AMERICAN HEALTH INFORMATION

COMMUNITY MEETING

June 13, 2006

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

List of Participants:

- Secretary Michael Leavitt
- David Brailer, M.D., Chair
- David Ayre *(representing Steve Reinemund)*
- David Brantley *(representing Robert Cresanti)*
- Nancy Davenport-Ennis
- Colin Evans *(representing Craig Barrett)*
- Ed Goodman *(representing Lillee Smith Gelinas, R.N.)*
- Laura Conn *(representing Julie Gerberding, M.D.)*
- Douglas Henley, M.D.
- Kevin Hutchinson
- Charles N. Kahn, III
- Scott Serota
- Tony Trenkle *(representing Mark McClellan, M.D., Ph.D.)*
- Mark Warshawsky, Ph.D.
- Jonathan Perlin, M.D., Ph.D.
- Nancy Kichak *(representing Linda Springer)*
- William Winkenwerder, Jr., M.D.
- Dr. John Halamka *(Presenter)*
- Dr. John Loonsk *(Presenter)*
- Jodi Daniel *(Presenter)*
- Dr. Linda Dimitropoulos *(Presenter)*
- John Thomasian *(Presenter)*
- Jerome Osheroff *(Presenter)*
- Dr. Jonathan Teich *(Presenter)*

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SECRETARY MICHAEL LEAVITT: All right. If everyone would take their seats. I'm sure we will be joined by a number of others as we move forward. We've got some who are here representing others and we welcome them. We're glad that you're all here. David, good morning.

DR. DAVID BRAILER: Good morning, sir. How are you?

SECRETARY MICHAEL LEAVITT: Do you have any opening remarks you'd like to make?

DR. DAVID BRAILER: We have a very different meeting than the last time. I would like to give a very quick capsule of what we're going to do today and that is to say that we're going to take a look at kind of where we go for the next several months and to pull together a lot of the thinking that has been going on in the background so this is a very good meeting and I think it will be very informative for the members of the Community.

SECRETARY MICHAEL LEAVITT: Good. I want to take a few minutes this morning and do as David suggests. We have had, I think, a very successful period of time. Last meeting we were able to advance standards to HITSP on a number of different categories. We are now ready to take another step. I thought it would be valuable to just sort of step back and refresh our perspective a little on where we're going.

I put together a couple of slides I'd like to throw up. I have been talking internally with these. I think it'd be helpful for all of us to discuss it. The point I have been driving inside HSS and different places around the federal government is how important to a comprehensive agenda on health care this discussion is. One of my colleagues, Kerry Weems [spelled phonetically] is very good at describing what the standards are we're trying to create. He describes in some gory details the blocks of how you put the first name and last name into a medical form, and how simply, how detailed they are. It is hard to imagine how details that minute could in fact drive the whole system. But those at this table know that they do in terms of how many boxes there

are for a last name and there has to be a space in between and you can't have -- one will accept a capital letter and the other one won't. But that's the reality we're dealing with.

The point I want to make with the next slide is that many of the things that we're working to do in the system are completely dependent upon these standards. So when we talk about comprehensive health reform, and we talk about being able to reduce medical mistakes and talk about being able to improve outcomes, they are completely focused on the minute detail it requires to actually make these systems work.

This morning, I had an interesting conversation with Dr. Perlin who told me of a piece of research that was released this morning and talked about in the New York Times and was done at VA and at least as a smidgen of inspiration, I thought I would call on him to tell that story. Dr. Perlin.

DR. JONATHAN PERLIN: Thank you Mr. Secretary. This is why I get so excited about the work of AHIC and your vision for making the data available and the standards interoperable. But by looking at all of the ICU episodes across VA, we're able to look at 216,000 patient episodes in the Intensive Care Unit.

Everyone knows that high blood sugar in diabetes is bad, particularly the patients critically ill, and in an intensive care unit setting. People never assume, doctors, nurses never assumed that blood sugar was as problematic in patients without diabetes and by looking across the entire system at 216,000 episodes in the ICU, using electronic data, a study was developed that showed that actually the mortality is highest in patients without a previous diagnosis of diabetes and very high blood sugar or very low blood sugar.

In fact, the risk of dying was 3.8 times greater in patients without a previous diagnosis of diabetes when their blood sugar was high. So this is a fundamental finding that really alerts ICU clinicians to improve in the care, reducing the risk of death for patients by this piece of knowledge that was singularly available by being able to look across an entire population, 216,000 episodes, and coming to a very new insight in terms of how to save lives and improve health outcomes.

SECRETARY MICHAEL LEAVITT: Good. I thought that was a little piece of inspiration this morning for all of us, and that all these lining up the capital letters and blocks really pays off.

I suspect a recurring theme that has begun to manifest in my comments to you each month has been the sense of urgency I feel. As of today I think we have 952 days left at the time I'm going to hold the wheel at HHS, as I've suggested if all goes well. I want to talk about what I think we can accomplish in that 952 days.

Go to the next slide. You won't be able to see this very well, but the kind of outcome Dr. Perlin has described is one piece of it. Another piece of what I am very focused on right now is the area of transparency in pricing and quality. Independently many of us have been working with AQA and HQA to develop different standards. I suspect at some point in time the kind of thing that Dr. Perlin has talked about will become a part of a standard of care.

What you see in the slide behind you is a representation of results on a hip replacement, but it also portrays the value of transparency of information. On the far left column it indicates the distance from six hypothetical hospitals, or at least the data is hypothetical, in Florida. It represents the degree to which -- of information that most consumers use today to make the decision. They generally make the decision on the basis of which hospital is closest to them or where their physician practices. But if we can provide them with more information, even information as fundamental as how many patients a year they do hip operations on, or whatever the procedure is, it begins to add information.

If we're able to then add even more information on the quality of the care that occurs in those procedures, it will add a good piece of consumer information for them to make decisions. Then if we can add cost, that will be even more helpful. The point is we're very anxious here to continue to drive on the vision that people need to know what they pay, they need to know the quality of what they're paying, and they need to have a reason they're paying for, and they need to have a reason to care.

Let's go to the next slide. I just summarized -- it occurred to me that it has been taking us about nine months to run a batch of standards through the process. We'll get better at it, but I refer to this as the gestation process of health and information standards as a result of that, and I thought I would lay out my view of how this is all working.

AHIC decides what's important, or what's doable. That's really what we are spending most of our time on, is what are the next logical steps in the development of standards? We, of course, then have developed Workgroups. The Workgroups have been -- where a lot of the detailed labor has occurred, and that has involved many other people, hundreds of people and organizations have been involved in the Workgroups, which I deeply appreciate, and we'll hear more from today.

Once the Workgroups have finished, then they go -- the work comes back to us where we review and accept or send back for more work. But those we accept are then forwarded on to HITSP where they are harmonized with other standards that we have developed. And then once they have been harmonized with other standards and we've accepted them, they go on to CCHIT, where the products can be certified as being consistent with those standards. I think it is valuable just to see those steps.

The real key, however, as we've all agreed is the acceptance of the marketplace. Let's go to the next slide. I have laid out what I believe we can accomplish in the next 952 days. As I look at the time it takes us to move a batch, if you will, of standards through that process, it appears to me in the next 952 days we're going to be able to get at least three batches through.

I think this is crucial, because if we just do one batch and it's accepted by the marketplace, that will be nice. But it will not have established in a clear certainty that our work is going to move forward and be the process by which we establish standards. If we get a second batch I think there is strong likelihood that we will have that effect. If we're able to have a third batch, I believe that we have now begun to change the industry. So I am focused at least on getting three batches of these standards through, and then creating what I believe to be an accelerated course of action through time.

Let's go to the next slide. The President established a 10-year horizon for every American to have access to a fully interoperable health record electronic. I think all of us recognize that the adoption curve on something like this shaped similar to the one you see represented, it takes a little time to get this going, but once you have a process in place, it begins to accelerate.

I've laid out on the bottom what I believe to be the five things we will accomplish in the next 952 days. First, we're going to make very clear that we're going to have standards, and that'll become clear because they will have been adopted by the marketplace and a process will be in place.

Second we're going to make a -- we're going to create a process. That's what we're doing right now for standards adoption. There will be a clear pattern on how standards will be developed.

The third is we'll be adopting the first three batches, as I've indicated, of standards.

The fourth is we'll establish an update process. Our work is not going to be perfect, it's not going to be complete, but we will have established a means by which this process can update and improve its work.

Lastly, we'll create a self-sustaining model. That's something we've got to spend some time on in the future. But I think those are the five things.

Let's go to the next slide. I'd like to talk a little bit about the adoption process. The marketplace ultimately is where this has to be adopted. And we started off in this by putting around the table representatives of the government agencies that have serious responsibility in the development and policy and the payment of lots of the health care in this country, about 46%.

I've listed the Office of Personnel Management, Medicare, Medicaid, VA, DOD, again, all at this table. When you add a few other public payers, that large box on the bottom represent 46% of the dollars that go into the health system.

Since our last meeting we have had a number of meetings to reaffirm the commitment of Federal agencies to adopt these standards and to make a condition of doing business over time with those agencies, the adoption of these standards. And I'm very pleased to be able to indicate to you that there is a complete unanimity on that point. And as we get forward to having -- as we go into the early fall that'll be made clear in a very direct, and I think, clear way.

In fact, as we speak, HHS is writing into most of our rules, now, wording that would make clear that we're going to be adopting it. Office of Personnel Management and their offerings is doing the same thing. Department of Defense, as they have contracts that are able to be written in that way or amended, they are committed now to do the same thing, as is the VA. So as far as that bottom box is concerned, this is the way we're going to be moving in the future and as we roll out standards and they become part of what a certified product will be, those who do business with us in the future will need to be paying very close attention.

The second box and the third box, I want to talk a little bit about. It's clear to me if it is only the government adopting these standards that we will not be accomplishing our purpose. I showed you that slide on transparency first because this is a matter that is of great importance to the

President and he has asked that we begin working in a deliberate way to assure that we're accomplishing greater transparency.

As you may have seen, we recently began posting Medicare reimbursements on the top 30 procedures. A small step but at let's it's a step. It will have some value to people but it will get better and better. There are a number of other initiatives that are happening among the hospitals and among physicians and others to do essentially the same thing.

I wanted to focus a little on the regional markets. I have been meeting -- I've had 19 meetings now in different cities with different employer groups. In many cities in America, as you are aware, different employer groups have organized for the purpose of being able to provide through their health plans, greater levels of detail, and more transparency on pricing and quality. They have had one major player missing from the table and it's been the federal government.

Some weeks ago, I announced that the federal government would now begin to join those efforts. Those efforts will be designed to pool our data, for the purpose of being able to identify quality indicators and create better price and quality transparency to go toward something that would look like that slide I showed you in the first of this presentation.

We're in the process of identifying a dozen communities where we want to focus to achieve one specific task. I am personally going to be going to those communities for whatever period of time is necessary to approach the employers, the largest employers in those areas, to work with an existing organization that's been developed for the development -- for the -- which has been formed to develop price and quality transparency. We're going to partner with them at HHS.

And we'll be asking both the government agencies and the private employers, and the providers and the plans, to commit themselves to do four things. The first is share data, so we have greater transparency. The second will be to adopt health IT standards that are created here. And the third would be to begin adopting standard pay for performance definitions. And the fourth will be to develop a consumer incentives within their plans, if they're an employer, or if they are an insurer.

By going after these regional markets, and we'll do roughly a dozen of them the first year and then as many as we can after that, we believe that we'll begin to create greater adoption of the standards that we're working on here today. We're also going to be, simultaneous to that, approaching the Fortune 100.

I should be clear there is no agreement on any of the companies you see in that box. They're listed only as examples, but I will be personally approaching them for the purpose of asking them to do those four things as well.

So this is about creating a sense of consumer, and payer, and provider momentum toward the adoption of our standards. I'm very pleased with the progress that we've made to date, having the first batch out, demonstrating we now have a clear process. It's that time for us, of course, then to move on to the next batch.

Our first batch we're basically on ambulatory issues. The second batch, I think we'll start getting closer to inpatient. The third batch will be ready to deal with some of the work we already have

going on health architecture. But in the next 952 days, the theme you'll hear from me at every meeting is urgency. I am feeling an urgency to make certain at the end of this time we have established a clear pattern, we have a process in place that's self-sustaining and a momentum that makes clear that there will be standards and that those who do business with those large players in the market will need to adapt to those.

With that, Dr. Brailer, I think we're ready to go to the next phase of the agenda.

DR. DAVID BRAILER: Great. Thank you, Mr. Secretary. And I would now turn your attention to Tab Three. Because the Secretary has laid out, if you would, the broad contours of how this deliberation and the American Health Community fits into many of the other pieces that are underway, and what I'm going to do now is drill that in to talk about the mechanics of our process on a going forward basis.

In doing so I want to acknowledge that we have had an enormous amount of work and contributions being made by the members of the Workgroups and we worked them very hard to come to the recommendations you received at the last meeting. And I acknowledged to them at that time that we're not going to continue that pace. We're going to have some time for more deliberations and to step back and look at the some of the bigger issues that were tabled.

So what I'm going to lay out is the draft for your consideration about how we see this process unfolding from this point forward.

So with that, let me turn to slide two. So obviously, we've established four Workgroups and made the recommendation at the last meeting to establish a crosscutting subgroup on privacy and security. There are co-chairs and members of these groups, there have been more than 20 Workgroup public meetings held.

And as you know the first set of recommendations came through at the last meeting, where seven from the EHR Workgroup were accepted by the Community, eight from the Chronic Care were received here, three from Consumer Empowerment, and eight from Biosurveillance, which is an enormous share of the recommendations that they put forward. Some as you know were tabled, or put back for them for further work, or were held here for further discussion.

But I think it is fair to say to the Secretary's point that we are now beginning to turn this wheel.

And so we're turning our question then to -- next slide -- how do we go forward? Because as you recall, we identified a charge for the Workgroups that was a broad charge, a very large charge, for example, with the Electronic Health Record Group, to promote the adoption of interoperable electronic records. A huge goal. But then gave them a specific charge, which is, in the instance of that Workgroup, a very narrow charge related to the portability of laboratory information with respect to the EHR.

So the obvious question is, how do we get to this broad goal from here, and what we're proposing is a three-step process. Which is first, that the Workgroups should begin collecting information through testimony, through reviewing written pieces, through their own deliberations for bringing experts forward, to be able to identify what we're calling the "critical components" that comprise the broad charge. In other words, to take this broad charge, and to

decompose it into a set of specific charges. To be able to say that the way we go from a specific to a broad is not to take on the broad holistically, but to decompose to a level of work unit to do what we did with the specific charge and be able to really have enough focus and narrowness of that charge to be able to have specific deliberations, yet they work directly towards the broader goal.

Secondly, to prioritize those. To recognize that these are not all created equal, that different sequences of components can get us to the goal faster or slower, and to be able to then create a roadmap and a work plan about how these critical components, or sets of specific charges add up to the broad charge. Essentially to lay out over the next two and a half years how we get from where we are, to being able to have addressed, or to be addressing the broad charge for each Workgroup.

And then finally, for each of these, to identify recommendations that flow from those the critical components. Let me show you an example in the next slide. I'll use Consumer Empowerment as an example here. And I'll just say as a disclaimer before I drill into this, all of the ideas are simply illustrative. We're not trying to suggest this is how it be done, but I thought this something that could help us understand the process.

So the group first turns its attention to the puzzle pieces here on the bottom right, about how does it decompose this huge broad charge of getting widespread adoption of personal health records into a set of pieces that build on the work that has already done in secure messaging. Which might include health literacy, defining what the core functions and elements of a personal health record are, the standards for the record, portability of that information across personal health record providers, incentives for use, et cetera, et cetera. There could be many things here. We don't know how many there are, but our sense is that it is probably single digits of types of ways to decompose this problem.

It then prioritizes those, puts them in order, if you would. Enumerates them as is shown here, and then for each, turns to the bottom left where sets of recommendations flow from those. So we keep repeating the process that's been done over the last six months with more and more refinement, the ability to go back and amend recommendations or to globalize a recommendation that's seen as crosscutting and then to bring those to the Community.

So if you think back to the picture the Secretary showed, this is a wheel turning, if you would, inside the bigger wheel about how we would orchestrate this process.

Let me turn to slide 5, and then I'll just open it for discussion. What we would then propose, is that in June, that the Workgroups are charged with developing this work plan, with laying out over the course, essentially of the early summer, how these pieces come together, and begin in July taking background information, testimony, other information to begin considering what these pieces are so that by, say, October, it's begun recognizing what the core themes are, what the inputs are, what the issues are, so that letters of recommendation can come forward in the next batch in November and then into December.

So the idea is we have one more turn of this process by the end of this calendar year and we re-up again at the beginning of the year. We're hoping these are less than six months turns. It's possible that they will be, certainly we hope they don't exceed six months in each turn.

But we're hoping that we can begin getting more and more refinement of the process, more and more legacy of information, knowledge build up, and they can turn in three to four-month rotations. Clearly, we think the Workgroups did an outstanding job of starting from a cold start, coming together with no history, with no, if you would, rapport of the groups, with very different issues, and coming forward with very, very far-reaching recommendations. We have an appetite to be able to do more, but we want to be practical about this and recognize that still the Workgroup members have day jobs and other things to do with their time.

So what we are proposing again, just in summary, is a decomposition, a set of recommendations that flow from each component of that, the first of which we want to have to this group for approval by the end of this calendar year, and have time for at least four more, if not six more turns of that process by the end of the Secretary's 900+ day count.

So with that let me stop and just open this to discussion or ask the Secretary to make any comments if you'd like, sir. So any discussions about this, because this really will be our methodology going forward. Chip.

