AMERICAN HEALTH INFORMATION

COMMUNITY MEETING

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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)*
- Robert Cresanti
- Nancy Davenport-Ennis
- Colin Evans *(representing Craig Barrett)*
- Lillee Smith Gelinas, R.N.
- Julie Gerberding, M.D.
  - Edward Sondik
- Douglas Henley, M.D.
- Kevin Hutchinson
- Charles N. Kahn, III
- Alissa Fox *(representing Scott Serota)*
- Mark McClellan, M.D., Ph.D.
  - Tony Trenkle
- Adele Morris *(representing Mark Warshawsky)*
- Jonathan Perlin, M.D., Ph.D.
- E. Mitch Roob, M.D.
- Linda Springer
  - Daniel Green
- William Winkenwerder, Jr., M.D.
- Mark Leavitt *(Presenter)*

TABLE OF CONTENTS

SECRETARY LEAVITT: Well, good morning to everyone. I look forward to these meetings. I -- since our last meeting I know there's been a great deal of work that's been done, both by the CCHIT group as well as all the Workgroups that have been taking place in various settings.

To set a context for our work today, I would like to mention something that's very much on my mind. A little over two weeks ago, we passed the mark -- the thousand days left in this administration. I keep a count each day. And as of today, we have 980 days that I'm going to have my hand on the wheel of this. And I want you to know that there's an urgency that that creates for me every morning.

We have identified a series of projects that drive the priorities and the vision of this department. Right at the heart of every one of those is the subject of health information technology. You've heard a great deal recently about the need for more transparency and the department's efforts in being able to drive that at the urging of the of President. Again, health IT is right in the middle of it. The efforts we're making on Medicare and Medicaid, again, health IT is right in the heart of all of that.

You can't -- we're doing a lot of work in New Orleans right now, again health IT is right in the middle of it. Virtually every project that I'm undertaking in this department in the 980 days left, health IT is at the center of it. And I want you to feel the urgency that I feel.

Now, I will tell you that lots of things happened in 980 days. They built the Pentagon in half that time. There have been lots of wars won -- started and won in far less than that. And that's a lot of time -- it's not a lot of time, but it's a time in which a lot can be done. And it's my intention to drive it -- that urgency today. I hope you'll -- my guess is by the end of the day, you will feel that as well.

Before I turn the floor to Dr. Brailer to guide us through the Workgroup sessions today, I want to acknowledge that there have been a few personnel changes that need to be recognized. The first one is, of course, Dr. Brailer. He has asked that I accept his resignation as the national coordinator. There's not a person in this room who doesn't understand the contribution he has made in his role. And I will tell you that he has done so with extraordinary personal sacrifice. Anyone who's made the flight between Washington DC and San Francisco once knows it's a long ways. And he's done it on a routine, regular basis. His family has been -- has sacrificed as well as Dr. Brailer. He has, he's just -- we would not be where we are today without him, and all of you know that.

He has been a teacher to me, and I think been an extraordinary leader. Now, he has agreed to serve on an ongoing basis as vice chairman of AHIC. And I'm going to be calling on him in a number of other capacities that will link this project and others together, so we will all continue to see his face, and we'll all continue to have the benefit of his counsel and advice. But I do want to pause as we acknowledge the fact that there's going to be some change in his role. We're in the process, of course, of being able to determine how best to fill in with the significant hole he will leave. But -- and I'll have more to say on that at a future time.

Dr. Karen bell will lead ONCHIT through what we hope will be a relatively short transition. All of you know Dr. Bell and know her capability. I have no question about the transition not losing a single step. We'll also have a change among our membership. I'd like to welcome Robert Cresanti, who is here. Robert, he's the undersecretary for technology at the Department of Commerce. He will be here in a -- on a permanent basis, as you remember Michelle O'Neill has been filling in, in her role as acting undersecretary. And I want to thank Michelle for the work that she has done.

It's also a pleasure to welcome a new director of the community: Katy Barr is here. She comes to us with a lot of experience on Capitol Hill. Most of you have had a chance to interact with her. I'm delighted by her willingness to come and to serve. She was a professional staff member for the Senate Committee on Health and Education, Labor and Pensions. She worked with Chairman Enzi on his health IT legislation. That background will be extraordinarily helpful. Before that she worked on the Senate Budget Committee with Chairman Don Nickles. She's already doing a great job, and we formally welcome her today.

I also want to thank you all again for the hard work you're doing to pursue what I see as merging tangible, urgent progress. And so today as we do our work, let's keep "urgent" in mind and "tangible" right in front of us. So Dr. Brailer, thank you very much for your good service, and let's drive on.

DR. BRAILER: Okay. Thank you, Mr. Secretary. And I would like to say that I've enjoyed working with you very much over the past 18 months, and I appreciate your leadership and the contributions you've made to bringing this topic to something that goes far beyond where we were even a year ago. And I appreciate very much the collaboration and close friendship that we've developed.

We have a lot to talk about today. We have an agenda that is quite full and represents the work of many of you, many people in Workgroups who are with us today, some who are not. And many staff from federal agencies and the Office of the National Coordinator. I would caution everyone that this is a very busy, quite substantive meeting. And this represents the urgency that we've felt for this topic to make sure that we're able to move forward, these short-term recommendations on a timetable that fits with the secretary's 980-day remaining schedule.

To that end, we will go through a process of laying out recommendations on a sequential basis for discussion, for action, potential further action. We're open to new ideas as this comes forward. And we certainly recognize that this discussion is one of many here to come, the next of which will be at the June 13th meeting of the American Health Information Community.

With that, let me say that we will start with the electronic health records. And this Workgroup's going to bring forward a number of recommendations. Some of which are what we call cross-cutting recommendations. These recommendations will be first discussed here. But we're going to remind you these are ones that would come up in every Workgroup. Such that what we're acting on on behalf of the electronic health records in some instances are recommendations that would be common across Workgroups. So with that, let me turn to john Jonathan Perlin and Lillee Gelinas for the discussion of the electronic health record report and recommendations.

DR. PERLIN: Good morning, Mr. Secretary, Dr. Brailer, members of the community and colleagues. It's a delight to be here with you today and to share with you what is really the product of a great deal of work, a great deal of discussion. I want to thank all of our colleagues. Let me assure you, Mr. Secretary, there was robust discussion, sometimes disagreement, but ultimately come forward today with a number of recommendations that we bring you in consensus, a consensus that's reached because we share your sense of urgency and a passion for putting electronic health record forward.

The President reminded us we are, in many ways, operating with horse and buggy tools in an information age. In our country, the information technology advisory committee finds that we have tremendous opportunity to improve the safety, efficiency, and effectiveness and compassion of contemporary healthcare.

We, as the first group, will also be sharing not only the direct recommendations of their committee but also some of the cross-cutting recommendations. Because the last to get the electronic health records further forward, there are a number of things that we all share as belief of in terms of identifying some tolls and utilities to make the electronic health record present and viable in the urgent time period that you set forward for us.

So we will be teeing those up as well. I want to thank my esteemed co-chair and the members of this particular Workgroup that you see listed ahead of you; all contributed substantially of their expertise, of their time, and really brought forward data to be able to support the recommendations. The next slide, you laid out for us two charges: a broad charge for the Workgroup as well as specific charge. Broad charge to make recommendations to the community on ways to achieve wide-spread adoption, certified electronic health records, minimizing gaps in adoption among providers. You challenged us more specifically to make recommendations to the community so that within one year, standardized, widely-available and secure solutions for accessing current and historical laboratory results and interpretations are deployed for clinical care by authorized parties.

Clearly we understand and offer recommendations today in the spirit that electronic health record adoption is a top priority for the community. And in order to really bring forward substantive recommendations for progress, we have to address both opportunities as well as challenges. And so we will -- we spent a good bit of time, sir, analyzing the barriers to adoption. And we hope to provide you with some recommendations that allow us really to transcend the barriers. And in fact, not only in the process get past barriers but develop tools, utilities that improve the efficiency and the understanding of the reasons for adoption of a health record. We believe that transcending those barriers, we owe the greatest [inaudible] to spurring adoption.

We were focused, as we described at previous community meetings, on lab data generally because it's boring as electronic data. And to quote Dr. Brailer, “That quality of being born electronic provides it with a more aerodynamic quality -- high lift, low drag -- in terms of really being a starting point, being very pertinent, useful information, but being information that can help to pull the remainder of electronic health records.“

We considered a number of issues, and we'll be discussing these sequentially through the recommendations. This need to support all of the necessary steps in evolution toward a patient-centric flow of laboratory results data. Urgent Need for endorsed, adopted and interoperable vocabulary, messaging and implementation standards to enable the exchange of laboratory results. We'll talk about some of the challenges and opportunities with respect to CLIA and HIPAA. And the technical considerations that they're really very cross-cutting relating to privacy and security with respect to patient identification, authorization and authentication to make the information useful and available. And the need for aligned business cases and incentives as well as assessment monitoring research of the experience of early adopters.

The President offered his charge as part of executive order 13 -- 3 -- 335 in April of 2004 and set out a ten-year goal, as we all know, to make health records available to most Americans. We are appreciative of the work that's being done by the Harvard school of Public Health and Policy as well as GW and Dr. Blumenthal, which actually gives us the statistic that perhaps about 17% of physicians have currently adopted electronic health records, and we know that 17% actually may be more encompassing, because it may not be the full spectrum of health information that I know you would desire [inaudible] that world where we never ever have to bring another clipboard or fill out that clipboard in a time of emergency.

We identified that there -- Dr. Blumenthol's group identified that there are barriers to contribute to low adoption. The lack of standards, in fact, contribute to a high cost to purchase and implement. And that results in the need to create custom interfaces that are essentially one-offs that really are required to [inaudible] most systems and data such as laboratory data to be broadly available. Because lab results are a component of 70% of clinical decisions, it seems logical that timely and easy access to comprehensive lab data is of high value to clinicians. I mentioned the high cost of acquisition at the moment. And the contribution of the lack of standards to having to do custom interfaces.

There are also other costs that are hidden. The cost of healthcare. For the lab corporations, they report that when they receive phone calls and faxes as well as the occasional electronic request for laboratory information, all these things contribute to the inefficiency and deteriorate the timeliness of care. And so the ability of electronically delivering lab results data at the point of care in an accurate, efficient, and lower cast way brings best value to the clinicians, to the care delivery processes into the country, and we propose that the standards and recommendations will help to transcend the barriers, decrease the cost of acquisition implementation and make the implementation of electronic health records more viable, more valuable and more attractive.

I'd like, at this point, to turn to my esteemed co-chair, Lillee Gelinas who's done a terrific job, who will take us through the first recommendation set.

MS. GELINAS: Thank you, John. And Secretary Leavitt, I want to emphasize two things: first of all, the amount of consensus that occurred in this Workgroup, but it was not easy. So, I want to make sure we honor and acknowledge the very robust discussion that went on behind the scenes. Also notice that Dr. Perlin and I have both signed the letter to you, indicating the consensus that also is at play here, and I wanted to point that out. I also wanted to point out the arc [spelled phonetically] report that we considered as a part of the tremendous background as Dr. Perlin has made clear, with 286 studies focusing on health IT and the barriers there. So the evidence base was quite robust in this work.

So let's move to our first recommendations. How can lab results be shared to meet provider and patient needs? This is our recommendation. And for our audience, this is recommendation 1.0. HHS should take immediate steps to facilitate the adoption and use of endorsed standards and incentives needed for interoperability of lab results within the current provider -- centric environment. ONC shall work with multiple stakeholders to develop a detailed work plan to achieve patient-centric information flow of lab data by 3/31/07. Secretary Leavitt, you will notice throughout all of our recommendations, we have tried to put hard dates on these

recommendations, and I'm sure that some of our discussion around this evolutionary path will focus on those dates.

The ultimate goal is to have patients' lab data available to all authorized providers of care enabling more coordinated and complete patient-centric healthcare delivery. We need to recognize this is an evolution, and I'd like for us to all understand that word, this is an "evolution" towards patient-centric flow of lab data, which includes adoption of standards that allow for more efficient flow of information.

Now we, as a Workgroup, understood that the ultimate goal that we're trying to achieve is not available today. And it is an incremental evolution that will need to take place. For example, many parts of the country are not in a place where the necessary infrastructure is in place to support this information-sharing model. Therefore, support all the steps in the evolutionary process towards this patient-centric model are essential and will include the broad issues of policy, stake holder interest, security, technical issues, et cetera.

So, we'll open the floor for discussion.

DR. PERLIN: Is there any discussion on this recommendation? Yes?

FEMALE SPEAKER: Thank you, and thank you for your presentation. My question is about the word "incentives." Can you tell us a little bit about your discussion around what policies might be included under "incentives"? And whether or not your view is that that word might also include regulatory requirements.

MS. GELINAS: I think we did talk about regulation and policy change as a result and you're going to see that coming up in subsequent recommendations. We predicted this question, didn't we? That -- and as we move forward with the recommendations, you'll see that we have addressed some of them. We didn't get into the nano details of the incentives to be honest with you. We just know that as a part of this process, we've got to put incentives in place that are going to speed adoption.

MALE SPEAKER: Any other conversation? Yes. Well, thank you both for a great presentation. Good work by the Workgroup, by the way. I'm very excited, Mr. Secretary, about all these recommendations today. On this one, a question for the two of you. I like very much your definition in the report of a patient-centric model and moving that way and how you've defined that.

As I mentioned in our last meeting, and I know you're probably still having discussions of this: as we allow for, in this case, laboratory information to flow from point A to point B to point C at the patient's determination, that patient-centric model that we're striving for, there is the issue of how do we know when the ordering physician has had a chance to review that information in the context of patient's clinical condition before it gets to other places in the system or if it gets to other places in the system before that review has occurred, how is it labeled as such so that the other providers know that it has not yet been reviewed in the context of the clinical situation? How are we going to deal with that?

DR. PERLIN: Well, first let me thank you for a terrific question. You tap a number of issues simultaneously, a number of which are cross-cutting and really the basis for subsequent recommendations. One has to do with the identification authorization, authentication. And just in short, the identification that we have a secure match with a specific patient, the authorization that the right people have the right use of the data, and the authentication that the parties who seek to use the information are who they represent themselves to be.

And if I might suggest we talk about momentarily because that, as you know, is a recommendation that's cross-cutting. We have the privilege of bringing it up first, as the first group. So we'll come back to that aspect. You're teeing up a question, and let me just use the term "patient-centric," suggesting that if I today had a heart attack at hospital "x" here in Washington and I, next week, came back with chest pain to hospital "y" down the road, that the information that was so useful in treating my heart attack and understanding my condition, today would not be available at hospital "y," even though I just had the information at hospital "x."

And so the idea that Lillee teed up in this recommendation was there would be an evolutionary path where we'd move to a situation where that information would be available to the patient, and thus the need for identification, authorization, and authentication. If I showed up at hospital "y" today, that situation likely hasn't occurred, that the information got there before I did. In VA, just as an example -- not to be too self-referential, we actually are now testing that, because we wouldn't want a patient to find out a new diagnosis of cancer, for instance, before the clinician, the physician typically would have the opportunity to assess. So, there happens to be a vehicle that we're building into the business roles that say, okay, patient counsel.

So, what we suggest is that there will be an evolution with experience with this. We can't get to that evolution until we actually have the standards in place and some agreement on authorization, identification, and authentication. But then there's an element where a business role is created just to assure that appropriate counseling and appropriate management have taken place. And that's something we will likely have to grow into, but that would be a very luxurious problem to face, because right now, I precede the information rather than the risk of the other way around.

MALE SPEAKER: Doug, I'd like to just comment on another aspect of your comment. This issue of primary care role has come up in other states in state laws where there are actually statutes that require certain activities on the part of the physician to make information available to others. And this is being addressed actually in the health information security and privacy collaboration that we're about to launch the state contracts for, to look at the laws and to understand how they introduce either barriers to care or enablements as well. And that report will come back here in a months.

MS. GELINAS: Dr. Brailer, if I could add what Dr. Perlin was describing as not vaporware. We actually saw the business rules in place at the VA Medical Center [inaudible] yesterday. Several members of the community were able to tour the medical center. I was enormously impressed by talking to one of the veterans who understood the business rules that his physician had to see his orders first. So it was very exciting to see both the practice as well as the vision. Wouldn't you say, Adele?

MS. MORRIS: Yeah. It's a terrific opportunity to see it in action.

MS. GELINAS: Mm-hmm.

MALE SPEAKER: Any other conversation? Yes. Kevin?

MR. HUTCHINSON: Well, as long as we're talking about word flow, I'm curious, did orders come into play in the discussion? I know we're talking about result delivery from the labs. But since we're looking at work flow of where the patient fits into the delivery of the result, it all starts with the order: is that part of the work flow that's going to be recommended in future recommendations, or is this something that we're going to do from the outset?

MS. MORRIS: Absolutely.

MR. HUTCHINSON: Okay, good!

[laughter]

MS. MORRIS: You know me well enough, Kevin!

SECRETARY LEAVITT: Any other comment on this recommendation? Our rules of consensus would call basically for me to determine if there are those who feel an objection to this recommendation. I would like to hear any who have concerns about it, if there are any. Hearing none, I'm going to declare a consensus and accept this recommendation and ask you now to move to item 2.

DR. PERLIN: Thank you, Mr. Secretary. Again, as I mentioned, as the first group we were teeing up -- we've been asked to tee up the cross-cutting recommendations, and the prior discussion really brought forward the need to move to standards. Recommendation 2.0 states that H-I-T-S-P, HISTP or the Health Information Standards Manual should identify and endorse vocabulary messaging and implementation standards for reporting the most commonly used laboratory test results by 9/30/06 so as to be included in the certification commission for health information technology interoperability criteria for March, 2007 certification. HITSB should consider CLIA and HIPAA regulatory requirements as appropriate. The idea behind this is that health information technology systems need to be able to receive electronic lab results, yet currently, the lack of uniformly adopted and easily implemented standards [unintelligible] barriers to this critical flow of information.

As noted to the outset, the cost of laboratory interface development is a significant barrier to electronic health record adoption. In fact, some estimates of custom lab interfaces are estimated to be $30,000 to $50,000 for the [inaudible] and $20,000 for the interface at the group practice office. So there's really an urgent need for endorsed, adopted, and interoperable vocabulary messaging and implementation standards for lab results data exchange.

