearly 500,000 adverse events and transfusion errors in the next 20 years. It also is hopeful that it will provide incentive for computerized physician order entry in an in-patient setting, also helping to drive e-Prescribing adoption. The second FDA rule that I wanted to note was the Structured Product Labeling Rule. This was adopted in 2003 and became effective in November of 2005. There are two things that this rule is doing that I wanted to highlight. The first is to establish a format for prescription labeling. This is the Structured Product Label Format, to provide accurate, up to date drug information using a standardized medical terminology in a readable, accessible format. And second, this rule requires certain prescription labeling content to be submitted to the FDA in an electronic format. There are three benefits that I wanted to note about this regulation. First, it can improve patient safety through accessible product information. The National Library of Medicine will have a website that will have this information available to the public as well as to clinicians so that information can be readily available and accessible on prescription drugs that are approved in the United States. Second, this regulation will allow product information to be electronically managed, allowing the user to electronically search information about the drug. Software can be designed to reach specific sections of the drug label like the product name, warnings, inactive and active ingredients, and the like, so that this information can be pulled off electronically rather than manually. And the third benefit is that this will simplify FDA labeling review and speed the approval process for labeling changes in prescription drugs. The third category of HHS activities I wanted to talk about are about adoption of e-Prescribing. Physicians that will incur the cost of adopting e-Prescribing hardware and software, but don't necessarily reap the benefits from adopting this technology, and this negative business case is what we see as

providing difficulty in encouraging adoption of e-Prescribing among physicians. What we've heard as concerns is that the Stark Laws and Anti-Kickback Statute, that are designed to prevent fraud and abuse, can stand as a barrier to the donation of this hardware and software by those that are reaping the benefits of e-Prescribing to the physicians that need to adopt e-Prescribing technologies. The Medicare Modernization Act required HHS to adopt a Stark exception and Anti-Kickback Safe Harbor to allow donations of hardware, software, and training for e-Prescribing. In October of 2005, CMS and OIG did put out proposed rules to not only adopt exceptions for e-Prescribing, but also to do the same for electronic health records. In the proposed rule, there is both a pre- and post-certification exception for electronic health records. The pre-certification exception is designed to be a little bit more strict because there aren't functional requirements and interoperability standards, but those restrictions would be eased and the exception would be broader post-certification for certified e-Prescribing … I mean, for certified EHR products that included e-Prescribing. We're currently reviewing comments that we received and hope to put out a rule as soon as possible for the Stark exceptions and e-Prescribing Safe Harbors. And finally, I just wanted to note that the MMA also authorized HHS to make grants to physicians for e-Prescribing. The authorization was for 2007 through 2009, so this is something we'll have to look forward to in the future.

In the private sector, there are numerous e-Prescribing initiatives underway in at least 20 different states and regions. And these different programs vary dramatically from one program to the next. In some cases, there are plans in physician organizations that are giving away free e-Prescribing software and services to physicians. Just last week there was a large health plan in Pennsylvania that announced it was going to be giving away hand held e-Prescribing hardware and software to physicians in southeastern Pennsylvania and in New Jersey, in order to encourage the filling and refilling of prescriptions electronically. In Nevada, a health plan, a medical records software company, and a medical society are working together to provide free licenses for e-Prescribing software to all physicians in that State. In addition to some of these e-Prescribing programs, in order to address that negative business case that I mentioned earlier, there are numerous organizations that are offering reward or incentive programs, or pay for performance programs as was earlier discussed today, and many of these include incentives for e-Prescribing. And of course as Dr. McClellan had mentioned, CMS is taking an active role in this area and in looking at pay for performance including pay for performance for e-Prescribing. The last thing I wanted to note is that the Certification Commission for Health Information Technology, who we'll hear from later, will be instrumental in assuring that there are functional requirements for e-Prescribing in electronic health Records, again, to encourage adoption of e-Prescribing in the private sector. With that, I turn to Kelly Cronin.

Kelly Cronin:
Since Jodi gave a great overview of the many different initiatives that are underway in both the public and private Sector, we thought it might be helpful to just reinforce what has already been completed, what is underway, and what do we anticipate to accomplish over the next couple of years. As was just mentioned, the Bar Coding Rule was published in 2004 and CMS also proposed the first regulation for Foundation Standards for e-Prescribing which are now in effect.

In 2005, CMS also proposed the Stark and Anti-Kickback exceptions that Jodi just mentioned, and the Structured Product Labels now publicly available through the National Library of Medicine. In 2006 now, obviously, the standards are in effect so that prescription drug plans that are now delivering the Part D benefit are going to have comply with these standards, as will physicians who choose to voluntarily e-Prescribe. As was already mentioned a couple of times earlier, we are now implementing four new e-Prescribing programs that will be not only testing the standards, but also will be looking at the return on investment, the impact that e-Prescribing will have on workflow, and other many important benefits to the safety and quality of medication use. Later this year, as Mark Leavitt will elaborate on later in the Certification Commission discussion, the Certification Commission will be addressing requirements for e-Prescribing that will enable true connectivity, so not faxing of prescriptions as we talked about during the last Community meeting, but actually sending a prescription electronically from a doctor's office on to a PBM or to a pharmacy. And later this year, we also anticipate to finalize both Stark and Anti-Kickback Exception and Safe Harbor so that we can encourage additional adoption that has already started to take place with some managed care organizations, and really tie that to certification as was described earlier, so that we can make sure that the products that are being adopted by physicians and clinicians across the country are going to meet the important requirements that are needed for e-Prescribing. In 2007, once we have the results in from the e-Prescribing pilots, we'll know what second set of standards should be regulated and we will go through a separate rule making process for that second set of regulations. We also anticipate that in subsequent years, the Certification Commission will be addressing additional requirements for Clinical Decision Support, and other features related to e-Prescribing that will be critical to achieve the full benefits. So just to recap on some of the barriers, we know right now, the current marketplace does not have a uniform set of standards to enable interoperability, nor do they have a minimum set of functions that are required to really have the ability to e-Prescribe in a way that is evidence based and really meets the patients' needs. So we have the Certification Commission that's now in existence and they're going to make a significant impact in creating criteria, both interoperability and functionality criteria for electronic health records related to e-Prescribing, but we still have a marketplace where vendors that could be installing products that could enable this connectivity, so not faxing, but actually transmitting prescriptions to Pharmacies, they aren't installing these upgrades. There's about 20 vendors right now that reach about 80,000 physicians and they are now, sort of, on a waiting list to be implementing these products. Clinical decision support is going to be needed to fully realize the benefits, as I mentioned, and this will have to be addressed in subsequent years by the Certification Commission. We also need to improve the negative business case and, as was mentioned both in the Quality discussion and by Jodi, there's some important work starting across Health Plans to get this underway. We also know that states have different requirements for e-Prescribing, both the transmission of information and the basic format of a prescription, so we need to be taking a more careful look at the state laws that could be barriers to implementing e-Prescribing. So given that we have a lot of work underway and there's a lot of existing authority and resources across a variety of stakeholders, we think that there is a number of potential accelerators that could be considered by the entire community. In terms of the federal government's actions, we are going to be continuing to evaluate additional standards to fully enable e-Prescribing and we'll

be working very closely with the Certification Commission to make sure that what we learn through those e-Prescribing programs and in addition to the expertise across the federal government and the private sector, that gets incorporated into the requirements to fully enable e-Prescribing that has the kind of clinical decision support and the connectivity that's needed to realize the benefits. We will also be considering guidance to possibly enable or do additional state preemption based on the evidence that we gather on state laws that are prohibitive or definite barriers to e-Prescribing. We'll also continue develop to EHR adoption strategies as was discussed clearly it's now going to be a workgroup that's very focused on this and we think that this really going to be one of the key levers to determine how we're going to drive adoption. In terms of what the Health IT industry can do, clearly in the CMS regulation, one of the Foundation Standards that is now in effect, is the NCPDP script, which actually does enable the connectivity between a physician's office and a pharmacy. We think that, not only should the Health IT industry be adopting this standard, but they need to actually implement the products that have already adopted the standard into the physician's offices so that the 80,000 plus physician's that we know of can actually start e-Prescribing this year. We also need to make sure that the Health IT industry responds to the existence of the Certification Commission and the process that will soon be in place to get electronic health records certified to meet key interoperability and functionality requirements. Physician organizations could play a role by communicating the benefits of e-Prescribing to their membership and to make sure that they understand that if they have already invested in these tools, there's a very good possibility that the vendor that they're working with does have a version that could fully enable the functionality they need. They can also access implementation support through some existing organizations. The Doctor's Office Quality IT Program that's made available through the Quality Improvement Organizations at CMS, has a program that's going to be offered to 5% of Primary Care Physician Practices across the country that will provide them with support through the selection process of electronic health records and the implementation. There's also good resources available at the Health IT National Resource Center and a Physician EHR collaboration that was started over a year ago. There's some member organizations that are trying to support their membership and then there's also a variety of regional organizations that are providing implementation support services. Health plans could do their part by making sure that they continue to offer incentives through pay for performance programs, and we know that that's already going on across the country and hopefully, we're going to see more and more of that, particularly at CMS, and the federal government does their part to move this along. We also think it's important for them to ensure compliance with the Part D Standards, not only is it Foundation Standards, but in the future we'll have a second set of standards that they'll need to comply with. And finally pharmacies, in particular small and independent pharmacies that don't have the software that they need currently to receive an electronic prescription, could be working with vendors and wholesalers to enhance their existing software systems so that they can actually start receiving these prescriptions. So all in all, there's a lot underway. There's a fair amount of existing resources that are available. And if everybody does their part, we feel that we could be realizing significant advances in this area.

Secretary Michael O. Leavitt:

Thank you. I would characterize that if the country had a breakthrough project, as in the way that we have established breakthroughs, that this would be it. I think from Congress to industry to health plans, there's a concerted effort being made. We obviously play a role in being able to inspire a greater adoption of electronic health records. You'll note that our agenda today, that I've chosen not to bring a large portions of this to the community simply because there's so much momentum already moving that I want to make certain that the community knows about that momentum and then can play into it and accelerate it. But given the nature … given where we are with respect to already promulgated proposed rules and standards and so forth, it seems most productive for us to know where that is so we can play into it but not necessarily be part of the direct process. Are there questions, comments, thoughts about that? I'd like to get us on to time schedule and on to our next topic in just a moment but I am anxious to have some conversation on this point. Nancy.

Nancy Davenport-Ennis:
Just one comment I'd like to make Mr. Secretary. Kelly, I think your presentation is outstanding. I'd like to encourage that perhaps in the area of potential accelerators, that we could add the category of consumers. We certainly know the power of the consumer to move when involved in direct to consumer outreach. If consumers can be educated to begin to ask for this service from treating physicians, in an effort to minimize potential medical errors in their treatment, it can certainly be a tool that may advance this initiative forward. I understand it would have to be a tool that would have to build through momentum, but if we can include them in this area of how we do accelerate the acceptance from the beginning, perhaps there's a real opportunity for us to lend some [inaudible] authority to it.

Secretary Michael O. Leavitt:
That's a very thoughtful point. The day that I am able to go to my doctor and have him or her electronically transmit my prescription to my druggist and have them filling it before I leave the parking lot of my doctor's office, will be a day I'll start demanding that, and I believe a lot of other consumers will also. And the day I can leave my doctor's office and go to my electronic health record and see that the prescription has already been recorded there, and I don't have to put it there myself, or otherwise count on waiting for it, that'll be a day I'll feel good. And the day that I don't have to deal with the billing on my insurance because it all integrated, is a day I'll begin to see the real value of this. And I think that's the reason this is such an important breakthrough project because every person on the planet right now, deals with this interaction. And it's an area where we can create greater efficiency. Chip.

Charles N. Kahn III :
I guess two points. One, the 80,000 number, I assume, is probably mostly mechanical. It wouldn't include all of the other kinds of algorithms and things that a doctor might use when they're making the prescription to see whether or not it's the right thing, whether or not there's an alternative generic. I assume that the 80,000 is just some kind of … because that's an awfully large number to have sophisticated systems that could be available to doctors. Is that … I guess I'm … Kev … I'm looking at Kevin because I think he's the one that was the source of that.

Kevin D. Hutchinson:
Well actually the number's low in the sense that it's the number of vendors that have connectivity to a network today that can do electronic prescribing. The reality of the number is about 150 to 160 thousand physicians out there today that are using some device that can electronically prescribe but are either being printed or faxed.

Charles N. Kahn III:
But that's the mechanical.

Kevin D. Hutchinson:
No, these are the large … I would say 90% of those physicians are using an electronic health record versus what some people traditionally call a stand alone e-Prescribing application. So … and those electronic health record systems, in fact, do have the capability to do the look ups as long as it's from the data base. Those EHR systems are not connected to the PBMs or to the payers or to the pharmacies in any type of electronic fashion which is the point, I think, Kelly is trying to make, is that there's a large install base out there that for the last ten years, have been starting to use electronic health records. And even some of the most conservative reports show 20 to 25 percent of physicians out there are using some device:
either electronic health record or an e-Prescribing application.

Charles N. Kahn III :
But, so what's going to make that interactivity happen? Because to know all … to know the insurance issues, to know the generic issues, to know a lot of other issues, there's got to be an interaction between that record and …

Kevin D. Hutchinson:
And … and I think that's the point.

Charles N. Kahn III:
… NRH Hub and the other…

Kevin D. Hutchinson:
Right. And that's the point because those systems are out there today but they're not connected. Their systems are certified so if the example that I think Kelly is giving is if Version 4 is what is certified on a network, they can reach PBMs and payers and pharmacies, but of those 80,000 physicians are on Version 2.5, then they're not connected, even though there is a version available to them today, if they were to upgrade to that version, they would have connectivity to the PBMs and the payers and to the pharmacies as well.

Charles N. Kahn III:
So what's going to make it happen? I guess that's one thing that I agree with you that there's a lot out there but the question is:

What's going to make that happen?

Secretary Michael O. Leavitt:
Well it seems to me that what we saw was the critical path. I have little question that adoption is still part of the dilemma, and yet we have the tension that has to exist between saying, "Let's go out and create widespread adoption of systems that aren't compatible." That doesn't seem to me it drives our vision forward, and so we're moving this forward in a deliberate way but a fast paced way by comparison to lots of other things that happen in the world. And I think the timeline that you saw is one that's realistically, I hope, can be accelerated. Kevin.

Kevin D. Hutchinson:
First of all, I want to applaud the work of HHS, and in particular David Brailer's group in the coordinator's role, in taking a leadership position in this. Where we are today with the roll out of electronic prescribing and the national agenda is because of the Medicare Modernization Act and because of all the work that the government has done to make this a focus. I agree with the decision not to make this a workgroup because of all of the progress that has been attributed to this. Standards that are out there. Regulations are out there. We're doing pilot programs now on those standards. So a lot of progress has been made. I guess two comments that I would have is:
under the Stark and the Anti-Kickback Exceptions, I would ask that we think about the audiences that could participate in deployment of technology to physicians. Do we include … I know we have hospitals under those categories, but I'd ask you to consider labs as well, who have a relationship with physicians who have been deploying technology to physicians for the purpose of delivering lab results to those physicians, either in a paper form which turns into paper and their charts, but ultimately are delivered electronically. So, they would be a very good source of ability to deploy, rapidly deploy technology into those physicians hands, if we could include them in that category. The second item is on the Certification Commission which I know we're going to hear from Dr. Leavitt a little later today. And I think we need to be very careful in assuring that the stand alone e-Prescribing applications have the ability to then from a certification standpoint to interoperate with the electronic health records and move the data from one application to the next as you migrate up from a stand alone e-Prescribing application to a full functioning electronic health record which we all know is the ultimate goal.