MR. CHARLES KAHN, III: I'm going to be a proverbial broken record here and I know we're going to take this up in August but I want to get this on the record again because I can't help it with the Secretary's introduction. If you look at the wheel, quality, transparency, and pay for performance are two pieces of it, and measurement is key to it. And if Jonathan's findings are ultimately made into guidelines, they'll have to be measured and that means you've got to worry about why something wasn't done as well as something being done, and then you get into complexities of tools for measurement, which are not generally integrated into the current architecture.

I think in terms of standards and certification, the work has to be done. It's not been done. We're going -- in August, we'll have some proposals about things that could be thought about, examples, but I think beyond that it's got to be integrated into this process because it's so key to the agenda, and we're just not quite there yet. So I'm beating on my drum again, but I just want to take one last shot because I still think it fits into agenda, whether it is a Workgroup or an aspect of the Workgroup's work, I think it can't be ignored, sort of, from each piece of the work.

DR. DAVID BRAILER: Chip -- for those of you that have not been following the work that is being done under HQA, the Hospital Quality Alliance, there is a report that is being prepared on the information that's needed to measure performance and how that relates to Information Technology and what's the practical ability to generate that information.

And we are planning at the August 1st meeting, a report on that work, to begin digging into this question and hopefully using that to set up a question to the Community about how do we engage this? Do we form a Workgroup? Is there another way to engage? I think from, at least the discussions that I'm aware of, it is very clear to us we have to engage on that and the question now becomes how, and with what charge. So that's, I think that is a very useful thing.

SECRETARY MICHAEL LEAVITT: I think a very good way to, again, illustrate the validity of what Chip has said. I indicated there were these 10 to 12 communities we have selected that we want to begin developing the kind of information I showed on that chart. Six of them already

have Workgroups going under the Medicare Modernization Act of 2003, a series of pilots were enabled, there were six of them. They're in cities like Minneapolis, Boston, Indianapolis, Phoenix, California, I'm missing a couple. But that work is currently being -- is underway right now.

But they're gathering the information by scouring through manila folders and health records to try to assemble it. Well, it will be useful information but it's absolutely not sustainable in that way. So while we're demonstrating in its most rudimentary form the value of it, this group has got to accelerate the capacity simultaneously to gather that data on an ongoing and sustainable electronic fashion, and I think that's the point that Chip is making.

There are at least three wheels that are turning here. One is the development of the standards. The second is the development of the process to develop the -- to automate the collection of the data, that's what we're engaged in. And the third is the development of the acceptance, which is happening both at this table and others.

So there is a lot happening and I want to endorse what Chip has said. It is absolutely crucial it starts with the right standard. That is hard work to get there. I appreciate the fact that it's happening.

DR. DAVID BRAILER: And I might also comment that in the spirit of this question, about how do we organize for this, the view that we've taken of the Workgroups is that they are organic. It is possible a Workgroup could obsolete itself. It simply can't make progress. Or that, as we've done with Privacy and Security, it could spawn other processes. So I hope the spirit that we bring to this is that we don't let structure dictate our process, but we create structures as needed on a temporary or standing basis to accomplish our goals. Other thoughts or comments? Colin?

MR. COLIN EVANS: Maybe this is a mechanical question we will get to at the end of the day, but when I look at goals, objectives, and strategies, which we'll discuss later, and I think about the Workgroup clustering, I am sort of struggling to map one against the other. We have a set of recommendations that are working on certain topics, and yet a set of goals. And I think it would be enormously helpful that if either as a team or part of your function we could somehow map those together and see where they fit, because it is not clear which recommendations go with which goal and so on and so forth… some sort of matrix that would help connect those I think that will be helpful to a lot of people.

DR. DAVID BRAILER: I think that's a good question. There is a significant degree of overlap between the broad charges and those four goals, but they're not designed to be completely concentric or overlapping. We'll certainly tell you how each goal overlaps each Workgroup or vice versa. I think that would be helpful to see. Other thoughts? Kevin?

MR. KEVIN HUTCHINSON: Just a couple of things. On the timetables, the testimony and background, it's the testimony to the Workgroups themselves, not necessarily to this Commission, correct?

DR. DAVID BRAILER: It's our belief the primary locus of testimony is the Workgroup, given the burden of these meetings and the time that's already committed. But you certainly as Community members could invoke your own testimony if you want to have other opinion or

there's dissonance in the Workgroup, or there's other reasons to have it here. But we see that being Workgroup testimony.

MR. KEVIN HUTCHINSON: Okay. Somebody from the outside. Another thought, is in looking at a lot of the Workgroup recommendations that have occurred, it seems if we could come to some agreement on certain types of conditions or patient populations to focus on, a lot of these activities in the individual Workgroups are interconnected so lab results delivered to EHR solutions that physicians are using as well as medication history to PHRs, and PHRs communicating with EMRs, it would be nice if there was a focused condition or specific population that when we get ready to implement that type of solution in some type of pilot project or demonstration project, that it's a condition that it is interconnected health care.

So we're not focused on asthmatics for medication hospital to PHRs and diabetics for labs to EMRs, that there is an actual connection, and actually connection between the PHRs and EMRs.

So I don't know where that work would be done, because individually we're coming up with our own patient populations and disease conditions that we want to demonstrate, at least in the Consumer Empowerment Workgroup, and I've seen a little bit of that in the EHR Workgroup. It seems there is an overlying need to make sure that we're focused on a singular population.

DR. DAVID BRAILER: I guess a couple of thoughts on that. I think it is intriguing that we posed the questions to the Workgroups, as you recall, something like this, where you need to provide specificity by creating segments, disease segments, or populations, do so. You know, if you want to talk about messaging in the context of asthma or diabetes or whatever it might be, or any of the other topics, do so. And all of them chose not to, after some deliberation. They viewed their goal as kind of going actually more broad than the specifics, as you know. So I'm not sure if there is a lesson there.

Remember, that in the background, secondly, we have asked the contractors, certification standards, the architecture contractors that you'll be hearing a lot more from over the summer, to be essentially the integrators of these pieces to ensure that the work that we're doing in personal health records that relate to drug data tie into anything we're doing on the electronic health record, or in architecture or in data collection.

And those we're operating, certainly, under a public process and with some direct communication here. We'll go back and repose the question about would disease specificity be helpful to that, to make sure that they're heading in the right direction. I know it is discussed at some length, Kevin, but I haven't heard it become an obvious must have at this point.

MR. KEVIN HUTCHINSON: I think it ties to the conversation that Chip was just having as well. It may not be specific in the Workgroup that has to make that decision on the specificity of the actual disease or the patient population, but once we get to demonstrating the improvement of the quality of care and the lowering of cost and the integration of care, it seems that we're going to have to have some measurable objectives around a certain condition, or population, to be able to do that. And maybe it's not in the Workgroups where that's performed; it's got to be performed somewhere.

DR. DAVID BRAILER: I mean, to some degree that implicitly happens already. If we talk about quality measurement there are certain diseases that we measure quality performance in and others we don't. If we talk about chronic care management, there are certain diseases that it applies to, and not others. So to some degree there is an implicit set of disease conditions.

I think it would helpful for me to ask the office to go back and look at some of the disease priorities in each of the areas, and perhaps if there is any interesting findings to report it back here about maybe even this question, are we going in the same direction with respect to the bundle of diseases that are on the table or not.

Other comments or thoughts on this Workgroup process? This will be occupying a great deal of your time and attention, not managing this, but certainly the results of it, so I want you to be comfortable with what we're proposing and how this will go forward. Any other thoughts?

Okay. I don't think this requires action, Mr. Secretary, so I think we are ready to move on with the agenda.

Now, for the remainder of the day, we have reports for you on three substantive areas that are going on with our background contractors. The first is the health IT standards panel, which as you know, is absolutely essential to the work that's happening here and with other efforts. Privacy and security, that is our effort that has been underway for sometime. And then clinical decision support.

So these are quite substantive and I'm going to ask you to ask all the hard questions you would like to ask. And then as was alluded to earlier, a discussion of the Office of the National Coordinator goals and objectives, and with some questions about how that fits into this process.

So with that, let me turn to John Loonsk, who is the director of Office of Interoperability standards in the Office of the National Coordinator, who is here with John Halamka who is the chair of the Health IT standards panel. Thank you very much, and this is Tab 4.

DR. JOHN LOONSK: Good morning. I'm going to talk a little bit about the challenge that stands before HITSP in moving forward with the activities we've talked about in terms of standards. We have recognized the needs for standards implementation, the Secretary spoke to that earlier. We have many Community recommendations that point at the September deliverables for HITSP. And I'm going to set the context for that a little bit. And then John is going to speak to the process that HITSP is using to address these -- this challenge. And unfortunately Bill Braithwaite could not come today, and John will speak to the future HITSP milestones and activities.

So to begin with, there are a number of standards issues that HITSP, most of which HITSP is grappling with, some of which will take all of our attention for a number of years. There are gaps in standards. Sometimes there are medical concepts that don't have terminologies associated with them. Medical concept knowledge area is broad, it's diverse, and it's a challenge to have those.

HITSP's going to be working on some of those gaps and encouraging the SDOs, the standard development organizations, to work on them.

But there are also gaps, for example, in some of the technology standards, just to be able to have different systems work securely across the internet and share data. The standards for that have been developing. And they're now reaching a certain level of maturity but they have not been here for that long.

There are ongoing issues with adoption in clinical care settings. I will talk about a couple of those and then I'll just mention the real challenge to HISTP of getting to the kind of specificity that really advances interoperability.

So some of the adoption issues in terms of use, is that this is not a green field. There are terms that are used in most clinical care settings. There are traditions for those terms, there's infrastructure that's oriented to the use of those terms. These issues have to be overcome. There are aspects of the way in which information technology is deployed right now, which relate to the effort of integrating systems and the fact that that is part of the business model for how some of the services are provided.

And then there is an ongoing issue that will be with us for many years in terms of moving forward with the structured way the data is stored. On the slide, there is an example on the far right of free text. This is the way in which most medical information is recorded now either through transcription, through handwriting, or at times now through electronic word processable files. The target for unambiguous data storage is really the coded data that's on the left. And the challenge here, to some extent, is that it's much easier to put information into the free text form than it is to put it into the very structured form.

The DOD and the VA are working on this issue, as are many others, nationally, in terms of the challenges of getting to this unambiguous specificity of storing data, but it is going to be an ongoing challenge.

Some of the other issues that we've talked about in terms of gaps, overlaps, and specificity are things that HITSP can work on, and HITSP is working on in the context of the September deliverable.

The final point to make here in setting this context is about specificity. Getting to not just the naming of a high level standard. These high level standards we sometimes call name standards. Some of these are terminologies for example, that contain thousands and thousands of terms. And while it's an advantage, it's necessary to start to use those terminologies as a set for how we're storing and working with data, it is really not sufficient. It is necessary but not sufficient.

The kind of specificity that is before us and is the real challenge to the Health Information Technology Standards Panel is represented in this example of implementation level guidance. This is an example of what the kind of product that HITSP will be producing will be. In this, it's really a highly detailed listing of every standard, more than just terminology, but technology, terminology, structure, et cetera, necessary to have an unambiguous implementation. This is the level of detail that HITSP is striving for and it is the kind of specificity that is really important in terms of having systems be much closer to being able to plug and play, interoperate, and carry on with many of the activities we are talking about.

So with that, I will pass this around so you can look at some of the detail here. This may not be rocket science, but at time it gets close, and John will talk about the HITSP process for getting there.

DR. JOHN HALAMKA: Thank you very much, Dr. Loonsk. Good morning Mr. Secretary and to the Committee. Always enjoy presenting to you and here to give you a HITSP update.

Most important is not the specific product that we're going to deliver in September, and we, of course, will make sure all of our deadlines are met, is the process of getting there. Making sure if we will do these rapid cycles as you've described, that we have truly defined a repeatable process that will take input from and turn out interoperability specifications with a known amount of resources and a known amount of time, in a highly repeatable process that's well respected by the Community.

HITSP was formed and chartered by AHIC and ONC to ensure that all the stakeholders in the community are represented. We've put together doctors and nurses, pharmacists, vendors, industry representatives, consumer advocates, attorneys, all of the stakeholders are there. Since my last presentation to you, HITSP membership has, in fact, expanded a bit, we now have 155 organizations and that is including the standards development organizations: 17 of those. But 114 non- SDOs, 15 government organizations, and very importantly, nine consumer organizations.

Given that this group has so highlighted the personal health record, it is very important to HITSP, it is important to all of us to ensure that we are defining those work-products that will empower consumers, because some of us are doctors, but all of us are patients.

Our board is reflective of our membership. We have eight representatives from SDOs, nine representativesfrom non-SDOs. Four representatives from government appointed by ONC and two representatives from consumer organizations, echoing, again, the importance of having patient advocates and consumers represented in the HITSP process.

So now let me walk you through what the process has been over the last few months. And here is a bit of terminology. All of you are experts at acronyms at this point. You have heard about AHIC and ONC, and HITSPIC, and HITSP and NIN. Well, here are a few more terms for you.

What is harmonization? Harmonization is really bringing together that set of interoperable standards, so that we ensure the use cases have you given us, down to the granular level of the event, have a complete set of unambiguous guidelines so that all stakeholders, all vendors, all doctors, all hospitals, all clinics, can implement this interoperable flow of data that we want to empower all of the patients, providers and payers.

Harmonization, to give you a key example, in the case of HITSP's work, which I'll describe in a moment, started with 570 potential standards for the initial use cases you have given us. Simply applying some rigorous criteria, which I'll describe, we've reduced that to 180 standards. And again, this month, in fact, tomorrow, I have a HITSP panel meeting. We hope to ratify a few dozen standards that will empower the use cases that you have given us. This process of harmonization has required incredible granular detail and rigor.

Not only are we refining the standard selection through harmonization process, but we're also identifying gaps. Certainly you'd think that if there are 570 standards there wouldn't be gaps to be filled, but yes, there are, in fact, areas of the processes those events, actors, and actions you have given us, that do not yet have standards well described. So we clearly have to identify to the standards development community, what are those gaps and request their assistance in filling them.

Well, there are also overlaps. Standards that seem to be duplicative or competitive. Now we have to be careful there, because it may very well be that some standards are good for a specific context or architecture, so there appears to be overlap, but they in fact have very different applications in the use cases you've given us.

Harmonization won't always mean reduction to one. It won't always mean unification. But it certainly will mean reduction to a small number of standards that are the most appropriate for a given use case with actors, actions and context. And of course our SDOs are those organizations that are developing the standards that HITSP is using in its harmonization processes.

So let me take you through a typical HITSP cycle. So you've described the need for having multiple cycles. You are our inputs. Your working groups provide us the input and our priorities, because we recognize there are hundreds of potential use cases. To date, you have given us consumer empowerment, electronic health records, specifically labs, you've given us biosurveillance, and now introduced chronic care coordination and secure messaging. So we take those as our charge.

Then, our technical committees, in a very rigorous process, map all of those use cases down to the level of every actor, every action, and event, and look at all of the possible candidate standards. Well, the real challenge is, I can tell you, there is emotion in the standards world. There is ownership of standards that have been around for many years. So how do you get by the emotion? The answer is: you create objective criteria that evaluate not winners and losers, but the most appropriate standard for a given event in a use case.

So what that means is, we have to ask simple questions. Okay, given the 570 standards, which standards are actually suitable for exchanging medication information or laboratory information? Which standards have a very open and transparent process behind them? If two gentlemen in a garage develop a standard and no one knows how they did it and there was no input, it's probably not a very good standard. Or similarly, if there is no way to update a standard because there isn't a robust organization behind it, that is probably not a good standard. You're going to be giving us continuous new use cases; we better have the ability to deal with SDOs and organizations that can constantly adapt to new needs.

Well, similarly, if a standard costs a million dollars a copy to use, it may be a fantastic standard, but the barriers to adoption are going to be significant. Or if there aren't good implementation guides, good documentation, good technical support, probably not a great standard.

At first pass these are called our Tier 1 criteria. We look at in a use case, at every event, which of those standards are going to pass those early filters.

And then we have to get more granular. Given the details of each actor, given the context and the green field that we have in the future, the brown field of existing systems we have today, what are those standards that are going to help us get from our current state to the future state that you've envisioned?

We use a very detailed set, of what we call our Tier 2 criteria, where we have established quantitative measures that help us assess the appropriateness of every standard. So our takeoff committees will list each event you give us in those use cases, and grade a standard on a scale from 0 to 3, how does it adhere to the Tier 2 criteria, which allows us to have a quantitative view, not an emotional view, of the appropriateness of a given standard for each use case.

Now again, recognize that this is an evolving process. I will tell you that I have supervised every one of the technical committees, and watched with, I will tell you, great satisfaction, the way that there has been an outpouring of support from all the stakeholder communities. We started with 155 organizations, and when we said, we're going to spend days harmonizing standards in Chicago, I thought, oh, we may get a dozen or two very interested parties. Eighty organizations were there for the harmonization activities. All were very vocal. All helped in process development.

The process that was just employed to get to our latest set of few dozen standards was rigorous, complete, and quantitative, but still evolving. Obviously, we hope to get to the point where the process is so well described as you give us new cycles, we will be rapidly able to turn around the HITSP work-products that you desire.

So where are we going beyond technical committees? Once technical committees take your use cases and develop a set of named standards, those most appropriate standards for each event in the use case, then the HITSP panel, all the stakeholders, and all organizations review the work of the technical committees and make comment. And that is what we will be doing in Washington for eight hours tomorrow, with our first set of use cases that you've given us.

So it is as of this moment on the HITSP website, www.HITSP.org, able for the entire public to see the work we have done so far, applying Tier 1 and Tier 2 criteria to get from 570 standards to a few dozen.

Well, then, as I've mentioned, there are gaps, and there are overlaps. So the technical committees work with the SDOs, we work through those gaps, and recognize that SDOs have their own processes that may take a few months. So when we get to September, it is my goal that we will, in fact, have the unambiguous cookbooks as you're passing around. But if there are a few gaps, a few standards that don't exist, those may still be in process from the SDOs, but be assured, we will, in fact, meet our deadlines for the deliverables that you require.