It's very fortunate that we have two groups -- HITSP and the Certification Commission for Health Information Technology -- to respectively resolve the standards, HITSP, and then the certification commission, including the HITSP-endorsed standards and certification criteria.

For those of us with some background in health information technology, the old saw was: Aren't standards wonderful? There's so many to choose from. And the truth of the matter is we need to resolve that because that economic barrier to adoption, both in the laboratory and the doctor's office and all of the other points of care that might want to play, is really being inhibited by the need to do a very expensive one-off.

And so we believe that the efforts of HITSP and CCHIT, the current barrier, is -- costly unique interfaces will be removed.

The first round, I should note, of the CCHIT criteria for ambulatory electronic health records was released on May 1st. It's also worth noting that the first certified products will be available in July. In March of 2007, CCHIT will release their criteria for the 2007 EHR certification.

And just to preempt or anticipate a little discussion on this, the next recommendation section will highlight specifically the CLIA and HIPAA issues that may raise issues in terms of resolving barriers to patients [unintelligible] laboratory data exchange.

SECRETARY LEAVITT: Thank you. Important recommendation. Any conversation or questions? Mitch?

DR. ROOB: Just practically, how close are you to getting -- and I'm not sure if I should address this to Kevin or to one of the board members -- one of the committee members. How close are you to the vocabulary -- to resolving the vocabulary issues? Do you think that's a major stumbling issue in laboratory results or is that -- you passed that threshold?

MALE SPEAKER: No, I want to ask [unintelligible] HITSP or CCHIT colleagues to offer -- add some insight on that specifically.

MALE SPEAKER: Why don't we do that? I could perhaps add just a high level response to your question.

There is pretty good agreement, and I say pretty good in that it's never been formalized, and that's part of what HITSP brings is a formalization to naming standards. There is good de facto agreement on what the vocabulary standard is for laboratory data.

It's not been ensconced to say, “This is it and that this is our standard.” The barrier is not actually, though, in the agreement. It is in the actual use and implementation of these, given how long it takes to put these into legacy systems, the switch-over cost -- laboratory systems have a very, very long useful life.

And so there's not a need to go out and turn them over as other software that’s used in hospital or other environments. So, if you would, the standard adoption, in fact, is really the barrier rather than the standard adoption de jure.

And so, this is a double challenge we have. And this recommendation speaks to making sure that our standards naming bodies formally say, “The discussion is over and this is the standard.” And the next two recommendations this group will come to will talk about how do we get -- getting past putting those into real use.

SECRETARY LEAVITT: Kevin?

MR. HUTCHINSON: I would just add to that. I agree with everything Dr. Brailer just stated. It's not the standard itself that has been the biggest issue.

I’d like to actually commend the lab industry for a lot of effort in work that’s been going on over the last several years to come up with standards around vocabulary as well as the exchange of information, and there has been a lot of work done in the background. It is time to formalize. It is to take it through the HITSP organization.

But the big challenge, as Dr. Brailer pointed out, has been the implementation of those standards. It's not the fact that the work has not been done or work has not been done in this area, but it is actually getting it implemented into those systems and the education of the vocabulary for the orders coming from physicians as well.

SECRETARY LEAVITT: What I'm hearing is that the -- it's important that we have deadlines, important that we drive this forward with respect to a commitment. Are there any other questions or comments on this matter? Yes, Nancy?

MS. DAVENPORT-ENNIS: I think just a comment that as you move forward with the identification of the implementation standards, that the standards be sensitive to the patient-centric model because ultimately, we want to be certain that that implementation allows for easy transference to the patient also.

MALE SPEAKER: I think that's a terrific point. Just this sort of example of a heart attack at two hospitals they offer this really the -- the reason -- to meet Secretary Leavitt's [spelled phonetically] charge, admonition, that I don't, at the second presentation, have to bring back that clipboard again.

SECRETARY LEAVITT: Any other comment? Any objection? Hearing none, I declare a consensus on this point. We will adopt recommendation 2.0 and move to the next, 2.1.

DR. PERLIN: Thank you, Mr. Secretary. The next is really -- a good segue was provided by Kevin Hutchinson -- some statement that the challenge is the implementation. And as I'm one of the federal agency -- representing one of the federal agencies, we -- feds are holding ourselves accountable for actually implementing, for actually adopting, and this recommendation states that federal health care delivery systems, those which provide direct patient care, should develop a plan to adopt the HITSP-endorsed standards for laboratory data interoperability by 12/31/06.

And this is [unintelligible] date certain. We note that there are a couple of terms that may cause some question in terms of a little bit of ambiguity. What does it mean to have a plan and what exactly does "adopt" mean? And without being too presumptuous elsewhere, let me share with you what I take this to mean for the agency I represent.

It means that as we as develop new software internally, our goal for it will be to use these standards to implement them; as we, in the future, set a contract with business partners, that we come to an understanding that we will use these standards for electronic data interchange; and that we believe through the use of these standards, we can deliver a safer, higher quality, more effective product.

So we hold ourselves accountable by dates certain to making commitment to internal systems to encourage forward, not to do anything to extend business relationships, but forward business relationships to put these standards as one of the requirements.

SECRETARY LEAVITT: Any comments about this? I'm interested to hear from Tony and I'm also interested to hear from Bill. Bill, why don't we start and move up down the line?

DR. WINKENWERDER, JR.: Well, from our perspective, a reasonable time frame is an important thing to consider here. We certainly endorse moving in this direction and getting there as quickly as possible, but we would say that it's important that the standards be built for information exchange, not to rebuild our whole systems.

And so, we're a little concerned about just the time and the cost if we're into rebuilding. I think if we're able to start from those things that we're currently using as part of the federal health architecture effort that we and the VA have really spearheaded together, then I think it's going to make it easier.

So, I think there's some technical issues there that technical people ought to best work out and… But we endorse it, we just -- it's with a little bit of caution.

SECRETARY LEAVITT: I think we'll get more specific on the next recommendation.

DR. WINKENWERDER, JR.: Yes. Yes, exactly.

SECRETARY LEAVITT: Why don't we -- what I hear you saying is, "We're all for it as a practical matter -- we're all for it as a policy matter, we've got -- as a practical matter, we need to talk about what it means."

DR. WINKENWERDER, JR.: I think that's right. That's good.

SECRETARY LEAVITT: We'll talk about what it means in just a minute. Tony?

MR. TRENKLE: Yeah, I would -- I agree with what Bill said and exactly what you said. It's -- we endorse it as a policy matter. We need to look at it from a practical matter in terms of how we can implement it. One of our concerns, also, is the need for the standards to be developed and implemented in a way that facilitates compliance with CLIA, because that's a major concern of ours.

MALE SPEAKER: Yeah. Just note, I think the discussion has been, you know, very good, and certainly things that I worried about in our agency -- and to be clear, we're not talking about reworking all of the legacy architecture. That would be cost prohibitive and in fact may not move us forward. But as we go forward and build new systems that we build off of what we're doing and move toward this as a standard.

The CLIA, if I might, I think we'll have opportunity for robust discussion on that because there is an interplay. But obviously, your point is extremely well taken. This would want to support compliance, but simultaneously, we want CLIA to help and HIPPA to really come together to help join and propel the adoption.

MALE SPEAKER: Yes, I agree with that. You know, our concern is just the consistency which is not -- which has been an issue to date.

FEMALE SPEAKER: Mr. Secretary, if I could add also, the voices of the Workgroup themselves, I want to really represent when we were to this date-specific conversation -- and it was a conversation, very robust dialogue -- there was some who were saying, "This isn't aggressive enough." There were others who were saying, "Oh, you have to give us more time."

So I want to make sure I represent the voices of the Workgroup that we were dealing with both ends of the spectrum here. And the date that you have in front of you was consensus around that discussion.

SECRETARY LEAVITT: I'd like to make clear that adopting it is important. I think ultimately have a date certain to which we're migrating is going to be absolutely essential.

I started this conversation today by counting the number of days that we will be certain of capacity to implement. And I have a strongly-held view that we have got to have demonstrated progress and commitment long before those days have run or we will not have succeeded here.

We'll have more conversation about that. But I'd like to know if there are any other comments on this point, particularly from among those who are direct providers and federal players? Any objection? Hearing none, I'm going to declare a consensus and approve -- announce -- or pronounce 2.1 accepted, and we'll now go to 2.2.

MALE SPEAKER: Thank you, Mr. Secretary. And this extents just the directory of discussion -- the federal agencies and departments with health lines of business should include or incentivize the use of HITSP-approved standards in their contracting vehicles where applicable. And to help find some business is a term that broadly represents any federal entity that is a stakeholder in health care. The focus, as one might imagine, really, both direct delivery and those entities which also purchase services.

SECRETARY LEAVITT: Any other conversation about this one? Bill, you want to talk about this?

DR. WINKENWERDER, JR.: Yes. I think here it is even more important from our perspective to proceed with some caution. We, of course, have our direct care system that we operate. In that respect, we're very much like the veteran's administration. It's not a problem because with that, that's something that we own and operate and have built and can move forward.

But with purchase care community, our contracted care community, we have got over 200,000 physicians with whom we work. So in some respects, we're a little bit like Medicare. And so imposing those standards through our contracted health plans could be a cost prohibitive thing.

So what we'd like to do is to start with our direct care system and work the issue with -- and think about -- because -- and actually, it's a good time to do it for us. It just so happens that we're looking at our next generation of contracts and the whole model for that.

SECRETARY LEAVITT: What year would that be? What contract years?

DR. WINKENWERDER, JR.: That will start in, like, 2009, I believe, 2008 or 2009. But the terms for that would be set within the next sort of 12-18 months. There's a long transition period, you know, to end a contract and to start a new contract. But this is -- so it's pretty significant in terms of the reach of it. And we're interested in doing this. We just want to understand what sort of requirements we might be imposing and what the costs of that might be, and that all translates into potentially significant dollars.

SECRETARY LEAVITT: Tony?

MR. TRENKLE: Yeah, I would agree with Bill. I think we do need to look at the contracts and what the timing would be with them. But I think this makes a lot of sense to use the contracts incentivized and included in the language as we do that.

MALE SPEAKER: In some respects, and in some ways not on this particular, we already do that. We have strong incentives in our contracts right now for electronic claim submission, for example, and for items to be done digitally. So this would just be sort of expanding, but then we'd be getting into a bit more descriptive detail.

But again, we endorse it and our proposal would be that we work with the VA to -- and others that are in the direct care business to sort of build a platform that, you know, that then could be used to extent of the contracted purchase care partners for the federal government.
SECRETARY LEAVITT: Dan?

MR. GREEN: I think this is going to come up Monday at the Federal IT Policy Council, I'm pretty sure of that. And so we'll have quite a bit of discussion next week on how we can implement this. We at OPM have already put our health insurance carriers on notice that we will expect them to adopt these standards as they are rolled out and as they are finalized on a very prompt basis.

So, we don't anticipate a problem in keeping up at any rate. And, of course, it'll take some time for some of our carriers where they're not as tied into the federal employee health benefits program as some of our specific carriers are. But we anticipate moving promptly on this.

SECRETARY LEAVITT: Nancy, comment?

MS. DAVENPORT-ENNIS: Yes. I noticed that in this particular recommendation, there was not a firm timeline. And I suspect -- though I will remain silent so that you can answer my observation -- I suspect perhaps part of it has to do with the very discussion that we're having today from the consumer perspective.

While I indeed concur with the recommendation, I must also note for the record that we would not want to see access to health care diminished for any American as we're moving through the process of requiring vendors who are contracted to provide these services to move into this level of compliance. That there does, indeed, need to be a process made available to them, both that would allow a timeline that's appropriate for their integration as well as perhaps some identification of: Is there a financial process available to underwrite some of the costs or to offer low interest loans to providers who are trying to comply with the recommendation?

So was there any of that discussion that perhaps would benefit us in this?

MALE SPEAKER: Absolutely. And some -- you know, important fact here, your points really encapsulate a lot of the discussion because simultaneously on one hand, we feel the urgency of the charge. Not only because of Secretary and President's task to us, but because of the challenges that all of us experience in today's health care from the consumer perspective. Some of those gaps are problematic.

But the implementation here in the discussion was envisioned, written like the last that, in fact, one wouldn't disrupt current activities. Those would sunset, but as new contracting vehicles came into place, that these standards would be expected as well.

This discussion itself and the adoption promulgation -- promulgation adoption of standards really should cue up for all those different parties that would be seeking to do business that, you know, the new world order is not only more efficient because of these standards but it's expected that we'll be using those in our commerce in support of health care.

SECRETARY LEAVITT: Let's go to Doug in the back, then Dan.

DR. HENLEY: Well, maybe -- well, first of all, let me say I'm very much in favor of these recommendations. But I guess with the last -- the discussion of the last two points that I've heard, I'm confused and maybe a bit concerned, and maybe you all can alleviate my concern.

As I understand it, we're adopting standards or we want HITSP to adopt standards that relate to -- that will relate to the certification process for the private vendor community. In essence, by doing that, we are requiring -- we aren't incentivizing, we're requiring the private vendor community to step up to the plate and modify their equipment to do "X," "Y," and "Z," based on these standards.

I'm hearing that perhaps in the public vendor world that we're giving -- we want -- we're giving them more leeway and giving them more laxity. And why are we using works like "incentivize?" Why don't we just say require these folks during the normal contracting people to implement these standards? The heck with incentivizing. Require it! I mean, that's what we're requiring the private people to do, private vendors to do.

SECRETARY LEAVITT: I'll hold my comment until last, but I want to make it now. If I am somewhere out in the world and I'm a vendor of health IT and I'm watching this web cast, I'm thinking to myself, "This is a pivotal moment because if the federal government agencies aren't willing to put up and commit themselves to a date, this deal isn't real."

DR. HENLEY: Yeah, exactly.

SECRETARY LEAVITT: And so, I'm going to speak with some urgency on this. Now, I have recognize that we've got issues within the federal family to work out. It probably won't happen at this table, but we need to come out of this with a recommendation that makes clear we're prepared to pick a date and prepare to back -- to create the back pressure that we have the capacity as payers to create. Or we've just got to go home. And I know that's not what's being said here, but I do think we're at the crux of the power of our capacity to act. And -- Dan?

MR. GREEN: One thing I'd like to point out that there's a complexity to this that exists that hasn't been brought up as yet. Within the FEHB program, we contract with health plans -- health insurance companies who subcontract with providers.

However, in the case of specifically laboratories, that is not typical. While some carriers do subcontract with laboratories for -- as a preferred provider, usually there are not contracts directly between the carrier and the laboratory.

So, this particular issue, this particular goal for laboratory standards, is going to be more difficult to implement than perhaps some of the others because of that sequential process involved. It's not that it's not doable, but that it will take some time because it's multiple contracts down the road.

SECRETARY LEAVITT: Let's see now. Ed, did you have a comment?

MALE SPEAKER: From a CDC point of view, this is actually very much related to some of the aspects of bio-surveillance. I mean, laboratory results and the interoperability and transmission of those are really crucial.

And I think all three of these, actually, are very consistent with where we're headed. In terms of the dates, you know, I think we need to take a hard look at CDC and where we are with our many, many laboratory systems, and see what it will really take to truly link these together.

One of the aspects we've had, actually, is building a system that actually can help translate from one laboratory system to another laboratory system. That seems to be working well. And that may be an option here that would help to sort of bridge between one standard and another.

But in any case, I think it's important not to see this solely as outside of the public health system but to see this as also crucial to what's happening in the public health system, and in particular, to bio-surveillance.

It seems like the laboratory results are really one of the absolute necessary elements in everything that we're doing, and it's certainly true in the public health system as well. So this has implications there as well as the context in which it's written here, which -- in terms of the health care delivery system.

SECRETARY LEAVITT: Good. Mitch?

DR. ROOB: Thank you, Mr. Secretary. I agree, this is the point -- this is the crux of the conversation. I was wondering whether or not you were including Medicaid in this, in your recommendation. Clearly, the federal government is the major payer of Medicaid in the country, though it's a partnership with states. And the current MMIS and MITA architecture that's being developed by CMS can -- needs to incorporate this kind of recommendation, the 9010 money that the federal government provides states.

It's unclear, frankly, from a state perspective whether or not that extends to the electronic medical record or not. So to operationalize this internally, I think that there are a number of relatively important financial issues that need to be addressed and articulated to the states.

MALE SPEAKER: With the -- to represent the discussion, we're really talking about the direct federal programs that purchase or deliver care. There would certainly be opportunity for further discussion. Just to tie something back is that there was a symmetry between this recommendation and the previous recommendation in terms, Mr. Secretary, in consideration of 12/31/06, as dates certain.

So I do want to represent some discussion the committee that there was consideration of a symmetry holding ourselves equally accountable for this progress.

MALE SPEAKER: And just -- I mean, that's important that we move forward with this, but I think you are leaving an enormous number of dollars that -- and enormous leverage opportunities on the table here, particularly because of the uneven distribution of federally-funded employees in America.

It is not evenly distributed in the same way that Medicaid is evenly distributed. So if you want to have an effect across the country, using a Medicaid -- engaging Medicaid is an effective way of doing that.

SECRETARY LEAVITT: Why wouldn't we include Medicaid? I mean, I -- that's -- Tony?

MR. TRENKLE: I need to check with our Medicaid folks, but I agree. We've been working with them to try to see where possible that they adopt some of the, you know, the same standards that we're doing at the federal level. So, I'll check with them and see what some of their feelings are. But they're very supportive of doing -- supporting the federal --

SECRETARY LEAVITT: Bill and then David.

DR. WINKENWERDER, JR.: Let me go back to recommendation 2.1, because we agreed with that. Just we're interjecting a note of caution there. But the way the recommendation reads is a plan to adopt. So, it's not adoption by the end of this year. So, it's a plan, an aggressive plan, and we would absolutely support that.

For my part -- our part -- I think it's reasonable that we would have a plan to do that with a purchase care. So, I don't -- it's not an issue of committing to a date or anything like that. But how quickly can that be implemented? I don't think we quite know yet from the standpoint of we haven't had discussions with our contract partners. We don't know yet what this might cost, and so all that ought to factor into how quickly we can get there, but we absolutely want to move -- we want to move as quickly as we can possibly move.

And I think, again, if this is not -- my people tell me -- difficult to do for us internally. But impose this, you know, on a large number of others. We just need to... But committing to a date to have a plan in place doesn't seem to me to be a hurdle that we can't jump over.

SECRETARY LEAVITT: Good. Good. Let's go to Dr. Brailer and then to Colin.