Secretary Michael O. Leavitt:
Thank you. Bill.

William Winkenwerder Jr.:
Mr. Secretary, I'll just offer up DOD's willingness to support this effort. I presume we probably had some participation in some of the committee work, but this is an area that we've had a lot of experience in and actually our pharmacy data track, PDTS we call it, Pharmacy Data Transaction System, is really a remarkable system that we've had in place now for about 2-2½ years. It preceded actually the start up of Alta [spelled phonetically] so we've re-sequenced these things and what PDTS does is it connects roughly 12,000 or so Physicians who e-Prescribe and roughly

55 Hospitals and several hundred clinics in the United States with 55,000 pharmacies across the United States. So, because of our networks we have and a relationship with a Pharmacy Benefit Management company who in turn contracts with all those pharmacies, a very broad network. We connect with every pharmacy in the U.S. So any military beneficiary can go to you name it, you know, Rite Aid, CVS, whatever, just about anywhere, and that information is available to the prescribing pharmacist from our docs who prescribe, and it checks for drug-drug interactions. And we believe we've eliminated, I don't know what the number is now, but well in excess of 100,000 adverse drug-drug Interactions, so we're really proud of this one particular system. We'd love to share, you know, and I just hope the sharings going on but I just want to lay that out there because it's a really great system.

Secretary Michael O. Leavitt:
Thank you. Given the fact that this is a conversation that could go on for some time, I'm going to simply suggest we move to our next agenda item to keep us on schedule. We'll now move to a briefing on Privacy and Security Solution for Interoperable Health Information Exchange. Dr. Brailer, I'm going to ask you to make further explanation. I'm going to, as pre-announced, excuse myself for a time and ask Dr. Brailer to Chair.

David Brailer:
Okay, thank you, Mr. Secretary. We're now turning to briefings from the partners and contractors who are working with us to develop the long-term infrastructure. And these are sequenced according to first, Privacy and Security. And you'll hear from Chuck Thompson at RTI and Scott Young at AHRQ, about the efforts they've put together to develop the Health Information Security and Privacy Collaboration and the work there, followed by the Nationwide Health Information Network from John Loonsk and Wes Rishel, and then the Health Information Technology Standards Panel from John Halamka, who is the elected Chair of that group, and then finally the Certification Commission for Health Information Technology from Mark Leavitt, the Chair of that group, whose been mentioned a number of times already this morning. We will do two of these prior to lunch, and then we'll break and then return for the rest. So with that, let me turn it to Chuck and to Scott, and thank you very much for coming.

Chuck Thompson:
Thank you. Good morning. Dr. Brailer, members of the community, and colleagues out there, it's really a pleasure to be here to describe our project. I think our project may be a little different in the focus but it certainly has an importance that will be far reaching. And I appreciate having Scott here to participate in the briefing. Before I move directly into the briefing, I just want to acknowledge the folks that are in that 8 font there on the front slide. You know, you never achieve anything alone and the team that we've got, with Lidadee Metropolus [spelled phonetically] and Mike Samuel at RTI and then my colleague John Thomasian [spelled phonetically] from the National Governors Association is out here in the audience, and then our teammates at ONC and AHRQ have truly made this a very, very productive project and I think when you see some of the things we've achieved in this short time, you will see that it's a hard working group. Let me just give you kind of a snapshot of the environment. Certainly Privacy

and Security has a lot of implications. People do have concerns about it. Consumers do. Certainly those of us in Healthcare and have watched the evolution of technology in Healthcare. It's always been a concern. And what we see in the environment today is that really the existing paradigm for Security and Privacy doesn't really accommodate fully the consumer participation in Health Information Exchange. And, you know, we see that time and time again, and so as you see the process we've designed in our project, you will see how we want to address that. We also know that consumers' organizations and state entities share concerns related to maintaining the Privacy and Security of Health Information. And we also know that in that third bullet when you see that there … we know there are varying practices within the industry as far as Privacy and Security, and a lot of it does deal with the business policies and practices related to information exchange. And as I was listening to the discussion this morning, I think, a lot of times, we undersell the implications of what users, including consumers and practitioners, what they do to accommodate technology. And so in many ways, some of the things we see have evolved to optimize practice, and even as a consumer, for me to get information about my Healthcare needs. We also know that there are many other things besides HIPAA out there that states have done to, in fact, protect Americans. So we know … and that to me is a part of this evolution. And certainly we know that from experience of major initiatives like this, the stakeholders, especially patients and consumers at the state and community levels, must be involved in developing the solutions. They really have a greater insight, many times, to the issues than we do. So the process that we are using is going to take advantage of that. And then we also know that there's a lot of interest out there at the state level in supporting health information exchange in order to improve the public health and healthcare quality, on one side of it. And then on the other side is, in fact, to preserve essential privacy and security protections. I'd like to go in to this project purpose and, again, this contract does have outcomes that are a little different in that we're basically, with this project, looking at variations in organizational level business privacy and security policies and practices. We know that these have evolved over time and again. Many organizations have designed this to optimize their healthcare. And we know that it has both positive and negative impact on health information exchange. And one of the things that, to me, is exciting about this project is:

Most of the time when we think about privacy and security, we start moving to the barriers and the alarms related to it, but in fact there are a lot of good practices, and Best Practices, that have evolved out in the … at the user level, and at the state level, and within the entities. So one of the objectives of this project is, in fact, to capture those Best Practices, to validate them, see how good they are, and then determine if they need or should be exported to a national solution. So it's a great way to look at privacy and security. And then, of course, we want to focus on:

What are the things or the barriers or the negatives that truly impact health information exchange? What are they? How can they be fixed? And how would you implement the fix? So we also recognize that we must preserve privacy and security protections as much as possible and, at the same time, end up with an interoperable electronic health information exchange process. So it is a balance there. Again, our belief is that users and stakeholders have the answers to these questions, and that's what we're about. We certainly want to incorporate state and community interests and promote stakeholders, identifying practical solutions, and implementation strategies that are through an open and consensus building process. And I think

really to me, the important part of that bullet from a user and a clinician, is these practical solutions and strategies that we want to know:
What is the issue, how can we fix it, and what is a practical way of doing that while meeting the goals of interoperable health and privacy and security protection? We certainly want to leave behind, in the states and communities, a knowledge base. We're building a lot of information at both the state level and at the organization level to inform health information exchange that endures after our contract is gone. So we see our role is to build an infrastructure and a process that will go on after we're gone. And I listened to Doctor … to Secretary Leavitt this morning. He described an open process that gives an opportunity to hear from everyone. That was his comment that his goal was to achieve. And I think you'll find what we have tried to do in this project is, in fact, to do that. That's the major goal of that. If you look at our approach, RTI, Research Triangle Institute, is the prime contractor in this. And we are in partnership with the National Governors Association, John Thomasian and his crew, and we are working very closely together to build an approach that is starting at the State level, at the organization level, and building up. The period of performance for this contract is 18 months which is a very, very short time when you think about it and everything we have to do. And when we get to some further slides, you can see it's a very, very aggressive schedule. But what we're going to do in this process is RTI will subcontract with up to 40 states and their entities within the states or territories, to look at … to identify the Best Business Practices that affect electronic health information exchange, to look at solutions and implementation plans. And then we will coordinate with the states and the entities to collaborate on regional and national meetings to develop solutions that will eventually roll up into a national solution. And then of course, we're going to provide a final report at the state level that gives them a very comprehensive look at where they are with privacy and security business practices and policies within their state, and then, not only the report on the policies, but the alternatives for the barriers, and then an implementation strategy. So it's a very comprehensive … addressing the whole issue. At this time, I'd like to turn it over to Dr. Scott Young who will talk to you about the slide describing HISPC. Dr. Young.

Scott Young:
I don't know which button to push.

Chuck Thompson:
There you go.

Scott Young:
Good morning. My name is Scott Young. I direct the Health IT portfolio at AHRQ and it's my pleasure to work on this project with RTI, NGA, and our partners in the National Coordinators Office. I want to describe to you some next steps in the projects, addendums that we envision. And specifically, I'd like to talk about the Health Information Security and Privacy Collaboration, or the Collaboration. We envision the Collaboration as really being able to take that rich body of knowledge that Chuck has just described and putting that in a format, or giving it an opportunity to become actionable, if you will. We're in the process of working with RTI

and NGA in a modification to the contract to allow this HISPC to be created or recognized, if you will. It will be an organization that supports the Collaboration both within and among states and foster participation among state [inaudible] both public and private. It will, in fact, work with our two partners, RTI and NGA, and will include members from state governments, federal governments, and leaders from key non-governmental organizations:
providers, consumers, payers, that sort of a mix. Again, it's to maximize the knowledge, that such rich knowledge base that was described before:
What do we do with that? How can that be utilized? What are the lever arms that it can be moved upon? Via the HISPC, we'll seek a consensus-based solution and implement the plans to many public community based models. So more on that later and let me turn it back over to Chuck.

Chuck Thompson:
Let me spend just a minute to tell you a little bit about RTI. Research Triangle Institute was founded in 1958 and it was the foundational element for Research Triangle Park. And RTI's mission is to improve the human condition by turning knowledge into practice. And to me, there is nothing that epitomizes that mission statement with what we're doing with this project because this is, in fact, a project that is going to bring in significant information and knowledge. But the exciting part about the project is it's going to go back to practice because it is going to influence what we do in the future with privacy and security. RTI really has a wonderful history of multidisciplinary research and policy analysis throughout the federal and commercial sector. I think they're known for solving critical social and scientific problems. And they have multiple areas that I consider relevant expertise, but I think the significant expertise that we bring to this particular project is experience managing large complex federal projects with multiple stakeholders. The process that we design, not only in our proposal, but as we made that real in operations, I think is very important because this is a complex problem of trying to get stakeholders together, trying to make sure that you have full representation, insuring that we have a very good RFP process for states to participate, so it is very complex and I'm excited that we're able to do it. I would direct you to www.RTI.org because you can, in fact, go onto RTI's website and there's a website … there's a link now to HISPC, and also to the state RFPs and the process, the transcript from our first bidder's conference. And so there is information already about this project online and we would hope that you take a look at it. Let's talk about some of the outcomes that we certainly are moving towards, and my team working with the NGA and our ONC and AHRQ staff, this is truly what we're working at. We want a full understanding of the variations in business privacy and security policies and practices at the state and organizational level. We hypothesize it there. We want a picture of what that looks like. And more importantly, what are the good things, the best practices? But also, how is this truly impacting information exchange and where we want to go with the National Health Information Network? We want to use the stakeholder process at the state level to design practical solutions and implementation plans and at the same time, as I stated, while preserving the electronic … preserving privacy and security. And then we want also, through the HISPC, to have a collaborative network that will be established for states and communities, that they, after we're gone, they're going to have an infrastructure in place to move the agenda forward. We also

certainly, and that's why this project fits in so well with RTI's mission, we want the increased knowledge of Best Practices and how to implement those within organizations and the states. We certainly want to use the process and our output to optimize the construction of the National Health Information Network prototypes to inform the architecture and standardization projects. And we're just now starting the collaboration with our partners in these other initiatives. And as we really get into this in greater detail, we will have more of that. And then we also want the states to have access to state, regional, and national Best Practices and solutions to optimize health information exchange. This slide presents the timeline in milestones. And this project was awarded the 30th of September, and we had our kickoff meeting the 7th of November, and it's unbelievable to me how much activity we've had since then. We started out the year with the release of the RFP to the governors' offices and we had 40 Letters of Intent of people interested in responding to our RFPs. We were just really pleased with a very good response because if you think about the timeframe of the holidays and everything going on, but the states are excited about this and they're interested. And then on January 11th, we had our first bidder's conference. We had 60 participants and 33 states represented. We have our second bidder's conference coming up the 8th of February. And then proposals are due in March. And then we have subcontracts being set, and so lots of activity starting. If you look, we have interim reports and solutions, interim plans. We're expecting to roll all of this up to a national meeting sometime in February of 2007, with this contract ending in March, and having all of the reporting, and all the process, and all the planning and information like that, available both at the State level and certainly to inform you as the Community, for next steps in how you want to go forward with this. That's the end of my comments and I would welcome any of your questions or comments.

David Brailer:
Okay, thank you, Chuck and Scott for coming. And clearly this is a very important part of our efforts:
to make sure that we have the protections in place as we move into this era of digital healthcare. And so this is something I expect the community will be hearing a lot about as we go forward. With that, let's turn to your comments and discussion about this project in particular, about the topic privacy and security in general. Mark.

Mark:
[Mark B. McClellan, Mark J. Warshawsky, PhD, or Mark Leavitt, Ph.D.?]
Just sort of an observation, maybe it will turn into a question. The approach you're taking is very much to do with the states and sort of then work through that mechanism. I presume and this is sort of a question, the state law that's relevant, but you also mentioned HIPAA, so is there a need for sort of any federal involvement? And I'm just curious as to whether there are other controlling authorities, perhaps, through professional associations, Physicians and others, that are relevant as controlling authorities here.

Chuck Thompson:

I can address that from my perspective and Dr. Brailer may have a perspective on that also. Basically, when we look at the stakeholders, we see them as full stakeholders, full representation. We also see the interaction with HIMS [spelled phonetically] and AHEMA [spelled phonetically] and many other organizations that will have an impact on this. So yes our focus is state. We also recognize that how we design the stakeholder groups, the steering committees, the different representation, and that's why we'd suggest you look at those RFPs because from the evaluation methodology, you get a sense of some of the things that we're trying to steer towards. So we hope to capture, we certainly, the focus is at the state and the local level so we know what those issues are. But we know that they will in fact … we will be interacting with not only the other projects, with Dr. Brailer and the entire to insure that the federal side of this is included.

David Brailer:
Perhaps a few thoughts on that, Mark. We're obviously quite aware of the interplay between federal rules under HIPAA and other things that drive privacy at the national level and in the state activities. We chose this vehicle to focus on states for two reasons. One, the majority of Americans have the minimum rules for privacy set by state actions, since many states have superceded HIPAA. And secondly, the particular issue that we're driving into here is the variations in implementation of privacy rules across states. And so this federal-state dialogue, this kind of federalism approach is very much a way to bring states together, but also with federal officials, in the HISPC and in the meetings that would lead up to that. Groups from my office, from the Office of Civil Rights, from the Office of General Counsel, other groups in the federal government that set privacy policies or interpret regulations, will be in direct dialogue with that group. The federal task force that will blend into the Health IT Policy Council, that the Secretary described, is already focused on some of the privacy issues to begin constructing an agenda for what does it take to set these in place. So it's not a value statement of one or the other; it is a value statement to make sure that it's not just a federal dialogue in that we have the states there from the get go. And we recognize that the state vehicle, not only in this area, but in others, can help us go much further faster. Ed ?

Male Participant Questioner:
Could you, let me just ask you, I guess, about outcome from this. Do you see as an outcome, a set of harmonized state policies or eventually a single policy down the line? What's your vision of what would come from this process?

Scott Young:
Well a couple of things. One is, as we described, we're trying to … if you think about these interplay between federal and state laws, regulations, and rules right now, it looks like a mountain range where the federal statutes are the floor of the mountain and there's a lot of different peaks. We're just trying to define what that mountain range looks like right now, develop that knowledge base. The next thing is to hand that off, hand that knowledge off, not only to state decision makers but also HISPC, and let them actually interplay with it and find out, you know, where does it make sense, you know, to change practices, to modify practices, to actually kind of create a clear path. So I think that would be one of the prime outcomes, just one

definitional, trying to actually discover what's known and what's not known. And the next is trying to, you know, encourage bodies to actually make decisions within that. I actually would like to turn over to David to build on that if you don't mind.