Well, the SDOs will also have to work together on overlaps. An important point, as I've mentioned, is that we'll define architecture and context so that it is very clear to an SDO how to optimize the selection of a standard, so that we can minimize overlaps and ambiguity. We want to ensure that vendors can be given one way to implement the standards necessary to fulfill the use cases you have given us.

Then, after we have had an opportunity to beta test, to make sure that what we suggested to the vendor community is implementable and rational, all of these standards will be delivered to you for your blessing, for your review and endorsement. And then, of course, working with my friend Mark Leavitt, we will ensure that CCHIT incorporates HITSP interoperability specifications and their certification criteria, so that vendor products can be evaluated as appropriately interoperable per the uses that AHIC has given to us and the HITSP documentation.

So that's the end to end process. It has very much evolved. I am quite comfortable that we are now at a level of concrete deliverables, where we have our criteria for objective evaluation of standards, a process in the technical committees that's well defined and consistent, and a mechanism for to us get to interoperability specifications over the summer to those September deliverables.

Just a couple of comments on our progress to date. We worked closely with ONC and AHIC on the initial sets of use cases, contributing all of the detail that lead to the harmonized use cases being delivered, finally, in March. We've worked diligently through the months of April and May to winnow down 570 possible standards to 180, and then in June, to get from 180 to a few dozen. And so that June deliverable to ONC is a very key document.

The September deliverables, and again, my commitment that these will be done to a level of completeness that will be not a draft, or a work in progress, but something that you can start looking at as a serious and final deliverable, for those use cases you have given us we'll deliver the unambiguous standards implementation guidance that will make products possible to derive from the HITSP work-products. And then of course we look forward to the prioritized additional use cases that will enter into a new cycle of process post-September.

Throughout this whole process we seek public open comment. We recognize that the only authority we have an as organization is our consensus process, and so we have tried to include all stakeholder organizations in the development of these deliverables, and as these are published on our website, we look forward to future public comment and comment from you and your organizations.

A couple of comments about the future. I have already mentioned the June deliverable, which we'll be finishing up tomorrow. I've also mentioned that we will, over the course of the next few months, be coming up with interoperability specifications, and there's a lot of education that has to be done for all of our stakeholders, so that they understand what are these are used for, and that they have meaning, and that they will be incorporated into the CCHIT functional criteria.

Also important is to sustain HITSP. We believe that the harmonization processes we've described will need to be done for hundreds of use cases for many years to come. We want to ensure that HITSP is supported by member organizations who derive value from our activities, and we're working diligently, as part of the contract with ONC, to develop a sustainable business model, so that HITSP can continue the harmonization work as long as harmonization is necessary.

With that, I open it up to your questions, and your concerns, and am happy to describe our work to date and into the future.

DR. DAVID BRAILER: Great. Thank you, John. And I'd like to say that as we looked at the landscape two years ago of how we could bring value to the standards process and not make it worse, this effort of harmonizing, putting together a new organization that was a cap stone was somewhat controversial. It was one of the many different options we looked at and I just want to applaud you and the members of your board, and the organizations that supported this, for really taking this idea much further than we thought could happen. So thank you very much.

SECRETARY MICHAEL LEAVITT: David, could I just add. Looking at the example of the standards. The feeling I have is just gratitude that the Creator provided people who have the capacity to wade through that level of detail [laughter]. It just exhausts me to look at that binder, yet all of us, as we've said earlier, our work is dependent upon it, and I want to express appreciation for the fact that A, you're there, and B, you're doing it.

DR. JOHN HALAMKA: Thank you. We have a very strong group of people putting in that level of granular detail. There is no question, the next few months will be key to getting to September.

DR. DAVID BRAILER: Let's open it up for questions. Any questions for either of the Johns? Gail, do you want to start?

FEMALE SPEAKER [GAIL]: Yes. Along the lines that Secretary Leavitt was talking about, I certainly appreciate the detail that you had to get into. But what I worry about is that as the products are being developed with the standards, that somehow we make it very clear that the end user always has to be in mind, whether it's a provider, whether it's a consumer, but it has to be workable for the people that are actually going to be using it, and I am a little concerned about that after seeing that book.

DR. JOHN HALAMKA: Right, see that is a very good point, and this is why in the process we've described that August will be a time for taking our work-product to that point and begin testing it. Giving it to those stakeholders who will use it, and getting their feedback as to its utility. Because one challenge is, we can't just name a standard. Use HL7 or NCPDP, because that's ambiguous. Well, neither can we come up with an interoperability specification that's a thousand pages long, because that's going to be impossible to maintain.

So one aspect of thinking about this, is how do we break down that large document into reusable building blocks. So we've said across your use cases, ah, authentication of a user, whether that's a doctor, or a patient or a payer, that seems to be a common building block. Well, if we have one guide to that, that we reused across all use cases, suddenly we don't have a thousand pages per use case, which becomes unmanageable and un-maintainable.

So we will certainly employ your thought, and with the use of building blocks, I hope, come up with something very digestible and useable by our stakeholders.

DR. DAVID BRAILER: Gail, I might add, and you and I have discussed this, that it's our hope that through this process, that consumer organizations themselves will develop some of the expertise to be able to translate consumer input into this process, which is something that 20 years ago provider organizations and plans started doing. Kevin.

MR. KEVIN HUTCHINSON: First of all let me just add, John and John, this is great work in a very, very short period of time to get to this point. I don't think any of us would have expected that you would have been able to filter through so much in such a short time frame. So to you and your team, it's kudos to you.

Two comments. One, what about mapping? In many cases, there are vendors and technology companies who map because they can't support a particular standard, but they can map to the standard without building it inside the application. Is that something that HITSP as well as the certification commission feels is okay, as long as it gets to the other end in that format, or is this something that needs to be native in the application?

DR. JOHN HALAMKA: Certainly. So let me address that with a specific example in your field. So we recognize there are multiple ways to describe a medication. There is a vocabulary called the NDC vocabulary that is specific to the kind of package. If you have a tablet of Tylenol in a purple bottle with a 20% off discount, that requires a separate NDC code from the green bottle without the discount.

Well, a doctor typically doesn't write for a level of granularity to the color of the bottle. So the doctor may want to say oh actually it's just Tylenol. Well, there are other vocabularies that are at less granular level, like Rx norm. So a question is, gee, you have two vocabularies, the NDC and the Rx norm vocabularies. Do those coexist, do you harmonize to one, or do you recognize they both need to coexist but have a map between the two?

So I think our answer has actually been complex, which says, some of the time you will need to persist two standards and a cross walk. Some of the times, you will have to say ah, there is a standard today that we know is good for today, but isn't good enough for tomorrow, so we will say our favored standard for tomorrow is over here. Here is what we have got today. We need a map between here and there, but in a finite time, that map will go away.

And then the third answer is, well, we know hospitals all stakeholders in this country have systems already, and the likelihood that they'll rip and replace those systems over the course of the next year to two is not great. So, maybe, if interoperability standards declare an unambiguous way to communicate, but behind the four walls of the hospital or clinic, there is a mechanism by which they can take what they have got today and translate into that interoperable new standard, that at least gets us to interoperability faster.

Ultimately, of course, we'll want CCHIT to have the native product, speak, whatever is the interoperable standard, but going from the current state to future state may require temporary mapping.

MR. KEVIN HUTCHINSON: And I think it is important to say there is a defined time line as to where that bridge or connection point would be allowed to occur. Even if it is a year or two or three years out, as long as there is a defined timeline to when it becomes native into the application.

The second comment is about, do you feel it is within your charter to look at -- it is one thing to allow the exchange of patient information and the exchange of health care transactions like lab

orders and prescriptions and other things like that. But it's a whole other thing to be able to actually have standardized medical terminology that allows us to go back and do measurements against health care standards, quality standards, and have it be effective. If we start exchanging information but we don't have that standardized medical terminology, or even like a standardized SIG in the prescription world, you're not going to be able to do effective measurement evaluations against that. Is that something you feel is in your charter?

DR. JOHN HALAMKA: Absolutely. So the charter of HITSP includes the content of the medical information, so that gets to the vocabulary, as well as the structure to how to send it from place to place and the transmission method to ensure it's secure and non-repudiatable.

So Betsy Humphrey's from the NLM is very engaged; he's on the board in fact. He's very often careful to remind us of the importance of vocabularies. A simple example as contributing to biosense, and this is an initiative that John in his former incarnation started at CDC, we have to contribute something called the chief complaint. Why did patient come to the emergency department?

Well, I'll tell you that today, if you look at [unintelligible] where I work, a typical chief complaint is "brought in by wife." There is no vocabulary control that suggests shortness of breath, fever, et cetera, it is free text. So how are you going to at CDC, do syndromic surveillance based on "brought in wife." You need vocabularies. We have vocabularies for labs called LOIC [spelled phonetically], we have vocabularies like Snow Med CT, we have the structured SIG that's evolving for describing medication dosing. All of these are going to be used.

But I will tell you there will be barriers. As a clinician, and I'm an emergency physician, it is easy for me to handwrite a note that says the patient is a 33-year-old with cough, shortness of breath. I think he has pneumonia, here are some antibiotics, go home. And the amount of time it would take to select a Snow Med term, a codified SIG, and all that is necessary to really benefit both biosurveillance and consumer empowerment and quality, et cetera will take additional time. So how do we get from current state to future state? I think the answer is there will be some interim balance, some free text, some structure, and evolve to more structure over time.

DR. DAVID BRAILER: Bill?

DR. WILLIAM WINKENWERDER, JR.: John and John, great job, and I think your presentations give us confidence that we've got outstanding skill, experience, and intelligence guiding this activity.

I just want to make a comment about the last thing you said, but then I wanted to ask a question or two. We at DOD with ALTA set out as a primary objective as we developed it, that all, or nearly all, of the data was going to be structured, or coded. And I think people now understand what that means and how difficult that is, even the clinical text. And especially the clinical data. So it would all be placed into a category or a defined packet, so it is reproducible.

One of the things that we've learned as we've done this, just to reinforce what you have just said is to get the clinicians to do that. So to point and click on each thing, versus the usual way of doing business. It is a change in business process. It is a change in really the practice of

medicine. And so we're struck -- to be honest, we are getting most people to do that, probably 70%. But there is probably one-third that just can't get there. It is a change.

SECRETARY MICHAEL LEAVITT: Generational.

DR. WILLIAM WINKENWERDER, JR.: It really is, and it is a different way of thinking about collecting information and storing it and so forth. So one of the things you have to do is demonstrate the value of doing this. And so we're trying to do that right now. How do we get back reports and information and epidemiological trends, and display that so that people see there is value in collecting this. Because if you don't, people say, why I am doing this? So anyways, that's just an observation. But I just wanted to build on what you said.

But my question is really related to -- given the importance of this whole effort, critical importance of it, can you talk a little bit more about transparency and developing trust among the barter community, and therefore the public communications, and sort of your plan for how you intend to do that? Because it seems like this is going to be a technical process, but it is also a political process. And talk, if you can talk about that?

DR. JOHN HALAMKA: Sure. I will start it and maybe John, you can you add to that too. At the HITSP website you will find documentation on every process, every meeting, every to-do item open to the public. Any organization in this country can join HITSP. Simply all we ask is that you attend the meetings and participate. The process that we use at the panel level is a consensus process, where we hope we can get to consensus, or near consensus, on all of the work products.

And to date, I think we have done a reasonable job. We have really tried to engage all the stakeholders of the general public, widely disseminating the work-products for review. Over the course of the summer, as we get to the September deliverables, it will be critical that we communicate what we are doing, because this will now be generating final work. Our work to date has been interim, it's been a snapshot in time. And so certainly we'll work very closely with you and with ONC to ensure appropriate communication.

DR. JOHN LOONSK: This process is strong. John referenced the emotion behind this. There are a number of passionate people in this area that are so enthused about their standards that they have a need to express that frequently. But that's is a good thing and it's healthy and I think that that's contributed to the process as well. The outpouring of participation from the community has been very impressive.

John has helped to shepherd that along without a dog in the hunt. So John has helped in that regard just by simply moderating the process, instead of being an active participant and advancing a particular approach.

DR. JOHN HALAMKA: I am a nonvoting chair. And so I ensure that I have objectivity and no particular agenda of my own.

DR. WILLIAM WINKENWERDER, JR.: Great. One little other final question. And that is, just in terms of review process, in other words, once a standard is set, it is out there. What is the

process for sort of validating that this is really working? Is it a look back at six months or one year, or you know, what is your thought about how you are going to do that?

DR. JOHN HALAMKA: Sure. One of the, I think, key aspects of all the standards that we work through is that it will constantly evolve. An example is that today we believe that genetic sequences may hold promise for the future. We all may be sequenced, we all may what diseases we could develop in 20 years. Are there well developed standards for security around genetic sequences, for the storage and displayed interpretation? No. Well, it's not been a use case you have given us but it probably will be. So we need to ensure when that use case now comes along that there is an opportunity to constantly revise and update.

So our process would be: deliver a specification that is used by the community, gather input from stakeholders who are implementing it, constantly amend and refine to ensure it is a highly usable document. And then as technology evolves and as use cases evolve, evolve the interoperability specifications.

SECRETARY MICHAEL LEAVITT: John, elaborate for a moment on what the safeguards are to create that place that is specific enough to work but general enough not to stymie innovation.

DR. JOHN HALAMKA: Ah, yes. Certainly what we want to do at HITSP, is allow the market to innovate. We will not be so prescriptive in what we do that there will not be opportunity for vendors to create useful products that are highly differentiated based on function. What HITSP is going to say is, we want whatever products to exist in the marketplace to be able to communicate with each other. How those products look and feel to the user, the features and functions that they may offer to the patient or the doctor is up to the vendor community and is up to the market.

So I do see us actually as empowering. Because I'll tell you, when I meet with vendors, they say the amount of effort we as an organization have to place in creating point to point nonstandard connections with all of the other vendors is actually exhausting and draining our resources from innovation where it really matters, and that is creating the products and services for patients and doctors that are highly useable. So I think we'll reduce cost, enhance value, and allow the marketplace to focus on innovation.

SECRETARY MICHAEL LEAVITT: And have you found the vendors to be as engaged as the standard developers?

DR. JOHN HALAMKA: Oh, very much so. And so when you look at the composition of HITSP, many of the major vendors are there, they have been very engaged and actually quite interested in participating in early pilots. So a couple of the vendors have said, yes actually, in August, we want to try what it is you are coming up with, and we'll give you early feedback as to how it is useable or not.

DR. DAVID BRAILER: And Bill, I'd comment to your earlier discussion about the value of structured information. We're going to have a presentation on clinical decision support later today, which I think starts to unfold where some of those value points are, not only to patients, but back to clinicians as well. Let me turn to Doug Henley.

Dr. Douglas Henley: Thank you. Kevin asked my question about mapping which John answered extremely well. I wanted to add my observation, Mr. Secretary, that I think why this process, which can be so technically challenged, has worked well. Not only is it transparent, but as we have seen today, it is sprinkled with heavy doses of diplomacy and good old fashioned common sense. And I for one appreciate that very much.

DR. DAVID BRAILER: Any other comments for John Halamka or John Loonsk?

SECRETARY MICHAEL LEAVITT: Mark has a comment.

DR. DAVID BRAILER: John.

DR. JONATHAN PERLIN: Let me just begin by adding my appreciation for the manner, not only the diplomacy, but the technical competence with which you've handled a very challenging area. And I would just come back to the concept -- I think, David, you made an important point about segue waying [sic] the structure back to the clinical decision support, because it really has to do with complexity, not of the standards, but of the cultural context in which the standards will operate.

Health care is a particularly complex endeavor and the role of the clinicians, the actors is very nuanced and context-dependent. I think there is a little bit of a trap, which is that with structure, one gets absolute specificity. And I'd just give a quick example. If -- take an issue of chest pain, and if one says, what is the concern? Pain. And location? Chest. And characteristic of the pain? Stabbing. That is a sort of classic example that the linguist would say, okay, does that mean the patient experiencing stabbing chest pain or stabbed in the chest. Very, very different set of circumstance, and likely a very different set of needs.

And so I think the issue I am really trying to drive at is the work is very nuanced. As computing power becomes greater, the ability actually to interpret or meta-analyze, or meta-index the free text that is nuanced, and then provide structure is really an attraction in the future. In the interim, toward getting to Chip's early point and the point that David makes, that the ability to provide meaning that's able to be interpreted and analyzed is one of the areas where I think clinical decision support and the record of structure is so very powerful.

Because right now, the first high lift is actually creating enough of a standard set that you can actually create interoperability, an interoperable system. That is a pretty formidable task. One that would be amplified significantly if one were going to try to change the structure of changing the culture of the way care is provided, and the use of language that is so much a part of that culture.

DR. JOHN HALAMKA: Very, very good observations. Certainly, if you look at medications, I think we're actually reasonably advanced in the way we can describe medications. If you look at laboratories, I think, again, reasonably advanced.

Now when we start getting into clinical notes, ah, that's where there is real challenges as you describe. Stabbing chest pain. To tell the doctor, oh well, here is a chest pain template, and it will take you 47 clicks to accurately describe the chest pain, is a bit of barrier to implementation. So I think our greatest challenge is to as you described, Mr. Secretary, let the vendor community

innovate with unique user interfaces that allow a doctor to get to controlled vocabularies and then we'll have the standards to transmit that information from place to place.

DR. DAVID BRAILER: Mark.

DR. MARK WARSHAWSKY: Just to follow-up, I think what underlies some of the Secretary's last set of questions and perhaps drive a little bit more. I'm not a physician, so I don't have a full appreciation of the technical standards here, but in terms of the marketplace, do you have any sense of, are we creating just a few vendors that will participate in this market, or will there be a few vendors with some specialization of smaller vendors, or will it in fact be dozens of vendors?