DR. BRAILER: I was actually going to propose a sentence that tried to ensconce your urgency and some of Bill's comments, so I don't -- if you want to turn to --

SECRETARY LEAVITT: Okay, let's go to Colin first, and then we'll --

MR. EVANS: I just wanted to, you know, represent Craig Barrett here and the technology vendor, the thing, on to follow up on your point, Mr. Secretary, about the -- what would the technology vendors be thinking at this point?

I think this corollary view to the federal commitment to understand the money to make change -- I think there's a vendor side of it which without some, you know, clarity on purpose here, I think you're asking a lot of people to make changes to software and other products and so forth without a clear target. It would be a very difficult thing to do. So I'd be interested in a discussion that took place in the committee of -- 'cause there was some, you know, technology vendors on the

committee. I'd love to know what they thought about these recommendations and whether they thought they were clear enough for them to invest their money as well.

FEMALE SPEAKER: I'll comment because having the technology vendors on the Workgroup was essential to our success, and I want to reiterate what we said at the very outset to the secretary, and that is: You have a Workgroup that had consensus. It was not without painful discussion, but there was consensus around this.

MALE SPEAKER: I can't imagine that there is a technology vendor who isn't mindful of the conversations we're having here. And I can't imagine that anyone's going to be particularly surprised, given the nature of the expressions we have made and the outreach we have done, that we intend to establish a date and that we expect that as a condition of doing business with federal agencies and the private sector, that they will, in fact, have to meet those standards.

And I think it is -- I think it's also reasonable to assume that everyone who has a proprietary interest in the current edition of their software will view the long -- that timetable is provided the better and that the rest of us will feel the shorter. And we'll have to find a place where that can be accomplished.

I also want to be sensitive to the fact that within federal agencies, the people who sit at this table -- myself included -- aren't entirely in control of that circumstance and we have to do is get a buy-in across the federal government. But given the fact that the President of the United States has indicated he wants this to happen, I can't imagine that it's not going to be a priority and I'm prepared to advocate it as forcefully as necessary to make certain that this situation is teed up.

I would like to come out of this discussion with a recommendation that's clear on the need for a date. I don't think we will be able to choose the exact date today, but I would -- at our next meeting -- like to establish to the extent possible that we come back with "the plan" that would include specific dates to be in the most available contract cycle we can meet that will, in fact, push the system. I mean, We have to represent urgency here.

Dr. Brailer, I don't know if that changes your suggestion. But let's hear it.

DR. BRAILER: I think that was it. We, I think, need two elements added to this: a date, but I think a concept that it is in the next contracting cycle that's feasible. And so without wordsmithing, I would hope that we put that forward as a potential modification of this recommendation and then we can start working that through the federal IT interagency policy counsel and other mechanisms to begin developing this plan.

MALE SPEAKER: The way it was written I took it immediately in effect. I'm not so sure a date is needed for this one but perhaps a need to somehow emphasize the fact that whenever the cycle begins, one should, in fact, be including this in the contracts. So I would be on the side I'm not so sure a date is actually necessary here.

I think the issue is where do the standards -- whatever standards are in place at a particular point in time, those are the ones that should be included with the appropriate technology to be able to incorporate any changes in standards that will eventually become national standards.

SECRETARY LEAVITT: if we haven't made clear, there will be standards and we're adopting them, we can choose between whether it takes a long time for those standards to be enacted or whether or not we make it a relatively short transition. And I believe the availability of a date by which we're going to get this done, in fact, will drive the length of that. Chip?

MR. KAHN: You know, it just occurs to me along the lines that Ed was talking. You know, part of the problem here is the word "should." It seems to me it should be the word "shall". In legislative language "shall" is pretty strong language and "should" is sort of like "ought to."

And it seems to me that if you put a date and you put a "shall" then that would give you the kind of power you want.

SECRETARY LEAVITT: I can certainly buy that. What I'd like to suggest is that we consider -- I like the idea of changing it to "shall." I like the idea of identifying the earliest possible contract cycle. There's going to have to be discussion outside of this meeting as to what that is. I'm prepared to commit to be involved in that directly. I think it's a very important discussion. And I think it likely will need to be a discussion that's teed up on a multi-departmental basis. Perhaps even at a principal's level. But it needs to be done.

Kevin and I guess -- Mitch and then Kevin.

DR. ROOB: At the Hall of States, as you know, I'll be asked questions about it, Mr. Secretary. Are you going to include Medicaid in --

SECRETARY LEAVITT: Yes.

DR. ROOB: Okay.

SECRETARY LEAVITT: Yes. Kevin?

MR. HUTCHINSON: My only comment, one, I want to commend the Workgroup for including this to put the teeth around what the Secretary has said multiple times, which is to use the leverage of the number one purchaser of health care to do this. I think of any recommendations that we're looking today, this is one we have to strongly accept.

FEMALE SPEAKER: Thank you. Would you strongly accept this recommendation -- but I don't want to leave it unsaid there will be at least some cost associated with this decision. And I'd like to ask the agencies who are most likely to be involved in these contracting efforts if we have any information about what the likely increase in the contracting costs might be relatively to not having this requirement. What do we know about what those costs might be?

MALE SPEAKER: I don't think that we do know. And I think we should have some idea. Mr. Secretary, I support a date to have a plan. And so I think we ought to hold ourselves to that. And I think we ought to pick a date to have a plan. But that plan ought to be informed by more work that can take place between now and next we meet.

SECRETARY LEAVITT: What's a reasonable time? June? Can we do it by the June meeting? In your mind, can we get an assessment of that by the June meeting?

MALE SPEAKER: That might be difficult to -- the plan on Recommendation 2.1 is by December 31. So, '06.

MALE SPEAKER: I think what the secretary is asking [unintelligible] -- was if by the June meeting we can have a date for the plan.

DR. PERLIN: Oh yes, absolutely, absolutely! Yeah. I think that's easy.

MALE SPEAKER: I just want to get clarity to what we're talking about. Because I thought we accepted 2.1 which is separate from 2.2. 2.2 is not talking about a plan. 2.2 is talking about a requirement for contracting the federal agencies to require HITSP standards. That's not a plan, that's a requirement.

SECRETARY LEAVITT: And we're stating here -- go ahead.

MALE SPEAKER: We have to have a plan associated with that to implement it.

MALE SPEAKER: I understand --

MALE SPEAKER: It's going to happen over one, two, three years.

MALE SPEAKER: And I think that goes back up to 2.1, which talks about the need for a plan and puts a date on a need for a plan.

But this particular recommendation is once you have the plan, which we have moved on past that. Are you or are you not going to require from a contracting perspective?

MALE SPEAKER: Yes.

MALE SPEAKER: These are different recommendations. 2.1 is about internal federal systems and their conversion and switch-over to using the standards. 2.2 is about using mechanisms with physicians in tri-care or people that supply services to the VA through the carriers for OPM, et cetera, around Medicaid.

So I think they have different aspects, although the federal agencies have to lead first to be able to receive the data coming in in those standards in their own systems before they can actually require the data to be imposed on the outside. So they more together.

MALE SPEAKER: I agree with that. But there's no wording in 2.2 that talks about the plan. That's my only point. We keep referring to the word "as long as we agree there's going to be a plan". And there's nothing in the recommendation --

SECRETARY LEAVITT: What we have to talk about is timelines.

MALE SPEAKER: Right.

SECRETARY LEAVITT: Maybe it ought to be we "shall" adopt and by the next meeting we will develop a timeline for adoption.

DR. WINKENWERDER, JR.: I just want to be realistic about what we -- not just speaking for DOD but for others what it would take to know what that timeline should be. I think we ought to commit to having a plan for imposing these requirements. And that's what they are, which is a good thing.

But have a date certain that we would have a plan and a scheme. I don't know that we can have a multiyear plan laid out within the next 30 days. I think that's a little unrealistic.

SECRETARY LEAVITT: I'm not looking for a plan. I'm looking for a timeline. It seems to me a timeline has to be established first and then you create your plan within the timeline.

If I've got between now and 2015, I have a different plan than if my deadline is 2008.

MALE SPEAKER: I think one of the things we're informed is renewal of contracts. And I think everybody has said with renewal of contracts, the requirements apply.

So, but we'd have to go out, as I suspect others would sort of inventory to find out when that would be, what the costs would be, and so forth.

SECRETARY LEAVITT: Tony.

MR. TRENKLE: Yeah, Mr. Secretary, we'll work with the appropriate people at CMS and come up with a timeline and I guess we'll talk with you, Bill, to see how that fits in with your timeline as well. But I think we need to move ahead.

SECRETARY LEAVITT: Dan?

MR. GREEN: Again, we would be -- I want to work with the other federal agencies in developing a plan and a timeline. Again, I want to point out that this is -- there are -- iterations to the process. It is not simply a changing contracts with our direct vendor, with our direct contractors.

The second thing I think we need to point out, is that there are issues that have to be addressed before we get there. And there's fine tuning about what an independent agency has authority to do as opposed to what this board -- this community has the authority to do.

So, I'd be careful with words regarding "should" and "shall" and that kind of thing. OPM is committed to the process and will drive it as fast and promptly as possible and effectively. But we need to be careful of what and how those directions are given.

SECRETARY LEAVITT: You properly point out the point that AHIC does not have the power to compel. AHIC recommends to the Secretary who then has to deal with the other agencies.

And the recommendation is, as I've heard it, that the federal agencies that contract with outside providers need to make as a condition of doing business, the adoption of this standard on a timeline that will, in fact, drive adoption.

MALE SPEAKER: We support that 100%.

SECRETARY LEAVITT: And your point on "shall" is a good one. There's more urgency to "shall" but we do have limited capacity here. [unintelligible]

In order to make this work, I as secretary, have to take this recommendation and work with each one of you who are members of this panel within the federal construct to come up with a timeline that can then be -- that will create the amount of proper back pressure to compel action, and to drive adoption.

And now it's been my observation from talking to lots of private sector payers -- I'm talking now about employers -- that they're going to watch this very carefully. And are inclined to adopt the same kind of requirement on their providers that we do.

But given the fact that we're 46% of the market including Medicaid, it seems to me this is a very important point and one that we need to develop.

And I would like to suggest we consider the point about "shall" and "should". Chip -- both good points. I think we should leave it as "should" given it is a recommendation. But I would like to commit ourselves as a group to come back to the next meeting with a timeline that could begin then to inform the plan that we need to develop.

And we need to make certain we're working within the federal family to measure our willingness to adopt that timeline. Because we're going to be -- I think in seeing lots of private sector purchasers adopt the same timeline. Do I hear any objection?

David, do you think you can draft something to that extent?

DR. BRAILER: Yes. And we in particular will work with the interagency policy council to coordinate some of the discussions as well.

SECRETARY LEAVITT: So the recommendation basically is going to be that the federal agencies and departments with health lines of business should include/incentivize -- let's just

leave it as it is -- the use of HITSP approved standards in their contracting vehicles where applicable.

And that a timeline will be developed by the June meeting to determine the --

DR. BRAILER: I would suggest that the EHR Workgroup developed by the June 13th community meeting, a time table for the implementation for this recommendation.

MALE SPEAKER: Okay. I would like to advise that. But I think this is a principle's issue [unintelligible]

SECRETARY LEAVITT: It is. We need to get a sense of where this is within the

MALE SPEAKER: Right.

SECRETARY LEAVITT: I mean, I think this is going to have to percolate up through the federal -- through the decision-making policy process on a multi-departmental basis. And I'm prepared to drive that. But I do need to have -- we've got to come up with a recommendation before we do that that will include HHS, DOD, VA, and also OPM. Are there others?

So I think one of the things we have to do is work on the development of a proposal that I can then drive through the multi-- through the policy process.

Any objection to that as stated?

Then I declare a consensus on the point that has been expressed and let's move on to 2.3 -- 3.0.

MS. GELINAS: 3.0. Now that we had that robust discussion about standards, let's move to CLIA and HIPAA and address regulatory barriers.

Mr. Secretary I will tell you again in the Workgroup this is a big one when we talk about regulatory barriers. If anyone was asleep up to this point let me assure you you won't be after 3.0.

By 9:30.06, ONC should review the possible models for the exchange of both current and historical lab information and determine which would require CLIA, HIPAA guidance, regulatory change, and our statute change.

We've talked about reviewing all of our models in that evolutionary path toward and including patient-centric data exchange from barriers to lab exchanged that are imposed by the current HIPAA and CLIA environment.

In order for electronic historical lab test results to be available in a patient centric fashion, to all authorized providers of care, all possible models for this data exchange need to be explored with respect to the current limitations that are imposed by HIPAA and CLIA. And although the HIPAA privacy rule generally permits the disclosure of protected health information to

authorized entities, it does not preempt more stringent federal or state laws governing the release of such information.

Important to note that regulations promulgated under the CLIA require that clinical labs disclose test results only to authorized persons. We've talked about that in committee before.

Individuals authorized under state law to order tests or receive test results or both and if applicable, the individual responsible for using the test results in the laboratory that initially requested the test such as reference labs.

Many states require that clinical laboratories disclose test results only to the ordering physician or his or her designee and are silent on disclosure of test results to others caring for the patient.

So, opening up for discussion now. But this is addressing regulatory barriers and whether or not we can remove them.

SECRETARY LEAVITT: Conversation? Bill?

DR. WINKENWERKER: We agree with this recommendation and we think it could help reduce barriers to receive lab results from civilian practices by making it possible to receive the lab results from commercial labs.

In our case, like the VA having a large electronic health system, when people go out into the community there's information that's collected. People are cared for. But then our big challenge is getting that information back into the system. So this would help take down a barrier. So, we endorse this and think it's a good recommendation.

SECRETARY LEAVITT: Any other thoughts. Dr. Brailer, would you like to comment on this?

DR. BRAILER: I would, Mr. Secretary. I know this has been arduously debated in the Workgroup, if I could use that term. And I know this is something that's both technically complicated in terms of the particular way the statutes and regs are written and how they interact, because they never intended to express commentary on this particular topic.

In addition to being technically complicated, this is an area that's transformational. It has a significant impact, both in terms of how federal or private delivery systems interact with data holders in terms of the peer portability of the information.

The comment I would make on this is that in my view this recommendation is a least common denominator meaning this is intentionally and directionally direct, but to the plan review the models and report on them is a minimum first step and it's one of many steps towards an ultimate goal of being able to express regulation changes or guidance or another mechanisms that could promulgate from this department to allow this to speed up much more.

And I know that the Workgroup worked very hard to construct this, but I think many if us believe that there is more that can be done here potentially and I hope we might discuss that.

SECRETARY LEAVITT: What else can be done?

DR. BRAILER: Well, I think the one theory that was put forward I think that was discussed by the Workgroup and I would turn to Lillee and Jonathan for comments on this, is that rather than doing this sequentially, this can be done in one larger step, that we could -- HHS itself could look at potential guidance or changes within the confines of statute to be able to offer those on one step towards what we can do to promote regulatory barriers or remove regulatory barriers to patient-centric information.

We don't know what we don't know about this topic. But the experts who do know are in the department or elsewhere, and we can do it in one step rather than two or three.

SECRETARY LEAVITT: Kevin?

MR. HUTCHINSON: I agree with that 100%. Would that include then the issues on the various different regulations at a state level with respect to privacy and exchange of information?

Are we looking at an entire review of both state regulations and federal regulations, or would this just be focused at the federal level?

DR. BRAILER: Edging further out on the branch, Kevin, it's my view that urgency is best served by making use of the statute that we have. If the statute gives us latitude to issue guidance or to make clarifications where it had an unintended consequence of preventing patient-centric data, i.e. it was never thought about when it was issued, those can be done quickly if we get behind a change of trying to drive statutory changes it's uncertain and very long term.

So maybe there's two aspects of this: to make use of available guidance and others mechanisms to offer things that remove these barriers within and on an urgent basis and to report back to the Secretary, perhaps, within the principles process in the government on what other changes could be sought in other ways so that the Secretary could weigh these and make a determination if that's what he wants to do.

So that could be two prong. One is kind of evaluative and one is more directed action.

SECRETARY LEAVITT: Any other thoughts here? Jonathan?

DR. PERLIN: At the risk of delegating to you, the Secretary, as David has expressed potential charge, that really was one of the things that was discussed and would expedite the review and the empowerment of CLIA and help HIPAA to help serve the patient centric interchange of lab information

SECRETARY LEAVITT: It won't last very long with me. It will get somewhere else quickly. But I actually think this is a very good idea.

Rather than go -- we ought to just deploy HHS's resources, at some point in time we ought to come back and have a conversation about the outcome. But in the spirit of urgency, Chip?

MR. KAHN: I just recommend that this sort of work be done in the context of what you can do rather than having to worry about what they would have to do to change it. Because I think that's an abyss. So to avoid the abyss you have to work within the four.

SECRETARY LEAVITT: …You mean…

MR. KAHN: The congress. I think you're going to have to work within the four walls of CLIA and HIPAA to try and solve the problems. It's going to be difficult to get any kind of legislative change.

Just as I guess in the next one, when you go to the states regarding the other issues it's sort of important to do but it's going to be very difficult to get the states to actually do anything.

MALE SPEAKER: It's important that CLIA and HIPAA be addressed together because they have interactions [unintelligible] very unintended consequences.

MR. KAHN: Oh, I agree. I'm just saying hopefully you can find solutions to the issues within the current authorities. If you can't, then you've got a problem.

SECRETARY LEAVITT: I'm inclined to believe, from what I've been told, that there are many places where -- that we can find solutions. Tony, any thoughts about that?

MR. TRENKLE : I would suggest we have an internal HHS, HIT policy council. And it seems to me it would be a perfect issue to take before that group because it has all of the effective parts of the department there at the policy level.

SECRETARY LEAVITT: I'm not hearing much dissent on this point. Lillee?

MS. GELINAS: Just one more from the private sector around this conversation. High level. Can regulatory barriers be removed? Let's go there.

There was the issue of safety and quality. We have a mandate to improve the quality of care in America. And this is one that helps put gasoline on the fire if we were to address it.

SECRETARY LEAVITT: David, compose some language for us.

DR. BRAILER: HHS shall issue guidance on how to achieve patient-centric flow of lab results under current CLIA and HIPAA regulations. HHS agency shall evaluate and report to the Secretary on other changes that could be needed beyond this guidance to achieve the goal of patient-centric data in the longer term.