David Brailer:
Well, I think yes, a great question, and I don't think we've tried to presume what the form of the answer looks like or how we structuralize the policy architecture to have uniform privacy and security policies that are also forward looking into this digital era. But one element that is quite important, and to echo off of the last discussion that we had about this under Mark's question, is that the states are directly involved in this up front. So we've looked very closely at things, for example, that have been done recently where in adopting uniform e-sales tax, e-commerce sales tax structures. And we now have 18 states that have adopted uniform and harmonized state policies around uniform e-commerce taxes. That's an example of a state based initiative built around replicating model legislation. And that structure could lend itself here because harmonization or alignment is one of the key goals that we want to have. Now the interplay of this clearly with Congress or with statutory drives are an unknown at this point. The goal of this is not to create a Congressional agenda but it's to identify what it does take and if there's a role for the federal government to set new minimum changes or to guide this process more than we will through the HISPC, then that clearly will become something that's identified and discussed. But I think given the way that we came to where we are, this has to be lead by states beginning to look at their policies. There's one other facet to it I'll mention which is because we're dealing with policies that influence the smallest doctor's office, a doctor and perhaps a couple of part time staff, to some of the largest healthcare organizations that have billions of dollars in revenue, there's a significant degree of business policy latitude allowed by public policy. Different private organizations, doctors' offices or hospitals, can implement privacy and security rules in different ways and still be within the law. And so I think there's also a role here for beginning to develop more uniform business policies around how this works. We could never regulate down to the line item of what it is that's done. And so this is one of the reasons that each state itself is convening a group of stakeholders to come together. But in this stage of feasibility and definition of the problem and identification of best practices, we're not trying to presuppose what the form of this solution looks like but again, our value statement is the states are ever present in leading this. Kevin.

Kevin D. Hutchinson:
I assume the mission of the group is harmonization of policy but it's not really looking at, when it says privacy and security, they're not looking at authentification processes or encryption levels for keeping data secure. Correct? It's more around the policies and guidelines around it at a state, local, and federal level. I just want to make sure I understand that.

[David Brailer?]:
That is correct.

Kevin D. Hutchinson:

Okay.

David Brailer:
Other thoughts, comments, or questions about this. Rob.

Robert M. Kolodner:
As you look at the policies, are you also looking into the future when we do have identifiers so that if there are technologies, or when there are technologies to identify us uniquely that the consumer themselves can play a role in terms of the … how their information is released in a way that today is more handled by policy than … or what signature than electronic solutions?

Chuck Thompson:
You know, Dr. Kolodner, I think what'll happen is because different states are in different stages of implementation of Health IT, I think at the state level we will find some of those that, in fact, will come forward because we're going to have a very robust group of stakeholders, definitely Health IT and Health Policy will be in there, and so I think some of the states will come forward with that and that will in fact be a part of their recommendation and solution. Some states will not, but I think that's what we're going to see in this project is because we're going to have this wide variety, we hope to get the full picture and we hope to end up with those futuristic things that will be a part of their recommendations when they come forward.

Scott Young:
It was interesting just in the bidder's call that we just had to see the wide spectrum of places where states are. I mean, all the way from some very forward thinking policy makers at the state level to ones who are dealing some fairly basic issues and everything in between. So you know, it'll be exciting again to see what comes out of that mix.

David Brailer:
Nancy.

Nancy Davenport-Ennis:
Dr. Brailer, I think there're just two comments I would like to make. First, let me say it is refreshing to hear the role of the consumer that you anticipate in the process. On behalf of so many consumers that are going to have health information being transmitted between their health plan and their providers. I think it is important to note for the record that there has to be collaboration between what's happening in the state and the federal level because we all know that the state is only going to have regulatory for those plans that are not being regulated by ARITHA [spelled phonetically] at the federal level. And so as we're looking at the issue of privacy and security and we're working with states to try to more clearly define where they are in that process of developing it, likewise we have to look at the federal floor for assuring privacy and security of this medical information that's being transmitted through the ARITHA [spelled phonetically] Plan process also.

Dr. David Brailer:
Thank you. Any other comments on this? Okay. Thank you Chuck and thank you Scott. You'll all hear more from them in the future, including the State leaders as they come forward to work with us.

Alright we're now going to shift attention to the Nationwide Health Information Network. This task is being overseen by the Office of Interoperability and Standards and the Office of the National Coordinator. And that office is lead by Dr. John Loonsk and he's working with, at our office level, Wes Rishel, who is an officer of the Gardner Group and a very highly regarded figure in the area of Interoperability and Standards and someone that has advised our office from very early on in our work. This work is unique in the Nationwide Health Information Network in that we have four contractors working in parallel and in concert to achieve the goals that we've laid out. So you'll hear from me to them quite briefly but the overview will given by John and Wes. Let me turn it to them.

John Loonsk:
Thank you David. The Nationwide Health Information Network is a critical component in moving the broad Health IT agenda forward. There are some questions to be answered but even more so, there are different approaches to be considered in how some of these activities will architected, how they will all fit together and that's what this project is about. I know that many of you have been anxiously awaiting the technical Geek talk, and this may be as close as you get to that. But we're going to start with someone who is definitely not a geek but has a lot of familiarity with the technologies and the history of the industry in this regard and that's Wes Rishel. So Wes is going to set the landscape and talk a little bit about the role for architecture in this.

Wes Rishel:
Thank you John. I consider myself a recovering Geek. The current landscape, the scan of the environment involves a lot of information that's been discussed already today between the comments of speakers and the comments of the commissioners. There's a famous quotation that came out of the work of the Institute of Medicine that said that the "practice of medicine has exceeded the bounds of unaided human cognition." And to this I'd like to add, the collaboration associated with medicine has exceeded the bounds of the fax machine. And we are clearly in a place now where we are losing opportunities to improve both the practice of medicine and the collaboration of medicine through the lack of better systems and better interoperability in the environment. The … a lot of the current activity that's going on, as is very typical in our country, is coming at the level of the regions. And there's a lot of reasons why this diversity is a very fortunate thing. The regions are really where, what Dr. Leavitt refers to as the sociology, is the most amenable to a collaborative solution. This includes not only attitudes and concerns about various aspects, but it also includes the underlying business problems that are different in a rural community than a bigger community. They're different in a community that's dominated by a few employers and a community that has a large number of employers or so forth. We've had a few successes in the area of regional networks and those have been exercises in building

up trust and solving of sociology problems. Those successes have also surmounted an extremely difficult technological hurdle which we hope to improve in the future which is they've had to develop their own technology solutions for the sharing of information. And of course they've had to … they've had the liberty of ignoring those issues of sharing information beyond the region because of their regional focus. What we need is a way to let those trust building collaboratives be freed of the technological risk associated with what they're doing. Doing any technology brings the risk of cost, of delay, and all of the general risks of being a pioneer. Each network being self developed or custom developed by a contractor is unique and carries the burdens of uniqueness in terms of cost. And once again, they're not directly addressing requirements for collaboration. If what we can do through our effort is create a market so that the needs of these regional and other sub-network organizations can achieve economies of scale and address the leverage, the experience of one region and another region and allow vendors to develop products that are targeted, that are nationally marketable, then we will have achieved the removal of one of the barriers towards Health Information Interchange. The need to do that is really not that different than a number of industries where the right amount of standards, standard architecture, standards of information exchange, is just enough to free us to be able to have a competitive market and to be able to exchange information. There's a number of aspects to that problem and the top most aspect is the sociology, the practices and policy, that go into the decisions of what to automate and what information to exchange. At the same time, we have to recognize that part of this problem is building an infrastructure. We don't build a separate set of highways for trucks and commuters, although there are truckers and commuters who wish we did. And we need to address the commonality among the different breakthroughs, among the different other major initiatives in healthcare so that we do have a common infrastructure. The policy of architecture really is enough to identify that commonality. The standards are then the enablers that allow multiple systems from multiple sources to interact just enough to be able to meet the needs and certification is the process by which we give the consumers of these systems, in this case the buyers of these systems, whether they be the direct buyers in terms of healthcare organizations, or whether they be the funders, the payers that might provide incentives or support, the assurance that they're supporting the right products. That takes this active role of certification. The work we're talking about today is the architecture and standards.

John Loonsk:
Thank you, Wes. Into this milieu, the NHIN project is intended to eventually develop a widely available and easy to use, inexpensive, and secure set of services to exchange health information. This is the guts of the exchange and interoperability necessary to realize much of the agenda for Health IT. There's a need to interconnect electronic health records. There's a need to move medical information to inform clinicians and follow the consumer as well as provide a platform for quality initiatives and support other activities such as [inaudible] health and bioterrorism. To do this, we're phasing the activity. As I indicated earlier, there are still questions and approaches to be considered. In the first phase of the activity is to develop some potential architectures, four in all, that will feed into the development of a broad accepted national architecture for how these systems can work and work together. The development of those architectures will include the delivery of information and needs to standards harmonization and certification and it will also

deliver four prototypes that demonstrate the viability of those architectural components. Finally, in the short term, we anticipate having a deliverable of a business model for the sustainability of such a service so that this can be carried on in subsequent years to support these needs and activities. So in the future, we will have this shared architecture with the best elements from these four prototypes. We will move toward operational implementations and we will develop this environment for sustainability of this widely available, or widely available services. Where we are with this is that Phase One is currently underway. Four contracts were awarded by the Office of the National Coordinator in Health and Human Services. These contracts are intended to help contribute to the development of the NHIN architecture and to develop these working prototypes that express this viability of the particular approaches that were taken into that particular architectural implementation. These contracts are really the … a consortia, each and unto itself. And each has a lead, which is a prime and those are Accenture, CSC, IBM and Northrop Grumman. But there are also a variety of different health information technology organizations participating in each of these as well as explicitly three healthcare markets that need to participate in the implementation of the prototype as well as working through the issues of architecture that relate to that particular implementation. In parallel to this, we will be having open public meetings where we will be taking the best aspects of the architecture contributions from these four different consortia and providing those for review and for advancement to get to this shared architecture for how the Nationwide Health Information Network can move forward. With that, I'd like to turn to each of the four consortia and have them briefly give an introduction to who they are and who's participating in their group. And we'll be starting with Brian Kelly who's representing Accenture. Brian.

Brian Kelly:
Good morning Dr. Brailer. First of all, I'm Brian Kelly from Accenture, a part of our U.S. Federal Health Practice and I'm very excited to be here today to just briefly tell you about the Accenture team that will be participating in this new contract. We're very fortunate that we actually have 13 partners in addition to the 15 provider organizations that will be helping us build an architecture that will facilitate sharing of data to support the interoperability needed to improve healthcare. What's really exciting about this is that our company, Accenture, as well as all of our partners, share very much the goals of what the nation's trying to accomplish here. Accenture, in the United States alone, is over 4,000 people, professionals dedicated to the healthcare sector. And one of our main goals is to try to integrate, basically, the payer organizations that we support, the provider organizations that we support, and the oharmaceutical industry that we support, to share data to improve healthcare. A little bit about our partners and our distinct healthcare markets – we will be performing the NHIN Prototype in Appalachia. We have three distinct Healthcare markets:
one lead by CareSpark, which is in the tri-city region of Tennessee and southwest Virginia. We also will be working with the Eastern Kentucky Regional Health Information Organization which is in the areas of Hazard County and Lexington, Kentucky as well as the West Virginia eHealth Initiative throughout West Virginia. Our partners include technology companies such as Apleon, a leading terminology vendor, Cisco, CGI-AMS, Creative Computer Solutions, eTech Security Pro, Intellithought, Lucent Glow, Oakland Consulting, Oracle, and Quovadx. As you

can see, we have a combination of both large and small businesses that bring the skill sets we need and the understanding of the local markets that we think we need to be successful. We're very excited about this project and look forward to working with all of you and our other consortia partners to make this successful. Thank you.

John Loonsk:
Thank you Brian. The second consortium is lead by Computer Sciences Corporation and we have Jared O'Dare [spelled phonetically] here to talk a little bit about that group.

Jared O'Dare [spelled phonetically]:
Thank you. Good morning. I am Jared O'Dare [spelled phoneticcally]. I'm from Computer Sciences Corporation and I am the Program Director for the Connecting for Health Team. Our slide introduces you to our team members and healthcare markets which offers seamless multi-stakeholder solution to meet the wide ranging needs of a NHIN. Many on the team, as well as others in this room, have worked together under the umbrella of the Connecting for Health Initiative. Connecting for Health is a unique, diverse group of organizations working together to develop consensus around flexible strategies to address the barriers that have slowed the development of an Electronic Health Information System. We are moving forward by building on the successes of the Connecting for Health Prototype work. Our approach to the NHIN is premised on a Connecting for Health common framework which offers a set of policy, principles, guidelines, and technical specifications to facilitate electronic sharing of medical information among authorized individuals and institutions, while protecting privacy and securing personal information. The underlying belief driving the model is that protecting privacy is of paramount importance. In our model, personal health information remains in the hands of those who collect it:
doctors, patients, hospitals, pharmacies. And these entities remain responsible for decisions about whether and when to share it. We believe that by marrying vetted policy principles to establish technologies, we can create an information environment where patients, healthcare professionals, public health agencies, can communicate using diverse applications and plug and play, just as with the internet. The role of the network is enabling interconnectivity and promoting interoperability. Development of a flexible network using standard data representation and protocols will enable the use of a great variety of applications including those that exist today and yet to be developed. Our plan is to leverage the common framework and develop a reference architecture at the National level. Our goal is to develop an architecture that in its simplicity will allow easy adoption and use. We have been working together on a prototype implemented on three different platforms providing a wide range of deployment options. Let me share with you the diversity of our healthcare markets that reflect the reality of our industry. Mendocino Health Records Exchange incorporating safety net clinics in a rural healthcare market hold some data centrally while other data is held by the institutions. They are dedicated to open source tools. Indiana Health Information Exchange and its work with the Regenstrief Institute is based on centrally managed data repository and is using commercial as well as open source java tools. Massachusetts Share takes completely federated view of data and uses Microsoft tools. Demonstrating the capabilities of the prototype in such diverse healthcare

markets is essential as no one wants to rip and replace existing investments. The members of our team have a strong working knowledge, shared interest and direct experience in achieving project goals to the interactions with each other, with the Federal agencies, and the private sector organizations, working to accelerate adoption of Health IT.

John Loonsk:
Thank you Jared [spelled phonetically]. The third consortium is lead by IBM and today we have Jenny Wagner who's here to tell us briefly about the participants in that consortium.