DR. JOHN HALAMKA: That is a very good question. I think actually dozens is probably the right answer, because let's think of fax machines for example. Before there was a definition of a standard how to send a fax, it was proprietary machines communicating one to another. Or you went to western union. Well, then suddenly there's a standard and now there are hundreds of manufacturers of fax machines. Some are have autosheet feeders and some are cheap and some are expensive. I have to imagine the very same thing is going happen with electronic health records, once there is one unambiguous way to send information from place to place.

DR. DAVID BRAILER: Any other questions? Kevin?

MR. KEVIN HUTCHINSON: It occurs to me as we are having this conversation that there are also two other points that need to be considered in this process, more than just the exchange of the information. Are the medical schools and the academia working as part of this process as well, from the training of new physicians as they're coming out of the medical schools? And then are the payers also involved in this process, because if we work on the standardized medical terminology but yet different information is required to get the claim approved, then we're going to hit another roadblock as reimbursement occurs. I'm curious if those two entities are also involved in this process.

DR. JOHN HALAMKA: Sure, so very good question. Let me speak from the Harvard medical school standpoint. So in addition to chairing HITSP, I'm the CIO of Harvard Medical School. I'm responsible for all the education, administrated and research technologies there. Harvard is in the middle of redefining medical education. 15 years ago it created the new pathway. Now we are creating the new, new pathway.

And part of that is now called a six-month introduction to the profession. Every medical student will have to learn not only the Krebs cycle and the revenue cycle, and understand how these new electronic systems and decision support will empower their work. So part of that curriculum, in fact, includes reviews of all of the major provider order entry and health record applications used in the Harvard community. I am an instructor in that particular course, so we are truly steeping the next generation of physicians to expect the use of these electronic tools.

But to your point, also understand that medicine is clinical care, but there also needs to be appropriate codification, for not only treatment, but payment and operations. How does the clinical application relay to the other aspects part of the training.

DR. DAVID BRAILER: Any other comments or questions relating to health IT standards? Colin.

MR. COLIN EVANS: A quick question. You said, John, you started with the number of 500 plus standards to get to 180. I presume that 500 to 180 was a function of the specific use cases you used to filter it, or was that generic cutting down? I have this sort of view that other use cases presumably will bring the other 320 back into play.

DR. JOHN HALAMKA: Right. When you look at the 570, we said what is the appropriateness, or suitability, for a given event. That came down to the 180. So we'll bring back a large 500 number as we get new use cases and do the same exercise. Our Tier 1 filter, our Tier 2 filter.

And I suspect that as you give us more cases we will get better and better at this. But I certainly want to make sure we don't overlook any stakeholder, or any standard, and therefore we'll start with a broader net at the beginning.

DR. DAVID BRAILER: Mark.

DR. MARK WARSHAWSKY: One more question. This standard that we're all looking at, could you put this in a context in which of the four groups and recommendations of AHIC this fits into, this one right here.

DR. JOHN LOONSK: That one right there is the example of the type of content, it is not specific to the particular use cases. So one of the things that HITSP has come to agreement on is that you need the cross technology standard swipe that, for example, comes from the work that IAG group has done. You need the content specificity of, say, an implementation guide. That is what is represented there. That level of specificity, across the technology and the related standards for structure and transport as well as the content and terminology standards of unambiguously identifying each term for every little block that needs to be filled out.

DR. DAVID BRAILER: Colin.

MR. COLIN EVANS: I am interested in the consumer group role as well on the panel. Because, having spent a lot of time working on standards on the domains, I'm aware that now we have created the environment where people have an expectation of interconnectivity of electronic data. We use global examples of, I get my money out of an ATM around the world, why can't I get medical data? That totally understates the complexity of the problem -- I think there is a role of education here, of the general public and of people who use the systems, in the sense not to tell them how awful it really is, but you know, setting expectation as to what can or cannot work over a certain period of time. So I am interested in role, your comments on either the education question or the role of consumer groups in that context.

DR. JOHN HALAMKA: Certainly. So on the HITSP board we have David Lanksy, from the Markel Foundation, and he is a very well known consumer advocate. He used to be the CEO of Fact in Washington. And we also have Allison Reign [spelled phonetically] who is from the National Consumers League, and they're providing valuable input that's guiding all of our activities.

One examples of what the Markel Foundation did a couple of years ago that I thought was brilliant, is they put together an advertising campaign, just as a mock up, that showed a person falling off a ladder. And it said, you have three seconds to remember your entire medical history. Now that is a very key and informative kind of visual.

And that kind of thing, I think is what is necessary among consumer groups to understand the value of why do we want to do electronic health records? Are they better than paper? How is it going to empower me as a consumer? And certainly, we're engaged in all the conversations that I, and other HITSP members have the with press, but certainly working with the Office of the National Coordinator, we will have to do further educational programs like that early Markel idea.

DR. JOHN LOONSK: Remember too, HITSP is not developing standards. It is using standards that have been developed in other standard development organizations. There are multiple bites in this apple. And John is right to point to the consumer participation and some of the other comments that were made today about opportunities for input there. But this is really not the first time for input. And at these different standards development organizations there is frequently that kind of input and discussion as well.

DR. JOHN HALAMKA: As I've mentioned, we have nine consumer representative organizations on the panel, and includes AARP, for example. So I think, you know, a lot of good input. As we go forward, we will continue to look to consumer groups to validate the work we're doing.

DR. DAVID BRAILER: Okay. Any final comments? Let me thank you both very much for spending time with us and for your excellent progress on standards. Before we come a break, I would like to turn to Tab 2, which is the meeting minutes from the May 16th meeting. And Mr. Secretary, if you are willing, I would like to go ahead and have these minutes approved.

SECRETARY MICHAEL LEAVITT: Are there objections?

I declare a consensus on the minutes, and they're approved.

DR. DAVID BRAILER: Thank you. One other announcement I would like to make before we go to break and that is you are not hearing today from the nationwide health information network project developers. But you will at a subsequent meeting. But I did want to comment that on June 28th and 29th will be the first NHIN forum, which is an open dialogue, where the first blush report on the architectural designs that are being developed in the four projects are going to be reported. And this in the spirit of what you just heard with HITSP is a public meeting, with public notice, with public dialogue. Anyone is welcome to attend. Any developer who has ideas that is not participating, anyone from the public, and anyone else to come and participate, and this will result in testimony to the National Committee on vital and health statistics. We will use that process to begin winnowing down what we learned and what the architectural components would be of our certification process and nationwide health information network architectures in the future. You can register for that meeting by going to hhs.gov/healthIT. It is at the NIH campus, and it is June 28th and 29th.

With that, let's turn to a break. And we would like to reconvene at 10:20am this morning. Thank you.

[break]

SECRETARY MICHAEL LEAVITT: Thank you, Dr. Brailer, let's proceed.

DR. DAVID BRAILER: Okay, I'd like to turn your attention now to Tab five and turn this to Jodi Daniel, who is the director of the office that is coordinating privacy and security, it's the Office of Policy and Research in the Office of the National Coordinator. It's one of our top priority areas. And we've made remarkable progress in this convening that's underway. And with that, let me turn it to Jodi to introduce our guests.

MS. JODI DANIEL: Thank you, Mr. Secretary and members of the Community. We thought it would be helpful to come back at this time and give you a brief update about the privacy and securities solutions contract that we have been working on, as well as an overview of some of the other privacy and security activities that we have going on through our office and through some of our contracts.

I will give just a brief overview and give you context for all of our privacy and security activities. I'll then turn it over to Linda Dimitropoulos, who is our project director on the privacy and security solutions contract that is forming the health information security and privacy collaboration. And then followed by John Thomasian, who is the Director of the Center for Best Practices, with the NGA, to give some perspective on how the states are viewing some of these initiatives, and state role in health IT and in privacy and security, more specifically.

We thought it was timely to come back and give you an update, and to talk about this after some of the discussions of the last Community meeting, and after some of the discussions at the Workgroup level. There was a lot of discussion at the Workgroups that was repeated throughout all of the Workgroups, there were conversations in the EHR and PHR Workgroups about identity proofing and authentication of users, how to match data with individuals and appropriate access of information. There were discussions in the biosurveillance Workgroups about appropriate information that should be shared and how to protect the privacy of the individual whose information was being used for public health purposes.

So these conversations are coming up over and over again, and we thought it would be helpful to explain some of our activities as well.

We very much understand that having the right privacy and security practices in place is absolutely critical. You can't be talking about the standards and the technology architecture without talking about privacy and security. These two are very much linked. So while standards is an incredibly important component of being successful in our health IT initiatives, so is identifying the right privacy and security practices and policies, and making sure that they're acceptable and serve the needs of all of the various stakeholders in these initiatives.

This is not only top priority for ONC, but it's also incorporated in all of our initiatives. It was established in the executive order as one of the primary goals of our office in establishing a

nationwide health information network that ensures the patient's individual identifiable health information is secure and protected.

While no system can guarantee that information is protected, whether it's in paper or electronic format, we strongly believe that using electric being health information systems offer opportunities for greater security and privacy protections than in paper format.

And I just want to give an example. If there is a patient who is in the hospital, the doctors and the nurses need ready access to that information for routine care of that patient, as well as in an emergency situation. So a paper record would either be at the bedside, it may be at the door to the patient's hospital room, so that the clinician can get access to that information immediately.

It also means, if it is in paper format and easily available, that it might be easily available to somebody who's passing by in the hallway, who doesn't need access to that information. A friend who is visiting might be able to see information about that patient that they should not have access to, and the like. And there is no way of knowing whether or not there has been a breach of privacy in those circumstances.

When you have electronic systems, you can make sure that the information is available for the clinician, readily and immediately, so they can provide the best care to the patient, but also prevent inappropriate access by others who should not be seeing that person's medical records. We think that, while, like I said, this is something you can't prevent all inappropriate access in any circumstance, but you can have much greater privacy and security protections with electronic systems.

We also understand concerns about technology getting ahead of policy. This is something we hear often. That is why we are focusing on these issues now. We are looking at standards, we are looking at architecture for systems, but we're also looking at privacy and security policies, and trying to interweave these discussions so that we're looking at these two issues hand in hand. Just like the technology development process is iterative, must be collaborative, and must involve all appropriate stakeholders, so must the privacy and security policy discussions.

I will walk some of our various initiatives, but it's hard have a conversation about privacy and security of health information without talking about HIPAA, the Health Insurance Portability and Accountability Act. This statute required HHS to come up with standards for financial and administrative health care transactions. But it's predicated on the belief that privacy and security must be considered at the same time as the technology standards, and Congress required that while we were coming up with those technology standards, we must also come up with privacy and security standards.

While the HIPAA privacy and security rules may not solve all of the policy questions that come up with respect to health information technology, they really provide a strong foundation for privacy and security of health information.

When we've talked to folks who are trying to set up health information exchanges, I've heard time and time again, and I'm always surprised to hear this and I'm always encouraged to hear this, that that foundation really makes the discussions a whole lot easier. People have a common language, they have a common set of standards that they're working toward, and it gets people so

much farther in the privacy and security discussions because of that baseline of federal requirements. So while this may not solve all of the problems that we have, I think it is a very strong foundation for privacy and security protections and health information.

So then ONC came into play here after those privacy and security rules were adopted. And the most significant initiative that we have right now to look at privacy and security practices across the country is the Health Information Security and Privacy Collaboration, or the HISPC.

The goal here is that many issues related to privacy and security of health information either are state based or organizational based. So while we do have this federal foundation, there are state laws that may be more protective of privacy, may cover additional types of information, and there are organizational level policies that may be stricter, may be different that those state and federal laws that may come into play.

So what we wanted to do here is to look at the policies and practices of state laws within a state, as well as across states, and where there are barriers to work toward resolutions and implementation plans that protect privacy of information while allowing electronic health information exchange for appropriate purposes. And Linda will tell you a whole lot more about that project and the goals and next steps for that project.

You just heard John Loonsk and John Halamka talk about HITSP. The only point I want to make here, is that in looking at the technology standards, HITSP will also be considering security standards as part of this process. So they will be not only thinking about how is the best way to move information, what are the right standards and implementation guides for the right pieces of information, but also looking at some of the security standards that need to be used for those use cases as well.

With the nationwide health information network contracts that we have, these contractors are working on prototype architectures that identify various technical approaches, but they also will provide a testing ground for privacy and security options that will be used in policy considerations. There will be a meeting later this year, a public meeting of the NHIN contractors to talk about security issues, and we hope that by then there will be at least some initial findings that are coming out of the states that can be discussed and than can help inform some of those discussions at the NHIN prototype level.

Currently, CCHIT has come up with ambulatory EHR criteria. One of the criteria that are included in here are security criteria for ambulatory EHRs. This will be a component that will be considered for other sets of certification criteria, as well as for updates to the ambulatory EHR certification criteria, and will be informed by the HISPC, the HITSP, and the NHIN process as well as by recommendations from the AHIC on privacy and security.

So we see these all sort of working together, and having some of the various processes help feed each other with respect to privacy and security. Like we saw in the Workgroups, the conversations can't happen in isolation. They keep coming up throughout all of the different contexts and all of the different issues we are talking about.

And finally, at the last meeting of the Community, there was a recommendation and acceptance of a recommendation, to form a privacy and security work group, so that all of these individual

conversations that were happening at the Workgroup level can be consolidated and discussed by a group of members that are dedicated to focusing on those issues. We're currently in the process of nailing down a chair for that subgroup and nailing down the committee members for that subgroup. We will be pulling members from all of the various work groups, so that the different use case issues will all be represented in those discussions. And we plan to have a meeting, a public meeting within the next month to start chewing on these thorny privacy and security issues that were identified at the Workgroup level.

So the hope here is that after all, through all of this hard work, this iterative process and these various different contracts and efforts that we having going on, that this will help inform the privacy and security policies and assure that we've considered these issues as we're moving toward the technological developments for interoperable electronic health information exchange. And with that I'm going to turn it over to Linda Dimitropoulos to give an update on the privacy and security solutions contract. Thank you.

DR. LINDA DIMITROPOULOS: Good morning Mr. Secretary, members of the Community. I am very happy to be here today to update you on the progress we've made on the project since the January update we provided to the Community.

Basically, the health information security and privacy collaboration is an initiative to engage the states in a process by which they will conduct an assessment of the variation in organization level business practices and policies and state laws to identify barriers to health information exchange related to privacy and security, and to analyze the variation, develop solutions, and work to develop implementation plans by spring of '07.

In January 4th, as a matter of fact, RTI released an RFP to the states to engage them in subcontracts through the NGA, who released the RFP to all 54 governors of states and US territories. In January, and later January and February, RTI and NGA conducted a couple of bidder's conferences to discuss submissions, the process, and answer questions that the states had. And both of those bidder's conferences were very well attended, with approximately 37 states attending each conference.

On March 1st, we received proposals, and the NGA and RTI continued reviewing those proposals in March and April. Then in April of '06 we also signed a subcontract with the health IT National Resource Center that's based at ARC to provide public web pages, private workspaces through the portal, and to develop the assessment tool for collecting and aggregating business practices. All of these tools are intended to help the states with their work. We have a very aggressive schedule. And they have a lot of work ahead over the course of the summer. So these tools were developed to help them with that.

In May '06, just last month, our prime contract with ARC was increased from 11.5 million dollars to 17.23 million dollars, by an influx of 5.7 million from ONC, and that was to fund offers to 33 states and one US territory, to subcontract and participate in the collaboration.

The subcontracting entities are all designated by the respective governors, so we have very strong support from the all of governors' offices, with all of the states who are planning to participate. Each of the states is organized with a steering committee that is a public-private partnership of state and organizational leaders that will lead their effort. They're working now to

develop their Workgroups that comprise broad range of stakeholders within each state, including patient advocates and consumers.

About middle of May, HHS issued a press release, that 22 states had already executed subcontracts and 12 were still pending. As of today, we have 32 of those subcontracts executed, and we have two in the works.

We've continued getting all the states on board, getting them acclimated to the process. We've conducted kick off meetings with all the states who have executed their subcontracts, they're busy assembling their teams, developing work plans.

This month we are also holding debriefings with states who were not offered subcontracts and we have plans underway to share documents, tools, and methods with the states that are not subcontracted to the project, in an effort to engage them as well. During the debriefings we know that these states are heavily interested, they're heavily motivated, they've got plans in place to conduct the work outside of the contract. And so we will do everything we can to engage them in the process and to share work-products and methodology that will be developed under our contract with them.

As I said earlier, we have a busy summer coming up. The assessment of variation will be conducted at the state level. And this will involve states forming multi-stakeholder Working groups to respond to a set of health information exchange scenarios that were developed in collaboration with AHIMA. And the scenarios have been pilot tested for several rounds and we're about to release those to the states this week as we begin training the states to use the assessment tools through the National Resource Center portal.

The stakeholder Workgroups will identify business practices associated with privacy and security, and they will code practices as either good practices that enable health information exchange, or barriers to health information exchange. Practices that are identified as barriers will be analyzed to determine whether that is driven by a policy or what the legal driver is behind the policy, so that they can start working on developing solutions.

In the fall, we'll also be holding regional and statewide meetings to share progress and information across the states. Again, we find that this is an opportunity to engage the states who are not subcontracted to the contract, or who are otherwise doing work outside of the contract and try to bring them in to at least share in the solutions and in the work that's been done.

The analysis of solutions and implementation planning, those deliverables are all due fall and winter, and then in spring there is a nationwide meeting and a nationwide compilation of the reports. So we have a lot of work ahead of us, but the states are extremely motivated and extremely well organized and just by the fact that they can execute so many subcontracts in such a short turnaround is evidence of their determination to be successful.