MALE SPEAKER: Just going further on the edge, can we put a date on that? Is there a time frame? At least a date on the review and the recommendation? I understand that there's a process for regulatory change and other things that will take a different timeline. But can we -- since we're focused on the lab exchange of information and now extended out to other data exchange.

SECRETARY LEAVITT: Let's at least have a report in September.

MALE SPEAKER: okay.

SECRETARY LEAVITT: I think that's a -- I can give you an update as to whether or not we're going to make that or not. But that's the point I think I feel comfortable in pushing HHS to do that. Does that seem reasonable to you?

DR. BRAILER: I think that certainly could be done.

SECRETARY LEAVITT: Any objection to that?

Hearing none, the Chair is going to have a consensus on 3.0 as amended.

Let's go on.

MS. GELINAS: I want to emphasize in this segment about regulation, it's not incremental, it's transformational.

In 3.1: based on the findings from recommendation 3.0, by December 31st, 2006, ONC should engage the National Governors Association and other state-based organizations to resolve variations in authorized persons under the various state statutes, regulations, policies and practices as a resource for clinical laboratory seeking to define access rights to electronic laboratory data.

Once the barriers are identified, ONC will work with the National Governor's Association and state principles to resolve these barriers and these variances.

And in the Workgroup, I have to tell you we were reflecting back on the presentation from the Southern Governors Association, the Gulf Coast Task Force at one of our AHIC meetings, and how impressed we were with their engagement, and they made it clear to us, how could they help? Because they have been on the front line of the issue.

SECRETARY LEAVITT: Well, if we can get it by September there's no reason why by the end of the year we couldn't get recommendations to them, in my mind. Anyone have a disagreement in that point?

Hearing no disagreement I'm going to declare a consensus on 3.1. Please move to 4.

DR. PERLIN: Mr. Secretary, again, Recommendation 4.0 is a cross-cutting recommendation. It's really a fundamental building block not only for the electronic health record, but the Chronic Care, and Boisurveillance Workgroups as well.

It has to do with the identification, patient identification, sharing with the right patient, assuring us the right use of information and authentication assuring that the use is by the right and authorized individual.

This recommendation reads: "The Community should create a consumer empowerment subgroup comprised of privacy, security, clinical, and technology experts from each Community Workgroup. The subgroups should frame the privacy and security policy issues relevant to all of the Community charges and solicit broad public input and testimony to identify viable options and processes to address these issues that are agreeable to all key stakeholders."

And so we're asking the Community to approve this additional work within the consumer empowerment Workgroup as a subWorkgroup, that it would have representation from all of the Workgroups. And it would really provide us with this fundamental building block that's germane to the work of the Community and progress as relates to the identification, the authorization, and authentication.

MS. GELINAS: And you'll see we did list out the issues to be addressed. For sake of time we won't read them but we did get very specific.

SECRETARY LEAVITT: Let me -- I've read this a number of times and have given a fair amount of thought to it. There's little question that this is a cross-cutting -- this is in every Workgroup. You tee it up because you give your report first. We have to resolve these issues.

However, I am concerned that as I look at those and I begin to see how many iterations of these there can be. By the time we are done we're we will have reorganized society.

And one of the things I believe we've been good at is focusing on the break-through projects. And I'm wondering how the group would feel about focusing on these issues as they relate to our break-throughs, not looking at them as a general subject. Are you thinking that way? Is that --

DR. PERLIN: I think that would really provide focus and make it a manageable segment. I think that would be a very good recommendation.

SECRETARY LEAVITT: How do the rest of you feel? Colin?

MR. EVANS: There's the suggestion that was somewhat the sense we had on one thing. And I was concerned about reading this, is, if you try and develop a solution that's agreeable to all key stake holders even on a narrowly defined topic, I think you end up with -- you know, the age cases, they're almost impossible to implement.

And I think in many cases, as we looked at it from [unintelligible] perspective, there are many ranges of privacy and security that are perfectly appropriate for different kinds of data. Not every piece of data needs to be, you know, protected by green kryptonite as it's circulating through the Internet. Something -- you know, one point would be that -- to come up with a range of possible solutions that would be appropriate in different circumstances might be a way to kind of get into this [inaudible] within the overall solution.

SECRETARY LEAVITT: I believe, if I've heard what you said, it's that if we can figure out a way to take these problems all the way to the -- get the water all the way to the end of the row on one row, we might be able to figure out how to do it in other situations. Is that --

MALE SPEAKER: Yeah. Yeah. I'd also that, you know, maybe the water doesn't have to go all the way to the end on every [unintelligible]. Maybe there are some cases where, you know, incremental improvements in privacy and security would be good enough for certain cases and we can tackle some harder issues later as they're actually required.

SECRETARY LEAVITT: Other thoughts? Kevin?

MR. HUTCHINSON: I think this is obviously getting into the meat of the work that has to be done. The infrastructure of the data exchange, authentication being one that's always near and dear to my heart on how we authenticate both patients as well as physicians that are using the technology to do the exchange, but I would agree that this is so cross-cutting across the organizations that it needs to be dealt with within the breakthroughs.

I would also encourage is, versus using a subgroup, is to use the mechanisms that are in place today with HITSP as well as NCVHS and other organizations and processes that are in place to address some of the more technical issues as associated with the infrastructure. There's certain things that within this group that we can do, and then there's other forums that bring a better technical expertise to the table to address in a public fashion many, many of these issues. And so, we should also look at those mechanisms that are in place within the process that exist today.

SECRETARY LEAVITT: Kevin, to your two points. First, the NCVHS tie-in: It turns out there's a significant overlap of privacy professionals on the NCVHS privacy subcommittee and on each of the Workgroups. We wanted to make sure that they were conjoined thinking and agendas to the degree possible. So I think that that would naturally bring NCVHS in, and I'm sure we will be talking more with Simon about how that group can be linked directly to this effort.

Secondly, with particularly with respect to the health information security and privacy collaboration, which is just at the launching point, this subgroup provides a very important receptor site for the work of that group to be received and to be discussed. It's going to be a very substantive and far-reaching exploration of state-based issues, and largely, this laundry list as you know. And so I think those can work more closely together. I think the question of HITSP is really one of: Does this group have the capacity in round one to be able to go as far as promulgating specific standards? Or is that something that's in round two? And our thinking

has been that's a second phase, but clearly, we want to be as ambitious as possible and to bring HITSP to this whenever it's appropriate.

Any other comment on this recommendation? There seems to be general agreement that we ought to pursue it with the Workgroup, but we ought to ask them to narrow their focus on the breakthroughs, and come back with solutions in those categories on our breakthroughs. And we'll work from there. Chip?

MR. KAHN: [inaudible] Well, let me bring up a side point here, which is coming in from left field, but I just want to take -- if I could take 30 seconds to do it. This is a cross-cutting issue and Lillee mentioned another one which is not up here which we talked about two meetings ago, which is measurement reporting, which actually sort of ties back into this.

And I just wanted to make the suggestion or the offer that the federation and Booz Allen are doing a paper on the issues that are raised in the architecture here -- and this is sort of an example of it -- for measurement and reporting. The problems that we face with measurement reporting, the obstacles to measurement reporting, with any of the systems we're developing.

And if we could just have a space on next meeting's agenda, even just 15 or 20 minutes, I'd appreciate it. And I think it's a -- it's going to be a cross-cutting issue that really is at the same level of maybe -- and maybe -- and maybe it's difficult for different reasons as the patient identifier, but if we don't sort of build in the measurement and reporting aspect of this, then we're going to miss a bet in terms of quality improvement.

SECRETARY LEAVITT: That seems reasonable to me. Hearing no objection and sensing consensus, I'm going to declare one. And as it has been adjusted, we now go to 5.0.

FEMALE SPEAKER: The next major bucket of recommendations deal with adoption. Recommendation 5.0. HHS, in collaboration with all key stakeholders, should both assess the value proposition and develop the business case for current and historical laboratory results data sharing across all adoption models, considering the unique needs and alignment of incentives for all stakeholders.

We had very robust discussion in our Workgroup around the need to fully articulate the business case for all stakeholders. We constantly heard from this stakeholder or that stakeholder: "What's the ROI? What's the ROI? Why should I invest time, energy, that type of thing?" And we just said, "We need to take this off the table, have the business case clearly articulated like we do for any other major assignment." And we had a great deal of consensus at the end of this discussion that there are actually stakeholders volunteering to be a part of developing the business case.

SECRETARY LEAVITT: Any conversation or objection?

FEMALE SPEAKER: Thank you. I agree with the general idea of trying to articulate, you know, the economic case, the business case -- however you want to think about it of interoperable laboratory results data.

However, my sense is that there's not a single value proposition or a single business case. It's a highly fragmented industry, a highly variable industry. And I'm not so sure that I would change the wording of this, but I would just add the note that as HHS undertakes this work, that we go into it with the understanding that there will be a range of value propositions and a range of business cases, and we shouldn't necessarily judge the -- you know, what those are going to be. I mean, there might be some negative business cases.

FEMALE SPEAKER: Unintended consequences.

FEMALE SPEAKER: Unintended consequences. There can be all sorts of implementation risks. I don't even know, but I guess when one does these things, one wants to anticipate that there will be a range in the results and in our endeavor to make a persuasive case. We should also be very realistic in that work.

FEMALE SPEAKER: You know, Adele, you bring up a point that I'm not so sure made it here, but in committee, we talked about not just economic case but the clinical business case. There's both a clinical and an economic business case that needs to be made, and that's not jumping out in these current words.

SECRETARY LEAVITT: I'm not sure I understand this. Are we saying who is going to pay for this?

FEMALE SPEAKER: No, I'm not so sure it was who's going to pay for it --

SECRETARY LEAVITT: Are we saying why would people do this?

FEMALE SPEAKER: It was to speed adoption so that it was very clear and transparent what the benefits are.

SECRETARY LEAVITT: Let's go to Bill and then over to David.

DR. WINKENWERDER: I want to just build on Adele's comments and say I agree. I think we -- maybe different words than business case, because business case implies the business interest of one type of entity versus another. And so I'm a little uncomfortable with governments identifying, you know, the business case. It suggests who ought to be the winner and who ought to be the loser.

I think we can -- the group could identify the economic, generally speaking, and clinical case for something. In other words, why this makes sense, why it will bring efficiencies to the system or to all parties involved. Having said that, there will be winners and losers, as there are in any set of business transactions across an industry. So I think maybe different words would -- economic and clinical versus business, and a lot of attention and care to not to try to suggest who the winners and losers will be.

DR. BRAILER: I actually will agree with Bill. I am a little worried about the government conducting a business case review because of the nature of those discussions and what really happens in the private sector.

I do think -- at least listening in on the discussion, and you're the co-chair, so you can speak to this -- the belief here was that if many of the adopters, doctors and others who are looking at these tools and standards, really looked at the economic issues, they would be much more likely to adopt them because they're not as simple as they appear. And so some of this becomes a dissemination and education exercise as well as this discovery. So perhaps there's a way to structure this that recognizes the part that should be in the private sector and then the role of the government as an educator as part of the President's agenda. I'll throw it back to you, I'm just -- this is an issue that I know has come up before.

MALE SPEAKER: David, I think your articulation is a very good one and I appreciate the comments that were made. In fact, I think the tenor of education and dissemination of information about the utility in improving safety, and reducing avoidable errors, and improving the cost of treating and follow-up [unintelligible], and enhancing quality, the consistency, getting to the right diagnosis and therapy earlier. Also, the resource [unintelligible], understanding of the efficiencies in a new economy.

In a sense, if one were doing this sort of study on the interstate highway project when [unintelligible] put forward, the value was not in the concrete but this incredible new framework for commerce. So the commerce in this instance happens to be a commerce, which for the very reasons that we convene, support safety, improves efficiency, improves effectiveness, and it was really understanding and perhaps educating about the ability to achieve each of those things.

SECRETARY LEAVITT: Other comments may want -- be desired? Yes?

DR. BRAILER: I sit here a little puzzled. This is sort of like: Is air good for you and water good for you? It's like: Did they study microwaves to see if they were going to prepare food better and faster? I mean, they just did --

SECRETARY LEAVITT: Somebody probably did. [laughs]

DR. BRAILER: Yeah. But my point is, it's like -- so we're going to do a study to prove that adopting technology in place of faxes and paper and -- is better and convince people to do it? If that's what this is about, I think that's a waste of time because there's too many stakeholders that will have their point of view.

FEMALE SPEAKER: David, I'll just chime in because we heard immensely from the private sector about this. This may not be in the government sector nearly as much as the adoption problem in the private sector. And so much of it is around "show me the money."

SECRETARY LEAVITT: But isn't this a place where the market is going to have to respond with ideas?

FEMALE SPEAKER: We would hope so. We'd certainly hope so.

SECRETARY LEAVITT: And that HHS developing a report on whether those ideas might come might not be nearly as fruitful as -- once we have standards set, once people know the direction we're headed, they'll find a way to get this done? Adele?

FEMALE SPEAKER: Yeah. I think the role for government in this instance is through the provision of information. If there really is an adoption gap that's attributable to a lack of understanding about the business case, I concede a role for HHS producing information that's useful to clinical care providers that helps address their concerns.

I also think there's a role to articulate the case for the federal government engaging in this effort as a society. I think one of the difficulties with a number of these technologies is that the benefits accrue to those who are not necessarily the ones responsible for adopting the technology.

So you have this fragmented distribution of costs and benefits. And there is a -- there's a framework for discussing that and discussing the role of government and policy to address that fragmentation.

But I don't think it's the role of government to necessarily, you know, provide business strategies for individual providers and try to make assessments about what returns on investments are going to be. So, there may be a role for information of the kinds I describe. I'm not sure this language describes that.

SECRETARY LEAVITT: Could the chair build a consensus around tabling this until we have a better picture of where we are? Bill?

DR. WINKENWERDER: One suggestion without getting into the business case part of it. I do think that there's a role for education. And so the mere collection of case studies or examples, both within government and outside of government, the costs that are associated, the benefits… You know, there is an emerging set of information about what the experience has been. And some of it is very positive. So, I think there's a role there. I don't know if that's something for ARC or others to show the impact of quality and efficiency. So, maybe that's the way to do it.

SECRETARY LEAVITT: Chip?

MR. KAHN: I think -- I guess I think the education role is okay. But the bottom line here is one -- at some point, the government may require some things of providers, either through incentives or through just the heavy hand of government. And then there'll be a market. You know, there's a market for technology firms to provide grouper software to hospitals because Medicare pays by DRGs and you've got to have the software, so hospitals have to buy it.

And in a sense here, one of the problems is that the -- there's a great deal of inertia on the part of providers to -- 'cause that's where Adele is right. I mean, for the average doctor, this is it not necessarily something that there's a business proposition for. But sooner or later, he or she may

not have a choice, either because it's just a cost to doing business they have to accept or because there's a regulation that requires it.

And either way, it's all -- it's going to happen, and I think you just let that happen. I think the education's great and we can have academic articles saying this makes a big difference, but at the end of the day, the question is: Is somebody going to require it or is it just a cost to doing business you can't avoid? And then you get to David's point is, people come in and innovate and hopefully provide it to providers in a way that can be affordable.

SECRETARY LEAVITT: One more comment, Nancy, and --

MS. DAVENPORT-ENNIS: Mr. Secretary, I think my comment is that what I would like to see the United States do through your leadership is to literally implement the same process that you have been committed to with AHIC since the first meeting that we ever had, which is the process of allowing for education and consensus building so that we can then lead this United States into universal health technology.

As one who joins everyone in this room traveling through the United States addressing provider organizations, there is very little awareness in the population about health information technology in terms of where is the future going. They know where we are in health plan information technology. They know where we are in laboratory technology. They know to some extent where we are in pharmacy technology. They know their own isolated hospital system or community clinic system has invested heavily in some form of health information technology. But the piece that's missing is the piece that we have the opportunity to provide to them, and that is to have a universal understanding of health information technology that: First, our government is embracing and has established magnificent models, one of which we saw yesterday, and they need to have the opportunity to understand that.

My sense is that when they do, you will have a very strong coalition of followers from the provider community. But we do need to do due diligence in trying to move through the educational process with them.

SECRETARY LEAVITT: All right. Let's hear Kevin and then Doug, and then I think that Barry has a suggestion.

MR. HUTCHINSON: I would agree with the dissemination of information and education. I think that is a critical role in everything that Nancy just pointed out is absolutely true.

My only caveat on the wording is I'm a little concerned that we're taking a subset of the overall process and just looking at lab information exchanges. And what we're really talking about is the adoption of clinical technology in physician offices and the value of automating the clinical process of the electronic health record itself.

If you just take a piece of the process out, you are going to miss a major component of the interoperability of, for example, labs and meds, which we are told time and time again by physicians, those are the two most critical data elements as part of this process. And I do get

concerned when we're doing information or even business case in this case, but information and education that is only focused on a subset of the overall process that we're trying to focus on.

SECRETARY LEAVITT: Doug and then David.

DR. HENLEY: Well, I would agree, Mr. Secretary, with tabling this. I'm not sure we need the recommendation. If we do, perhaps in different language. I think they're speaking on behalf of the physician community. I think there is a strong opportunity and responsibility for the medical professional societies to provide this type of education and support as well to physicians out there. I know, just speaking on behalf of the American Academy of Family Physicians, we've done a lot of this and our EHR adoption rate is 30%, not 17%. So it can be done and it's an important role that professional societies can do.

SECRETARY LEAVITT: Let me just -- before I go to David, let me give you my sense of this. I worry that we're seeing some mission creep with our task. There is an adoption problem. We're about standards, and I sense this is about creating an environment for adoption. And I -- that needs to be done. HHS has places where that can be done. We need to play a role in it. What I sense here is that we got lots of work to do on the adoption of standards here in the community. And, David, unless you've got some language that would go a different direction, I'd like to at least measure the consensus we could get around tabling this, at least for the time being.

FEMALE SPEAKER: And Mr. Secretary, I'll just comment that the Workgroup at this point, we were addressing our broad charge. [unintelligible] what the broad charge of the Workgroup is, is around adoption.

SECRETARY LEAVITT: But we're not rejecting. We're simply saying, "Let's get a little further on our standards," and I would declare a consensus on that point hearing no objection. Let's move on then to the next.

FEMALE SPEAKER: The next two recommendations may very well address this whole adoption conversation. And if I could, Mr. Secretary, read 6.0 and 6.1 together, because they're both about learning from early adopters.