Jenny Wagner:
Thank you and good morning. It is really my pleasure to serve as the Project Executive for the National Health Information Network Prototype Project for IBM. IBM is very excited about this project, both as a technology firm, as an employer, and personally for all of us on the team, as consumers, for this project. As you know, IBM is an international leader in all aspects of information technology serving in research, development, consulting, and delivery. I think everyone knows that. We're a full service company:
hardware, software, services, consulting, delivery. And we fully intend to leverage our extensive business partner relationships for this project, both business partners and our client relationships. IBM has a long history in developing new and innovative solutions across many industries, to solve real business problems. Over the past few years, however, IBM has made an extensive investment in healthcare and life sciences, and we intend to bring that to bare for this project. We have current special focus on the information-based medicine that has been evolving over the last year or so in IBM. We're bringing technologies and services that contribute to solving the issues facing our healthcare system today. We will apply information in technology that we have in diagnostics, drugs, medical care, and interoperability among the various stakeholders within the healthcare system. And that should involve consumers, by the way. I reflect and embrace what I have heard here today. It may be of interest to this group to know that IBM has recently announced and is adopting the Personal Health Record for all of our employees worldwide. This week, IBM announced that for the 13th consecutive year, we have topped the U.S. Patents Office's annual list of top Patentees. We have 4500 inventers at IBM that have developed more that 2900 Patents in the past year alone. We have eight world-renowned laboratories including Watson and Almaden in the United States. And we have a specific research area in Healthcare and Clinical Research in those areas and those will be leveraged. The core team for IBM is here with us today and you can … I would certainly invite you to talk with them at any point in time. They all are healthcare professionals that have been in this field for quite some time. Our healthcare markets are the Taconic Health Information Network and Community represented by Dr. John Blair, the President and CEO of Taconic IPA, and he is here in the audience with us today. Our other two Healthcare markets …
[end of

Female Speaker:

…the North Carolina Information and Communications Alliance. There are two separate areas, distinctly different:
the research triangle area, of course an urban area, and then the North Carolina Healthcare Information and Communications Alliance of Rockingham County, and that's a very rural area. The interesting thing about our healthcare markets is this is the greatest concentrated area of IBM employees anywhere in the country. So we feel that there is potential for great interchange there as well. Our other partners are basically Argosy Omnimedia, Business Innovation, Sysco, HMS Technologies, Ideal Solutions, and [unintelligible]. They will be providing staffing to our project. The ones that are not listed are the business partners that will have relationships, and those will be driven by the healthcare marketplaces, the selections of the products that we'll be working with. We think that's very important that that happens so that we'll have stakeholders' participation and selection of those products. But the thing that is most important is that we're product agnostic and really believe that this has to be as CSC just stated, it has to be a plug and play. And it has to be so that the investment that has already sunk will continue -- will not be in vain for the people that have made that investment. Physicians, hospitals cannot afford to have that happen. Thank you.

Dr. Leavitt:
Thank you, Jenny. And last but not least, Rym Cothrin [spelled phonetically] from Northrop Grummun [spelled phonetically] will tell you a little bit about that consortium.

Rym Cothrin [spelled phonetically]:
Thank you Dr. Leavitt. My name is Rym Cothrin [spelled phonetically], I'm chief scientist for Health Solutions, the program manager for the NHIN Architecture Prototype program for Northrup Grummum[spelled phonetically]. Many of you may not be awareof Northrup Grummun's [spelled phonetically] dedication to and experience in health information technology and is probably illustrated best through a few of our programs. We support the development and deployment of ALTA, which is the enterprise EHR system developed for the DOD and currently supporting over 7,000 physicians and over 7 million beneficiaries. We support the development of FHIEBHIE which is a nationwide health information exchange that links VA hospitals and clinics together, and most recently provides by directional health information exchange with selected DOD medical facilities. And we support the public health information network and other surveillance and response initiatives of the CDC and state and local governments. What this means is that we apply health information technology to support the individual personal health from the soldier that's on the ground in Iraq to the aging veteran's that here at home. And we support public health from the community to the entire US population. So as you can imagine we're very excited to be part of the NHIN program, that will be part of bringing electronic health records to every American citizen. Our strategy in addressing our healthcare markets is to both leverage existing collaboration in health information and to foster new collaborations. Our healthcare markets include the Santa Cruz Rio and Santa Cruz County, California, which is really spearheaded by Western Medical Associates IPA where they're using health information exchange, workflow tools and collaboration tools pn the desktops of physicians both in the hospitals and in independent practices. The greater Cincinnati

Healthbridge, which is a self-sustaining Rio in the greater Cincinnati area that not only incorporates hospitals, clinics, specialty clinics, imaging centers, laboratories, and independent physicians, but also overcomes the artificial boundaries that are state lines and includes members in Ohio, Kentucky, and Indiana. And then a number of institutions in the Cleveland area that include University Hospital's health system, the Cleveland Clinic health system, and MetroHealth system. Where rather than having an existing exchange among these institutions, they can leverage their current institutional electronic capabilities on top of the NHIN framework to produce something new. We're also seeking clinical advice and guidance from three other institutions including Swedish [spelled phonetically] medical center, where they have an ongoing information exchange among the hospitals there in Seattle, from the Waterbury Health Access program in Waterbury, Connecticut, the developing program that emphasizes at least in part electronic health records for safety net providers and Economa [spelled phonetically] Health System in western Pennsylvania where we're hoping to ensure that our architecture addresses rural America where automation electronic health records is largely absent. Finally, we're rounding out our team with a number of technology partners that include Oracle and See Beyond [spelled phonetically], now part of Sun Microsystems, which bring technologies and expertise, and health information management and integration, includes CSSS.net and Spherecome Enterprises [spelled phonetically] which are small, disadvantaged business partners who are providing security and testing services, and Axlelottal [spelled phonetically] First Consulting Group and Emdion [spelled phonetically] that all have technologies and experience in deploying electronic health records and tools to use them from private physicians through clinics, and into hospitals and Rios. Finally, I want to say we're very excited to be working with you, and to be part of this important effort. Thank you.

Male Speaker:
Thank you, Rym [spelled phonetically]. So a brief timeline for the next steps in the nationwide health information network project. Tomorrow, the various consortia will be contributing to the documentation of some of the breakthrough opportunities that this group has been talking about. In the spring, each of the consortia will be contributing and working through detailed technical designs and architectures, as well as recommending data and technical standards and security policies. In the summer, we're going to have some detailed deployment plans, and operational plans for the prototypes as well as revenue and cost models for the business models for sustaining this activity in subsequent years. In the fall, we'll be finishing prototype development, and then there will be live demonstrations and an evaluation of the different functional prototypes. At the same time, we view there to be some low hanging fruit, and early opportunities for moving these architectural activities forward that include a better understanding of the requirements of these breakthrough opportunities, an identification of the architecture and standard needs that must be there to support the breakthroughs, as well as fostering the critical data exchange for these activities and setting the way for how some of that can be done. At the same time, much as in the relationship between the infrastructure and the breakthroughs in Dr. Brailer's first slide, there is a need to develop some common foundational capabilities to support the growth. There's a need to make sure that these breakthroughs can work together, and some of these common capabilities can support multiple breakthroughs in advancing needs such as

patient-record locators, the general internet standards that are applicable to these different activities, approaches for authentication and access control, as well as approaches for privacy protections and solutions in that regard. With that, I'd like to thank you for this opportunity to talk about the NHIN and we'll be open to questions.

Male Speaker:
Okay, thank you, John. Thank you, Wes. With that, let me turn to the community for discussion. Craig?

Craig:
What happens at the end of '06? You've got at least four separate solutions, maybe 12 if I understood each group has three separate implementations. What do you do with them?

Male Speaker:
We really have two parallel processes. One is to get to more viable prototypes that can be demonstrated through actual operation on clinical data. But the other is to throughout the year to be working a joint consortia activity of teasing out the architectural elements that are common and the needs that are common to feed the standardization needs of the standards-harmonization process that you'll hear about in a little while, and to feed the certification needs of some of the interoperability need for these activities. So out of these activities, of this year, we intend to have an opportunity to bring together the best architectural components from these four consortia and move into a next step of then taking those shared architectural aspects and implementing them in operational activities in subsequent time. David?

David Brailer:
Perhaps a comment on the side comment you made, about twelve, not four. The reason that we've asked each of the contractors to test in three markets, is in fact a stress test that they're able to develop a more robust solution and implement a common non customized solution in three different markets. So this should be four, and not twelve. Now clearly the issue becomes, when does the integration end and the customization begin, such that in fact they're not common solutions, and that's one of the discovery items that we're going to learn about through the project. But we expect that we will ask for continued funding to support this project, in '07, perhaps not in its form, but to build on where it is. But in the end, we want to do two large things with this. One, distress test the work we're doing in standards and certification to make sure that they're not just academic exercises that generate paperwork; that they actually can be built under real solutions. And two, to induce the supply side to step up and have solutions that can be made available to regional projects and to others. So that over time we expect for industry investment to replace government investment in this area, and the question becomes when and how much effort does it take for that to happen? And this is one of the things we'll learn during this first year effort. But we're committed to this for the long term, to make sure that this can under way. Ed?

Ed:

I really appreciate the level of geekness in this, for one thing, but the -- how intense the feelings are, the parts of the people who just spoke, you can really feel that. I think this really very, very exciting. There is something, though, that I was kind of struck by. When I think of a healthcare market, I think of it in the term that you just used, David, which is regional. But it wasn't clear to me that all of the markets that were spelled out here were regional in the sense of comprehensive, for all of the people in a region. It certainly seemed to be the case with the last set of three, but I don't know those in any detail. But some of them seemed to be, if I'm interpreting right what I saw, it's picking a portion of a population within a region.

Male Speaker:
And I think that's a good insight. And you know, part of what you're saying here is the spectrum of maturity of regional organizations. And some that are here are relatively primitive regional infrastructures. And others are very sophisticated and pretty mature. In fact, are some that I would identify as leading the nation. And so there is a diversity first. But secondly, and I think to a large degree more importantly, the question you're asking is one of how do we turn the principle of working with the region into contract language that the federal government can administer? And we ended up actually laying out particular criteria of the number of different types of competing organizations that could constitute a market. And each contractor had to pick three different markets that were not overlapping, and each had to be constituted by a certain number of possibles, or doctor groups, or others, that were there in various types of each of those. So it wasn't just a solo hospital market, or just a physician group. So part of that is just how we administer the actual contract process. But we believe through our evaluation process, and this was a highly, highly competed set of contracts. These four contractors were evaluated to a large degree on the quality of the market partners that they brought forward, and our due diligence about are these market partners able to deliver their piece and participate. So I actually think this is a very good representation, because we didn't want to just deal with only the most mature regional organizations. So some of these have more work than others to be able to pull some of their markets forward, but I think it's going to teach us what we need to know about how to make this very broadly available across the United States.

Male Speaker:
I think an interesting part of the evaluation then, would be to look at it from a geographic point of view, and look at the population. And for some of these, see what portion of the population has access to this network, and what portion doesn't have access to it. And I think that would be some very interesting and useful insights into how to move forward.

Male Speaker:
Definitely something we'll take into advisement as we go into the evaluation phase. Mark.

Mark:
Just one question. In Slide 13 you had revenue and cost models, or you call them business models. Is this something that you are going to, in the office, going to impose on each of the

contracts in terms of the same assumptions, the same approach, or is each contractor going to do it on their own, and are you sure that it's going to be pretty consistent across the four contracts?

Male Speaker:
It is more the latter, where we're looking for input from the different consortia as to how that business model can be composed so that it can be sustainable. Like the other activities, there's going to be a need for harmonization of these different architectural components and other products from the consortia, and that's one of the things we anticipate coming from these shared public meetings that we're going to have.

Mark:
So you think that'll be enough to make sure that's consistent.

Male Speaker:
We think that each of them will feed elements to an eventual model, but that there's going to be a need for an additional process on top of that to make that into a consistent activity.

Male Speaker:
Well, Mark, I think it's worth bearing in mind this is an issue we've thought a lot about. That each of the contractors is developing an independent technical and business solution to this problem, such that the way they would view the cost, or the revenue accrual process against that could be quite different simply because of how they view the solution working. So it's inherently differently, and what we're bringing to this through the collaborative process across the contractors, because they're not competing in the sense that there's going to be a rank ordering of who won, or who lost. They're working independently, and actually quite collaboratively, developing a common language for how to specify the elements of the business case. How do we measure cost factors, how do we take into account depreciation costs or the marginal costs of technologies that are leveraged because they were in place for other purposes? Or how do we deal with the allocation of fixed costs, whenever shared across community infrastructures? Likewise, in the revenue apportionment methods, the question becomes how do we account for overhead costs and other things. But largely there, we're looking for how it is that one can view how units of service can be measured and therefore posted against business volume. So our hope is to give them a common framework, or a common vocabulary, common set of rules, probably not down to accounting rules, that they can work again, so at least we can compare the different kinds of apples in a relatively common purpose. But we don't want to tell them how they should think about the actual elements of the cost model themselves. Does that help? Kevin?

Kevin D. Hutchinson:
David, can you clarify with the pilots -- are these to be viewed as potentially scalable to be a national network, because there's recently been quoted as saying the Rios need to morph into maybe something else in the future. But from a regional perspective, are we still looking at a

regional information network tied into a national structure, or are these pilots something that eventually could be a national structure?

David Brailer:
Yeah, I've had more discussion about that one sentence that I was quoted on in the past few months. Getting a lot of letters. The overarching answer is, we will see from this project how far that can go. Let me go back to the core issue. We know that we do not want to end up if we can achieve an interoperable world, of a dozen scores or hundreds of interoperable silos, where each region can actually share data around their periphery but they can't officially transmit across that area. Is that better than where we are? Sure. Does that lose a profound opportunity for the American public? Yes. So we're going to go for broke here and try to make sure that the capacity to share data is a national asset. But on the other hand we recognize that it's not a technology solution to the Secretary's thoughts, the sociology, the governance of this, we believe, should not be national. The federal government, or a national party, should not govern how information is shared across the whole US, because of the huge variations in regional attributes of markets. Therefore, we think there is an interplay of regional oversight with a technical infrastructure. So the possible solutions could be the following:
there is a national network that literally ties itself directly into the EHR in a doctor's office. And the overlay of business rules and things from the regional oversight determine what's happening with that, but it actually doesn't provide connectivity. Secondly, there's a regional network that's tied to a national network that bridges across them. That could be a solution. Or there could be a national set of tools that are built by various regional or super-regional projects to be able to collaborate together and they could also be non-regional projects, for example children's hospitals or cancer --

[end of tape]

…are not really a regional concept, but they are certainly a community of common interest. I think it's going to be something more like all three of the above, some highly mature regional projects will build their own infrastructure. They're already far along, and the national effort would be to tie into that. Many rural areas and others, I don't think, will be able to develop the economics or the technical capacity to build a regional network, and we can't rely upon that happening as a matter of course. In those circumstances, we have to be prepared to tie directly in, and I certainly hope that we can make it easier to the third point, for every regional project to not be software companies that they don't want to be. This has been the rate-limiting step in many, many projects, that they choose to do something, they have common goals, they can understand how they're going to do things, and then they start working through the technical issues. They're expensive, they require very, very specialized knowledge, and they become a real rate-limiting step on projects. So it's our hope that at the minimum to make sure that if I'm a regional effort and I'm ready to go, that I have a group of willing national suppliers that can bring me a solution that is compatible with the federal efforts.

In the end, we expect these architectures to be turned over to the certification commission to be certified, and the concept here, in a very simplistic way is a certified architecture can plug into a certified electronic health record, and we begin getting some degree of modularity about connecting health information. That's a long way. That's probably a couple of years out, before we can get to that point, but we're moving in that direction today. So I see it really being a world where we decide over the next year what the real contours of implementation solutions look like, but today I've encouraged every regional project to continue doing what it's doing until there's a better alternative, and our goal -- all of our goal, I think, is to provide better alternatives.

Male Speaker:
That -- well, you -- you had me -- there's been something about this whole discussion. It's just been kind of gnawing at my gut, and maybe people will start writing me letters after a while I want to say David rather than you, but [laughter] I think -- think you know about half of providers and patients that we will have missed a huge opportunity if, at the end of this exercise, we don't have a national network for transmitting this information. If I'm a patient, I want my physician or other providers to be able to send information to wherever I want it to go, or it needs to go, whether it's to another physician, to a hospital, to an ER, to a laboratory, whatever, vice versa, or to go from me as the patient to my physician's office for -- from my physician's office into my personal health record -- whatever it needs to go, it needs to go, and I don't want state or regional or capitalistic enterprises getting in the way of that. We will miss a huge opportunity if we don't have a national network that allows this to occur. I -- you know, I can use the internet that way now, I just have to have a way to get on the internet, but once I get there, I can send things wherever it goes, and I don't have to worry about other artificial barriers. We shouldn't have to worry about those barriers here as well, and if it takes the community to make that statement, then I'm prepared to make that statement as a member of the community. We need to make that happen.