DR. JOHN THOMASIAN: Thank you, Linda. Mr. Secretary, Dr. Brailer, members, thank you for having me. I should first start out and apologize. I did not bring a powerpoint. My short remarks today probably don't justify one. But I sense that I may have short changed you, so if any of you have a sense of loss or emptiness after this, please let me know. Call me and I will send you one, from some presentation in the past. [laughter]

Let me just remark on why this project is so important, and let me begin by once again commending the Secretary and Dr. Brailer for the approach taken. As Linda mentioned to you, we went into this through the governors' offices, and that is very important. The governors are major advocates, if you don't know it, I want to tell you now, on health IT. And by recognizing the key role of governors in bringing stakeholders together, we've made an important step forward. Health IT is to be built up from the bottom, I agree, but we also need to build it from the top down. By engaging governors in this critical work we're building an institutional framework, I believe, that will help us address the regulatory, financial, and policy challenges that will face health IT deployment long into the future.

I should find out it is evidenced by the 34 qualified applications we had. We had a great deal of enthusiasm for this project. The reason for this is simple. The governors recognize, as you do, that the nation's health care systems cannot be fixed until we first improve how we exchange data.

And let me give you some numbers. In this year's State of the State addresses, 96% of the governors mentioned health care as a major challenge for the administration in their states. 64% called for wide spread reform. Almost 25% just in their State of the State addresses mentioned initiatives around health care information technology.

As I mentioned, the governors believe that the first step in building a more cost-effective and efficient system is to establish the ability for patients, providers, insurers to exchange health care electronically in a secure and safe environment. And I should tell you in addition to the State of the State addresses, at least 27 governors over the last two years have launched their own initiatives in electronic health information exchange. And I say their own, these are in addition to the ones the federal government has launched with them.

These activities range from establishing task forces to creating road maps for state deployment, to offering state financed grants for pilot programs that demonstrate an aspect of electronic health data exchange. In the coming 18 months I truly think we'll see a great deal of experimentation in how we deliver and cover healthcare around the nation.

As many of you may know, states are already looking to use the new flexibility in the Medicaid law to fundamentally change how services are delivered, so that they're more tailored to the individual's needs and employment status. At the same time, states are moving forward on initiatives to provide health care quality and provide greater transparency. So you're seeing a number of states also moving ahead on quality but also working to try to post pricing information on health procedures.

Many of these efforts are being coupled, and we're seeing it, with initiatives in health information technology and let me give you an example. In another project we have that's also funded by ARC at HHS, we recently had the opportunity to award nine states and two territories a chance to work through a year-long process. We call this a policy academy at NGA, to develop quality improvement initiatives in their state. Now these initiatives would cover both public and private programs, so they were broad based. They were designed to cover a wide population.

The states were required to bring their major providers, networks, and insurers to the table. It is important to note every one of the states and Puerto Rico that are engaged in that policy academy also engaged in the RTI effort. Many of the same team members -- many of the same team members in these states are working on both projects.

I had a number of calls asking me if we bid on this, can we use it to see how it works and complements the work we're doing with the RTI contract. I said absolutely. So I think we are building a very strong framework of progress. I think as we come out the other end of this project, you will have at least 34 governors' offices closely aligned with a network of stakeholders in their own states, very knowledgeable about the issues that confront them as we deploy health information technology.

So we're very excited about this project. I hope in the coming months I have an opportunity to perhaps come here and talk about what we're learning. But the beginnings are very sound and very exciting. Thank you.

DR. DAVID BRAILER: Thank you, John and Linda, and Jodi, very much for the good presentation and the very hard work that I know that's going into this effort. It's been a lot of background work in getting the contracts in place and getting the legal clearances set up, but I think we're going to see remarkable progress now, that, in my opinion, will begin defining a new dialogue about privacy and security in the digital era of medicine. So thank you very much.

With that, let's open it up to comments. Mr. Secretary, I don't know if you wanted to start with comments, sir?

SECRETARY MICHAEL LEAVITT: John, when you talk about the 34, are those the states that made some kind of departure from HIPAA, or why 34? What is the significance of that number?

DR. JOHN THOMASIAN: Well, 34 is more evidence about the enthusiasm for trying to look at this issue and move it forward. I think all states have probably made some departure from HIPAA. I'm not sure they all know how far they have departed.

SECRETARY MICHAEL LEAVITT: 34 is the number of …

DR. JOHN THOMASIAN: …number of subcontracts.

SECRETARY MICHAEL LEAVITT: Give us a sense that is going on in the minds of the other 16.

[laughter]

DR. JOHN THOMASIAN: Well, to be fair, to be fair, and I suppose we weren't supposed to mention this, we actually had 43 applicants. We determined that 34 were qualified. That really only leaves us, if we include the territories, with 12 that weren't engaged. I can't be sure, Mr. Secretary, to some extent -- in a couple cases we had a change over in governorship and I think that knocked one or two of the applications.

SECRETARY MICHAEL LEAVITT: Do we have the big states involved?

DR. JOHN THOMASIAN: Were many of the big states involved, the big states are involved. Big states were involved, but some of the awardees include Wyoming, which, as you know, has the least dense population in the entire country. We have Florida, we have New York, we have a mix -- we have California. But we have the heartland, very engaged. I think if you look regionally, we're touching everything, touching absolutely everything.

And those states that were perhaps disappointed because their applications didn't qualify, we are finding ways to bring them in the project as well. So really, Mr. Secretary, I would look and say we've actually brought into the table 43 states. I'll do my job to make sure I get to those other 12. Because I know that is what you care about.

SECRETARY MICHAEL LEAVITT: Good. Thank you.

MS. JODI DANIEL: If I could, also just respond to that. We had originally said that we would consider up to 40 states. And there was an issue of funding. We -- Linda had mentioned that we added some funding to the project. The goal there was to try to bring in more of the states so that we were trying to be as inclusive as possible and to create as broad a base of work as we could, make sure we were hitting all the geographic regions and making sure were working with some advanced states, some intermediate states and some beginner states.

RTI and NGA in looking at the proposals really tried think about those issues and make sure that we were getting a good cross-section so that the learnings that came out of this work would cut across the varying, different types of states and their progress in health information exchange. So there were some limits as far as funding and being able to bring in all of them, but we tried to bring in as many as we could in this project, and we're trying to consider ways that we can bring in the other states, either by making some of the tools available, making sure that they can participate in some of the meetings and discussions, as well as through some of the other activities where we're looking at how else we can engage the states.

SECRETARY MICHAEL LEAVITT: Our previous panel, we heard reflection of the fact that when people establish standards, they feel emotionally committed to them. And that it requires compromise and attitude of collaboration to get to a standard that can be universally accepted. Could the three of you reflect on your sense of the state of mind in terms of the states? Do they see the need? Do they feel a need to begin to harmonize this in a way that we can overcome the barriers of difference?

DR. LINDA DIMITROPOULOS: I think that the states do feel the need, and I think that's evidenced by just, their energy around getting involved in this initiative.

SECRETARY MICHAEL LEAVITT: It wasn't just the money?

DR. LINDA DIMITROPOULOS: No, it certainly wasn't just the money. Many states contributed to the process financially, through in-kind donations in their own contracts. I think that the discussions will be heated at times, and I think that there is enough leadership and there is enough breadth across stakeholder groups to ensure that it is a good process, a good healthy dialogue, and that there is enough transparency that we will see the outcomes will be very positive.

MS. JODI DANIEL: I would say -- I think -- we were actually concerned when we first started talking about this, that the dollars were not -- the dollars were not sufficient, and the time was very short, and the requirements for bringing in so many various stakeholders from across the state was so large. We were actually worried about whether or not we would get enough interest in participation. I think the fact that we did get so much interest is a real testament to the fact that the states are really committed to this work and want to be a part of this process. So we actually, I think, were all pleasantly surprised at the interest, the enthusiasm, the fact that states did commit.

Many of the states did commit their own resources in addition to the subcontracted amount to this process. And you know, a couple of the states that we did not grant contracts to were actually disappointed and want to find ways to engage in this process. I think that there is a lot of enthusiasm, buy-in, and interest in trying to sort through these issues, and I am very encouraged that we will have a very good collaborative process at all levels.

DR. JOHN THOMASIAN: I will just add. What I hear is there is a belief, first of all, and I think you all agree with this, that we can move forward and still preserve the fundamental privacy and security protections that we have. But that through this process, we may discover that we have some things that just don't make sense, that don't further that. And I think the states are interested in uncovering those, and fixing them, and looking at harmonization where it makes sense.

There is an absolute interest in moving this forward. There is a sense at the gubernatorial level we cannot just rest on status quo. But there is an understanding, too, that the stakeholders must own this as well. So there's work to be done, but certainly it is being driven by an interest to move forward and see harmonization where we can.

DR. WILLIAM WINKENWERDER, JR.: Thank you for your work and for your attention. This is off an important issue. Really important. I wanted to just share a few observations based on our experience at the DOD that I thought would be useful to this group, and also offer a suggestion in terms of a way to think about at least part of this issue going forward.

The first observation that we would offer is that achievement in this area is multidimensional. It's difficult, it's almost certain to be fraught with mistakes and stumbles. And we've experienced those ourselves as we've put more and more data into electronic formats and moved it around. What we have learned is that this is a continuous process, and that the bar moves higher, so you got to just keep moving with it.

Secondly, is that people and mistakes, not mal-intended mistakes, but just mistakes people make, as well as the lack of huge detail to, and attention to, procedure and process is the source of most breaches and problems. As much as we worry about the person or the entity that is trying to hack or break or whatever, that it is really more of them occur because of just mistakes people make.

The third is that physical security is important. Physical security is a big reason we tend to think of hacking and hackers because that is -- but physical is a security.

The fourth element would be that the whole infrastructure that supports all of this in the country, the power grid, electricity moving, and being able to move, is really important and we haven't given that enough thought. So having said all that, when we experienced --

SECRETARY MICHAEL LEAVITT: Are you using that metaphorically or do you mean literally?

DR. WILLIAM WINKENWERDER, JR.: I mean literally.

SECRETARY MICHAEL LEAVITT: You're talking about the architecture of the system, or you talking about the literal power grid.

DR. WILLIAM WINKENWERDER, JR.: I'm talking about the US power grid.

SECRETARY MICHAEL LEAVITT: Help me understand that.

DR. WILLIAM WINKENWERDER, JR.: Well, for us, because we're sort of a contained system, in one respect, but for movement of certain secure information and so forth. But in other respects we rely on the US power grid. And we, you know, had outages and stuff. We move information around the world. So, you know, we've seen problems happen. And so there is a dependency there. No matter how well orchestrated and organized and planned our system is, there a dependency there that relates to the behavior of others.

So the way I think about it, after we've experienced a couple of problems is, you know, the value of these databases with huge amounts of information, you know, the analogy that occurred to me one time when we had a problem was, you know, think about a bank. How much money, time, resources, procedures would you put into protecting $100 million or $200 million or a billion dollars if it was sitting there? Because the value of the data is huge as the databases get bigger and interconnected.

It sort of re-gauges your thinking in terms of what level of resource and effort and ongoing commitment is necessary to protect.

The final thing that I would say is just that, I would add to security -- and privacy and security, the concept that I think is related. So I'd suggest that maybe it be part of this whole effort, and that is continuity of operations. I mean, it is one thing for the data, the information to be private and secure, but then is it always available because the continuity of operations. Because as you move more and more, and that is where we are getting to at DOD, and I know John will comment, maybe on VA.

Everything is dependent. It is all in electrons. And when you get to that state of mind, boy, when it goes down, it goes down. You know, how do we think about that? How do we work with the other players that maybe are not even at this table today that we rely upon? So…

DR. DAVID BRAILER: I might comment on this --

DR. WILLIAM WINKENWERDER, JR.: It's a national security issue, I guess is what I'm getting towards.

SECRETARY MICHAEL LEAVITT: That is a new dimension I hadn't thought about. I can see how real that would be.

DR. DAVID BRAILER: There is particular attention to this as we move towards real-time live telemonitoring. For example, the physician in the command center that's monitoring an ICU patient that could be at some distance from them, or monitoring someone in their home who is able to be there because of the remote sensing capabilities. This concept that this life-critical application really operates in real-time. For this reason there have been a number of public dialogues about whether or not health IT should be begin to be considered as a critical infrastructure that has certain kinds of redundancies and support that are built into it like we looked at air traffic control and power generation.

DR. WILLIAM WINKENWERDER, JR.: Absolutely. That is what I am getting to. That's a whole other dimension of this issue is there is more and more dependency that is created.

SECRETARY MICHAEL LEAVITT: I was wandering in the Virginia countryside this weekend looking for some location that I'd never been to and I was completely dependent on the GPS, and the satellite went down. And I realized I have no idea where I am.

[laughter]

DR. DAVID BRAILER: We should add that to the list also. Thanks. Mark?

DR. MARK WARSHAWSKY: I want to get a little better understanding of the overall project and maybe what one might call the methodology. Do each of the states that are participating in this project, do they have a similar understanding of what we mean by health information technologies, such that they're all going to be looking at the same things and then therefore it is in essence, a massive experiment, if you will, of finding each state's own view and all the stakeholders? Or is it each state is going to sort of do the project on their own with very little guidance, and we will find that information that way? I just want to have a better understanding of how this project is working.

DR. LINDA DIMITROPOULOS: There is a -- well, our goal is to have a standard process across all the states so that we don't just turn them loose and see what we get come fall. And so we did develop a micro-iterative process where each state starts with a variation Workgroup, it's what we labeled it, that's a multi-stakeholder group, and they will actually be trained. They will conduct these moderated sessions, where they will review the scenarios, they will identify the business practices that their organization has associated with those scenarios, enter those into a database that we have set up for them that will allow them to check off whether or not certain practices are barriers or if they're enablers of health information exchange. And then they'll be able to review their input, they'll be able to send that to their steering committee for review and comment.

And ultimately, they will be able to, and they're expected to, develop stakeholder Workgroups who will then also have an opportunity to comment on those practices and the coding that has been done. They'll be -- they will be allowed to not only comment, but they'll actually be

allowed to add to the database. They can look at what has been generated at this level and then they'll be able to actually generate further sets of business practices at that point.

And so we will have these monitoring steps in place so that in addition to training up-front on the process and the use of the tools, but then monitoring steps in place so that we can catch anything that's going awry at any point before it gets out of hand.

Ms. Jodi Daniels: I just wanted to jump in. This is something that we are very much focused on and worked with RTI on. We wanted to be sure that we had some consistency across the states so that they were talking about the same issues and they were trying to uncover practices for the same types of scenarios.

And so RTI spent a lot of time and worked with AHIMA to develop tools and scenarios that will be used across all of the states so that they will all be reacting to the same types of issues, the same types of health information exchange situations, so that we are getting similar types of information and people are thinking about the issues the same way.

In addition not only to having trainers go out and train the states on how to use these tools and how think about these issues and how to manage this process, they also have state liaisons who will be working with a group of states so they can make sure that there is always a point of contact for the states to check in with, and for somebody who's always checking up with the state to make sure that things are moving along, things are moving smoothly, things are moving consistently, and to help address any challenges that may come up along the way. So they've really set up a process to help work with the states, they're not going to just let them run loose, but to work with the states every step of the way, as well as to give them all the tools that they need so at the front end they can be successful down the road.

So we have really taken a lot of effort, and part of the reason that we are now just getting started, starting to look at these practices because we spent a lot of time on the front end, not only to get the right states engaged, and to go through that process and make sure it was a fair process, but also get the tools in place and get the materials in place for the states to use so when they do jump into this, they are -- they're successful at the back end.

DR. DAVID BRAILER: Jodi, we can share those cases with the members of the Community?

MS. JODI DANIEL: They're still being finalized, I believe. But once they are, sure. That would be no problem.

DR. DAVID BRAILER: Okay. We will make sure those come back to you to look at. Colin?

MR. COLIN EVANS: Yeah, just sort of building on that a little bit. Obviously you are in a state of gathering data, where people are and so forth. Clearly, as the Secretary pointed out, a potentially emotional topic that people get into.

But I am interested in the process that you intend to use. Because already you are talking about filtering out good practices versus not good, and talking about variations. So that implies you have something in your mind as to what goodness is, and what some baseline set of capabilities are that we should be sort of comparing against. I would like thoughts on that.

And it also seems like this is a moving target. As Dr. Halamka pointed out, we'll be talking about genetics and how to protect that and so forth. So looking at the target, I'm sort of interested -- I'm not a hunter, but I think you have to aim at a duck a little bit, so I am interested in the thoughts on -- do you already have a definition as to what we're trying to get to that perhaps we could all look at? Or do you think that is an evolving target? And if so, how do you get to it?

DR. LINDA DIMITROPOULOS: I think one, right now, good practice is, at the highest level, a practice that would allow interoperability. Now if it's cumbersome, if it's a work flow that isn't readily adaptable and people try to avoid going through it, that certainly wouldn't be, "an enabler." That sort of coding structure is still in development.

And I think it is a moving target. And I think one of the purposes of this project that was set out at the beginning was, that it is going to be an ongoing process. One of the goals is to actually leave in place in the states, when this contract ends, is an infrastructure that will allow them to continue to examine those issues that come up and continue their work along that line.

MS. JODI DANIEL: I actually was going to make the second point about trying to establish knowledge base, get thinking on the issues, get the relationships in place and a platform in place for further discussion. We are also thinking about other ways to continue these discussions in the future, beyond this project. I know there was some recommendations by the Community at the last meeting about bringing states together to discuss some specific issues like licensure and CLIA and things like that. We're also looking at ways that we can not only create a state convening process to discuss those issues but to continue some of the work that comes out of this contract on privacy and security, so that there can be developing dialogue as new issues come up, as medicine changes and the like.

So we are very much thinking about those issues as we're setting this up. This is a first step in the journey. We intend it to be an iterative process. Collaboration is a messy process; it's not something that's easy to do. We're taking the first step in that approach. But we are trying to make sure to build in mechanisms for continuing discussion and continuing collaboration and leaving a knowledge base and a platform behind.

DR. DAVID BRAILER: One other aspect, Colin, that I would raise, that wasn't brought out in great detail here, is that in addition to the within state convening, there is a cross state convening that happens as well, that allows this dialogue to be occurring about not only what are the best practices that a state considers, but what is the context that they see across the United States that we can begin having that.