6.0 reads: By March 31st, 2007, ARC, in collaboration with CDC and CMS, should develop a proposed study methodology to measure the extent and effectiveness of the adoption of the first stage of HITSP standards as well as the adoption and utilization of aggregated patient-centric data as they become available. And as you consider this particular recommendation, it's important to highlight the work of the early adopters because we thought that they could light our way if we understood what the early adopters had been able to achieve and how they had established their own best practices model.

6.1, recommendation 6.1 reads: By December 31st, 2007, ARC, in collaboration with CDC and CMS, should research best practices in the implementation and utilization of patient-centric laboratory data stores and how to implement this knowledge. So if I could say, as a group, we were trying very much to look at who were the better practices; who were the early adopters;

what were their better practices; and could they shine a light on the path so that we could learn from them very quickly.

And this may be, if I'm hearing the group correctly, more of our education role. Find out what the better practices are, and then educate the field.

SECRETARY LEAVITT: Any other thoughts about this? David, do you want to comment on it?

DR. BRAILER: Well, I just wanted to suggest that these were the recommendations that had substantial merit. And so I certainly support these in lieu of the recommendation that was tabled.

SECRETARY LEAVITT: Any other comments? Yes, Adele?

FEMALE SPEAKER: Well, there's a sort of a broader thought of measuring the results from all of the recommendations from all of the Workgroups, and maybe rather than looking strictly at, you know, this Workgroup and its recommendations and assessing results, maybe we should think about the bigger picture of measuring results from all of the Workgroups.

SECRETARY LEAVITT: I'm also starting to wonder if there's a need for us to have a Workgroup on education or some group that takes on work of -- that falls outside of the development of standards. I want to keep this group focused on developing standards. We have so much to do that I'm -- again, this is a place where we can get into organizing society in different ways and trying to change mores and philosophies, and I don't think that's what we can accomplish here. And I support the need for this to be done in my role of Secretary of Health and Human Services. I'm not sure that this is the place to do it. Bill?

DR. WINKENWERDER: I would agree with that. I think we need to stay focused. It sounds like maybe the physician community or others in the provider community would want to sponsor some educational sessions, and it could be informed by participation from HHS or some of us who've had more experience with, you know, electronic health records and we could support it. But maybe it's a task that could be taken on by the private sector.

SECRETARY LEAVITT: Could we get into other groups' recommendations? Why don't we bring the three back, because there may be others that in fact deal with similar tasks and revisit them in the context of that. And on that basis, I look for a consensus around tabling them. I declare a consensus around tabling them with the idea that we'll bring them back. We have --

FEMALE SPEAKER: One more.

SECRETARY LEAVITT: One more.

MALE SPEAKER: Mr. Secretary, you asked an additional charge of the electronic health record Workgroup. I think in part inspired by the poignant testimony of the Southern Governors' Association, the experience of Katrina, you asked how would we be able to insist --

assist insuring that first responders serving at a disaster or emergency situation can obtain the critical health information that they need electronically. And this was a highly consensus-driven set of recommendations. It may, sir, be the first time that there's been the depth of convening, from the most local to national to all across clinical, administrative, jurisdictional group of individuals. It included testimony from American College of Emergency Physicians, Department of Defense, Louisiana Department of Health and Human Services, a EMS stakeholder representative… Five groups.

And Kevin Hutchinson sort of identified everyone knows -- in fact, there was broad validation that there were four data elements that would be broadly useful in an emergency: Medications that a patient's on, any allergy's that they have, their diagnoses, and advanced directives. And so the Workgroup's recommendations and next steps are that we begin to not only receive additional modifying input on this, but that we coordinate with consumer empowerment Workgroup, coordinate with other federal efforts, emergency response preparedness.

And along those lines, at a very pragmatic level, practical level, is what can we do if we face a crisis? What can we have? And before we get to the personal health record or electronic health records that's there, very easy with -- knowing that these are the most critical pieces of information for us to bring forward, a consensus document that identifies these and serves simply as a template for a patient or a family or an individual to list their allergies, their medications, their main diagnoses, and their advanced directives, and some individuals who might be contacted in an emergency.

And indeed, Dr. Vanderwagon [spelled phonetically] has a mock-up of what this would look like. This doesn't get us immediately to electronic, but it's the core set of information for the electronic. And with some of the work that the groups are doing, it would serve as basis of information that could populate that. But right now -- not sometime in the future -- right now, it could serve as a core set of information that people could have so that they could present it, share it with other family members who might be distant from where they are, should we face again any circumstances such as the threat of Katrina.

SECRETARY LEAVITT: Does this require approval or is this just for information?

FEMALE SPEAKER: That's a good point. The sense of urgency around this was incredible.

SECRETARY LEAVITT: It is high. Hurricane season starts June 1.

FEMALE SPEAKER: It was approved -- two weeks. I know.

SECRETARY LEAVITT: Particularly where --

FEMALE SPEAKER: Yes.

SECRETARY LEAVITT: Well, I would like to just receive the report. And without objection from the members of AHIC, I'd like to just advance it into that process. It's going to get better as we go, but there is a sense of urgency about it right now that we're responding to for other

reasons, and it seemed like a very logical place to go with it, and we appreciate the service that you provided in being able to help us refine it.

MALE SPEAKER: Well, thank you, Mr. Secretary, Dr. Brailer, members of committee and colleagues. That concludes -- almost felt like real time but a much condensed version of a really great consensus building process where a lot of really thorny issues were dealt with and brought forward. And we appreciate the guidance of the community, the acceptance of others, and some tasking for further work. Thank you for your support.

SECRETARY LEAVITT: Well, I -- you've done a wonderful job. You've teed up important issues today and we've dealt with them here, and we've got more work to do, but you've driven it forward in a very positive way. And I want to thank you and members of the Workgroup for the work that you have done. I think we've about earned a break, haven't we?

MALE SPEAKER: We have, and we reconvene at 10:40 promptly.

SECRETARY LEAVITT: Before we go on the break, could I just mention two things? I think we do need to have an approval on the minutes of the last meeting. I neglected to do that. I would -- are there recommendations on changes on the minutes? Hearing none, I'm going to declare a consensus on the minutes.

I'd also like -- I saw Robert Roy [spelled phonetically] here and I wanted to make Robert known to -- Robert is another member of the ONCHIT team that is making some career changes right now. And I just wanted to tell Robert in all of your presence how helpful he has been and how ably, I think, he's conducted and driven this forward -- looking forward, in whatever way I can find a way to associate myself in the work of ONCHIT with you in your next duty. Thank you very much, Robert.

[applause]

SECRETARY LEAVITT: With that, I'd like to recommend a -- what do we got? Ten minutes? Fifteen minutes? In 15 minutes, we'll convene at quarter to 11.

[lunch break]

SECRETARY LEAVITT: I invite everyone to come back to your seat.

DR. BRAILER: Take your seats, please. Could you take your seats, please? We're now turning to the Chronic Care Workgroup with Mark McClellan and Colin Evans sitting in for Craig Barrett. And I'll turn it over to them.

DR. MCCLELLAN: Thank you all for the opportunity to be with you. I'd like to start out by spending a few minutes discussing the Workgroup's charge and our membership, then Colin and I are going to do a tag team bit about the work we did, the background and our recommendations.

Before I begin, though, I want to highlight how much help we've had from all of these members on developing recommendations on a very important topic. Chronic care is where the bulk of health care dollars are spent here today. And there is clearly large number of opportunities for improving the delivery of quality care.

We know all too well how often patients don't receive early recommended interventions, screening for chronic diseases and most importantly, effective ongoing management of chronic disease. This is something that's of first hand importance to me with the Medicare and Medicaid program, where the vast majority of the dollars we spend go to dealing with the complications and treatments for chronic diseases. And many of those complications, we know, are preventable.

There's been a large amount of interest, including interest from many of the Workgroup members in finding ways to improve the quality of care and reduce the cost of care for chronic illnesses.

And this would highlight, as you can see on the slide that's up now, the membership of this Workgroup includes people in government who are working to improve quality for chronic disease care in programs like Medicare and the VA. It includes members from the private sector who also have a direct and strong stake in getting to better quality care for chronic diseases.

Now, the use of Health IT can obviously have a big impact on chronic disease management, and in particular the use of secure messaging to improve communications between patients and clinicians has the potential to contribute to better outcomes. I'll going to go through some of the evidence on that -- Colin will -- in just a couple of minutes.

This is -- it's important to note, though, that all of the members of this committee have had a lot of experience in improving the use -- improving the care for chronic diseases through health IT steps like secure messaging as part of broader efforts to get better quality and lower costs and I particularly want to thank the members for the discussion at the last AHIC meeting.

You all recall we had a lot of back and forth about the tremendous potential here to improve quality of care and lower the overall costs of care through steps like effective support for secure messaging. We've had a lot of discussions since then about how to best achieve that goal. Better quality and lower costs for chronic diseases with health IT in general and secure messaging, in particular, playing a key role.

If you go on to the next slide: just a reminder that the broad charge for the Workgroup was to make recommendations to AHIC to get to deployment of widely available, secure, and effective technology solutions for remote monitoring and assessment of patients and for communication between clinicians about patients.

And again, at the last meeting, we had a lot of discussion about how we can best promote this effectively to get to adoption of technology that achieves improvements in quality and reductions in the overall cost of health care for chronic diseases.

The specific charge to the Workgroup that came out of that was to make recommendations so that within one year -- and I want to highlight the importance of recommendations that can be implemented promptly. We can get to widespread use of secure messaging as appropriate, I think meaning in ways that are effective in improving quality and reducing costs as a means of communicating between clinicians and patients about care delivery.

And I'll turn it over to Colin now to talk about the background for this topic.

MR. EVANS: Thank you, just a couple of pages on background here. First of all I would like to pass on Craig's apologies for his absence. He's been very committed to the work of AHIC and he's been very actively involved in the chronic care Workgroup as co-chair and he's disappointed that he can't be here.

With that, the background of the chronic illness Workgroup, as you know, over 15 million Americans live stably with chronic care. This number is -- demographics indicate this number is actually increasing and is likely to increase in people with younger and younger age given the demographics of the wave of care coming through into the system.

And as Mark pointed out, this is clear. There's an 80/20 rule in terms of overall health spending. 80% of the money being consumed by 20% of the people. As a bank robber says, this is where you go because this is where the money is.

In terms of trying to deal financially, the system and obviously, also the second point here is most of the chronic care takes place outside the physician's office. 80% of the people manage their own care whether it's dealing with diet, weight, blood sugar measurement, titrating medications, and so forth. This is something they do individually and could well do in many cases with a very good support system for doing that.

These are people that need frequent communication typically with clinicians and the overhead both terms of time and trouble of visiting a physician in many cases is better replaced by electronic communication with many of the things they actually need. So, the idea of secure messaging between patients and clinicians is a key of the underpinning of the basis for chronic care, regardless of whichever chronic care you're talking about, all of them can be underpinned by the ability to receive guidance outside of the clinical setting.

I'm going relatively quickly here. Given the robust discussion of the last Workgroup , we're encouraged to go quickly on that so we'll see if we can all have the discipline to do that.

The -- why secure messaging seems pretty obvious that obviously when the clinician and the patient are in the same room, they can securely communicate. We need to replicate that same secure communication whether it's done electronically or by other means.

There are a number of things that patients may wish to talk to their physicians about: consultation online, requesting prescription refills, scheduling appointments, requesting referrals, receiving routine test results -- that actually ties back to the previous Workgroup discussion -- and as well as reminders and instructions to help them stay on top of whatever process they're going through.

There are clear guidelines for use. AMA and IMA have got recommended uses for secure messaging in the clinical setting. And they're emerging clear methodology for assessing value from the Institute of the American (inaudible) association.

So, early studies appear to demonstrate the improved quality of patient satisfaction. There are some barriers to that which we will talk about as part of the recommendations.

And there are national and local payers that are beginning to recognize the cost benefit and quality improvement that can be done here, and are beginning to and reimburse for that. There are examples from the [unintelligible] Blue Shield system, and penetration in multiple health care delivery systems.

So, with that as background, we -- the Workgroup identified five key issues. The last one on privacy and security has already been discussed in the previous session. So, we really only need to focus on the first four here.

Reimbursement term, Mark will tackle. Medical liability and licensure, standards for the messaging and supporting systems that go around that. And the issues of consumer and clinical access, clinician access to the appropriate technology. So with that.

DR. MCCLELLAN: Okay, thank you, Colin. Turn to the first set of recommendations. First set of recommendations are all related to reimbursement issues.

There are three of them, And I'll go through each in turn. This is obviously area where CMS, particularly has a strong interest, just like other health care payers, we want to set up systems for reimbursement that promote high quality care and help keep costs down.

So the first recommendation here is related to developing and regularly updating the evidence-base for informed reimbursement policies with respect to secure messaging between clinicians their and patients. This should include monitoring and reporting of the effect of secure messaging on costs and quality of care and patient and caregiver satisfaction as well as medical legal issues.

Speaking from a CMS standpoint, we are undertaking a number of activities in this area right now. We have implemented some major payment reforms including putting much more emphasis on our Medicare advantage program, on paying differently based on the expected health status of patients, so called full risk adjustment of all of our payments to Medicare Advantage Plans.

With that we're seeing a lot more emphasis among the plans on trying to attract and retain people with chronic diseases. And a good way to do that is to provide a support system including electronic ones with secure messaging for those patients.

And there is a number of Medicare Advantage Plans that are now doing this now. And we are in the process of evaluating the impact of some of the secure messaging techniques that they're using.

Same thing goes for other types of care being delivered in the Medicare programs I'll talk more about in a minute. So there seems to be a strong level of support for compiling and for assessing and then compiling this information more effectively. I'll stop there and see if anyone has any comments.

SECRETARY LEAVITT: Is there any objection to this recommendations? In the interest of time or burning comments that need to be made?

Hearing none, I'm going to declare a consensus on accepting 1.0. Go to 1.1.

DR. MCCLELLAN: All right. Turning to 1.1, similarly, HHS should compile and assess the effect of various reimbursement methodologies for secure messaging on clinician work flow, in various care models, and report on best practices.

Again, this is something where we're already doing some works and from talking with many of the other AHIC measures, they want to participate in the efforts as well.

SECRETARY LEAVITT: Any disagreement?

Hearing none, I declare a consensus. 1.2.

DR. MCCLELLAN: Okay, now turning to 1.2. This is a long sentence. So let me go through it and some of the key elements.

Private and public payers including CMS should contribute to the evidence for an information base on reimbursement strategies through direct reimbursement, pilot or demonstration studies, or coverage analysis for internet-based patient/clinician encounters.

In accordance with guidelines developed by the AMIA, AMA, and the Massachusetts Health Data Consortium for structured, secure messaging including, but not limited to, encounters that qualify under CPT Code 074T. And I believe -- and there are others that are experts on CPT codes than I am, I think that's a secure messaging related code.

Let me just make a couple of comments here since there was a lot of discussion about this issue and some different viewpoints.

One of the -- and I'll do this from a CMS standpoint and maybe we can throw it open to broader discussion. This goes to actually adopting different kinds of reimbursement strategies. If you

kind of read from the 2nd or 3rd line down to the last line, it specifically hands reimbursement on this CPT code 074T, that is kind of fee for service or direct reimbursement for secure messaging.

One of the reasons that CMS had expressed some concerns in this process -- and there are other views from other members of the Workgroup was that we are first of all, unsure if we have the authority to do this.

And, second, the resources in the short-term, as many of you know, CMS has had a huge emphasis lately on payment reforms that focus reimbursement on paying more for what we want: which is better quality care and lower costs.

As part of that effort we've supported a broad range of private/public collaborations like the hospital quality alliance, the ambulatory care quality alliance and pharmacy quality alliance, that have been working together, through a privately led effort, to get consensus based adoption of consistent, effective measures of what it is we want to pay for in health care.

And again, that's better results for patients with particular kinds of conditions or treatment needs. And lower overall cost of care, greater efficiency, better coordination and lower costs in episodes of care.

And we've also seen a lot of support from Congress for this effort. Right now we've been mandated by Congress to do a set of demonstration programs related to these kinds of performance-based payment reforms.

This includes, for example, a pilot program or chronic care improvement program in fee for service Medicare. And we've also developed our high cost care management program. And both of these initiatives are paying more for better quality and lower costs and we're in the process of evaluating the impact of IT modifications and secure messaging as part of many of the pilot programs in these initiatives.

We have a number of performance-based payment demonstrations underway for hospitals, for large group practice, and small group practice physicians. And this is really where a lot of the agency's resources at the direction of Congress have been directed in the short-term.

So, from the standpoint of meeting our specific policy goal, what can we really accomplish within one year to get to wide-spread adoption. The biggest emphasis per the direction of Congress and our existing authorities and limited resources has been on finding ways to promote the adoption of effective IT systems through getting payment systems focused on quality and on lowering cost.

And, again, it's a huge effort right now with us, with many other private sector payers and participants in these quality alliances.

So, the caveat that we'd add here, I think, is that we're not sure that we're going to be able to implement this kind of step certainly within the next year to get to more direct reimbursement

for secure messaging itself. Rather, where we can move very fast and very effectively is in reimbursement that promotes the use of effective, secure messaging and other IT steps to get to better quality and lower costs. We're already seeing this start to happen in the demos that are underway now and that are getting underway soon.

Different payers and different members may have different perspectives on this but that's just a caveat I wanted to raise about how we're having a little bit of trouble meeting this particular formulation of the recommendation in the next year.

SECRETARY LEAVITT: Let's have some discussion about it.

FEMALE SPEAKER: [inaudible] I just want to agree with what CMS Administrator Mark McClellan said. And we have about 10 plans, Blue Cross Blue Shield plans, across the country that are doing various forms of secure messaging.

And we think it's premature to look at the actual reimbursement of it on a wide-spread way right now. We think a lot more needs to be learned from the existing pilots that are out there. We would be pleased to share a lot of that evidence.

What we're learning that sometimes free isn't cheap enough. I'll give you one example: one of our plans just actually paid not only for the secured messaging for the doc's expenses but actually the software in addition.

And they found that there was problems with both providers and consumers using it. The consumers were concerned about trusting it. And the providers found that it didn't work -- fit into their workflow.

So we found there are really other issues we need to address before we could commit to making this happen. And we think it would be great to -- as part of this recommendation is to really learn from and develop this evidence-base. So we would be pleased to do that.

SECRETARY LEAVITT: Any other conversation? Doug?