Male Speaker:
I think that is -- that is the value statement that my office has been founded upon. That's the charge that I've gotten from the President and the Secretary, and the question becomes, "How do we actually implement that seamlessness?" Does that mean a single unified national set of pipes that go every place, or does it mean something that allows the flexibility for where there's a big corporate network because of a big health care system has a lot of that in place, and we don't tie everyone of their hospital, but just to one point of access, or regional infrastructure that is there. Those are, I think, the questions that we should absolutely expect seamlessness from, but the question that we're dealing with here is:
how far can we go, and do we need to go to have the tools or the capacity to reach out and connect to things? And now we're going to learn that, and the reason we have a diversity of markets in these experiments is to find out exactly what the difference is between a very mature network, and one that's primitive in terms of it's -- it's early in it's process, but we absolutely expect to have a seamless set of information flow around doctors, hospitals, consumers, labs, pharmacies, etc., to be able to achieve the goals that have been laid out, and particularly by the

way of -- as we add on the other goals of biosurveillance, quality reporting, you know, there's a compelling national interest in having a unified architecture beyond just the platitudes of "it's a good thing to do." We have to have that to achieve our operating goals. Nancy?

Nancy Davenport-Ennis:
A comment, I think, to follow on your comment, actually, Douglas, and to also direct to Mr. Lunes [spelled phonetically]. Thank you for a compelling presentation, and certainly, I think consumers in America want to join hands and hearts with the initiatives that you've set forth, and with the four contractors that have been hired to do this. I would have just four fundamental observations. One is, as we look at the formulation of a nationwide health information network, and we do want the American public to feel that it is a national asset, perhaps that begins by looking at slide number five, where we have the architecture slide is a part of the solution, which I concur with the analysis that we had walked through, but I would encourage that under the comment how standards and requirements support business opportunities. Perhaps we add "and consumer information," because at the end of the day, moving forward with constructing a national health information network, we need to have the consumer voice present as an integral part of every step of the process, and I know that that will take a bit of expansion as I look at the organizations that are being included with many of the contractors for this particular project.

I would also look at slide number six and encourage that under the third bullet point there, transport electronic medical information to inform clinicians, and follow and inform the consumer, because at the end of the day, the consumer is the benefactor of this national asset that we're going to have in the form of these national records, as we look at the contracting work that is being done in each of the areas. Again, I would encourage that each subcontractor invite a very deliberate consumer voice to be represented within the working groups, so that those working groups are much the same as that of the community, where the community voice is represented, the consumer voice is represented within the community. I look forward to the results and the reports of the contractors and know that at the end of the day Americans will be benefited, and particularly the patients that most desperately need the network in place.

Male Speaker:
Thank you Nancy, and let me just make one side comment related to something John mentioned, and I just wanted to make sure that I tied it back to your comments, and that is that these contractors and their consortia of other entities and healthcare markets, all of which make relatively large teams, will not only be working together, but working in concert with all the other contractors, and doing so in open forum. We will be inviting anyone from the public, and any other technology company, any other provider organization, any other regional enterprise that wants to come and replicate what they're doing, learn what they're doing, comment on what they're doing. It's been a critical contracting exercise for us to make sure that all of our contractors themselves develop public-private process to be able to have transparent and open dialogue. So there's lots of opportunities here, and I hope that we can work with you to get relevant consumer groups to participate in this process and help connect this, because this gets very jargon-y very quickly, but decisions made here will have a huge impact on a range of

choices that are ultimately made available to consumers about health information. So we'll be working with you in the community to make sure that that's done. Thank you. Chip.

Charles N. Khan III:
I guess I'm -- I'm sort of having trouble with what Doug said, sort of coming to some conceptualization of how this all ends, but maybe that doesn't matter at this point. But it seems to me that whatever your goal is, I don't see the end of this. I see a lot of development of different ideas, and sort of different processes in regions across the country, but to bring it all together, I mean there's going to have to be, you know, a tax on premiums and a contribution from Medicare, or something, and a commitment that this is going to pay for whatever the ultimate structure is that everybody agrees to, and whether we don't want the government to house it, I don't know, but it just seems to me at the end of the day, whatever the best ideas that come out of this, you've got to pay for it, and in the short run this experimentation is great, but you know I travel a lot, and I don't really need a -- I'd be better off having an electronic health record in Washington, but you know, all of my doctors are in the same building, and you know, paper and phones work, but you know, what if I had a heart attack in -- you know, anyplace else. It would be an issue if I wasn't conscious, and I guess what I'm struck at -- with, is this is great for developing the regional things, but the great linkage -- first, whatever is the best of this, it seems to me that we ought to be having a contest, rather than collaboration maybe, and having these guys work against each other to see who comes up with the best model.

Collaboration is great, but competition, that's what the country is built on. And second, once they come up with whatever the best model is, then we ought to figure out a way to pay for it, and it probably needs to be paid for by the public sector. That's sort of a radical suggestion, but I guess -- and I don't think we need to settle that now, but it seems to me at some point in '07 or '08 we're going to have to fish or cut bait on whatever looks like it's best and go with it at that point, and you know, it's just like -- it's just like, you know, Beta vs. VHS or whatever. At some point, we can't have a thousand flowers blooming here. Probably okay now, but I think there has to be an understanding that's got to end at some point.

Male Speaker:
This may be a --

Male Speaker:
Let me help you out.

Male Speaker:
All right, thank you [inaudible] [laughter]

Male Speaker:
Now that we've got a worldwide financial system, there's a different architecture in every bank and every country in the world, they all communicate with another in common interfaces and standards, information flows, you go to an ATM anywhere in the world, you get back -- you get

local currency, you get back to your bank account, it's deducted. They don't all have a common architecture, but they had some interface standards and some interaction standards. I think that's exactly what Dave is talking about here, but there's a big difference, and that is that there's money flow there, so there's somebody to pay for it, the banks -- this isn't free, and you --

Male Speaker:

You, we, this group already eats up, what, 18% of the GDP of the United States. That's not money?

Male Speaker:
The problem with that -- the problem has always been with healthcare is how do you grab some piece of it, and the average physician out there, even if you get them to do all this kind of stuff, you know, where's the money in it for him, or where's the money in it for the hospitals, and that's part of the problem. They can't siphon off the money like the -- you know, the banks take, I don't know, .00000 -- you know, 1, or whatever it is cents off of each transaction.

Male Speaker:
Every time I looked at my health bill, it seemed to me somebody was siphoning off something somewhere. [laughter]

Male Speaker:
I understand that.

Male Speaker:
They're not doing it for gratis, I don't think, are they?

Male Speaker:
Well, somebody's got to agree that that's going to happen in this case, you know? Scott's got to agree, you know? Mark's got to agree.

Male Speaker:
Yeah, and there are clearly perverse incentives here -- we know that, and we've talked about that a lot, and we certainly don't, at this point, have the rosy-eyed view that because this is a superior solution, it's just simply going to permeate healthcare, and these economic issues are important. The problem that we face today, Chip, is we don't know how much this costs to build, design, and deploy. I've seen some academic estimates, and I don't know if they're right or wrong, because there are large assumptions made that we're going to put to a test here. Secondly, you know, it's our presumption that the key drivers of this over time are going to be consumers themselves, who want their information, and want it to be portable, and we don't know what the economic implications of that are. Thirdly, the issue of who operates it is something that we've been moving through these contracts and through a process towards a market-based mechanism, not the government operating a data switch for the US, but the government sponsoring and

supporting switches or a switch that's operated to allow health information to be shared as needed. So certainly it's our hope that as we look at the business model, we can create the circumstances where private capital is invested in this in a way that achieves these public good aims. Those are the questions that we're going to be looking at this year, through part of this project, so I wish I could tell you the pat answer, but you know, right now, I think we've got the questions in sight, and you know, we've given these guys, as well as all of our contractors a very short timeline to give us the fodder for asking these questions so we can actually get the answers, and you know, this is going to be a topic that this group will talk about at great length over time, because it is probably the key issue of how do we make sure that this becomes inevitable, and is something that happens sooner rather than later, and broader rather than narrower, but I think it's exactly that kind of question. Kevin, I didn't know who was first -- Mitch? Okay, Kevin, then Mitch.

Kevin D. Hutchinson:
Well, mine's just a quick comment. Maybe the challenge that people that people have in getting their arms around this is because we sit in the National Health Information Network, I don't think your suggestion or anyone's suggestion -- we're not out laying cable. This isn't something that is going to build a different network. It really is more of a national health interoperability architecture than it is this health information network, and I think the struggle that we have in looking at the various different ways of speaking about it is that there's going to be some special network that's only used for healthcare, and I think that would be a huge mistake for not leveraging the existing technologies in place today, like the internet, like security, like encryption, like SSL and a bunch of other things for the exchange of information, but it really is getting to Craig's point about the interoperability of this architecture, more than anything else.

Male Speaker.
Right. From that perspective, I guess a way of asking about this presentation is:
given what you're going to hear about our efforts in standards harmonization, what you're going to hear in certification -- why this? And I go back to John's slide number five, where we believe that this architecture, this network is the common pathway that ties all those things together, that gives us a linear business and technical process for achieving the goals and making sure that the standards, the certification, economics and policies relate to each other, and without this in the middle, we thought we would have a set of disconnected policy efforts or academic papers or other efforts that probably would not result in the kind of goal we have. We think with this approach, we've got all the pieces there. There's still many other factors that are left open, but we think we have our arms around what it takes to drive this forward and to achieve the goals. Mitch?

Mitchell E. Roob:
The question of whether or not the data -- their data is resident, and where the data actually lives, does it live in people's -- in the doctor's office or one national location, or some hybrid of those is an incredibly difficult question, and really ought to consume this effort. I think, to your point about the difference -- one of the differences between this information and financial information

is that this information can be -- it if is able to be -- have fewer rather than more repositories, it's more able to be queried by academic physicians for research, and this is a terrific opportunity to do medical research, and to find issues of drugs as they come out of the market that we should not pass up, and as we -- as we -- as this body or other bodies consider how many data nodes there are -- we ought to keep that in mind, that the fewer data nodes that exist, the quicker, the better we're going to be able to do medical research off of this data.

Male Speaker:
That clearly, you know Mitch, the issue here is there are very compelling reasons for a high degree of centralization. Research, adverse event, drug surveillance, bioterrorism surveillance, etc., quality of reporting, on the other hand, you know, there are significant concerns about that as well. We've pushed towards this starting from a perspective of being highly decentralized, but highly coordinated, or highly linked, and these architectural contractors are really putting that to the test, to say, "How far can we go? What degrees of freedom do we really have to deal with this?" My vision, pure vision, is whoever has data on paper today will just have it electronically and it's tied together. Maybe that's not a feasible solution, but that's what we need to find out through this process, though, you know, a year from now -- I promise you, I don't know what the answer is going to be, but I promise you will have the data for this group to discuss it and start really coming to some very practical issues about what are we facing to achieve this goal for the United States. Mark.

Mark:
Yeah, just to follow up on the discussion that Chip started, let me state a presumption, and if I'd be -- like to be corrected. Each of the contractors in the revenue / cost models will propose one or more ways in which this can be paid for, in which this can exist, and I presume that that's not a centralized -- not necessarily a centralized approach.

Male Speaker:
We certainly are not encouraging them to come back and say this should be a tax increase or something like that. We're really asking them to look at, most importantly, what are the potential revenue models? Are -- you know, can transactional models work for this? Is this population-based? Is this something that is more based on the value and usability of the information, not the actual transaction of it? And so I think that's more important than putting a dollar value to the revenue, because the question of the cost model is going to tell us, really, what costs we have to offset, but how to factor the revenue process is really one of the things that we think will contribute to our ability to understand how this can be apportioned, and really the question that's being asked, without putting the economic

[end of

Male Speaker:

…you'd appreciate is to what degree is this a public good where it can't be apportioned, and to what degree is it really something that is able to be linked to very specific realizable problems where value -- economic value is realized, because a population is cared for better, and that leaves money in the hands of payers or others like that. That's what we need to find out, and that's the process that we're laying out with this project. Bob?

Bob:
I think, of the things that we're going to hear today, this actually is the glue that ties everything together, in having electronic health records, having information that's out there, having the standards. If they're in isolated silos and can't flow smoothly across for whatever purpose, whether it's for a consumer to have their own personal health record, and take care of their health, which -- most of which occurs outside the realm of healthcare encounters, or whether it's for administrative views of quality of care, other kinds of things, this really is something that's critical, and the idea of having to get beyond the regions, I mean there are a number of entities, DOD and VA and Indian Health Service and Kaiser Permanente and others, play in many markets. We can't afford to have individual connectivity, so we need those standard interfaces that we can have a solution that connects into all of those, and that means that if we can do it, others can do it as well, and we'll see how the market goes.

As far as the finances, Visa or other kinds of things have shown that you don't -- that you can find ways of having this information flow at a very low cost when you leverage what's there, and given the amount of costs that we have in administrative overhead, somehow on healthcare we might be able to find some way of redirecting a small amount of that to help get this efficiency and improved quality.

Male Speaker:
And just as a comment on the revenue side again, the most simplistic analysis of this is: how do the benefits accrue to the data holder vs. the data user? And, you know, there are various administrative or clinical processes that apportion in both directions, and so this is one of the things that we really want to discover about what types of information are linked to what types of apportionments. Scott?

Male Speaker:
I guess what I was going to say follows on what you just said, and that is, to me, the paramount issue is where does the value accrue, and that should help us determine the revenue model to fund this, if the value accrues to the provider, to the payer, to the consumer, then those are the people that should be financing the ongoing cost. Now, the cost of developing infrastructure and things of that nature probably will have to be apportioned in some other fashion until we get it going, but you know if you follow on Craig's bank examples or financial systems, the consumers viewed it of enough value to pay a transaction fee when they go to the ATM's. They pay $1.50 or 30 cents or whatever the amount is, because it's of value to them to be able to access that information. Likewise, there will be a value to your records being available, and there will be a value to you provider, and we need to assess and apportion that value in to determine the costs of

the system. But I think if we get -- if we start the process by being hung up on a lot of these stumbling blocks, and you know, I've been in this business 20 years, we've been having this same conversation for 20 years. I mean, I think the time to move forward in doing the kinds of things that you're doing is now, and the value will become readily apparent, I think as we work through these issues.

David Brailer:
And speaking of timing, I think it's time for a few last comments, and time for lunch, so with that, let me turn to Barry.

Barry:
David, just -- this is just a quick question, because as a federal employee, I have to be very careful not to take sides. I think we've got two viewpoints on whether this should be top-down or bottom-up, perhaps, and how the system develops, and I think Scott's comment just now, just getting forward, going -- moving forward with some approach is a very good thing to be doing. One of the questions, though, that I'm not sure that this project addresses is:
has there been any instance of competition in the same region between different entities that are trying to establish a regional system? I know we both come from California, and there's beginning, I think, to be a bit of overlap, and is that something that we anticipate is going to be a problem down the line?

Male Speaker:
There are a number of markets where I would describe there as -- describe a competition. But often, I think it is an organizing or an organized effort, competing with some pretty large proprietary networks that themselves have the scale to be kind of region-wide, and so I'm not sure it's the same type of competition that you're asking about, and really, the question there is: does the regional project become overarching, or does it become a congregation of those outside of that large network? And I think it's -- in some markets, it's playing out that there is a partnership developing. In others, I think it's -- it's still yet too early to tell. And we're clearly taking an agnostic view of that. We're letting them decide how they play those out without giving them guidance or direction.