This project is the beginning, it's not the end of this normative effort to try to lay out this policies. But this will create the database to start feeding what that kind of effort looks like. And I think to a large degree a lot of the states that were interested in participating saw the tools and the framework validating something that they felt they had to do anyway, that it gives them a context to really make it done in collaboration with many other states that they could do it with.

MR. COLIN EVANS: I just feel that the opportunity for creating a monster here, from a technology perspective having to cope with -- obviously our goal is to get to some degree of

harmonization to make this thing easier for interconnectivity. But I fear there are too many if/then, else statements in the code when we're done here if we're not very careful.

DR. DAVID BRAILER: It is a worry. Clearly we would all be better off if one could just articulate what the tenets of privacy and security in the digital era look like. We not only don't have them, we don't know who to talk to about them, to some degree, because this is a process of collaboration, this is not, at this point, even being considered as a regulatory effort. So we are trying to create the value statement of who through the organization of the states.

And secondly, let that group begin defining the what. Which is what is the substance here? And then look at the process to begin deciding how that becomes something that does develop real consensus, and then develop mechanisms for that to play out. Would it play out in states and their policy level and national level, et cetera. That's a question we haven't come to yet? Let me turn to Kevin and then Tony.

MR. KEVIN HUTCHINSON: Two questions. One on the funding constraints side, which I know played a big part in the number of states. But I heard you make the comment a couple of times about a state that did not qualify. 43 applicants, 33 were awarded. What made a state not qualify?

DR. JOHN THOMASIAN: Very low scores on the technical review. That's basically it. There was a cutoff point that we felt was a level of qualification and not…

DR. DAVID BRAILER: Could you just embellish on what some of the technical review was just so people can understand that?

DR. LINDA DIMITROPOULOS: Sure. The technical review -- when the proposals were received, we separated them and we did a technical review against the criteria that were listed in the RFP, and used standardized score sheets. We developed teams comprised of the RTI project team and some members of our technical expert panel.

The NGA followed a parallel process where they organized teams to review clusters of the proposals. So each individual team member reviewed a proposal against the objective criteria and created a score and then they returned to their team where they discussed each proposal and each score and then came to a consensus on that within the team.

And then we came together, the RTI teams came together with the NGA and again worked through the process of coming to an agreement, a consensus on the scoring for each of the states. And then we basically rank ordered them.

What we looked at, because we initially said we can rank order them and fund to here. Then the question came back, well, if we could increase funding, would there be another point? Is there a point where to get the work done within this time frame, and successfully, are there scores that simply don't reflect the capability to get that done? And the answer was yes. So there was a cutoff drawn there. Then we sought additional funding.

MR. KEVIN HUTCHINSON: Okay. As part of your objectives in the last panel we heard from HITSP and they touched on the authentication of users. Is that part, did you look at the privacy,

security, are you also looking at rules, policies, processes around authentication of whether it's a consumer or a physician? Are there some types of health care providers, and are you also looking at role based access, policies, process for, if you are a physician or pharmacist or medical assistant or a nurse, there's different access points for different roles within health care. Is that part of the process as well?

DR. LINDA DIMITROPOULOS: Yes, it is. Yes, it is.

DR. DAVID BRAILER: Tony?

MR. TONY TRENKLE: I had a question for you on Number 4, which was about the stakeholders. One of the things that I've learned over the years being involved with policy related to privacy and security is a lot of them are formed because of perceptions that have developed either rightly or wrongly as a result of incidents, whether a security incidence, improper disclosure of information, and I'm wondering how you're going to deal with it. I think what you're doing is an important first step, but I think there is a big education and outreach effort that needs to be done to deal with a lot of perceptions that are formed or otherwise you're going to continue to have issues forming, as Colin said, as we move along the time line with additional issues related to medical information.

So I was wondering -- that is why I was wondering if you could talk more about Number 4 and how you're going to get down to the patient and consumer level.

DR. LINDA DIMITROPOULOS: Well, part of each state's obligation under their subcontract was to demonstrate that they could reach out to the broadest base of stakeholders -- the stakeholder community within their state. And so one of the ways that they're doing that is by having a public process where they do invite stakeholders to come register, join their community, get the opportunity to participate in the stakeholder working groups, they can also register to receive, you know, information as the process is developing. And states are working on outreach plans to reach out to all the corners of their states and across the whole range of stakeholders who exchange health information, including consumers and patient advocates.

MR. TONY TRENKLE: Initially, you are going out to gather information, but then after that, there is an education outreach process which I would assume would be the next step after your contracts would be part of that done.

MS. JODI DANIEL: And one of the requirements under this contract is not only to identify solutions, but also for the states to come up with implementation plans. So that's something that we have worked with the states on, on thinking about, and coming up with their implementation plans. Not only how are they going to -- what are the right practices and identifying the right practices, but how are they going to then implement those solutions, and I think that's where there are going to be questions and issues about how do you reach out to the broadest base of folks. How do you educate folks on policies and procedures regarding privacy and security? I think that that's probably the place where those will be incorporated in.

This contract only goes to the implementation plan stage. So then of course, there is the harder question of actually implementing those plans. And so that is something we need to consider. I think trying to incorporate in the implementation plans, training, education, reaching out to the

right stakeholders and the like, could be part of that process and would be an important component.

MR. TONY TRENKLE: I would stress a key objective to this is have every state have a broad base of stakeholders in government and private sector folks own the analysis, own the results, and own some of the solutions. So not only will they help identify issues, but they will own the step forward. That is why I think it is important. So what you may sacrifice for a centralized once analysis approach where you go into each state, you gain by creating ownership out there for moving forward.

DR. DAVID BRAILER: Gail?

FEMALE SPEAKER [GAIL]: I have a process question. How will the state project interact with the privacy subgroup that is being set up now?

MS. JODI DANIEL: That is a very good question. We are -- like I said, we're in the process of trying to establish that subgroup now. So we haven't quite gotten it all figured out and worked out. Hopefully -- the plan is to do that within the next month.

What we're hoping is in that privacy and security Workgroup we're going to be hearing testimony from various members of the public. There may be an opportunity to feed in some information based on some of the experience folks are having through testimony.

It may be also that there are recommendations that are coming out of that subgroup that can help inform some of the discussions and we can feed that information back to the states. So I think there is an opportunity for give and take here. If there are suggestions the community has for how we should doing that, we would be open to hearing them. But I think that -- like I said this is an iterative process. There are going to be some findings and learnings and solutions coming out of that process which I think we can use to help provide some information for the Workgroups so they can chew on some of those issues based on that wealth of information, and vice versa, if there were real strong recommendations coming out of that subgroup, they can be fed back to the state subcontractors for them to incorporate into their thinking and their solutions.

DR. DAVID BRAILER: Any other comments or questions regarding the security and privacy project? Thank you three very much. I appreciate you your time and report today.

With that let me turn you to Tab 6, there is a handout insert that is not in the agenda book for Community members. This is Clinical Decision Support.

I would like to welcome Jerry Osheroff and Jonathan Teich who will be reporting out on the efforts in the American Medical Informatics Association project with us to begin defining what a roadmap for Decision Support looks like. And with that I'll turn it to Jonathan -- to Jerry.

MR. JEROME OSHEROFF: Mr. Secretary, Dr. Brailer, and members of the Community, we appreciate this opportunity to present this roadmap for National Action on Clinical Decision Support, on behalf of the steering committee that lead its development.

The definition of clinical decision support used in this roadmap is very broad. It involves giving clinicians, patients, and others, relevant information in context that helps them make better decisions, prevent errors and improve care quality and outcomes. We emphasize the role of decision support for patients and individuals, which will become increasingly important as quality transparency and related initiatives engage them more actively in their own care.

CDS interventions include guidelines, alerts, order sets, tools to interpret patient data, answers to clinical questions, and others. Many studies have shown significant value from CDS, including improved guideline adherence, safer medication use, improved disease management, and other benefits.

The activities of this Community's Workgroups illustrates opportunities for CDS to augment Health IT and performance improvement efforts. The Workgroups are improving exchange of key health care data. CDS can help recipients organize and interpret this information, and offer guidance and alerts to ensure that it drives good decisions and outcomes.

In this way, CDS can help amplify medication lists into tools for reducing medication errors. Laboratory results into tools optimizing disease management, secure messaging into increased consumer guidance and care efficiency and so on.

Despite demonstrated benefits, the full potential of CDS to drive performance improvement in our health care system has not been realized. A variety of causes for this are reviewed in the roadmap. For example, CDS knowledge and tools are not interoperable. So vendors and providers reinvent the wheel, building and implementing the same interventions from scratch. CDS adoption is limited and often difficult. Many providers struggle to identify a clear CDS strategy and business case to support best care. Usability and deployment problems are frequent because there is little pooling of experience and application of best practices. As a result, well-documented quality and safety, and efficiency problems persist in health care. despite the opportunity for CDS to address them.

DR. JONATHAN TEICH: Thanks very much. Good morning, Mr. Secretary, Dr. Braile,r and Community members. I am now going to turn us to the CDS roadmap itself, which is being released today by the American Medical Informatics Association, under a contract with ONC. I regret that we do not yet have an unpronounceable acronym for this work, but we have our best people working on it.

The CDS roadmap is an ONC commissioned blueprint for coordinated national action to ensure that usable and effective clinical decision support is widely used by providers and patients to improve health care. And there’s a lot in these words; they really speak to some of the barriers Jerry has outlined. Some of the practical things that people have noted as they reviewed the work, and to a specific, highly practical work plan involving consensus statements, development of specific tools and enablers and a means to demonstrate improvement and embed it into real systems.

Over 70 experts and stakeholders of various different kinds of organizations have participated in reviewing initial materials, in face-to-face meetings at the Institute of Medicine, in comment periods and in e-mail exchanges. It was absolutely necessary to get this wide swath of

stakeholders on the case, lest we fell into the trap creating a wonderful elegant solution that would never see real development and real use.

The participants in the roadmap identified three pillars of specific improvement and six strategic objectives most likely to bring about the pillars and to bridge the gaps. The first best available -- best knowledge available when needed is to ensure providers and health IT systems developers can easily obtain and deliver accurate, intelligent knowledge without having to reinvent the wheel at each location and at each company.

The second: high adoption and effective use helps to ensure these systems are implementable, learnable, usable, cost-effective, and that clinicians in fact feel comfortable buying them and safe using them.

The third: continuous improvement of CDS methods and knowledge means once we develop something that works, we have to learn from that experience, we have to move what has been successful at one institution, make it successful at another one. Learn with the experience, understand what one person is doing so that we can improve it somewhere else.

The six objectives of the work plan are tied to these three pillars. Addressing the first pillar, best knowledge available. Number 1 is to develop practical standard of formats for representing CDS knowledge and CDS interventions. There have been other formats developed in the past, but these have not generally been widely used in existing systems. In the preliminary discussions in the roadmap group, we're are focusing on 90-10 solutions and low hanging fruit, and making use of real experience, so that current knowledge can be found and used, and new knowledge can be rapidly prepared for use in electronic health records even right out of the journal.

Imagine if appropriate guidelines for flu treatment or reminders for cervical cancer vaccination were available to your doctor’s office system within days of their official approval.

Objective number 2 tags onto this and is to establish standard approaches to organizing and distributing CDS. We want to make it easy for vendors and providers to incorporate new interventions into their own systems. There are several models for this, including centralized public collections and private competitive distribution systems. These have all been discussed and are under continuing discussion.

Addressing the second pillar, adoption and use, is objective three, to remove liability concerns and to incorporate CDS quality into payment into meaningful and practical way. Doctors shouldn't have to feel nervous that having a CDS system exposes them in a greater way to liability. They should feel they not only can afford to use CDS, but that they can barely afford not to.

Objective Four really addresses the problems that we’ve heard talked about in terms of usability, systems that get turned off because people don't quite understand how to use them and can't fit them into their efficient work flow. Compile and disseminate best practices for usability and implementation. Some sites know how to do it, other sites don’t know how to do it. Some of this information exists but more is needed. And what we do know needs to be used more widely by those who develop and deploy CDS. So the objective here is to compile this, organize it, and communicate it in appropriate ways.

The last two objectives speak to continuous improvement of CDS and knowledge. Just as we have standards for data and transport, so we need to develop and use standards to collect, learn from, and share the national CDS experience. For only if we have a common language and a common set of experience describing how people use CDS, what works and what doesn't, only then will we be able to get the successes in one location to have any bearing on what happens somewhere else.

Finally, Objective Six really closes the loop. We should close the loop by using identified data from interoperable electronic health records, to determine that scale which approaches lead to the best outcomes. Dr. Perlin mentioned this morning that they were able to use the EHR data to understand something new about morbidity and mortality in ICUs related to blood sugar. This is exactly what this objective addresses. There is lots of data out there in electronic health records that is able to, in fact, add to our store of knowledge and bring this back to practical and usable use.

So as I mentioned with each of these things, there are defined work tasks mentioned in the roadmap. I'm going to let Jerry conclude with the critical path for definitive and visible action.

MR. JEROME OSHEROFF: The CDS roadmap provides a comprehensive work plan for achieving these strategic objectives. Cross cutting critical path steps are proposed to build momentum and demonstrate near term value. The first step is to establish an ongoing leadership group and forum for stakeholders to integrate and accelerate CDS efforts.

Second, intensify education strategies to ensure that the best practices for developing and deploying CDS become common practices.

Third, develop pilot projects that use the strategic objectives to demonstrate that CDS can be applied in a scaleable way, to improve quality in high priority areas, such as medication errors and disease management. These pilots can identify a feasible, standard based approach to CDS that can more readily deliver benefits across the health system.

Fourth, leverage activities outlined in the roadmap to support health care transformation efforts where CDS plays a valuable, though not always explicit, role. The CDS opportunities in the Community's Workgroup's efforts mentioned previously are a prominent example.

The objectives and activities outlined in the roadmap are intended to ensure the potential for CDS and health IT to improve care, safety, quality, and efficiency is realized.

Thank you again for the opportunity to develop and present this roadmap. We welcome your questions and comments.

DR. DAVID BRAILER: Thank you. The floor is open for comments or questions. Mark? Mark, then Scott.

DR. MARK WARSHAWSKY: David, perhaps it is really a question to you more than to the gentlemen on the panel. I must admit that I don't quite recall where does this fit into the Community's goals and tasks.

DR. DAVID BRAILER: It is a good question, Mark. The answer is, simply put, it doesn't quite have a home. Because it's just spread across much of our work. If you look at the four Workgroups, for example, each of them as, they start looking at the next broader charges, early in their own roadmaps they're going to touch clinical decision support issues. We just had the discussion that Bill raised about structured data. And I think if these gentlemen will tell you that much of the clinical decision support effort comes from having relatively structured data about these efforts.

So this is an update we wanted to give you because we have been chewing on this question of where does it fit it in, in particular, where is the next step we can take to help advance this. Everyone agrees it's life saving, everyone agrees that some of the keys to efficiency are tied up in this, that the value back to the clinician of using these tools is wrapped up in this. But this is an enormously complicated area in terms of how do we move it forward because of the operational, the technical, the policy, the liability. They have listed many of these issues. So we are certainly going to keep this involved in the Workgroups, but we're looking for insight from many of you about what else we should be doing here and how to build on this roadmap.

SECRETARY MICHAEL LEAVITT: Can I just comment on, or at least talk a little bit about the integration that I can see here. We're dealing with interoperability today and in AHIC. There is an entirely separate debate going on nationally, about adoption and how we're going create enough incentive for, particularly small practice physicians, to adopt this.

Simultaneous to both of those discussions is a conversation going on in Congress about how we're going to ultimately resolve physician reimbursement rate issues. And it's clear to me that a component of resolving that discussion will be a conversation about pay for performance. And it's very clear to me that unless we are able to link good clinical decision-making into our pay for performance standards, we will not be able to persuade physicians and other clinicians to use this.

So actually, from two different avenues, both from a financial standpoint -- let me just link back into the adoption piece. It becomes clear to me that one of the ways in which we will acquire a broader adoption will be saying to physicians one of the ways in which we can compensate your use of IT will be additional payment that comes by achieving pay for performance objectives.

So all of this links together. The financial incentives, and the broader adoption, and then doctors being willing because of the belief they have that it is improving their patients' care. I think it's very important that we figure out how to integrate this at many levels.

DR. JONATHAN TEICH: Secretary Leavitt, thank you for that comment. That basically echoes one of the critical path recommendations in the roadmap, recognizing that there is a lot of activity going on in these pay for performance initiatives where clinical decision support has the potential to play a very important role on the short list of ongoing entities to get connected with and engage this dialogue. The pay for performance initiatives are an essential part of that.

DR. DAVID BRAILER: Scott.

MR. SCOTT SEROTA: I have a couple comments on this. First, I am extremely supportive of the concept of a clinical decision support tool because I think it is a very practical use of the data that we are collecting and ultimate output of interoperability.

But I have a couple concerns, the first of which is, adoption is low because the business case can't be made for individual physicians. And it appears to me that we're moving very quickly down the line of developing all the protocols without looking at the business case. And as a result, we're going to have a wonderful tool that nobody will buy.

So I think more time needs to be spent on developing a sound business case for physicians and ultimately for payers like the blues and others that make sense for us to incorporate these kinds of things into our operations and into our reimbursement methodologies and things of that nature, which necessitates a lot of work and liability. It necessitates a lot of work on outcomes, and just a lot of work on adoption rates and things of that nature. So that's concern one, is that we're not focusing enough -- we are spending a lot of time on the sexy part, which is can't we make -- look how much better we can make health care and that makes for good headlines. But to get adoption you have to have a solid underpinning of a business case. That concerns me.