DR. HENLEY: Well, I speak very much in favor of the recommendation for a couple of reasons.

One, I think the importance of secure messaging being between physician and patient I think does have all the world to do with improving quality and probably can help to control cost in a major way.

I think there are some studies that show when you implement secure email communication, asynchronous communication, that that in fact can happen.

There are lots of pilots going on. And at least my read of this recommendation, is it's calling for some additional pilots to study that. It's not a broad application of a CPT code throughout the

whole system at one fell swoop. It's asking for demonstration studies and pilots at the CMS and federal government level on this particular issue.

It is occurring in the private sector. I agree with what Mark said: there are many other processes, projects, programs, pilots going on in Medicare that relate to the overall issue of chronic care management, care management fees, alternative methods of physician and other provider reimbursement. And the physician community's heavily involved in those, including issues that may evolve eventually into the pay for performance.

But I think to stimulate this issue, secure messaging, reimbursement is critical for that. And to study that through pilot programs and demonstration programs seems apropos as to what we're about.

SECRETARY LEAVITT: Other comments?

I have a question. Contained in our other work with various standards we developed, the standards for having secure messaging physically go -- having the digits organized and going to medical record, do those exist?

DR. MCCLELLAN: We're gonna get to a recommendation on that next. They don't fully exist now, but…

SECRETARY LEAVITT: But presuming that at some point they do, then the question is on reimbursement. Mark, would I be correct in assuming that we have the ability -- that the Secretary would have the authority to use demonstration projects?

I'd be interested to see many of these in different forms so that we could begin to find where the innovation is and how best to reimburse and where we get what we, as you suggest, we want, which is better quality.

Is there any reason to believe the Secretary wouldn't have adequate authority now through CMS to develop additional…?

DR. MCCLELLAN: As you know, Congress has legislated in a lot of areas where they want to see demonstration programs, and that includes many of the performance-based reimbursement programs that I mentioned. Congress put a lot of emphasis put a lot of emphasis of us supporting the effective adoption of health IT by paying more for better quality involving ICU's.

I don't think there's a reason to think that we could not do a demonstration program specifically on a particular standard for IT reimbursement. But where we tended to focus is on the goal. And then supporting the technology to help -- to get to the goal.

In regulation that's out for comment now on modifying the so-called stark and stark rule and anti-kickback rule, for example, we've made clear that we would modify our restrictions on

allowing interactions between different parties in the health care system when they adopt standardized messaging.

So we clearly have some authority to support the development and effect of adoption standards, we've just mostly done it in the context of getting to a particular goal like better quality care at a lower cost.

SECRETARY LEAVITT: Here's what I'm hearing in this discussion. One, we would all like to see a secure messaging e-mail. I'd like to a transaction with my physician and not wait in line. If I could figure out a way that it would work into their workflow, I'd be happy to get my prescriptions renewed and in some way like that. We've got e-prescribing, we've got other things going in that direction. We're all feeling, I think, a sense that this is a good thing.

I've heard the plans say we've tried this in a bunch of places and it has promise but we're not there yet, for wide-spread adoption. I've heard CMS say we're not ready for prime time yet but we're anxious to figure out how we can reimburse it.

It would seem to me a logical place to go with this would be to recommend that CMS and other government providers create a series of pilots under existing authority to see if we can figure out different alternative ways in which this can be reimbursed to achieve the promised goal. Could we develop a consensus around that statement?

DR. WINKENWERDER: Excuse me. We would support that. We would like to do that. We're able to do some of this today, right now, internally, with our beneficiaries, through an identification card that they can identify securely who they are and authenticate and then can connect and get there information and communicate with their provider.

But we don't have that for nonmilitary -- people who not in the uniform -- beneficiaries. So the technology of how we can assure that this person is who he or she says he is, is something that's important.

And I think that needs to be developed to ensure that it's secure messaging. But we would love to join in with CMS and others to do the pilot studies.

SECRETAR LEAVITT: Whenever I travel I'm accompanied by agents from the Office of Inspector General. And I routinely ask them what their raised concerns are in terms of cases they're seeing.

And there are trends. And it's clear to me if we don't get this one right, this will be one of the trends. And rather than inject it into the environment without -- on a broad base -- my sense is we're all thinking it is a good idea but let's pursue it in small pieces until we can determine how to do it better and then we can expand it. Mark and Colin, is that reasonable?

MR. EVANS: I think it is reasonable. One of the things the Workgroup heard was that secure messaging as a way of the clinician doing their job, unless it becomes -- there's some critical

mass component to this. That If it's incidental and opportunistic for them, they will not adopt and change or adapt their work flow to it.

So the real benefit seems to come when there's a 30% tipping point when it becomes a big enough part of the doctor's workflow they adapt their workflow and can more effectively use those. In looking at studies I think we should bear that in mind as we go along.

SECRETARY LEAVITT: We ought to be looking for demonstrations that provide that.

MR. EVANS: Narrow, but substantial ones.

SECRETARY LEAVITT: I'd like to suggest that we move to the next recommendation. And I'm going to ask Dr. Brailer if while we're doing that he could double task and come up with some wording that might modify that recommendation. We'll come back to it. Let's go ahead.

MR. EVANS: Okay, moving to 2.0. It has to do with liability and licensure, particularly in a multistate context. The background to this, I think, is quite a critical recommendation. That disease and disaster do not honor, you know, state boundaries. So, whether people -- I call it the three D's: disease, disaster, and dislocation, there are people -- effectively need to get treated across state lines.

And here we see secure messaging, as technology arriving into an environment where the rules are set from a previous way of thinking about medicine. So current state-based licensesure prohibits a doctor to provide care to a resident in another state, even though he could provide [unintelligible] could provide care if that patient came to their state.

And I think there's some -- you know, clearly there are issues here with creating reciprocity and so forth that seemed to be evidence from other countries that the people have figured out how to do this.

So the recommendation is that HHS should convene the appropriate state agencies and professional societies to develop and adopt new licensing alternatives which shall address the ability to provide electronic care delivery across statement boundaries and while still ensuring compatibility with individual state requirements. There was a question about which agencies, but this seems to be a critical barrier to movement here.

MALE SPEAKER: Thank you, Mr. Secretary. I would also add that, you know, if this will get much more play from the states when you tie it to -- frankly, to Medicaid funding, right. So if you have a relationship in our particular state's case, a child who receives services in Chicago and lives in Geary, that we pay -- we use Medicaid dollars to fund that care while it occurs in Geary. But obviously you can't follow up that service back in Indiana. So I mean, it is a barrier to care.

But to really motivate, I think, the state folks to move more quickly, tying it, as Mark well knows, to reimbursement, or making sure that Medicare and Medicaid can pay across state lines will move a substantial portion of the market in this direction.

SECRETARY LEAVITT: While I was governor we were working a telemedicine project. And one of the major medical centers was contracting with a small town across the border to provide advanced imaging and they -- the state obtained a cease and desist order because the physicians in the state across the border weren't licensed, or in Utah weren't licensed in that other state, and consequently they were -- and it became fairly clear to me that it was an economic issue. This was a rice bowl issue, not a competency issue.

MALE SPEAKER: Absolutely.

SECRETARY LEAVITT: And so, I think this is a significant one and I would -- is there any objection to this as a recommendation?

I declare a consensus. Let's move forward.

DR. MCCLELLAN: Turning to the third recommendation. This is another cross-cutting one and it's one that we've already touched on in the discussion so far: the importance of having standards to help promote secure and effective patient/clinician messaging transactions.

So the recommendation 3.0, here, is that the Office of the National Coordinator should direct HITSP to define standards for secure patient/clinician messaging transactions so they may be interoperable with electronic health records.

And, Secretary, going back to your point a minute ago, having standards in place that help ensure smooth and wider use will be an important step towards getting secure messaging that can effectively have an impact on quality and cost.

SECRETARY LEAVITT: Any objection?

DR. MCCLELLAN: And recommendation 3.1 is related to this for integrating secure messaging. And, two, the electronic health records. The Office of the National Coordinator should direct the [unintelligible] to establish certification criteria for system interoperability with patient/clinician secure messaging which would really help make secure messaging a part of an interoperable IT system.

SECRETARY LEAVITT: Any objection?

Consensus.

MR. EVANS: Okay. Moving to recommendation 4. We can get that on the screen? Okay.

So, this is the question of access by both consumer and clinician to, you know, the internet as implied -- and not necessarily need to just be with internet, it could be wireless service and many other ways of delivering secure communication.

And it seems certain populations are less likely to access health information services like electronic records and others, and not all clinicians are in an environment where they've got, you know, collective high speed internet connections or whatever they think they need to provide that level of communication.

So this really leads to a need to create viable strategies to mitigate this issue of disparate use to make sure that systems and tools are available to those that need them.

So, the recommendation 4 asks that -- actually, it's a synthesis of current knowledge from existing studies of health information technology use by elderly, ill, and underserved populations, including an analysis on barriers and drivers. This analysis should elucidate for which populations barriers can be overcome and how.

So basically, what are the gaps and how do we close them to provide more uniform access to the technology so we know that the barriers get resolved?

SECRETARY LEAVITT: Is this critical to the development of the standards or does this fall more onto the education side?

MR. EVANS: It's not a standard development question. It's a deployment practicality question. An adoption question more than a standards question.

SECRETARY LEAVITT: Any objections or comments?

Hearing none, we'll accept it and move forward.

MR. EVANS: So the final recommendation -- oh I'm sorry, 4.1, says that HHS will work with appropriate organizations to report on secure messaging availability to providers across the country and report on a plan and timetable to make secure messaging available uniformly. That's really 4 and 4.1 should be taken together.

SECRETARY LEAVITT: Any comment on this one?

I'm not sure I fully understand it. Maybe you can run it by me again.

DR. MCCLELLAN: This is aimed in particular, for example, at the safety net providers, others who are facing a technology or broad brand barrier to being able to get access to these technologies. So this is something where it would invoke some of the activities HERSA has underway and some other federal agencies that are not in HHS, actually, that reach out to the safety net.

So Colin's right. It is a mirror image of 4.0, which is aimed at the patient side.

But it in particular is recognizing that grants and other things that are already being given out for technology should take into account this secure messaging aspect to ensure that the safety net comes out at the same time that the core health care system does

SECRETARY LEAVITT: Any comment?

Hearing none, we'll declare a consensus and we'll move to 5.0.

MR. EVANS: Well, 5.0's actually already been -- that's one of the cross cutting ones already discussed in the previous section, so I think we're done.

SECRETARY LEAVITT: So in essence, we will adopt this by reference, recognizing that it is limited to this breakthrough, this is as one of the breakthroughs.

MR. EVANS: Exactly.

SECRETARY LEAVITT: All right. Do you want to go back to 2.0?

DR. BRAILER: We have a redraft of 1.2 as redirected. Can we bring it up on the screen?

So, the draft is public and private payers should implement and report on pilots or demonstration programs, -- I think that should say projects -- that evaluate a possible forms of reimbursement for secure messaging. Integration of secure messaging and to position workflow and impact of secure messaging on patient involvement in their care. Which I think picked up the three aspects of the discussion that were here. But in the spirit of the direction, it's much more purposefully aimed at building the evidence-base and going out directly and testing.

MALE SPEAKER: It should be forms.

MALE SPEAKER: Or forums, too.

MALE SPEAKER: I think that could be forms.

SECRETARY LEAVITT: Any comment on the proposed wording in letter or spirit?

MALE SPEAKER: Dr. Brailer, would that include a review of the actually defined cost savings as a result of that?

DR. BRAILER: The spirit of this, since we were talking about pilots and demonstrations which is aimed at going out and actually testing the evidence-base itself, not something that's more secondary or meta-analysis.

I think the recommendation that 4.0 really should speak to some of the auctorial analysis. W can make sure that that's included in that, because that was part of the intent of looking at secondary data and other existing evidence.

MALE SPEAKER: Is there any recommendation on a timeline for these pilots? Or, you know, what, specifically, what agencies should be tasked with doing this, or private payer? I mean, who is committing you to sign up to do this and by when?
SECRETARY LEAVITT: Mark, what's a reasonable timeline?

DR. MCCLELLAN: Well, I was going to ask a related question. Going back to your comment, it seems like these might want to make this relate to the recommendations and recommendation 3 and 4. But particularly the recommendations related to standards for secure messaging.

So as those get developed, the faster those can be implemented, the faster those can be developed, the faster we could implement pilot programs that build on the standards that we like to see to get to more wide-spread use in physician work flow and so I think there's a bit of a question of, you know, how fast that that can all occur.

SECRETARY LEAVITT: David, what's a reasonable time frame for those standards?

DR. BRAILER: This is actually an area that is a very clean standards area. It's not a highly complex standard. It's more of a communications content standard or, if you would, an envelope as opposed to the message content.

It's our expectation this standard can move on very quickly. I think the September timetable that we have talked about for others is something that is, something I would at least at this point, say we have reasonable confidence of.

And I do agree with Mark, we don't want to go forward in the absence of those standards, not only because we want to evaluate them, but part of these pilots are to create critical mass on the market that can begin moving it in the right direction. And we can certainly this to reflect that in the antecedent sentence.

SECRETARY LEAVITT: I would feel good about reflecting a September meeting, both for the standard and for at least an RFP that could follow the standard. Kevin?

MR. HUTCHINSON: Just to get clarity. I know we're talking about standards which would imply exchange of information. On the previous slide for the wording of what we're looking at 1.2, the impact of secure messaging on patient involvement and their care, is that also going to measure the features of secure messaging, so is it the interaction of an on-line visit, is it a requesting a schedule an appointment, is it requesting a refill?

Because it looks like it's trying to look at what's going to drive patients to want to use these as well, which is a little different than standards. I just want to make sure I'm understanding it if we're going to assess that as part of the impact of secure messaging on patient involvement in their care and not --.

SECRETARY LEAVITT: It seems to me that that ought to be written into the RFP. What I envision is saying to the world, "If you have a clinic with "x" number of doctors and you can show us a laboratory where we can assess this, here's what we want to know. Does it help patients? Do they like it? How do you pay for it? And can you show us how you would come out better off in the end both in quality and cost?"

MR. HUTCHINSON: Right.

SECRETARY LEAVITT: And so say to the world broadly, here are the things we're looking for. If you think you're a good laboratory for that, send us a deal.

MALE SPEAKER: I was tying back to the certification commission one that we passed. Where on the certification commission with EHRs we focused also on features that you had to have within an electronic health record to become a certified electronic health record.

Is that, given that previous recommendation that we've already accepted, are those two tied to where we would also include as certifying secure messaging applications with that level of detail? And I would agree that the impact, we need to do the analysis on the impact.

DR. BRAILER: Well, first with respect to the standard, remember that secure messaging actually is conveyed largely through an existing standard, which is how we all do secure messaging in a variety of ways.

The issue here is particularly how that message ends up in the electronic health record. And that's why I think it's a pretty clean envelope standard. And that piece is something that HITSP would do. I think it's a separate question for CCHIT of when it actually deems that to be ready for commercial entry in terms of putting it into the minimum set of features for ambulatory electronic health records.

But all the contractors are directed by our office look at the Workgroups, and the breakthroughs, and the recommendations, to include that in their efforts. So in a sense it's implied for CCHIT. If you want to memorialize it, it could certainly be done by amending 3.0. But it's not on the critical path here, like the EHR, given the work that they're doing.

SECRETARY LEAVITT: Adele?

MS. MORRIS: I have a related question about 3.0 and I'm looking back at our broad charge, which also refers to communications between clinicians and remote monitoring and assessment of patients. And I have to tell you that one of most compelling things of our tours yesterday at the VA Hospital was the discussion with some of the young physicians there about how they can monitor and interact with the care of their patient remotely. If they have to go home with a sick child, if they're on vacation, if they're somewhere besides in the health care facility, they can order lab tests and see the results, very complex imaging procedures. It was most impressive.

I'm looking at recommendation 3.0, and it's very focused on patient/clinician messaging and I think from my understanding that's the specific charge but, you know, looking at the benefits that accrued from broader messaging, I'm just wondering, maybe somebody can comment on the prospect for further standards for both the clinician/clinician messaging and I don't even know what you call the kind of messaging that we discussed yesterday where the physician is at a remote site and is interacting with an EHR.

DR. MCCLELLAN: Thank you for the kind words but really, to comment on recommendation of 3.0, in a sense, I think, is so important because it's one of the building blocks. Colin

mentioned that, you know, one of the challenges was integrating with the emerging or normal workflow. And, in fact, the structured messaging in itself ultimately finds its home with electronic information that can support patients at a distance and also facilitate communication.

Just parenthetically, our experiences with the ability to structure a message to make it secure, that is other than a regular e-mail, can, in our experience, facilitate the interactions so that -- you know, you can communicate with me when it is convenient for you, not just when I happen to call you. And then it's very powerful.

Same holds true just as [unintelligible] mentioned, that the clinician/clinician might have the interaction. So we really see this as a fundamentally important recommendation both so it is a component that feeds into the broader health record but also that supports other sorts of communication. That's probably not what was envisioned in this specific, but it's one of the set of tools that builds the more powerful usefulness of health records.

SECRETARY LEVITT: Bill?

DR. WINKENWERDER, JR.: This deals with the issue of patient/clinician secure messaging. Was there some discussion or recommendation about clinician to clinician secure messaging?

MALE SPEAKER: Well, there was an initial scope discussion about -- actually, a triangular relationship at least in the clinician/clinician to patient, but also patient to other caregiver, family member and so on and so forth. And I think we saw some of these recommendations as Jonathan said as being building blocks for that. But given the immediate charge we had, was actually one leg of that triangle, not to try and worry about -- we think a lot of the things we can equally applied to all three sides of triangles. But we focused for now just on one initially for the short term charge of the group.

MALE SPEAKER: On reason, I have a practical and self-interested reason for bringing that up. Again, I go back to a higher issue right now trying to communicate with 230,000 physicians from within our system. We're electronic, you know, many of them are not. But just that one aspect of having secure messaging. If we were very interested in working on the standard, we have a very strong interest to help develop that with anybody else who is working on it. So, I wouldn't want to leave the clinician to clinician effort out of there, because right now a referral goes out, a patient gets seen, but the information doesn't get back electronically. And that's the gap.

SECRETARY LEAVITT: David?