But you know, the question, ultimately, about how much mass there would be, how much, you know, whether there's on regional effort or one market is another design question. For example, it's not unheard of, for example, in various southern networking areas for the following to be true -- a hospital could participate in a regional network. He could participate in an overlapping Children's Hospital network. He could participate in a research network. He could participate in an FDA adverse events surveillance network, and it could, all at the same time, be a VA hospital, so it has, you know, that. So, you know, this concept of how many networks or social groups am I in I think is a question that ultimately will become one that resolves this issue of:
is there one network, or a network of networks in the United States? And it really depends on, I think ultimately, how doctors, hospitals, insurers, and perhaps ultimately consumers, if we can ever present this question in an intelligible manner to them, decide they want their information

flows governed, because I don't think it's a technical question, I think it's a question of who decides who gets to see what data and when for all of these various purposes on a day to day basis. So that's not completely in the scope of this year's project, but that's clearly what we're setting up, is that dialogue, particularly as this group works closely with the privacy and security collaboration to begin understanding how those two things play off of each other.

Any other final comments? It's been a very good discussion, I appreciate it very much. You will clearly hear a lot more about this part of the project. We're going to take a 30-minute lunch break. We are taskmasters, and when we reconvene, we'll talk about the other two contracts. You'll find these to be quite delightful. In the back of the room is a listing of restaurants, and there's food set up outside that is available for purchase.

[end of transcript]

Okay. I suggest we go ahead and get started. Thank you all for taking such an expeditious lunch break. I was a very good discussion in the earlier part of our meeting and we're going to continue that with our next presentations. With that, I will refer the community members to tab 9, to standards harmonization and our presentation will come from John Holamka [spelled phonetically]. John, thanks for being with us, and look forward to hearing from you.

John Holamka:
Great. Thank you so much, Dr. Brailer and the community. I'm very happy to be here. Well I think the analogy was already used, but let me repeat it. I was traveling in rural Japan a few weeks ago. I went to a post office with my ATM card, and going up to a Japanese machine, I couldn't actually quite figure out what it said, but I could more or less figure out what the buttons seemed to indicate. Put my card in and instantly a hundred thousand yen from my local bank in New England was dispensed. Well these were proprietary machines on either end, and my ATM card was uniquely issued by my bank, but I was able to do this transaction, why? Because of standards. There is clearly interoperable standards for the industry in financial exchange that enabled this transaction to happen. Well today I'm going to be talking about HITSP, and talking about the way in which standards are part of this national interoperability solution for healthcare. Let's start with the first slide. So what is a standard? Now certainly all of you use standards in your various jobs and industries, but a standard is a well defined approach that supports a business process that is a publicly agreed upon mechanism. This is done openly and transparently, consensus based. Based on expert input. Now standards typically will provide rules and guidelines, and it's not just for software, it can be anything. It can be the width of rails for a railroad or the kind of steel that's used. Standards cover materials, products, processes, and services. They're available in an accessible format which means there may be a guide, an implementation document that describes how a standard should be applied, a cookbook if you will for making these business processes happen. And a standard evolves. It's subject to change and to review. Who would have predicted in the mid-'80s the Internet would exist, and yet today, we have august bodies and testing fascilities, and worldwide interaction that's constantly evolving based on internet standards.

Now if that's what a standard is, what is harmonization? It's certainly a word you've heard used quite a lot today. Harmonization is necessary where there are competing standards or overlapping standards or redundancy. In fact, I think David, it was you who said, "One of the wonderful things about the standards in this country is there are so many of them." We would be, in fact, overjoyed if all we had was VHS and Beta max. Well, we have many, many standards that overlap and are redundant and so hence, as we try to implement these national, interoperable architectures, we have to get to a common means, a common cookbook of making data interchange possible. So the healthcare information technology standards panel is a group that was charted, brought together by HHS and David's office to harmonize the standards for healthcare data in the United States. This is a multi stakeholder panel. It includes not only the producers of standards, the standards development organizations but also vendor organizations that implement standards and their products, consumers of standards, and of course that refers to clinicians, patients, payers, all those individual stakeholders in our healthcare system that need standards to execute business process. HITSP is today 150 different organizations. That's 12 different standards organizations. A very large number of payers, providers, patients and employers all coming together in a community in an open and transparent way that enables all the stakeholders to discuss use cases such as the ones that have been outlined by AHIC and the community. And also really thinking about how standards are going to empower the national health information architecture we've been discussion. This panel is convened and overseen by ANSI [spelled phonetically], which is a not for profit organization that has been a voluntary standard organization in the US since 1918. And you can see, the board members are covering this very significant degree of stakeholders from standards development organizations like X12, the American College of Physicians, a number of individuals in this room, Dr. Colander [spelled phonetically], for example, represents the VA. So covering governments and industry, covering patients, covering providers, clinicians, they're all there.

So the ultimate answer with HITSP is we are, over the course of the next year, going to be working on the use cases given to us by this committee and we are going to take a national inventory of all those standards that exist, overlay it with the use cases, identify where there are redundant and duplicative standards. Standards that if you ask an individual in Indiana or an individual in New York or Massachusetts to implement an interoperable health network, they wouldn't be sure which standard to use. But we'll also identify the gaps. There may very well be needs for new standards. For example, in Massachusetts, we recently implemented a link to Department of Public Health for biosurveillance kind of information, but we weren't really quite sure what of the existing standards to use. So we did the expedient thing, created a point-to-point connection. It's a one off; it's not scalable. We felt there was a gap, so HITSPE [spelled phonetically] will also address gaps. The end result of our work product will be a set of implementation guides of interoperability frameworks that enable vendors, that enable consumers, that enable clinicians to get at the information they need using commonly accepted standards guides.

So what is the current landscape? Well, as I mentioned in my example in Boston, it's often

expedient not to solve a scalable national problem, but to implement a point solution. A one-off. And that one-off solution may work very well for an individual organization or a region, but it certainly doesn't foster interoperability. To use the ATM analogy, it's a bit like an ATM that only works at the home branch of your bank. Does work fine, but if you travel, you're out of luck. So that's the current situation. There are disparate messaging systems, disparate data elements and disparate vocabulary. A laboratory may call a blood count a white blood count, a WBC, or a CBC. And the challenge is, sure, we could implement one hospital system interacting with one laboratory that knows what that means, but it doesn't scale on a national level. It's not creating interoperability.

So what have we been doing? Since HITSPE came together this fall, first thing that we have done is build trust. One of the I think -- as David has said -- important aspects of what we're doing here is creating a climate where we can simply discuss the issues, learn to trust each other and work together. So these standards organizations that I describe that have in the past for very good reasons created proprietary and at times redundant solutions now have a forum of coming together in a way that an open and transparent fashion can build trust and discussion. Within weeks of HITSPE being formed, 150 stakeholder organizations joined, and we have had a panel meeting and a board meeting where we have brought together all of these organizations and had a wonderful conversation really understanding how we're going to work together to meet the goals of the community and to meet the goal that [unintelligible] has outlined in our contracts. During 2006, we will have a very defined set of deliverables, but let me just say, rather than focus on deliverables, the most important thing that HITSPE can do is set up a process. A process that is sustained for the very long term that provides a convening body where all the nation's standards organizations and stakeholders can come together for not just the use cases and breakthroughs you've outlined today, but for the hundreds of use cases that will be outlined over the next decades. Today we're addressing consumer empowerment, today we're addressing e-prescribing, and we're addressing quality measurement, we're addressing a number of the things that you have brought up, but what about clinical research? What about what will be in the future, the need to exchange genomic data? We know these use cases will come about. And HITSPE has to be an organization ready in a stakehold -- a multi-stakeholder fashion to address those particular use cases.

Our deliverables beyond setting up this ongoing process that will be self-sustaining, are to take the use cases that are formalized through Onc [spelled phonetically] and this body and develop a set of implementation guides. Those implementation guides, as I said, are kind of the cookbook. The non-ambiguous beans by which standards are clearly documented to empower the use cases, to empower data interchange across multiple stakeholders. Now of course there's going to be great dependency of the work of HITSPE on the work of the CCHIT that you'll hear about in a moment, and the national health information network contractors. All of us will work together so that if HITSPE comes up with designs, the CCHIT group will certify and develop functional criteria around most designs to ensure that vendor products adhere to them, and the National Health Information Networks will be creating use cases and standards of implementations which will inform HITSPE and vice-versa, so all three of those organizations in 2006 will work

extraordinarily closely together. By mid-summer of 2006 we will have our first implementation guides ready for public comment, and we expect that in fall of 2006, we will have delivered, per our contracts, all of those detailed implementation guides that are necessary for the initial three use cases. Just in conclusion on this slide, developing an ongoing business model to sustain HITSPE is also an important deliverable. We know that you can fund organizations for a short term by passing a hat, or by getting grants, but the right answer is if this is going to be a convening organization for our standards organizations and stakeholders for the very long term, it needs to be sustainable and it needs to have a business model. And we have a group working on that in 2006.

As I mentioned, we will collaborate with all of the contractors. This morning, workgroups were discussed. I imagine we'll be collaborating with those workgroups as well. There will be -- we will ensure, in working with CCHIT and NEHIN [spelled phonetically] and HISBC [spelled phonetically] that all of the elements that David's office have outlined will be brought together into our multi stakeholder forum, and we will, together as a community, deliver the standards that are necessary to make all the other contractors successful. And why are we doing this? Well, because we believe if we are going to have successful electronic health records for this country that are interoperable, that empower consumers and empower the clinicians, that we need to have those non-ambiguous standards guides ready for consumption by today's contractors, the vendors, and all stakeholders. So in conclusion, HITSPE was formed to harmonize standards, to identify redundancies and to identify gaps, to convene a process that's sustainable over time, so that this issue of too many standards, of having so many differences of gauge of railroad that you can't get from New York to Los Angeles becomes a historical anachronism. And with that, I'm happy to answer any questions.

David Brailer:
Thanks, John, I couldn't think of the more exciting way to overcome our post- [unintelligible].

[laughter]

I appreciate it. Never thought I would say that about a standards presentation. I did have a couple of just specific questions, if you could just illuminate these for the community members. Could you just differentiate the panel from the board, and what those two mean and how they interact?

John:
Sure. The panel of HITSPE, again, comprised of 150 different member organizations, is really the decision making body. Now in many companies of course, the board provides strategic guidance. Well, in the case of HITSPE, the board is really an administrative entity that ensures that we have good process, appropriate agendas, deal with governance issues, but all votes of substance, how those standards are going to be harmonized and building a consensus for the community is done at the panel level with all 150 members. I'll tell you, we've very much tried

to work on consensus, and not simple majority or super majority or voting, it's because the only authority we really have as a panel is the fact that all the stakeholders agreed on what we're doing. So specifically, that board provides purely administrative works, the panel provides strategic decision-making.

David Brailer:
And then secondly, differentiating the panel from the community of standards organizations. Do you have a hundred percent membership of standards organizations of relevance to healthcare, and if not, what does that practically mean for those that are members of the panel versus those that are not?

John:
Membership in the panel is open to any organization that represents a standards development organization, or a stakeholder. Consumers, doctors, various hospital organizations, peers, so we today have 12 standards development organizations on the panel, which do represent those major standards producers for health care. And certainly, any new organization that would be formed would be welcome to join. I mean, the criteria are really quite simple.

David Brailer:
Thank you. With that, let's turn over for questions, discussion, comments, etc. Who'd like to go first? Kevin.

Kevin D. Hutchinson:
John, you're not working on medical standards, right? Medical terminology standardization and things like that, it's the technical standards of interoperability that you're most focused on, is that correct?

John:
Well, when one thinks of standards, they take many forms. So certainly there are standards of content. How do we describe a certain medication in an unambiguous way, or a vocabulary? What's a fever? How do you define that term? And so although standards comprise content, structure of sending data from place to place, transmission standards, we'll focus on whatever the use cases require us to focus on in the short term, and in the long term, we may very well have to answer issues of vocabulary. So I would say, our charter is to really focus on all of those elements, content, structure and transmission standards as necessary to empower interoperability.

Barry:
Just a comment to the community members here in case you're wondering can this kind of a system -- a loose-knit system work or not, the ambulatory care quality alliance you heard about this morning is a very similar organization that's been in existence for over a year now, has done a remarkable job, I think, of bringing together very diverse people, many of whom are in competition with each other in the particular niche of healthcare that they're in. So I think this is completely analogous to AQA to a lesser extent to HQA that Chip was describing, and Mark

when he was here earlier also. That's a more narrower group that has the same principles. So at first glance, it sounds like, how can you get 150 people to agree, but it's a very workable model and I think something that we're going to see more and more of in collaboration on healthcare issues.

David Brailer:
The difference here, Barry, being that the standards, if you would, that AQA and HQA are dealing with are clinical content standards about medical evidence and appropriateness of care that can be used for measurement, in here, it's the data structures and the interchanged standards about how does one actually collect that data. So as we come to how do we have a system of measuring quality of care, it really takes standards of both these groups to come together over time to make that happen. Is that a fair summary?

Barry:
Yeah, I think that's a fair summary. I think the other common analogy, though, David, is -- you're absolutely correct -- is that there is disagreement among the standards, or we use the word, “measures,” I think, in the QA, than standards, so there can be gross disagreement, or even, again, competing measures that different groups are using, but people hash those out, come together. I do think, though, that your comment about the need to come together is very appropriate.

John:
And certainly, we are leveraging the work of all those individual organizations rather than reinventing something. So as you mentioned, the notion of building consensus is to take all the good work, expose it to the community, identify those standards that are most appropriate, and then select them by consensus. Now, does that mean there may be winners and losers? Well, certainly, we believe that there are ways of reaching middle ground, of bringing together best practices and ways such that all the stakeholders feel like they've contributed to the consensus. We think it will work.

David Brailer:
And perhaps, John, if you could just give us -- to the extent that it's possible -- your first glance look at the use cases in terms of the work of standards harmonization. Do they look big, are they small, are they obvious, are they facing significant complexities, do you have the right membership to deal with them, what's your initial glance at those use cases given that the work of the standards harmonization panel is really one of the key enablers of achieving those use cases?

John:
Sure. So the couple of sources for use cases, HITSPE itself has a use-case committee that has been meeting from the very day that HITSPE was formed, and has aligned it's efforts with Onc so that it is producing those detailed artifacts that describe, what are the actors, actions and events for biosurveillance, for consumer empowerment, for electronic health record exchange,

and they're fairly detailed. So let's just take an example. Consumer empowerment: well, if we're going to identify who the patient is, and assuming we don't have a national health identifier, assuming in the next five years that there isn't going to be a new national number, there somehow has to be a means by which we can use the name of the individual, their phone number, their address, whatever other demographic indicators exist. Well, that means that we're going to have to have the standard to describe who you are, and to exchange information that would be your demographics, registration, clipboard kind of information. Well, there are standards that exist already, that provide that kind of information, so that notion, your clipboard use case as you described it, seems like a very reasonable initial scope. Medications: there are a few competing medications standards today. HL7, SCPDP, so there's clearly some harmonization work to do, but again, there's such maturity in the e-prescribing world that it looks like there's a lot we can leverage. So across consumer empowerment, it does appear that that use case will be something we can come up with a very coherent set of standards well described to solve. EHRs, laboratories, well, again, laboratories have already done a lot of computerization, and so the last decade has prepared us for the exchange of laboratory data, I think, in a good way. And yes, there's work on vocabularies, and work on the differences between a normal over at this lab, and over at that lab is a different kind of test, and therefore a different range of normals, but still, again, doable. And biosurveillance, there's been many demonstration projects that have been done already, such as Biosense. And we obviously will leverage the learning that has been had, and again, complexity. Very significant numbers of data elements to be gathered, to empower that use case, but from what I've seen so far, all within the time frames you have outlined.