The second piece of this is the more that I've listened today, the more concerned that I become we are throwing too much at providers too fast. And I think we don't -- maybe you have, Mr. Secretary, or David, you do, but somewhere a master plan that says here are the things we want to get implemented in these periods of time so that an individual doctor can step back, or a payer, or a hospital, and look at this and say, how am I going to get this done or can I realistically get all this done. Or from a priority standpoint, okay, I'll do EHR now, then I'll do CDS, then I'll do this. I mean I am worried we are throwing this out there, and the provider will throw their hands up and say there is no way. I am overwhelmed. I cannot deal with this.

And I don't see a good sequencing saying here's the first priority, here's the next priority, here's the next priority. I see us kind of attacking all the problems at once, as opposed to sequencing that. I am thinking about the private doc and the one or two-man practice saying, there is just no way. I just can't do this, at a time when my reimbursement is going negative, not positive.

SECRETARY MICHAEL LEAVITT: This is an important and interesting conversation. I'd like to see this erupt into a conversation for a minute.

[laughter]

We're weighing stark exception rules. I'm not going to comment on anything specific related to that. But it's clear to me that it's an important regulation because it ultimately will be the means by which many of those small providers begin to connect into their -- into a system. And this business of -- the business of creating a revenue stream that provides a return on the investment of someone, through the savings that are achieved, the "pay for performance," it seems to me to be a vital part of this.

And maybe as you say, maybe it is a piece of it that we're not spending enough time on. And maybe this isn't the place to be doing it, but there certainly needs to be someone that is thinking about how we're going to link all this together. I can see quite clearly the component parts of this coming, I'm just not sure all the gears line up as perfectly as they need to. My guess is the

answer to your question is that it'll be the link between the hospital and the clinician or the clinic, that ultimately drives the pace of adoption, not just of having the system but in terms of its implementation.

MR. SCOTT SEROTA: I think that clearly that is a piece of it. But there are other ramifications of linking the physicians and hospitals so closely together that restrict practices and restrict physicians from moving from institution to institution and a host of other things which have to be considered.

I'm also concerned just about a master plan. Because while all of these discussions of systems are going on -- we're considering health IT bills which talk about implementation of ICD 10 coding and a host of other things which have costs in the multitudes of billions of dollars, and it just appears that we have a series of random events, as opposed to a master plan for IT, that says, here's the sequence: We going to do this in '08, this in '09, this in '10. And somewhere we ought to have that chart, whether you share it with the public or not. It ought to be up in a room somewhere on the wall that says here's where we're going. And here's what comes first, here's what comes next, here's what comes next. Otherwise we may have picked the highest priority, but you might have to do nine other things before you can get there.

SECRETARY MICHAEL LEAVITT: You're talking about something like this, that begins to lay out what we will do when.

MR. SCOTT SEROTA: But it needs to incorporate the other activities going on as well because there is just only so much money.

DR. DAVID BRAILER: Maybe, Scott, if I could comment on that. I certainly don't think that we produced something that is succinct and as specific as that 10-year roadmap that lays out, essentially what the sequence of developing and offering kinds of tools or advancing those would be.

In fact, I've asked traditionally, my old office, to exercise restraint and not making that top-down. But what you're hearing, I think, is a glimpse of the future, which is, I think, the topic of this meeting. Today, all we're asking a clinician to do is pay attention to products that are certified in the ambulatory space, which we'll be having made available in June and July.

But what you're hearing today with decision support, what we'll hear at the August meeting with quality metrics are examples of inputs that we're feeding into the certification commission to begin asking how does this fit in their road map for what the EHR should have as a minimum feature going into 2007 and 2008. And they have an obligation to lay out a roadmap for several years that starts to begin laying out what is considered minimal features of these products.

And we're doing the same thing on the architecture side. What types of information should be shared in '07 and '08 -- begin looking at these. So I agree, it is kind of a little bit piled up today in a sequential way, but we do think that the unit of attention that clinicians need to have at this point is on what's available as a certified system.

MR. SCOTT SEROTA: The question is, should the certification commission be the one determining the priorities? What is happening by default if we're saying the clinician should use

a certified programs and we're empowering the certification commission to define those terms, then we've essentially advocated the strategy role to the certification commission.

SECRETARY MICHAEL LEAVITT: But it seems to me that the role of the Community is to determine the priorities and what is doable, when. And that what happens at CCHIT is completely dictated by what we ultimately send them.

MR. SCOTT SEROTA: That was my understanding as well.

DR. DAVID BRAILER: Right. And to that end, you know, none of the contractors who work for the Office of the Coordinator are making decisions without the approval of that Office. That Office looking to this body for those advisory opinions. The roadmaps are still in formation. It is my hope that by August we can have those roadmaps.

The other reason is in addition to why this group needs to do it is, it's not just certification. It is moving along the roadmap for privacy you just heard about for architectures. There is only one central component of those that we want to have but it is a little bit early for us to be able to articulate it, because all those groups are still working on it. So if not by August, I think at the meeting after that, we should be able to say, here is what it looks like, does this make sense to you? ` And we can then give everyone, not just those bodies, but people in the private sector, a sense of real direction about where this is heading.

Male Speaker: I was going to simply comment on measurement, which I'll come to in a minute but I can't help but take point in this conversation. Because I think that Scott's point, is, with all due respect, Mr. Secretary, when we talk about pay for performance, it changes the whole dynamic. Because whatever is done here, we're going to create that market. And you know how the market is going to be created? Because something is going to be required on physicians or hospitals. And we can say at first, oh, we're not requiring them to do it.

But the problem with the way Congress and possibly the administration, but at least Congress, is dealing with paid for performance in Medicare is shown by example in DRA, regarding pay for reporting. We didn't get 2% to report. We don't lose 2% to report. It's taking money that otherwise ought to be there and saying well now, because we're adopting this new game and you have been, in our mind, under performing, we're going to pay you to perform.

I am not bad-mouthing it or saying that we haven't, in many cases, under performed, so maybe there ought to be a penalty. But let's not kid ourselves. This is a question of application of a penalty, not a positive reinforcement for proper behavior. And that is the way it's going to proceed.

Now some of the private payers will proceed that way, some of the private payers may provide an add on payment, but over time, let's not kid ourselves, it's not going to put new money in the system. It's going to reward, hopefully, positive behavior, but it's going to performance, rather than under performance.

The reason I bring that up is because we can talk about -- this is great stuff they're talking about here. I can see the link between this and measurement. Because the issue with algorithms -- this is all dependent on algorithms, and the issue with how records work that make this whole issue

of measurement problematic make this problematic. And if you can solve the issues here, you'll solve the issues of measurement.

And at the end of the day, I think you're going to have your business proposition. It's going to be that if doctors don't buy this stuff, and if we don't make sure that it works right for them, they're going to be in real trouble. Because they're not going to be able to do it in small practices. But they're not going to get their Medicare increase unless they play. And we can say we're not going to make the information technology incumbent upon playing, but we're going to make certain kind of reporting incumbent upon playing, and the poor guys with three or four doctors in a practice aren't going to be able to do it because they don't have the nurses to do the record stuff without something like this being online.

So we really desperately need to get this out there in some form, that it can help with management and can help with practice in this way. Otherwise they will be in a real bind because they're not going to be able to live up to what you want in terms of giving them a zero increase, or a 1% increase rather than a 4% cut, and asking them to meet all kinds of new standards. I am not saying that any of that is not good policy. I am just saying, that as Scott's pointing out, all that's going to pile in on people at once. It is only beginning. We're going to have some problems there.

But it means that the work here, as with measurements got to really be speeded up, because we have to certify products that are going to meet your expectations. I think it would be great if it was a grand plan and it was all done rationally, but Congress isn't going to act that way. Congress will have a budget bill next year , and they're going to make more requirements on people. I can smell it. [laughter]

SECRETARY MICHAEL LEAVITT: I'm going to have to slip away for a competing demand. I'll be back, but I don't want to interrupt. I don't want my departure to be misunderstood.

[laughter]

DR. JONATHAN TEICH: Thank you. I think just one comment I'd add to this that one way or another whether we are talking positive funding advances or negative, we know, by lots of evidence that improved quality improves the cost picture. We know that we at Brigham Women's Hospital have seen significant reductions in malpractice costs because we're delivering this kind of stuff. We know that we've seen better deals from our payers because it's clear that these things are delivering better quality.

CDS is a proximate way to deliver quality. There's all sorts of different studies which'll tell you that is has to be figured in. It delivers payment reform. The question is how do we get this so that it comes back to the people that have to buy it and use it.

DR. DAVID BRAILER: Doug?

Dr. Douglas Henley: Well, I want to put the politics of pay for performance to the side for a moment, and just speak to the fact that this discussion that we are having about clinical decision support tools is extremely important. When we met the day after the last AHIC meeting and discussed kind of your roadmap, David, and I brought this issue up at that point in time.

And at least speaking on behalf of the physician community and especially for the AAFP, we see clinical decision support embedded in EHRs as the next frontier, a very important frontier, in moving rapid adoption of the EHR technology. The first parts were standards development, then the certification process, which we now have. That -- those two processes which we have been involved in, have brought great stability to the market in the minds of physicians that now it is time to begin to thinking about seriously writing that check with a vendor to adopt EHR.

Clinical decision support is the next leg of that three-prong stool, from our perspective. We've got 30% of our members have implemented EHRs. We're working on the next 30%. And it is this topic, clinical decision support, that they bring to the table every single time to bring value to the EHR that they want to purchase now. So the more emphasis that we can place on this, it is extremely critical.

It is also critical because it relates, as the slide showed, as the presentation indicated, it relates back to the personal health record, not just the HER, as it relates to the consumer, the patient, in terms of the collaboration between doctor and patient for improved patient care. It's important, it's necessary. Let's put the funding and the resources into it and make it happen sooner rather than later.

DR. DAVID BRAILER: Nancy:

MS. NANCY DAVENPORT-ENNIS: David, I think to continue with Dr. Henley's comments from the perspective of the consumer and the patient, I think the pay for performance discussion is an integral part of this discussion today, as it relates to moving forward with EHRs and PHRs. I think it would be an interesting survey to survey different physician groups, particularly the specialties, such as oncology, to have them define their definition of what they are using pay for performance income to currently offset. Because I know that for us within AHIC, we're looking at those dollars and we're saying, well, indeed, they could be used to offset their investment in this clinical decision support tool.

If we go to the American Society of Clinical Oncology meeting for five days, what we're hearing repeatedly from that population, is that those dollars are already committed to offsetting other cost and other services that have been traditional within their practices for their patient community.

So I think for AHIC, we probably could benefit by having discussions with several of the physician representatives. And together, perhaps, develop a way to get the funding, Doug, that can move into the system more efficiently with the greater leveraged result at the end of the day.

DR. DAVID BRAILER: Bill and then John and then Mark.

DR. WILLIAM WINKENWERDER, JR.: I'm going to leave pay for performance aside, too, as a payer. We will leave that off the table for right now. That is something we are actively thinking about as well.

I do want to say in terms of clinical decision support, I agree with what Doug said. It is very important. I think it's very valuable and there is an emerging, you know, evidence base of it, of

its contribution to improved quality health care. However, having said that, it just seems to me that it wasn't quite clear, I share Mark's comment about where this fits in this agenda that we have set for AHIC. It wasn't -- it is not clear to me.

I'm just wondering, because there are lots of things going on out in the vendor world and clinical decision support, and of course I think so many of the electronic health medical record systems are so new we don't have a lot of -- I'd like to see the data emerge, I guess, before we get into the business, at least at the government of certifying things, this, that, and the other, in this particular area. I think it's out there.

There needs to be a lot more discussion and a forum created around how to advance, you know, the use of clinical decision support systems. But it's systems. It's not, as everybody knows, it's not one system. I mean, it's different things. It depends on what types of decisions you're trying to support, whether it is the decisions of an oncologist or cardiologist or primary care. It is a whole bunch of different things, or home care for asthmatics or diabetics.

So anyways, I just think that my vote would be for going a little more slowly in this in terms of certification, or standards, or whatever. And let's see what develops in the field with the implementation of electronic medical records, health record system.

DR. DAVID BRAILER: I think this discussion represents, in many ways, a lot of the ambivalence that we've felt, recognizing on the one hand that we won't get any of the promise of value or efficiency out of simply computerizing offices if it isn't for kinds of things that decision support does.

But on the other hand that this is an incredibly complicated area, not just technically and academically, but with the respect to the policies that support it. And for that reason you see some pretty aggressive actions that we've taken in the past year, but yet we're simply supporting a roadmap dialogue in this area, because we are trying to understand how we can move forward on it.

I would just comment though, remember that not all clinicians are created alike. On the one hand, we're trying to think about how to spoon feed some decision support through EHRs into one or two doctor offices, but on the other hand to recognize that many or our large academic centers and large groups are far, far, far down the pathway of developing incredibly sophisticated decision support capabilities, some of them sitting here at this table. And you know, we are trying to really watch that and understand what the next steps are.

At this point we have no item, no action that we're seeking from the Community on this. This is advisory, and again, I think again your feelings are very much representing what we feel at this point, that we need to walk this direction very gingerly and to recognize that there are a lot of efforts that need to move in parallel to make it happen. So I appreciate that thought. Let me turn to John Perlin.

DR. JONATHAN PERLIN: Thanks, David. I too want to put aside the pay for performance and just reflect back to where the Secretary started the discussion. Visions of the future that included price transparency and really, quality transparency and give the perspective of an entity, VA, which both payer and provider. And I want to talk to a couple of the issues because they're

things we deal with in a real operational way, and that's the issue of liability and provider burden.

But I want to contextualize this with where we are in health care today. I hope that there is no one in the room who feels satisfied that American health care is where it should be, that our quality is where it should be. Goodness, the Rand study showed that Americans only receive evidence based care 54% of the time when a broad swath of indicators in prevention and chronic disease treatment.

And I know in terms of the provider burden, there is no clinician of any stripe who comes to work and says gee, I really want to do a bad job. But the fact is we operate in an information deficient world. And if you ask clinicians about whether they do simple things, like providing appropriately a flu or pneumonia vaccination, they'll tell you, yeah, I get most of the patients. If you actually go back and audit charts, almost invariably the rates that they estimate off the top of the head absolutely overestimate what the reality is and that's absolutely consistent. Otherwise we wouldn't have a country where the rates of pneumococcal vaccination are less than -- approximately 70 for over 65 and even less for individuals less than 65 with chronic illness, and those in environments where data is reported.

It's really in that context that we have tremendous opportunity for improvement. Let me talk about the liability first. Liability -- two of the largest sources of liability are failure to diagnose and failure to prevent. And pneumonia vaccination may be fairly straightforward. But in VA's experience alone, just for patients with emphysema, chronic constructive pulmonary disease, between 1995 and today when we increased the rate from 27%, which was only marginally below the national rate of 33% to a national bench mark rate of 94 today, just for patients with emphysema, it saved 6,000 lives.

And even in the context of doubling the number of patients that we treat -- more than doubling, halve the number of discharges for community acquired pneumonia. Now 10 years ago there were no physicians in our system who cam to work and said, Gee, I think I'd like to deprive patients with emphysema the ability to have an appropriate vaccination. Yet absent the information resolution they just couldn't do it. Context sensitive, time sensitive, clinical decision support, it resolved also the measurement issue.

I think that the writing is on the wall, whether it is a plus up or breaking even. The future requires greater accountability and the toll to support is the system is this information system that'll allow you to do the right thing and actually improve the health outcome.

I just close with this statistic, I mentioned that the VA population has doubled. Between the secular rates of inflation and the doubling of the population, we have continued on current trend, our budget today would be in excess of 60 billion, not just a little bit over 30 billion. So there is huge opportunity to simultaneously improve the quality and improve the efficiency. And frankly, I believe, reduce the liability and provider burden. It's not all borne on the back of the physician alone if you have a smart system.

I think we are trying to -- we're not going to this in the next year. But in the President's time horizon getting out to 2014, I think we should really set our sights high in the interest of improving the health of the American population in a rational fashion that shares the burden,

reduces the liability, but ultimately really supports the goal of safer, more effective, more efficient, and ultimately more compassionate health care.

DR. DAVID BRAILER: Thank you. Any other final comments. Mark, were you going to make another comment?

DR. MARK WARSHAWSKY: Yeah, actually, I wanted to move to actually a question on the prior discussion, moving away from the clinical decision support, but related to the discussion we're having about physician adoption. Do you have a concern as we put out these standards sequentially, batch one, batch two, batch three, that physicians are going to be concerned about -- that they adopt today, and they won't be compliant with batch two and batch three or maybe asking the question another way.

In a sense, have they committed, once they committed to one, that they are going to have to commit to everything else, and they don't know what everything else is going to be?

DR. DAVID BRAILER: I think when you see the level of gap we have between where we are and where we need to be, and the amount of legacy investment that occurs in the system knowing the next investment becomes legacy soon after that. It is a concern, that we can't either pilot it all to the back end and get it all worked out, and launch it on the industry at once, and we can't just incrementalize it without creating distortions.

And I think the approach we're taking which is a periodic update, if you would, and annual, or I think in the case of the Secretary, I think it's three in two years so a little more compressed, but a cyclical update, given the very long lead times that are involved with the update of the systems with the acquisition of them, I don't see another way to do that.

We tried to make the promise to the clinicians that we will be as backwards compatible as possible, but each of the standards that you've heard talked about that have come from the use cases are being updated on a regular basis. And it's not unlike the operating systems or other things that one has.

In the end, we're relying on this premise, which is to go from a non-standardized, non-engineered solution, to one that is engineered. It's quite a lot more difficult to go from an engineered, standardized solution to a variation of it. It is -- even though it is a technical change, the work flow, the culture, the decision-making, the way the business operates of health care is less affected by it. So certainly, you know, it is a long process. I don't think it has a beginning, middle or an end. But in the end, the starting point is that we want to get this bite size so people can begin engaging and getting involved.

So I'll take certification as an example. It is a minimum set. It will be updated every year based on a lot of these standards, all the inputs that we've been talking about. And it's possible that a clinician system might not be certifiable in the future. But we're certifying at the market level, not at the adoption level. Meaning that as long as the physician bought it when it was certified and got the benefit of that, it is up to them to make decisions about their future certification in the future.