DR. BRAILER: This is perhaps a good time for a "you are here" type map of our journey, because, you know, we're really at the end of the short term break through recommendations. It's possible that other things would be discovered in the Workgroups that are relevant to the short term breakthrough, but it's our expectation that we're going to now turn the Workgroups towards the longer term goals, the broader charge

In this case, enormously broad charge of remote monitoring, which is doctor/doctor,

doctor/doctor/patient as Colin points out, but also doctor/[unintelligible] the interactions of physicians with direct sensing devices in patient's homes or bodies. It's an immense area, but the key concept we've tried to bring forward with all of these so we're not, if you would, boiling the ocean in the name of standards, is to be use-case driven. To find a particular instance and then develop a standard.

So the first task we're going to ask the Workgroup to do as they reconvene after this meeting, is to start mapping out new use cases. New examples of what is the business problem we're trying to solve. Is it doctor/doctor communication about a referral, is it post discharge communication, is it an insulin pump? And then from that we can feed those to HITSP and to the other groups for standards.

MALE SPEAKER: Going for 80/20, using 80/20 rule, I think most of the interaction is just on a referral, referral primary care doctor to --

DR. BRAILER: Yeah, that's come up a lot.

MALE SPEAKER: And that's where most of the interaction is, so being able to get back that referral and just the consult report to me, in a secure message, is the most valuable thing.

DR. BRAILER: Yeah, that's clear to come up in the background due diligence, right?

SECRETARY LEAVITT: So why couldn't you add that to 3.0 now? I mean what -- it's basically an envelope, and it's just going in a different place. Why would we not want to add clinician to clinician, and patient/clinician.

DR. BRAILER: I don't think we don't. I think there's a large degree of content difference between doctor/patient, which tends to be simple transactional. I have a question, you have an answer, you have a fact, I give it to you, versus the doctor/doctor communications, which is much more structured and much more content rich. Meaning that it does go beyond the envelope, as Doug well knows, to start and talk about the kinds of information. So it's a bigger problem. So I think we can move there quite quickly, in terms of, I think, it being obvious that the doctor/doctor communication and referrals are critical, one, or around the doctor/doctor change for a patient changing doctors. But there still are some decisions that we want to make before we just turn it over to the standards group to say go to it, or we'll set up the world where we've been in, in the past, where there's not enough scope boundaries or limitation for them to know what problem we want them to solve.

MALE SPEAKER: Just a naïve sort of question. Secure messaging, and there are a lot of secure messaging products out there. In terms of between the patient and the doctor, you can do secure messaging now, that's not that big a deal, and now between the doctor and the doctor, there if you're actually sending information that would have to fit into another electronic record, then I guess the issue of interoperability comes up, because you may not be able to -- you can send it, but then they couldn't open it or they couldn't instill it in their record.

But it seems to me between patient and clinician, it's pretty simple, isn't it?

DR. BRAILER: Yes, that's why we thought we could have the decisions made on that within a very, very short period of time. Weeks to months. It really is an area where standards are not the rate limiting step.

But to the Secretary's point, and to the methodologies we tried to lay out, we want them to be done in a jurist way, so there they're actually named and blessed in a formalized manner, so we can all say that's it. And that step has to be done, but it's short. It's much less time than the other things that we've talked about here.

SECRETARY LEAVITT: I'm sensing that we'll come back to clinician to clinician fairly soon. But why don't we go back to 1.2, and act on the amended language. Is there any objection?

And hearing none, I'm going to declare a consensus on the amended wording. And I believe that --

[low audio]

SECRETARY LEAVITT: That is correct. With the expectation that it will be done in conjunction with the September date. It will be done in harmony with the standards with the anticipation it will be in September.

DR. MCCLELLAN: I think this language gives us a lot more flexibility to support different ways of getting to the goal of secure messaging as part of effective electronic care for chronic illness.

SECRETARY LEAVITT: Good.

MR. EVANS: We thank you.

SECRETARY LEAVITT: Thank you very much for your good work. And we have another list of topics for you very soon.

DR. BRAILER: We've now come to time for lunch. We will reconvene at 12:15. A very short time. But we appreciate everyone's effort to keep us on track because we have a lot more to do this afternoon.

[lunch break]

DR. BRAILER: Okay. If you can take your seats we're going to go ahead and get started.

The secretary asked me to go ahead. We're going to turn our attention to consumer empowerment. Before we start with that, we do want to come back to the draft recommendation 1.2 that was under Chronic Care. And just take a quick look at the language to make sure everyone's comfortable with this. It's being passed around.

So what you have in front of you now is recommendation 1.2. This is no different than what was discussed. It's now just committed to paper. So I'll just ask for any comments on this, and in the absence of them we'll just revert to our consensus. This is really to make sure we wordsmith this appropriately. Any comments on this?

Okay. This stands as consensus adopted.

With this we'll turn to Nancy Davenport-Ennis and Linda Springer. Thank you both very much. And the report of the Consumer Empowerment Workgroup.

MS. DAVENPORT-ENNIS: Thank you, Dr. Brailer. It is a pleasure to be addressing the AHIC committee this morning. We would like to thank you all for your attendance and for your participation in this discussion. It's also a pleasure to address those in the audience and as well as those who are with us in web cast as we have our discussion.

I think there is particularly special recognition due to the members of the Consumer Empowerment Working Group, and a special thanks to Dan Green and Gail McGrath who have worked with Linda and I in preparing the materials that we will review with you today.

Additionally, there is a special thanks to Mary Gorman, the vice president of education of the Pediatric Steering Group who provided information describing pain, a patient-centric and patient-owned PHR that is offered through many of the children's hospitals in America and that had great relevance to some of the work we were doing.

And there's also a special thanks to Carla Smith with a document she prepared at our request, identifying what are indeed some of the similarities and differences between the use of an atm bank card and trying to move our nation to an information technology system. And so, it is with special gratitude that we recognize each of these people.

And with that, I would like to recognize Linda Springer.

MS. SPRINGER: Well, thank you, Nancy. What we want to do just to kick things off is to review briefly the broad charge for the Workgroup. It's up on the slide, which was to make recommendations to the Community to gain wide-spread adoption of a personal health record that is easy to use, portable, longitudinal, affordable, and consumer centered. Then additionally we had the specific charge of making recommendations to the Community that so that within 1 year, a pre-populated, consumer directed and secure electronic registration summary is available to targeted populations, make additional recommendations to the Community so within one year a widely available, pre-populated medication history linked to the registration summary is deployed. Those are the two charges with which we were given and started off.

Now, the Workgroup recognizes that most enablers for registration summaries and medication histories are the same for PHR adoption. So it's important to note that. That means that many of the Workgroups' recommendations address the broad charge, which will in turn lead us toward achieving the short-term goal.

We expect to continue to refine our recommendations as the Workgroup hears additional testimony and deliberates on complex issues as they relate to the broad charge.

MS. DAVENPORT-ENNIS: Thank you, Linda. In terms of background of the issues the Consumer Empowering working group has been dealing with, I would like to review these and give further comment.

Consumer involvement in self care and care management could be encourage with the successful deployment of some form of easily accessible personal health information. Consumer commitment to PHR's could increase efficiency in the health care system. Lower overall cost and improve access to health care information.

We also feel that it has the opportunity to additionally reduce medical errors. Likewise, making a medication history and registration summary widely available to targeted patient populations is an incremental step to realize progress in the short-term.

The Workgroup has held many discussions on the value proposition. Consumer involvement could be encouraged when consumers have easy access to their health records. Currently as we have sited to this body, it is difficult for many consumers to get access to their health records without at least a delay.

Consumer commitment to PHR's could facilitate efficiencies in the health care system, leading to lower costs and enhance access to health care information when it is needed most at the point of care. And for fulfilling the specific charge to the Workgroup will be an important step toward real progress.

The key issues that our working group was dealing with: first, the issue of privacy and security safeguards and consumer control of personal health information need to be established and enforced. This has been a very strong position taken by the Consumer Empowerment working group.

I would like to say to this audience that certainly we feel the consumer has the highest stake in this process, because, indeed, when we think about personal health records for consumers and electronic health records about consumers, we know that as long as those records are secure, they are safe, and they are not breached, the consumer is advantaged by them. However, if we fail in our effort to secure them and to keep them private, it can have an impact on the consumers' entire life, whether it's their ability to remain insured, to procure loans, to move forward with new professional job opportunities. So, a very important issue.

There is no accepted widely definition or functional specifications for the features of the PHR. While there are programs and PHRs available for consumers to buy into and have access to today, there does not seem to be a universal platform, a standard definition or functional specification. There are no standards or functional specifications for populating PHRs, rather it is more familiar for consumers to subscribe to or buy into one of these programs and then to self populate.

The appropriate incentives for consumer and provider use of PHRs must be identified and supported as we're moving forward. I think consumers will demonstrate once again their willingness to cooperate with this process and find it inherently valuable in their daily lives, as long as we can give them the opportunity to understand the tools and use them effectively in their lives.

Generally consumers are unaware of availability and value of medication histories and electronic registration summaries. I would point out to this committee, as I have on other occasions that the consumers as formally represented are perhaps the newest members to these discussions. There have been long-standing discussions with health care providers, with pharmacy benefit providers, as well as with health plans, about health technology and the value of health technology.

Now, the consumers are ready to move into place and begin to become involved in this issue. In order for consumers to feel comfortable using personal health records they have to know that their information will be protected. The issue of privacy, security, access, transparency, authentication is of critical importance to consumers.

MS. SPRINGER: Well, as we've said, a registration summary and a medication history are two subsets of a comprehensive PHR. So we believe, the Workgroup believes that a technical policy and business infrastructure should be established, that could enable the adoption of a registration summary and medication history.

We believe that the HITSP should serve as the key resource for this Workgroup, in addition to others and identifying the technical and data standards needed for both the summary and medication history.

So if you look at Recommendation 1.0 it really, as a cross-cutting recommendation, encapsulates that, that the development of both the technical and data standards enable the availability of a core registration data set and medication history including vocabularies, messaging, authentication, security standards, and appropriate documentation, that recommendation should be undertaken, it should be done with a due date of September 30th of' 06.

Now, important in there is that parenthetical about comprehensive review of the recommendations for registration and medication history that were provided by the Workgroup. We recommend that those recommendations be reviewed very carefully and the registration date appoints the medication records, we think, were given a lot of thought by the Workgroup and should be an underlying piece of developing those requirements and standards.

DR. BRAILER: Okay, Recommendation 1.0 has been discussed in two of the Workgroups so far and this is cross-cutting and this is a parallel structure to those. So I'll ask for any comment

here that would be exceptional to the two times we already approved this recommendation. Is there any discussion?

FEMALE SPEAKER: We recommend approving it but I just wanted to point out that Blue Cross/Blue Shield Association and AHIP, America's Health Insurance Plans are working on a joint project to identify, and working with HITSP to develop the standards for personal health record, and we should have that done this fall. I just wanted to share that.

DR. BRAILER: September 30th?

FEMALE SPEAKER: Thereabouts, yes.

DR. BRAILER: And that work with and through HITSP?

FEMALE SPEAKER: We're coordinating and our contractor is work being them, yes.

DR. BRAILER: Okay, good. So that brings really good synergy. Any other comments on this recommendation? Adele?

MS. MORRIS: I have a more general question. I'm just looking ahead to our various recommendations. I'm trying to remember with great clarity the problem we're trying to solve. The -- as I understand, we're getting ready to set standards for certain class of data. And when I hear registration information I hear basic demographics, name, address, birth date, that sort of thing. And medication history.

And my best recollection was that the primary function of this data was to help eliminate the clipboard in the doctor's office. Is that ... Where we were -- I mean I know my name and address. The whole point of having a database is so that somebody else can get that information in a convenient way so that I don't have to keep providing it. Was that the --

MALE SPEAKER: That was the intention of the registration summary. I think the medication history was something that was not necessarily coined in that phrase of the electronic clipboard. But the reason the two are working together is because they have very clear dependencies back and forth. One of the key enablers of the registration information is drug data and drug data obviously relies on that central core of the registration information.

MS. MORRIS: Right.

MALE SPEAKER: So there's two separate business problems, and we've written these as separate business cases that the Workgroup has looked at. And so the standards directive that we're giving here would go in partnership with the scoping documents that have already come from the Office of the National Coordinator to the Workgroup and now to HITSP to say exactly what does this registration summary problem mean, what does the medication history problem mean, as well.

MS. MORRIS: Okay, so the -- so my primary point is I want to know exactly what lens I'm looking at these recommendations through. And I think you've answered my question.

So for Recommendation 1, for example, that mean's that is the core registration data set is what HITSP is going to conclude is the information that should be on a clipboard, essentially, and how it should be articulate it --

MALE SPEAKER: Yeah, largely speaking, we've not asked the standards community to make the business decision of what data is needed. But there's already been a lot of discussion about the kinds of data that would construct registration summary or medication history. But here it's to say, how is that information stored, communicated, and accessed? What's the, if you would, the interrogation and inquiry rules?

So if I'm a doctor and I have a patient that walks in and they say, well I'll got my registration data stored at some place, I know how to access electronically and it can download to me without manual interventions. And same with the medication history, although that's viewed more as a patient accessing mechanism, where they get access to their medication history, per se. Does that help?

MS. MORRIS: Yeah, that's very helpful.

MALE SPEAKER: Okay good. Any other comments on 1.0? And objections to it being adopted by consensus?

It is done. Let's move to 2.0, please.

MS. DAVENPORT-ENNIS: In terms of the 2.0 recommendation, how can access to and value of medication history and registration summary be demonstrated, it's our recommendation that HHS through CMS, ARC, other interested federal agencies and private sector partners should pilot programs that measure and demonstrate the value of an electronic registration summary and medication history to patients with chronic disease. The sponsoring organization should strive to implement pilot programs that meet all of the objectives identified by the Workgroup, no later than December 31st,' 06. And an evaluation of the initial results should be reported to the community by June 30th, '07.

I think that there were several points made in the discussions with our Workgroup when we were trying to come to consensus on this recommendation. I'd like to share those with you. We did consider various targeted populations to be considered for the demonstration and pilot projects. Patients with chronic conditions requiring frequent use of the health care system or consumers who would be most likely to obtain immediate value from an electronic registration summary and a medication history. In that discussion there was much time addressed at at piloting and running demonstrations within two primary populations, perhaps. The pediatric population that may already be dealing with chronic illnesses and for whom in many instances we have high utilization of personal health records.

And, number 2, the use of these tolls with our chronically ill seniors and disabled who are in the Medicare population. So those are the two areas that we had great discussion about trying to pilot.

The department of Health and Human Services and its agency has the capacity to implement pilots that can demonstrate value for consumers, particularly those with chronic conditions who may have greater needs. The work ground recommends that HHS undertake this assignment, and implement pilot programs by the end of this year providing, as we cited earlier, the results by June 30th.

And just as a summary close, the obvious point that within our discussions, it was important to us that the pilots and demos be culturally sensitive and culturally diverse, that the health literacy, we be sensitive to that, and that we also, within the pilot groups, look at what the basic internet skills are with those users so that we could try to get the highest degree of feedback possible from the pilots and demonstrations.

With that, the floor is open for discussion. Dr. Brailer, any questions and comments?

DR. BRAILER: Okay, any comments and I would like to hear from DOD and VA, in particular, and CMS, because we've discussed this in the name of another Workgroup but to understand how it this could be different than that discussion. So the floor is open.

DR. WINKENWERDER, JR.: I think from the Department of Defense perspective we would like to do pilots -- or participate in a little bit concern that we can actually initiate these and implement -- I think begin to implement but implement by the end of the year. I just don't know what the workload is to accomplish that. It's pretty aggressive time schedule.

Not necessarily, you know, suggesting changing the timeline. I think staying with it, aggressive timeline is probably okay. But I think, just to be realist, to get a pilot up, start it, evaluate it, and so forth, in a year's time is going to be a pretty high task.

DR. BRAILER: Would you know the feasibility of this, Bill, by the time we come back to the June meeting…

DR. WINKENWERDER, JR.: Yes.

DR. BRAILER: …when we're going to talk about that other time table? So we can move forward with this with the caveat that we might have to revisit this if we find fatal issues.

DR. WINKENWERDER, JR.: I think so. Yes.

DR. BRAILER: John, how about VA?

DR. PERLIN: I would feel very similarly to Bill and that would be supportive. I have to do a little bit exploring but I would also expand the comments both to Recommendation 2.0 and 2.1.

I think it's important that the VA would partner as well with vendors and other business partners as well as looking at expanding the ability to look at this internally. So absolutely supportive.

DR. BRAILER: Tony?

MR. TRENKLE: David, we talked to our Medicare beneficiary [unintelligible] system folks and they feel that we can support something by this type by the end of this year. They feel fairly confident we can do that. We've been discussing with ARC partnering in this area as well. So I think we're already a fair amount down the road on this.

DR. BRAILER: Very good. Other discussions -- Doug?

DR. HENLEY: Very much in favor of the recommendation. But when it speaks to demonstrating value of these PHRs to patients, I think it's also demonstrating the same value not only to patients, but to physicians, other clinicians, and health care institutions, et cetera. So I think we should look demonstrating the value a bit more broadly than just to patients when we speak about PHRs.

DR. BRAILER: True. Any objection to that? So we could perhaps write this to say in line 4: to patients with chronic disease and their physicians or clinicians. Is that better? Good. Okay.

Other discussion here? Any objections to this recommendation as modified?

Great. Let's move forward. Thank you.

MS. SPRINGER: All right. So Recommendation 2.1 really is a partner to Recommendation 2.0 that we just discussed, and again since our focus is on the consumer, it may well be that there's, you know, another dimension of the provider although I think we acknowledge it here, but we believe that to make these pilots effective, that there's an element of education and outreach that's needed to encourage participation, good participation, in the pilot and to really make sure that people understand what we're trying to achieve.

We think one of the ways to accomplish that is to reach out to some private sector organizations that regularly do provide health education to their constituents and already have established an effective means of communicating information and doing that education function.

So our recommendation is that in the next six months that the HHS agencies that are sponsoring pilots would work with their -- an appropriate group of private sector health organizations, such as the patient advocacy organizations and some other medical professional societies to promote that education function and participation by both providers and consumers in this targeted outreach initiative.

DR. BRAILER: Okay. Discussion on 2.1? John and then Adele.

DR. PERLIN: First let me articulate support for this, just as in the spirit of the last one. But let me ask, is there any reason you wouldn't include [spelled phonetically] HHS other federal

partners and the parallel structure to the inclusive list in 2.0? We'd be pleased to support and participate as we work with our constituent --

MS. SPRINGER: I think that's fine.