David Brailer:

Further comments or questions or discussion here? Barry?

Barry:
One more, this is a question, John, for you, again, your milestones, very good, similar to what AQA has been addressing. The steering committee met last week, and one of the pieces you had here is about communications, and getting the message out to a general community. Could you expand a little bit more, are there any definite plans about that yet, or is that something to be addressed?

John:
So we have to have communication both internal to the process, and then external to the process. So every week, on Friday afternoon, the HITSPE secretary issues an email to all 150 members saying, "This is what was done this week." These are the challenges this week. These are going to be the work products that we are going to have in the upcoming weeks. So that there is, across the communities of all the stakeholders, a very good understanding of what's going on. But then, toward the end of May, beginning of June, we hope to have some initial work products. These implementation guides, interoperability frameworks that we can then begin to circulate in a public fashion for comment, and clearly there's going to need to be not only the stakeholders I've

described, but a lot of education that takes place, because obviously we want frictionless commerce. We want information to flow from place to place, and we want to eliminate fear and process barriers to having that information flow. So come that May/June timeframe, you'll see a lot of communication and work products openly circulated for public comment and feedback.

David Brailer:
Okay. Thank you very much, John. I appreciate it. I refer the community to tab 10, and we'll now discuss the Certification Commission for Health Information Technology, and the presenter is Dr. Mark Leavitt, no relation to Secretary Mike Leavitt.

Mark Leavitt:

Thank you. Thank you, Dr. Brailer [spelled phonetically] --

David Brailer:

I stole your joke.

Mark Leavitt:
Pardon me?

David Brailer:
I stole your joke.

Mark Leavitt:
Not only did you steal my joke, but every good analogy and metaphor has been used, so I'm not going to start with one.

[laughter]

But thank you for inviting me, and members of the community, I really appreciate the time, and it really is an honor to be part of this strategic initiative which I believe is going to succeed, so I'm very happy to be here. If we could talk a little bit about CCHIT. Let's start with our mission statement, which is on slide 2. There we go. Acceleration the option of robust, interoperable health IT. By robust, we mean it delivers the benefits people expect, the quality, or safety, or cost savings, efficiency. By interoperable, well, I'm not going to redefine that. We have entire groups that define that for us. But what's important is how are we going to do this? We're only a small part of the solution, but our role is to create a mechanism to certify the products, and that mechanism has to be efficient and sustainable, so we don't want to add cost to the health system, we want to add value. And it needs to be credible. And I'll come back to that later, because the entire success of certification depends on credibility. Basically our number one most important product is that this process is credible, and a lot of what we do is focus on making it credible. If we could go to the next slide -- just a little of history. Now I know we got mentioned a lot of

times in the course of the day, and that's not because or work is any more important or successful or relevant than our fellow contractors. I think it's because they figured we were going last, and they just sort of pile it all up on us. But actually we've been around a while, and so we've had a chance to actually get products out there, we were --

[end of transcription]

...in July of 2004 by 3 non-profit health IT associations, AHIMA, HIMS and the Alliance, and Linda Kloss, the CEO of AHIMA is in the audience. Linda, if you'd like to stand, we really thank those organizations. They've funded and donated not only money but staff resources, and I was one of those. I was Chief Medical Officer of HIMS, and I was donated in terms of time, and now I'm full time on CCHIT. We also received additional funding from eight other organizations, sort of a second venture round for those from the private sector, and to say with the private sector analogy, and I guess here is an analogy, the mezzanine round of funding is really the government contract, which as you know, tasked us with developing a certification process. It's about $2 1/2 million this year, and it's a 3 year contract, so a total of about $7 1/2 million. But something very important is that the government contract does not support our continuing operations; the government contract is developmental money to do the hard work of developing the first set of criteria for each domain, and then we have to become self-sustaining. And I'll use that to mention that we've just hired an executive director who will focus on a business plan to make us sustainable, and that's Lisa Ray [spelled phonetically], who's also in the audience, if she wants to stand up. There's Lisa. Just joined us two weeks ago, so don't ask her too many questions yet. On the next slide, how we're organized. And one of the reasons we're able to do the work with credibility is that the bulk of the work is done by people in the industry who are the stakeholders, being certified or using certification as a guide to purchase. We have a fairly small staff, but a very large number of volunteers, actually totals over 75 now. The commission itself, and we now have five workgroups. Dr. Henley [spelled phonetically] was a commissioner until he was appointed to the community. And we have other commissioners in the audience like Wes Rishell [spelled phonetically]. The workgroups focus on complementary aspects of certification. One focuses on what is the functionality these products should have, what should they do, the other of interoperability, another on are the secure, do they maintain privacy. And then two other groups work on just how do you test them, what is the certification process? How much does it cost? How fast is it? How do you actually test the products? And then all of us, the commissioners and our workgroups interact with the stakeholders. And our stakeholders are diverse. And they cover both the private sector and the public sector. If we could just stay on that previous slide for a moment. The vendors who make the products are clearly a very important stakeholder. The providers who purchase products, again, a key stakeholder. And the payers and purchasers, who ultimately will offer incentives for implementing information technology and improving quality are a big stakeholder. Equally important are other groups such as health consumers, because it's their health. Quality organizations, researchers, and of course all of the public sector agencies. We can go ahead and move to the next slide. And I want to talk specifically about steps we have taken, and are continuing to take to ensure this balanced in credibility and openness in our work. In the

commission we have a defined composition of having at least two from each of those first three stakeholder groups that are most heavily affected, and at least one from the other groups. We actually have two from the Federal Government. And our workgroups, we recruited the first pool of applicants in November of 2004, and we had 275 applicants. We arranged them by qualifications and adjusted each committee for balance. Each workgroup has to have two co-chairs, not one. They need to come from two different stakeholder groups, so you can't have undue influence by one stakeholder on a workgroup, and there's about ten members on each of the workgroups. So we're -- we spend a lot of time thinking about how to make sure that this process has balance and fairness built into it. On the next couple of slides is just a list of the commissioners, and I won't go through their names, but as you look up there, you'll see representatives of both small practice -- the small practice universe as well as hospitals and large health systems. Informatics and consumer organizations, quality improvement experts, public health specialists, representatives of the government, and on the next slide you'll also see some commissioners that represent the vendor community, payers and health plans and standards development organizations. Going to the next slide, what I'm trying to illustrate here is our role within the landscape, and I don't mean to imply that because we're the biggest box in the center that we have the biggest role or a central role, but what we really are -- I notice each vendor put their box in the center, that's just the easiest way to talk about it. But what we are, I think the way you should think of us is an interface between the strategic initiatives, and the rough-and-tumble private sector health IT marketplace. We are basically the lever that the strategic initiatives can use to nudge the marketplace.

Now it's really important, since this is a voluntary initiative on the part of the private sector participating that they perceive it as a velvet lever and not a baseball bat. And certainly, there are people that say, "Why don't you just fix this thing, and make them do this and make them do that?" But it's all too easy for the entire community to just run away if we do that, so we have to find that optimum balance of nudging and guiding but not pushing so hard that they fall over, but at the same time, we know there's urgency to solving this problem. We absolutely feel the urgency. And as you see, the three other contractors and actually the six, because there's four national network prototype contractors, standards harmonization which John Holomka [spelled phonetically] talked about, privacy and security which Chuck Thompson talked about this morning. Their material is a substrate for us. We can only certify against a standard. We can only certify a network if we know what it looks like. We can only certify that it preserves privacy if we understand what privacy policies need to be protected and supported by the products, so we're kind of downstream from a lot of this work, and then we take it to the marketplace and by certifying some products and not certifying others, we basically guide the marketplace in the direction that we all want it to go for our mutual benefit.

Let's go to the next slide, talk a little bit more about the details about how this lever operates. Really, we have four objectives for success. One is we think we can accelerate adoption by reducing the risks of investing in health IT. There's lots of stories about failed implementations or disappointing results, and it's basically caused providers to hold back. We believe there's significant, pent-up demand that could be released by reducing that risk. The second is not only

will this product work for me, but will it connect to this emerging network that we're talking about developing, so we can prevent the betamax/VHS catastrophe if we do our work properly. The third thing is to unlock these incentives, the coupling of use of IT or IT improving quality and service and safety with incentives, and we understand payers want to be sure that those incentives cause the right kind of systems to get installed and cause them to be implemented the right way. And then finally, we need to protect privacy. Now as we create a network, we basically create a chain of links, and then the old adage about the chain only being as strong as its weakest link when it comes to privacy really comes into focus. So it's very important now that each and every product in the chain, whether it's an electronic medical record system in a physician's office, or a website that a consumer goes to to check their records, or the network, the invisible network through which the data is transmitted. Every one of those is a potentially vulnerable link, and that's where certification also plays a significant role.

Let's -- going to the next slide, maybe a little more details than you want, but this is our contractual timetable. The structure of our work is that the first year we are tasked to develop criteria for ambulatory care electronic health records. The second year, phase 2, we develop criteria and certify inpatient, or hospital based electronic health records, and then the third year, we start certifying the networks through which they interoperate. And these actually -- they step up in complexity and they step up in difficulty, and of course the networks don't even exist yet, so it's really a good thing that's the third year. But a very important point to make is that our work doesn't stop after the developmental year. Once we've developed the criteria for ambulatory EHR, and we've published our first set at the end of November '05, we have to update those, and enhance them. So what we do is we publish a roadmap that always looks one and two years ahead. So in November of '05, we published our criteria that we'll begin to test against in March '06, and our projected criteria for March '07 and our projected criteria for March '08. They're still a little fuzzy, March '07 and March '08, but we're signaling the industry. We think this is where we're going. Because the vendors need a chance to respond. The reality is a product development:
six, 18 months, two years to add a feature or a security feature to a product.

Now during each development phase, I talked about credibility and openness. We do a lot of activities to invite the entire community to participate, so we have two cycles of formal public comment in each of those phases, and besides those formal public comment where you comment in writing, we hold town halls. We'll hold a town hall in February at a very large health IT conference called HIMS in San Diego, and we'll have a two-hour session. It's a town hall. We do town calls by the phone; we do specific outreach to groups. We did that to consumers. We were having trouble recruiting consumers into this, and we actually just finally reached out and got a consortium of them together and had about 12 leaders of consumer organizations on the phone, and talked this through, and of course they were very interested in what's happening here. So a lot of the efforts are devoted to that. We continue to update the criteria in subsequent years, and then as we come out the outside of this, on the end, you have a basically an organization that's self-sustaining, probably paid for by the fees that vendors pay to be certified, that no longer needs government funding.

Last slide is they asked us to touch on some milestones in 2005 and in 2006, and of course, 2005 we had a big milestone. We met our contractual requirement to publish proposed criteria for ambulatory care EHRs, and we are now in the middle of the pilot test. And a key benchmark was the sign-up for the pilot test. There was some concern -- you built it, will they come? And we had 30 vendors apply, and we really only have room for six, so we just randomly selected them. But we are in the middle of the pilot test right now. We are set to complete that by February 28th, and then we'll publish a report, and then as quickly as possible, start certifying for real, not just a pilot but the actual production certification of ambulatory EHR products. Hoping to have the first stickers on the products in June of '06. Not much time to rest, though. Now we normally set our requirements for each March, but in -- we decided at our commission meeting leading up to the March ‘06 criteria that we couldn't wait until March ‘07 to have an impact on e-prescribing and laboratory results. Even though the standards hadn't quite gelled. There was either two standards, or one that wasn't official yet. And we didn't want to wait for March ‘07, so we pushed and said we're going to add a special off-year date of September 30th, 2006, and start requiring e-prescribing and by this I mean an EHR being able to transmit the prescription electronically, structured, not by fax, so it gets to the pharmacy in structured form, and to receive laboratory results. Now that's still dependant on some of John Holomka's work on [unintelligible], getting those standards finally harmonized and some work of some others, but we think we can do that with good industry cooperation. And literally, a month after that we're supposed to be publishing our first proposed criteria for the inpatient electronic health records. So it's a lot of very interesting work. We've had tremendous support from the industry in the form of volunteers, active dialogue, terrific leadership from the Office of the National Coordinator, and our project officer. Thanks for listening, and I'd be happy to answer your questions.

David Brailer:

Thanks, Mark. We appreciate it very much. With that, let me just turn it to you for comments, questions, or dialogue.

Lillie Gelinas:

Dr. Brailer, and Mark, maybe you can answer this as well, and some of the other presentations, there were great slides around barriers to implementation. I don't see a barrier piece here. Does that mean none exist?

Mark Leavitt:

Barriers to our success?

Lillie Gelinas:

Yes, barriers to your success.

Mark Leavitt:

There are plenty of challenges. The first challenge was market rejection. And I actually think we're over that, having 30 vendors apply for the pilot got us past that. We still have that risk as we move to inpatient and networks that the market would reject it, the vendors decide they don't want to come. But I think right now a bigger challenge is the potential complexity of what we're trying to certify, and the risk that we can't find what are the simple five, or ten, or 15 things that we need to focus on, because hospital systems are much more complex. In ambulatory care, there were 250 specific criteria in about 30 major areas, and we're -- we believe that the tests might take a half a day or a day per product. Well, the inpatient systems are much more complicated. So we have to quickly focus, is it computerized physician order entry, is it interoperability between health systems, and we already know the answer to that. That's a big one. Are there two or three hot spots where there's market failure? If we can focus on certifying things that are a market failure, true interoperability and some other areas, we can have the necessary impact without being exhaustive, certifying everything that every product could possibly do. We don't have the bandwidth or the resources to do that. So that's our primary risk right now.

Male Speaker:
Mark, what does it mean if after the ambulatory EHR certification criteria are out and products are certified, if there's no shift in the market towards certified systems?

Mark Leavitt:
We need the providers -- we talked about the vendors not coming and signing up, but if the vendors sign up but the providers don't preferentially purchase certified products, then you didn't have an impact. Because of that risk, we actually are funded to do a formal communication effort to the physician community. And of course, this is a tough community to reach, because they're busy, they're mostly in smaller offices, it's just expensive to reach them, and we actually have a substantial part of the contract goes to a communication program, so my frequent flier ticket is definitely punched for the next year, in terms of speaking at physician conferences or getting physician leaders at the conferences to talk about certification. We'll put quite a bit of effort into communication outreach to those end users that buy the products.

Male Speaker:
And just to be clear to the members of the community, the certification commission is responsible under our contract for evaluating its work, and having it evaluated, that in the end the real question with electronic health records being certified or not is do they lead to fewer errors? Do they have more protection of data, and can they share data more easily? And those kinds of end-stage functional outcomes are not the things you're going to evaluate, but we expect the research community to begin looking at those questions over time.

Mark Leavitt:
I think, what we do, we can certify that the product in the hands of someone that wants to improve quality, will fulfill their needs to measure quality and improve quality. We can't make the hospital or the doctor -- we can't motivate them to take the steps to improve the quality. We just make sure that the tool they bought can do it. But by unlocking these incentives of pay for performance, quality measurement, all the other things you talked about, and consumers, who are eventually, I think, a huge driver. I mean, when I changed doctors myself about a year ago because my health plan changed, we've all been through this experience, and I'm at one that has both an EHR, I can go online and see it, I can email securely, my physician, back and forth. Once you've done that, you don't go back. Once you tell your neighbor, they say, "I think I'll switch doctors." So ultimately, they're really the driver, once they realize how much power is potentially here, and how much better life can be. So we can't make all that happen, but we can make sure that the tools are there so that these other drivers and motivators can be effective and aren't blocked.