So it shouldn't affect, if you would, the tail of the investment. It should affect the period of the investment and try to make that their guiding. I think that is true with all the standards efforts. John, do you want to make a comment on that?

DR. JONATHAN TEICH: Regarding what you say about it, I just wanted to point out that this shouldn't be a matter of do we have to grind it out and be forced to adopt these things. There are places, many places, where these systems, where CDS and other systems are quite happily adopted and are seen as an enthusiastic supporter of the way the physician practices.

But it is not a universal thing. And part of the work that we're trying to do, is to take some of the things that have made people so content and happy with it in some places, and try and translate those lessons, because it is really a communication that hasn't gone on. It shouldn't have to be a burden.

The other -- I want to make real a quick support on what Dr. Perlin said. Quality reporting quality and transparency is derived from the same kind of logic that we're using for clinical decision support. The denominators are exactly the same. In another project that I'm doing with Price Waterhouse Coopers, we're working on quality measures, trying to simplify the reporting and data requirements for quality measurement. The denominators, the calculations, are the same things that one would use to do clinical decision support. So it really does tie in very well.

DR. DAVID BRAILER: Okay. I think we have time just for a few final comments. Chip and then Scott.

MR. CHARLES KAHN, III: I really disagree with Bill and I'm totally with John. I think we -- the question it seems to me, is conceptually, what are we talking about. Are we talking about coming up with an entire framework, whether it's on the measurement side, or the clinical decision support side, which I sort of see as sort of the same thing, and saying we're going to start a Workgroup and put that into, as a component, or are we thinking about whatever we do, that this has got to be the foundation of the house? And I think it is a different way to approach it conceptually.

I think we cannot proceed from where we are now and not, at least in terms of building the foundation of the house, be thinking about how this will be integrated in. Going back to this batching, John's point, we're talking here, not about, generally, sort of complicated, you know, algorithms for various kinds of sophisticated treatment. We're talking about blocking and tackling. That is all the measures do now in most cases anyway. So it's a question of, did you give them the shot or didn't you give them the shot, and somebody asked the question, whether it's in taking the measurement or in the clinical decision, the thing that pops up on the record. I don't see how we can avoid it. I think it is a must.

Let me also say, in terms of Mark's question, that at least in terms of hospital purchasers, and I can't speak about physicians, they're writing all of this stuff into the contracts. Right now, my guys -- it's been hard for the vendors. The vendors have been pushing back. But my guys will not sign a contract with anyone, unless there are pages and pages about what happens next when certification requires, over a brief period of time, higher and higher levels of compliance with some set of standards. So whatever the vendor is selling them off the shelf now and whatever

they modify, they've got contracts that protect them for some length of time through the kind of process you're talking about.
I don't know whether the physicians are doing the same thing. I assume large group practices are, but anybody who is buying anything now better be buying that as part of the contract because it is moving too fast. And that is a problem anybody using it has got to be willing to recognize immediately.

DR. DAVID BRAILER: Scott?

MR. SCOTT SEROTA: I just would make a couple comments. I also come from the camp that clinical support has to be a cornerstone of an EHR. I don't think you can really realistically build one without building that mechanism in. That being said, I think this is worthy of a much deeper discussion by AHIC and others for a couple reasons.

One is, I'm interested in understanding the politics outside, not beltway politics, clinical politics, of who sets the algorithm? Who creates the rules? Is it the specialists who tell the primary care that the ultimate goal is refer everything to me because you're not competent to take care of these things? Is it the primary care guys who say, no, the ultimate goal is to keep everything in my practice and never refer anything out? Who's going to determine those and as one who's been in this business 27 years on the payer side, I've watched those politics evolve on capitated arrangements and a whole host of things about who ought to be.

The raging debate about is an OGBYN a primary care physician is still not answered, and it's been going on forever. So how is that going to fit into the algorithms, and who makes those decisions, and if they are certified, there must be some entity somewhere that's going to say this is the one. I'd to understand more about how we're going to get to that point. That is point one.

My second point is, I don't see how you separate the discussion of clinical support systems and pay for performance. In deference to those of you who who said you want to separate those issues, they're inseparable. Somehow you have to pay for this. And paying for it means -- if we're assuming it's a zero sum game, and if I talk to my customers they would say it's not a zero sum game, it's a negative sum game. You have to tell me how the rates are going to go down, not how you're going to keep them the same.

And if that's the underpinning of the financing of this, we have to have the conversation about how are we going to convince people to invest in this technology, if the payout is down the road. And clearly it is. I agree with everything said, that it is. But the guys who are paying the premiums today got to be sure they're going to be around when that payout occurs. And that's been the debate, again, in my 27 years of doing this and trying to incent people to do preventive care. The employers used to tell, that's all well and good, but my people stay here three years. Three years from now somebody else is getting the benefit of the prevention I paid for.

So you know, we've have been round and round on these issues. We have to put it all into context but we have to do it. We have to have that conversation, we have to build it into the record and we have move forward. I don't think we can do this short shrift. I don't think we can take 30 minutes on the subject and say, yeah, we ought to do it, move on. It is a cornerstone.

DR. WILLIAM WINKENWERDER, JR.: Let me say one other thing. I wanted to respond to Chip. I don't want my comments to be interpreted as anything less than enthusiastic support for clinical decision support systems.

My concern, I think Scott has articulated them. They're just what he said. That's the concern about how you go about this, and who makes the decisions and then is the government involved in something that really ought to be driven in the clinical community, then who is it in the clinical community that decides all that. That's the concern. We have to get it right.

DR. DAVID BRAILER: I think to some degree, the Secretary, this morning, discussed at length his vision for how health IT and transparency come closer together. Part of the underpinnings of that is this very discussion. That it is hard to artificially separate them into categories because of the inner dependencies. And so I think you'll be hearing certainly more about that from him in the future. I think we had -- Kevin?

MR. KEVIN HUTCHINSON: I have been sitting here trying to resist the temptation to state the obvious, but we've gone on so long I felt I actually had to state it. The physician vendors -- if you look at the financial records right now in the second half of last year and first quarter of this year, there is adoption that is occurring. There absolutely -- is there incentives, are there pay for performance programs, are there needs for long-term payback ROI against those things, absolutely.

As we sit here today, someone is signing a contract with some software vendor to implement an EHR vendor with a number of physicians in their local community. So adoption is occurring.

In the years that I spent implementing EHR systems, one of the things that's very clear to us is, and every physician will not use the EHR system exactly the same way. I don't think any of us are suggesting there's going to be uniformity in every physician using every functionality. Some will use clinical decision support systems, some will use it simply as a means to get access to their own information and exchange information and do referrals and a number of other things. But they will adopt a technology at their own pace, and are adopting technology at their own pace.

So while we do sit here and debate the clinical decision support, we're all in agreement, sounds like, that clinical decision support is ultimately the holy grail of where we want to go. But adoption is occurring and we are seeing the rollouts occur, but we do need to see those longer term incentives put in place.

DR. DAVID BRAILER: Any final comments on this topic? Jerry?

MR. JEROME OSHEROFF: I just wanted to reiterate that one of the cornerstone items on the critical path of the roadmap is to create a forum for just the kind of dialogue that you're talking about to bring the stakeholders together in a room and sort through some of these issues so that we can move forward starting tomorrow to make these things happen.

DR. DAVID BRAILER: I think we'll certainly keep this discussion in mind, when we, in August, talk about the quality performance measurement and how the dependencies here could be institutionalized in our next steps. Thank you very much. I appreciate the very hard work and

discussion that certainly went far in substance and time beyond what we planned. But this is very helpful.

Given that we are now approximately 50 minutes over our planned time, we want to stay true to the scheduled public comments, as well as some people that we're going be losing if we go much longer. We are going to only turn to Tab 7 for a brief review of the updated strategic plan of the Office of the National Coordinator. To present it to you simply to upload it for your thinking, get any brief early comments and then revisit this on August 1st, when we have a chance for a more substantive discussion. And certainly, if any of you have thoughts or comments that you want to share with us between meetings, it's fine. But the purpose of this document is really to communicate some of the issues that we talked about.

So I think -- am I doing this? Okay.

We had planned a much broader discussion. So I'm just going to focus on a few slides and give you an orientation to what is here. You have in your packet, a document that is called the Draft Office of the National Coordinator's Goals, Objectives and Strategies, and it's a 16-page document that enumerates four goals, and then objectives beneath them and strategies beneath those.

So if you turn to -- then there's also powerpoint slides in your packet. And if you turn to slide two, the original strategic framework was released in July of 2004; it announced four goals and 12 strategies. It was called the framework because it did not attempt to operate at the level of a plan, which is guiding tactical or action level work. It was simply a compilation of where we wanted to go and what the key themes were.

This has been vetted, discussed, refined in numerous setting. Many, many, many that I know of and certainly many that I haven't been in. It reflects a significant amount of discussion, but it's, to recall, it's market based, it's being used internally to develop performance measures to make sure that the Office of the National Coordinator knows what it needs to do, and as importantly, other federal agencies can work against the same common framework. It's a communication vehicle, as well, to answer a number of the questions that have come up today about where are we going.

If you turn to slide 3, the strategies fit into three categories. There are strategies that are underway. We already have actions underway, a number of contracts, or groups, that are working. We consider those strategies certainly not sacrosanct but beyond the level of dialogue and action.

Secondly, strategies that are under active considerations: one that we consider kind of up close, ready to really begin getting a serious look. And then thirdly, those that are out there, more longer term, they're future discussion oriented.

And so, we have, at this point, 10 strategies that we consider to be initiated. And I'm not going to go through each one, but on the next slide, you see that they're organized over the next three slides by goal. And I would tell you that the -- one of interesting discussion items is that the four goals we started with, we have come back to. We see those fitting the test of time and being able to give us ongoing guidance. But you will see at the strategy level, that they have changed quite

a lot. Certainly not in intent or substance, but in the way they're presented, the level of detail, the level of specificity, the organization of them are certainly different.

And so we have a number of goals and strategies here that are under way, and what you can see under these 10 strategies -- again, I won't review them in detail, is to identify that each of the actions you have heard the Office of the National Coordinator discuss or contracts that we initiated or work that is going on here, have a home in these strategies, or said another way, we were not able to find actions that we have taken that we couldn't identify a strategic base for, which I think it is a good, if you would, validation of this plan.

Likewise, each of these strategies that are initiated are not complete, simply because of the actions that are underway. The contract that is being done, for example, with -- for example, with strategy 2.1.3, if you go back one slide, exercise federal leadership in federal and health information standards adoption. The Workgroup recommendations are one key action that are underway. We don't believe the work is complete because of those Workgroup actions. But it's underway, we are engaging this, we're recording how well we're doing, et cetera, and I won't go through the rest of the details.

So 10 strategies out of the plan are initiated. There were six that we identified that we considered active consideration. Meaning that we are not acting in these today, in any formal manner, but we consider these the next area for significant focus. I'll just enumerate them.

Slide Seven. Under the goal inform health care professionals, under the objective, lowering the cost and risk of EHRs is to foster economic collaboration for EHR adoption. To be able to begin bringing together different parties to support some of these business case issues to recognize that it's not just the total amount of capital in the system but often it's who the benefits accrue to and over what time. And to begin looking at what we can do to help frame better ways of creating economic alliances to do that.

Page Eight, under Goal 1again, again under the same objective, lower the total cost of EHR purchase and implementation. This is not, as it might read at first glance, an effort to try to set or control prices. This is an effort to recognize that the total cost burden that's carried by the electronic health record reflects far beyond the price, the opportunity cost of implementation, the cost of all the services that go along with that, that are very inefficient. The whole effort with standards is about, in many ways, lowering the cost of the products, because they become easier to plug and play.

Page 9, under Goal 2, which is the interconnect health care goal, to make health information exchange sustainable, which is to look at ways to stimulate private investment in health information sharing. Much of the Workgroup recommendations touch on this, but they don't really touch on the question of sustainability. So this is a question we are looking at. Some of the efforts that we're going to be pushing forward, perhaps through federal contracts or other things, could be aimed at this as well.

Also under Goal 2 Objective 2.2, Strategy 2.4 on Slide 10: support state and local governments and organizations to foster electronic health information exchange. We see this recognition that these regional efforts, these state efforts are beginning to get traction in some areas and some not

in others, but to recognize that these are good units of support for these efforts and to begin exploring what we can do to support those more.

Slide 11, Goal 3: personalized health management Objective 3.1. Consumer use of personal health information. 3.1.1: Strategy: establish the value of personal health records including the aspects of consumer trust. This is quite large. In fact, this strategy could probably be decomposed into others, but this is a thrust of thinking that we feel is quite timely and quite important now, and we're going to be investigating what actions we should be taking here.

And then finally under improved population health Slide 12, efficient collection of quality information. Develop patient-centric quality measures based on clinically relevant information available from electronic records.

Remember, as Chip has pointed out, there's two sides to this discussion. How do we use electronic data to measure the measures that are in place today? And the flip side is how do we begin taking into account what we can and can't measure, as we develop measures in the future? I've used measure too many times in that sentence but I think you understand the intent. [laughter]

So this is an area that we're concerned about, and I think it'll overlap with some of our August discussion. So these six areas, again, this is where had hoped to have some substantive discussion today, but we'll hold this over and ask you that bring back your thoughts on August 1st. If you have overarching thoughts on this today, feel free to say so, but we're not going to be taking any significant actions in these directions between now and August 1st.

And then finally Slide 13, 14, 15, are 16 strategies, the remaining ones, that we believe are important to lay out where we are going and what's important. But that we are not actively considering today in a meaningful way. Meaning that -- not meaning that they're unimportant, not meaning that we don't have priorities in those areas in some cases, but recognizing we're not prepared to move on these.

And so what I'd like to do, again, in the interest of time, is stop just for a few minutes of comments or questions, but to recognize that this discussion warrants real time for it that we don't have today. So with that let me open the floor to comments or questions about why we have the plan, what it is in it, or what we're trying to do with it, and the role of the Community in dialoguing about it.

Okay, I will take silence as validation as that's the direction we'll go. I appreciate it very much, and I'm sorry that we ran over time but the last discussion was obviously quite important, and we do want to give time for this strategic plan discussion when we can all focus on it.

With that it is time to turn to public input. And so we'll open the microphones to anyone who does have a public comment. I would again caution that your comments should be brief, they should be not a commercial solicitation or endorsement, and we certainly welcome any comments that are helpful in our discussions. Please.

FEMALE SPEAKER: Good morning, I represent the Association of American Physicians and Surgeons, which is one of the biggest stakeholders that you mentioned. We are probably the

largest national organization of the physicians in private practice. And I always hear you talk about the physicians, the one, two-person office who are probably going to be your slow adopters on this, so that is the group, so I hope these comments are helpful.

I keep hearing you say that if we can communicate the advantages of adoption, and if we can make it affordable, then you'll be able to convince more my members that I represent to adopt. But our concern is that you're not addressing some of the basic contentions that we have with the technology and with the use. So you can -- even if the job you put in your goals, even if the communication is excellent and it's affordable, we still have basic concerns that aren't being addressed. What I'm hoping is that you will be responsive to those concerns as you keep moving along.

For example, the issue was raised about who is going to decide the standards, particularly for clinical decision tools. We know that there are, shall we be kind, and say territorial issues, even in the practice of medicine, as it was raised, and those territorial issues frequently become political. And things like standards can be used to someone's -- to protect someone's territory or to make a political goal. We still have concerns over privacy, security, and confidentiality. We've seen a number of things go on this week about records, electronic health records. So we are still not feeling secure that those issues have been addressed.

The big issue that we have that I hope you can address, and it's come up as you talk about trying to separate pay for performance and evidence based medicine, that pay for performance is the place where we have issue. Because evidence based medicine is a good thing, but, it's when mandatory and used for payment, used as a carrot or the stick for the purposes of payment that we get a concern.

What I'd like to throw out, for possibly discussion for you, is another concern we see is that as we move toward someone setting standards, that could end up being the government setting standards, with evidence based medicine or pay for performance, do you see us moving towards a national certification of physicians, or national licensure, or less than licensure, some sort of national certification if we have pay for performance and adoption of evidence based medicine standards.

DR. DAVID BRAILER: Okay. Thank you. Could you state your name just so we have it in our record?

FEMALE SPEAKER: Oh, I'm sorry. It's Catherine Circs, the Association of the American Physicians and Surgeons.

DR. DAVID BRAILER: Okay, great, thank you. Any other comments that anyone would like entered into the public record?

MALE SPEAKER: I'm Gary Digginson, representing [inaudible] health. As I listened to the discussion, as I look at the progress of the Workgroups, as I look at what the HITSP deliverables, my concern again is that we are focused on -- too focused on short term goals. And have not taken the opportunity to discover where we really want to be in 2014, which is the electronic health record for everyone, I believe. And one is assuming that this is a persistent, indelible

record, that can be measured for persistence or indelibility, can be authenticated as to source and authorship, is auditable, and so forth.

The kinds of discussions that are going on, the kinds of architectures that are beginning to float forward here seem to be on the order of building cul-de-sacs, not on the order of building a super highway that is secure for the purposes intended for the interchange for robust electronic health records.

So my concern is that, particularly looking at the HITSP deliverables, the types of interoperability that are being described are using point to point transient messaging, and that cannot be what we ultimately need for persistent legal health records, and the interchange in a secure way, manner for those. So I think it's important that we really get a focus on where we ultimately want to be and ensure the objectives are stated up-front. So that as this work moves forward, we can ensure the deliverables are in the context of those ultimate objectives.

DR. DAVID BRAILER: Great. Thank you, Gary. Any other comments to be made today?

Okay. With that, are there any other comments from members of the Community?

We stand adjourned. Thank you very much for your time today and for your very, very good discussion.

[Whereupon, the meeting was adjourned at 12:30 PM]