Male Speaker:

Can you talk a bit about what some of the criteria are in the ambulatory --

Mark Leavitt:
Sure. For example, in functionality, just in broad topics, the system has to be able to maintain patient identity, which is an obvious thing. Keep the charts straight. Maintain a problem list, every provider should be able to focus on the six, or ten, or three big problems or diagnoses that this patient has, maintain a medication list, maintain an allergy list. Have basic drug interaction checking, so that you're warned of drug interactions. Have some basic workflow, meaning the doctor can assign a task to the nurse or the front desk, and they can say it's done, and there's a way of checking and closing the loop so you didn't forget to call the patient about the abnormal mammogram, or whatever -- things that happen, really, in paper-based offices. There's about 20 more. When you describe them, it sounds dumb and simple. It's amazing we don't have systems to do that now, but those are the kind of things it includes. Now in security, it includes things like requiring passwords, automatic logoff if you walk away from a workstation, audit trail. Things like that, basic protection against viruses has to be either provided, or you have to include specifications on what the end-user should do. It's all pretty basic.

Male Speaker:
Do you have anything -- are you more specific in terms of content, more specific elements that should be recorded from a visit? For example, one of the points that I was struck by this morning is we really had a heavy focus, I think, on what happens in hospitals. And I think that's appropriate, but I don't want prevention to get lost in all of this, and I think we're still at a point of still understanding all of the things that should -- that need to be done, or that will be really effective in terms of prevention, but I think it's an important -- especially in the future, it's going to be tremendously important. So do you get into more specifics?

Mark Leavitt:
We get into ensuring that the electronic health record has the tools to support it. For example, let's talk about preventions. Actually, in the first year requirement it has to have basic reminders. So you can say, every year remind me to tell people over 65 to have an influenza vaccine --

[end of transcript]

... right? But we don't require that the product have it turned on and implemented in this particular way. We say the tool must be there. Because -- an example is reminding people about cancer screening, right? Well, if it's a colon cancer specialist, they don't remind their population about colon cancer screening, they have had it. And if you specify the systems too rigorously through this mechanism, you get something that people will not use, or will reject because it doesn't fit them. So you basically say the tools are there, turn them on if they're appropriate for the type of care you do, and stop at that point. Now, then, the quality organizations will say, you have to have it turned on, you have to report these specific data or we're not going to rate you, and that's fine. We just make sure that the tool is capable of it.

Kevin D. Hutchinson:

Mark, we've had a little bit of experience with getting some vendors on the network to reach pharmacies, and one of the things that we've discovered is when you have vender A and vendor B working side-by-side in a closed environment working with a paper process, maybe equal in their workflow function capabilities, but once you get into interoperability, it actually changes the dynamics of the workflow quite a bit. For example, if you're receiving medication history now electronically. How they process that information, or highlight that information, or give flexibility to the records that get stored inside that, when refill reminders, or requests are coming from pharmacies for an authorization, whether that's being highlighted, or not highlighted, or it's just being buried in some messaging that he has to go check on a regular basis. So what are we doing from the certification commission to take into account that once you add interoperability to these applications, that actually the functionality and the workflow, and I actually learned from you how important workflow is, what are we doing to make sure those certification requirements change?

Mark Leavitt:

A good question. In the first year's criteria, we're definitely not at the point to tackle measuring -- I'll call it workflow efficiency or usability. But we structured the testing in such a way that we could measure it in the future. So the way we test the products is not to say, "Here's 100 features, go through them." It says, "Here's a clinical scenario. Here's a patient, they come in, they get examined, they need a med prescribed, it interacted." And so the vendors go through this real-world scenario. So if, in the future, you wanted to count the clicks or time how long it took, or maybe just time how long it took the computer to respond, now how long it took the human to do his or her piece, you could do it. Not doing that at this point. But the thinking is

there that ultimately, the products have to be judged in a real-world test environment rather than in sort of a sterile --

Kevin D. Hutchinson:

Well, I was also thinking in the form of clinical as well, for example, you receive medication history. Are you receiving alerts if a certain patient, diabetic, over the age of 65, is not taking their medication?

Mark Leavitt:

That's in the test scenarios. So the test scenarios may say, prescribe this medicine, prescribe this. Did you see a warning, because you put two medicines in that interact?

Kevin D. Hutchinson:

This is actually -- if med history is being received from a payer, PBM, pharmacy, whatever, and they see that this patient is actually out of compliance, so they're not being adherent with the physician's orders, they're picking up their meds every 45 days or 60 days, or in a mail-order capability, maybe they're getting it every 120 days versus every 90 days, so you can see that a patient is actually somewhat out of compliance with the order, and so are you highlighting these things, are you alerting? These are things that we've discovered, once you add interoperability into these applications, the functionality requirements change dramatically of whether you're actually utilizing that to the nth degree.

Mark Leavitt:

It's true. But I think we should keep in mind, generally the users will drive the marketplace to improve usability. That's not broken; what's broken is that there's no way to plug the systems together without hiring a consultant and paying him 20,000 or 50,000 dollars per site to plug in your lab or plug in. So I don't think we should try -- we're trying to set certification as a basic bar. Think of it as an automotive safety standard. A basic bar, capability everyone should have. We're going to let the vendors differentiate themselves over the really fast, slick, extra features, artificial intelligence, whatever, but the basic stuff that protects patients' safety and doesn't lose their information needs to be in all the products. Again, a balance between letting the market drive this, which is really the most efficient but fixing what really is broke now, on this basic level that isn't there.

David Brailer:
Other comments, Doug, and then Craig.

Doug:
Comment, and a question, Mark. The comment, I think you will -- I would anticipate you will

find the physician community very receptive to your communication outreach. I think physicians in general are anxious to understand the seal of certification approval in terms of going that next step to purchase electronic health records, so I think that will further push the wave that I've referred to before. The question is, is there anything that this community can do, this group of commissioners can do to foster the certification process at the EHR level, ambulatory and inpatient next year that we haven't done so far, that would help the certification process?

Mark Leavitt:

There's really nothing I would add. I think the fact that this is being discussed at the highest level validates it, and I think really, it's a big contributor to whatever success we've had and whatever success we will enjoy is the endorsement at the top from the Secretary for the National Coordinator, from leaders of federal agencies and private sector organizations, you're doing it. When you talk about it here, and you talk about this strategy and how it fits together, you are doing the most powerful thing you can do for it, really.

Male Speaker:

Quick question. My impression is you do something of -- somewhat a kind of schematic functionality certification as opposed to trying to figure out if the latest version of Excel, or Word works perfectly every time. Is that true?

Mark Leavitt:

Yes. We're not doing QA on the products. Now people might complain that product quality should improve, and we wouldn't have any comment on that. It's also a challenge to develop products, so we won't get into that. We're not doing the Quality Assurance function for the vendors. What we're doing is certifying that it has basic functionality needed by this population, and that when you plug it into the network, it's going to be able to send information securely.

David Brailer:

Craig?

Craig:

Just to expand on what Doug was saying about providers and outreach to them, too, I think the Secretary and Dr. McClellan [spelled phonetically] and Dr. Brailer have sensitized senior leadership at CMS, certainly, to want to be a complimentary to the efforts that National Coordinator's doing, and reaching out. And I think, along those lines, you heard earlier, Kelly Cronin [spelled phonetically] mention this morning, that our QIO program is going to be outreaching to 5% of physician offices this year to discuss various options in the way of health

information technology. So one opportunity here, and depending on what the community decides to direct us to do, is to collaborate a bit more to be sure we're not doing anything in conflict with what the strategy of CCHIT is, and certainly not the Secretary and the National Coordinator's offices. The other thing which is a next step down, but I think takes a lot of thought, and again, requires direction from the Secretary and ONKIT, will it be our pay for performance efforts, and other agenda items that might stimulate adoption more rapidly, and steer people in the direction that this community wants to go in also? So we're here ready to assist in that, you just have to make sure you tell us what we should be doing.

Mark Leavitt:

We appreciate that. We've actually already started conversations at the individual QIO level with the California QIO, but we want to do it at the national level, and of course when you start talking about Medicare, and Pay for Performance and coupling that to IT and certification, then that's really the ultimate powerful driver for adoption, I think, and we want to talk more about it and plan to.

Male Speaker:

And Mark, just to -- perhaps a final question, the output of the certification commission is in the public domain. It'll be available via your website so that doctors, hospitals, consumers can look at it?

Mark Leavitt:

Everything we do is in the public domain except the actual looking at individual products and looking at their screens and seeing what they do, which is highly confidential between the different vendors. But once you get beyond that, all of our work is public. CCHIT.org has our certification requirements, our test plan, they'll have the pilot test results when the pilot test is over at the end of February. It'll have the assessment three months after that of the first year, and everything is on our website, yes.

David Brailer:

Any other questions? Thank you.

Mark Leavitt:

Thanks for inviting me.

David Brailer:

Okay. With that, we have concluded the formal business of the community. We still have time

reserved for public input, so I'd ask for -- there are microphones available in the central hall, so everyone who would like to speak could come forward. And while people are queuing up, I'd just like to step back with the community members and go to the early part of our discussion this morning, which seems so long ago.

[laughter]

It's your memory test. That we laid out this picture of these breakthroughs moving quickly through towards consumer value, and then these technology infrastructure components playing out towards transformation over a longer period of time, noting the intersections. And I hope what you've seen in the discussion today that with your approval of the workgroups, we now have essentially all the perimeter elements underway, and we have a lot of issues that are going to come up for my office, for the community, in terms of how to deal with priorities, with conflicts, with keeping all of these on track. So I think the business here will change somewhat towards beginning to look at how we really get our arms around these challenges and deliver the results we all want. But we've got a lot of really good foundations set, and a lot of really talented people working to achieve the goals that you've all come here to participate in. So with that, I'd like to just thank you all for your time. I know it's been a very long meeting, and we certainly respect the fact that you all have many other things to do. With that, we'll open the microphones. I think there's someone at the back microphone. Please.

Kelly Nelson:
Are they on, or do I need to --

David Brailer:
It's on, if you could just tell us your name and organization.

Kelly Nelson:
Sure. My name is Kelly Nelson [spelled phonetically], I'm from a small corporation in Huntsville, Alabama, and we develop encryption software. Your organization, the community, everything was brought to my attention about two months ago, and now I am so intrigued by what you guys are doing here, and I want to extend thanks for your efforts and for the energy that you're putting into this, because I think it's just wonderful. As I'm sure everyone else in the United States does. One thing that my company is concerned about is security, especially for digital data. And for years, developers and programmers have tried to develop systems for digital security that's easy, that's easy to integrate, that's interoperable with multiple systems, that's customizable, scalable, and not expensive. And it has yet to be done, until now. The developers at my company, they are very talented individuals, and they have developed an encryption technology called Secure Random Key Infrastructure. I sent every one of you a package about a month ago, before the end of the year regarding this infrastructure, and I know that right now, this meeting was primarily about just the applications that are going to be involved in building this infrastructure, but my purpose of being here is to bring our technology to your attention, because I think we have something to offer you that a lot of people have not

discovered yet. We could save your community and the health care industry at least 40% on your budget as far as digital security goes, and we're sure of that. We have started communications with SAP in Germany, we're going to be providing them solutions internally and externally. We're talking with the Parliament in the UK government, supporting some things for them. We're talking with Hitachi in Japan. DISA has committed themselves to be a sponsor for us to take us to NSA for the classified arena. We'll have our FIP certificate next month, and we are very excited about what we can bring to you. And I don't know that all of you read the package that I sent to you. I know you're all very busy, and I understand that if you did not see it, I'd be glad to send it again. Because I'm really, really concerned about this, and I really think we can bring something to you that would help you so much. Because of the infrastructure you're building, you've all said, over and over and over again, this is huge, this is huge, this is huge, and one of the questions you have is how are we going to make this region, and that region, everyone -- how are we going to be able to make them all communicate nationally? With our infrastructure, as far as securing what you're building, we can customize encryption for whatever you select. Any digital data at rest, in motion, radio discussion from an ambulance, from a med-flight unit to a hospital, to a VA hospital in Germany to California, we can encrypt any of that, and we can make it customized to fit into what you select is the best for your platforms.

David Brailer:

Great. Thank you very much. I appreciate it. Any other comments to be made on the public record? Please.

John Ruis:
Dr. Bailer, members of the commission. My name is John Ruis [spelled phonetically], I'm with the National Association of Community Health Centers here in Washington, DC. Community health centers represent 15 million patients across the country. They are the medical home for those patients. We represent 1,200 grantees, with over 3,000 sites across the country, over 40,000 FTEs. I want to thank you for this day; it's been rather interesting. I want to thank you for the opportunity to know what is happening around the initiatives that are occurring around health information technology. I've taken the time today to meet some of your staff, Dr. Brailer, here, and with several intentions. One of them is to raise the visibility of the community health center's patients and the safety net providers that they are. I was pleased to hear a number of times in the dialogues this morning questioning the inclusion or the -- making sure that there are populations that do not fall through the gaps in your works being done here. So I would like to address two things. One, with your current initiatives, to talk about raising the visibility of the CHC's safety net providers, and also to offer our desire to collaborate with any of the initiatives and any of the workgroups that are being pulled together, and any of the work that's being done. What do we bring to the table? Well, first off, there's a critical mass of data and patients that are available through the community health centers. Second is the expertise at the community health centers from the administrators that are familiar with the deployment of information technology at the health centers. The clinicians that have the familiarity both with the processes and the

needs for managing data at the health centers. The finance directors and the information technology people that have long been working at the deployment of information technology at health centers. Many of the health centers participate in networks that have long been funded through the Bureau of Primary Health Care and Health Resources and Service Administration, so they bring knowledge of what it does take to deploy information technology at the health centers, not only at the health centers but also within their communities. Many of them are also in the process of implementing and have implemented electronic medical records, so they are familiar with what some of the challenges are, what some of the barriers are and what some of the opportunities are. Finally, they also have familiarity with portability. Many health centers serve migrant populations that travel across the country, where the challenge is, how do we provide continuity of care if there isn't that information? And then I guess, one more that I need to add is Katrina. Many health centers around the Gulf Coast area did experience the loss of medical information because their facilities were devastated. So they are familiar with this and are working with this to be able to bring their operations up to speed. I'd like to talk about the future, and in terms of rapid adoption, I'd like to address it and call it, I guess, the buzzword is digital divide. And there is digital divide for both groups:
the patients who often do not have access to computers or to electronic information. So as we talk about empowering consumers, we also need to think about how we go about getting them access to the electronic information that would be used in any future. And then, finally, the CHCs themselves. Many of them are in rural communities were connectivity is an issue. Many of them also are small, non-profits. They're community based organizations with scarce resources for being able to purchase the systems that we're talking about. Many of them are smaller; they do not have those resources. So I guess my question to you, and I'm also glad I brought it up, how can we collaborate with you in order to be able to make sure that the safety net providers of community health centers are at the table and are working with your staff and with the workgroups that you have established? Thank you very much.

David Brailer:

Thank you very much. Any other comments today? Okay. With that, let me again thank everyone for taking time. I'd like to thank my staff, and the staff of the Office of the Secretary for their work in planning these meetings, for all of you and your staffs in supporting it, all the things you weren't able to do, and the people and all of our contractors and others who were able to help us do this. We will see you on March 7th. Thank you.

[end of transcript]