DR. BRAILER: Yeah, we'll substitute the word federal for HHS on line 1. Thanks. Adele?

MS. MORRIS: Okay, I know I'm being a little dense, so I want to be sure I understand that this is solving the problems we just agreed were the problems we were trying to solve.

As a patient, if I populate this registration summary, where in the recommendations is it captured that physicians are going to be encouraged to actually access that summary and relieve me of the burden of the clipboard?

To me, the sales job is with the physicians. I mean I can hear it now "yeah, but we need this in our format". "Yeah, but we need it so that it's consistent with our records." The liberation as the patient will be going on the internet and typing it in once.

FEMALE SPEAKER: Adele, I think your points are well-made. And certainly I think it's a point not lost on the working group in the discussions that we had. And I think that the floor is open for discussion if there is any concrete recommendation you would like to proffer at this point. I think perhaps the floor is open for discussion and we can entertain that.

MALE SPEAKER: I'll try here. I equate this to going to a hotel and when they ask you for all that information saying, here's my business card and they attach it to the form and then it goes. The standards are identified correctly and the information is there.

It's about the content, not about the form. And I think if we get the standards correctly -- correct, then it's all about putting it in. And I think the consumer who is the customer in the hotel drives the behavior by continuously showing up and saying here's my business card. I'm not going to continue to do this. That's my thought.

DR. BRAILER: That was clearly the thinking in this Workgroup. Let's turn to Doug and there was another hand. Kevin was that you? Doug and then Kevin.

DR. HENLEY: I would agree with David's comments. Remember we adopted a recommendation I think in the previous group about making sure that PHRS were interoperable with EHRs. So assuming that to be the case -- and we're doing pilots to test all that -- then if the patient shows up in my office or whatever, it doesn't have to be re-keyed, it will be interoperable with the EHR just plug and play and it's there. And the data goes either way.

If the patient has entered new data at home, that gets plugged into the EHR and updated into the EHR. If the physician updates the EHR as a result of that visit, it goes back the other way.

DR. BRAILER: Okay. Kevin.

MR. HUTCHINSON: In this particular pilot, I agree with Adele's comment. I think that maybe we could more descriptive on what we're talking about with respect to a pilot. Because that is exactly what the pilot would do is to have physicians as part of the pilot and patients as part of the pilot that are not using the clipboard for a select group of patients, with select conditions to see the value that goes into that. But that would be under the definition of what we consider to be a pilot.

And in some cases where there are EHRs available and that's being downloaded, that's right. Where EHRs may not available, we would expect the data to come from payer systems, pharmacy systems, that could pre-populate the information with those PHRs as well.

DR. BRAILER: Other discussion on either the point that Adele raised or on this recommendation more globally?

Adele, are you comfortable or do you want to offer a revision?

MS. MORRIS: I'm comfortable with the wording. I find it very general. I think I'm looking through the discussion in our -- the papers and I couldn't see, like, that crystal clear vision of how this recommendation maps to the discussions we've been having about the problem we were trying to solve.

And I think it's incorporated in here. And maybe all we need is an understanding of the objectives. So I don't have any specific edits to the language but I just kind of like the idea that we have a meeting of the minds of the objectives.

DR. BRAILER: Sure. Yeah. To some degree, these, once they're enumerated after the decimal point 2.0 and 2.1, operate as a family together, so you do have to read this in the context of 2.0. The spirit was to make sure that when we do these pilots, which we have pretty ready mechanisms of reaching out to clinicians for, that we also bring consumers along, given that that's a novel inclusion, in this project.

So I think together they do read as a system, making sure we cover the whole water front. Any other discussion here? Bill?

DR. WINKENWERDER, JR.: Just one other thing, and I think the big challenge everybody faces in maintaining good and accurate and up to date registration information is the constant movement of individuals, you know, in society. Their addresses, phone numbers, contact information, just changes all the time.

So, really whatever is done here ought to highly focus upon something that is the individual directed or consumer directed with the ability to update from that point because providers -- it doesn't matter how hard we try. We're always behind, you know, in about a 20% error rate, at best.

So, whatever we can do to allow the individual to update his or her personal information I think is the direction we've got to go.

DR. BRAILER: Okay. Any other discussion on 2.1? Colin?

MR. EVANS: Just one comment. I think the other party here that's highly motivated for the potential efficiency benefits that come from this are employers. And I'm not sure whether the group meant, when you said in 2.0 “and private sector partners” you meant employers, or whether you meant private providers of healthcare. But I think -- I don’t have to do it, but I think enrolling a target group of employers that would be highly motivated.

I think a lot of consumers feel individually powerless to make this thing happen, but if they were backed up by their employers, making it a condition of doing business, then I think that would give a lot more impact to some of the recommendations.

FEMALE SPEAKER: Thank you for the suggestion.

DR. BRAILER: Okay. Any further comments on 2.1?

In the absence of those, we will treat it as adopted by consensus. Let's turn to 3.0.

MS. DAVENPORT-ENNIS: And 3.0 as we know from earlier discussions, this is a cross-cutting recommendation. And when we had the electronic health record discussion, this was approved.

There was one point I would like to call out here on our slide program. And that is that the Community should create a consumer empowerment subgroup comprised of privacy, security, clinical and technology experts which we agreed to earlier today in the consensus.

The next sentence is very important to members of the Consumer Empowerment Working Group. The subgroup should frame the privacy and security policy issues relevant to all the Community charges, and solicit broad public input and testimony to identify viable options or processes to address these issues that are agreeable to all stakeholders.

And I think that sentence is very important to the Consumer Empowerment Working Group and candidly I think it's equally important to all of the other breakthrough groups that are making the same recommendation. And so, we fully concur with the consensus that was adopted earlier today but just wanted to call attention to this point in the process.

DR. BRAILER: This recommendation, Nancy, has consensus in your Workgroup?

MS. DAVENPORT-ENNIS: It does, it does.

DR. BRAILER: Very good. This has been adopted twice. Is there further discussion on this?

We adopt it again. I think you had some discussion items today, too.

MS. SPRINGER: We do have several and it's important to underscore that the Workgroup recognizes that consumers need to have a certain comfort level with the privacy and the security of the consumer information and that candidly consumers are often the last ones to be engaged in these types of discussions.

And so, our continuing concern will be that we continue to find ways to bring them in, whether it's pilots, whether it's throughout the whole effort. But the consumers are involved. They're the ultimate audience and focus for our Workgroups. And that we need to deal with whatever policy issues or barriers might exist that might need to be dealt with in order to make sure there's general public comfort with the direction that we go in.

We recognize that additionally, that the recommendations that we make and continue to make are going to be subject to scrutiny, they're going to be subject to periodic review, and candidly that there will be fine tunings and revisions that occur as we go forward. There are certain questions that we think will come up.

We've listed a few of those in the materials but some of those deal with the market. How much do you let the market just kind of find its way and allow for innovation, or how directive should we be? Are there minimum criteria, minimum sets of standards and how far do we go and what's the right balance that we strike there?

So I think thank the Workgroup expects, and anticipates that it will challenge itself and be challenged from external sources in identifying those issues. And candidly, again, ones that we talked about today are a big start in that direction but we've put a few out here.

DR. BRAILER: Okay.

MS. DAVENPORT-ENNIS: There was also much discussion within the Consumer Empowerment Working Group around the issue of certification. Some think that certifications of PHRs would be a positive voluntary market-based mechanism to ensure privacy and security of personal health information and interoperability. Some think we don't know enough about what consumers want to develop requirements for PHR certification.

Would certification of PHRs advance the specific and the broad charge? Is the timing important and is there a sense of urgency, given the diversity, complexity, and mobility of today's population, and the demand for availability of PHRs at the point of care. And I cannot leave this point without citing, if Hurricane Katrina did not teach us anything, it certainly taught us very difficult lessons that we have to be prepared at a moment's notice to have personal health records available to consumers, and available to medical providers, so from the point of view of our working group, item number four, yes indeed, the timing is extremely important.

Should the Workgroup's recommendations in this area include a definition, a process, a measurement system? Again, these are universal questions, that as we are as a working group, we will be addressing and providing concrete answers to. We invite each of our colleagues

within AHIC to look at the questions that we've posed. And if you have thoughts around these questions, to relay those to us so that they can be part of the consideration as we continue the work we're doing.

DR. BRAILER: Clearly the personal health record is several years behind the electronic health record in terms of technical sophistication, the user need, just our experience with it, the technical definitions. And really what you're signaling to the group is where your Workgroup is going is really beginning to plow into that issue: go to your broad charge.

So this is a good time for anyone who is on the Community to give any thoughts or guidance or advice to the Workgroup because they're going back immediately after this meeting to reload to begin thinking about this much broader charge. And I I would add, on a longer timetable, we know that people can't keep working at the rate that we've been pushing.

So with that, let me just open the floor to anyone that has comments or thoughts or questions that can help shape their deliberations as they go offline again.

MS. GELINAS: Nancy, I know we've talked about this as well but I don't think that we should delay at all the third -- or forth bullet around timing being important. We shouldn't underestimate the consumer's interest in doing the right thing. If we didn't learn from Hurricane Katrina, then we're not ever going to learn.

So giving the consumer the ability to create their own personal health record and the 80/20 rule, start with the 20% that are ready, that are electronic savvy, that want it to happen. But we have a whole region of the country that I think that if you were to use them as a use case, as a starting point they would be very, very receptive to anything that would be recommended around getting PHRs to a much more sophisticated level.

MS. DAVENPORT-ENNIS: Lillee, thank you. I think you are certainly reaffirming the members in the working group in many regards and I think you are right. I think the Secretary has admonished us on more than one occasion that entire movement into personal health records and electronic health records will indeed be the result of the consumer leading it. And the consumer can only lead it if the consumer is given the opportunity to be engaged.

FEMALE SPEAKER: If I could just follow: yesterday we, at the Veteran's Administration, we met a VA consumer. He actually addressed us. Showed us his own personal health record that's created online, so it's not vaporware. It's something that actually exists. And he went in and showed us how he tracks his blood pressure and his weight and absolutely says that the reason he's here today is because of that consumer-oriented medical record that he was able to take control of his own health and bring his health into alignment. So I was so impressed with that gentleman. I wish I could recall his name. Orlando, I think. Mr. Sellers.

And we've talked a lot about vaporware versus what's in place now. And this was clearly in place. And I think he made it clear that he wasn't very computer savvy. You know, he's been around a while but he sure made it clear that once you begin, you can begin some place and make a huge impact on your health.

MALE SPEAKER: Made it feel like our work was done well up there. I hope there are many, many stories like that in a few years. Doug?

DR. HENLEY: Well, consistent with the conversation that Nancy and Lillee just had, while it's important that we have the standards to ensure interoperability of PHRs and EHRs, I think it is too early now to have a certification process for PHRs because we need the innovation to continue in terms of determining what that really is going to look like, much less 6 months from now, but 2 years from now, in terms of what consumers need.

So to me, the interoperability is the key issue here that we're addressing very effectively. And I think it's probably premature for the certification process to occur in that venue, compared to the EHR world, which, as you said, earlier, David, is much more mature.

DR. BRAILER: Right. Other thoughts? Any other advice? Tony.

MR. TRENKLE: I would differ a little bit from you, Doug. I do agree with interoperability is very important. But I think certification is also important, I think it is something that would evolve over time. Last year we did a request for information that went out to the Community to ask about CMS's role in relationship to PHRs. And one of the themes that came back strongly from the people who responded who came from a wide variety of groups was that there should be certification and that CMS and HHS should play a role in helping with that certification.

And we're concerned as our beneficiaries become more involved with PHRs or their families, that there is certification in place at least to allow them privacy and security concerns to be dealt with to some extent. We realize it's an evolving area. We realize there's going to be changes over time and requirements and other types of activities but we think it's not too early to really begin the certification process.

DR. BRAILER: I mean there's no doubt that as innovation occurs -- and I would argue it is still happening a lot in the electronic health record world -- that certain minimum features probably do need to be agreed upon that are immutable. And the question I think, becomes one of, "a", what they are, and "b", what form do they take?

And so this is something that I'm sure the Workgroup will be looking at, and this group will have a chance to discuss in more detail. And perhaps, Tony, I know you've shared some of those findings with the Workgroup, perhaps at the right time, key elements is that RFI response could be shared here as part of our discussion as well. Good, thanks. Bill.

DR. WINKENWERDER, JR.: David, just would be interested in the perspectives from our representative from Blue Cross Blue Shield with respect to the discussions between the insurer community and AHIP, America's Health Insurance Plans, and Blue Cross Blue Shield, with regard to any emerging vision they have with respect to PHRs since I would expect that health plans may well be one of the principle sponsors or creators of that kind of tool for their members.

So particularly in light of consumer-directed products and high deductible plans and so forth.

So, what can you -- how can what you described of this ongoing conversation help drive maybe a minimum baseline of what a PHR ought to include. I don't know how that gets all the way to certification. But sort of a minimum baseline of information or data or what have you.

FEMALE SPEAKER: We'd be happy to share the experiences we've done: focus groups, we've identified what are the minimum data elements we think should be part of the PHR. We're looking at how to get consumers to feel confident in using consumer information and also looking at providing some level of trust with the physician community. Those are things we're exploring and will be pilot testing and would be happy to share that information.

MALE SPEAKER: Okay. Very good.

DR. BRAILER: Other discussion on this topic?

Thank you all very much. Thank you for your Workgroup, thank you for your report. With that we'll turn to Biosurveillance and hear from Julie Gerberding, Chip Kahn, and Mitch Roob.

DR. GERBERDING: Thank you. I'm here to start the discussion of the Biosurveillance Workgroup. And we're going to start on the first slide by just acknowledging the various members of our Workgroup, including my colleagues Charles Kahn and Mitch Roob who have diligently cochaired with us a number of workshops and Workgroup meetings as well as an astonishing array of members.

One person who's not included on this list is Laura Conn from CDC who's been doing a very large share of the work behind the scenes to help prepare us, and make our Workgroup meetings go well.

Our broad charge is defined here. Particularly, emphasis on supporting realtime and nation-wide public health event monitoring and rapid response management. The dual functions linking public health and the health care delivery community. And our specific charge so that within one year essential ambulatory care and emergency department data are derived from existing electronically enabled health records to be transmitted to authorized public health agencies in a standardized and anonymized fashion within 24 hours of generation.

So, we have been working hard on trying to develop some specific recommendations about the charge and I think for the record, we would define consensus in our Workgroup as good enough to go ahead agreement but not necessarily unanimity in all cases. So I wanted to be specific about that as we go forward.

We did think about a number of scenarios and potential utilities for the kind information we would be gathering. So we considered a variety of circumstances that would require realtime information from electronically enabled health records as a very important component of maximizing our ability to effectively respond and manage certain public health situations and threats.

Scenarios included environmental signals from other detection systems, outbreaks of illnesses,

suspicious particular threat or emerging infectious disease, intelligence warnings, our ability to monitor an event once it is in place, which is often an under appreciated element of these kinds of information and [unintelligible] support systems as well as estimates of scope and magnitude of a particular health threat.

The background here really is a definition of the specific functions that we would want to have supported with this electronic health data. Again, much emphasis traditionally on initial event detection. The so-called syndromic surveillance sort of of approach acronym which we don't necessarily endorse at CDC but the concept of using realtime health records to detect changes in health status in a community that indicate an onset of an event or an outbreak. But also just more generic situation awareness to assess the ongoing health status of a community, to manage an outbreak, and to successfully use the information in the system for decision support and knowledge management around what are the appropriate interventions and how well are they working to protect and improve the public's health.

We have two very significant groups of stakeholders from the public health side there were engaged in the conversations our Workgroup had. ASTHO, the Association of State and Territory Health officials as well as NASCHO, the National Association of Sitting County Health Officials, both participated in a survey process to give us some specific information.

From the state health official perspective, we learned that in general there was broad-based acceptance of the importance of this kind of system, that 89% of the states who responded already have an active relationship with at least some clinical partners to develop the capacity for electronic exchange for notifiable diseases or surveillance. The main obstacles for either participating or scaling participating was the lack of [unintelligible] and the trained personnel able to connect and utilize the information.

Similarly from the city and county health officers, we learned that, again, the vast majority are actively involved with clinical partners for local preparedness planning. Many of them expect to receive information from electronically enabled systems in the near future, but the obstacles for participation again included lack of funding, lack of technology, infrastructure and lack of personnel.

So these surveys should not be construed as necessarily representative. For example, the city survey, and this last survey, are large populations, but nevertheless I think they signal to us a good enough to go ahead constituency of interest in evolving capability that indicated we were doing this at the right place at the right time and that we should be able to make accelerated progress.

So I'll just end with the key issues here and we'll move then to discuss the recommendations. Key issues really relate to what is the content of the system, what are the specific data elements and the technical requirements necessary to support the functions I defined. How can we share data across the public health system so that people at every node in the network have the information they need to make the decision and interventions that they are responsible for? How can we protect the confidentiality of the people included in the system.? And how do we

really know that we have what we want and that it's working and how can we monitor and evaluate the impact on a rapid time scale?

So I'll move to my colleagues to pick up where I left off.

MALE SPEAKER: I'll go through the recommendations. Let me sort of start off by saying there was a number of themes to start off the points that Julie just made, that I think are important here.

One, there was a consensus that the Secretary needs to know and needs the information. That CDC needs the information in order to meet the challenges of various kinds of public health threats. Second, obviously, from the provider's standpoint, it's going to be voluntary in terms of cooperation.

Third, need to know here, only information that you need to know is an important theme because we want to minimize the requests and requirements on those who choose to participate, provide information. Opportunistic, the assumption is that there now is information available or easily tappable in electronic systems in hospitals and with other providers that might not have previously been as easy to tap into.

That it needs to be same-time or as close to same-time as possible. That it has to be dynamic and obviously -- and this was a constant theme through the discussions -- that we need to protect the prerogatives and responsibilities of state and local public health as well as CDC and federal public health.

I'm going to go through the recommendations now and the one difference in our structure from the earlier recommendations is for the Recommendation 1 we went through all of 1 and did the exception -- or did the consideration at the end because they're sort of cumulative, each of the recommendations.

So I'll start with Recommendation 1, which is that by 6/30/06, HHS would act in collaboration with state and local government, public health agencies, and clinical care partners to establish, convene, and oversee a data the steering to carry out the activities described in the recommendations below. And Recommendation 1.1 would be the steering committee will identify the data elements and the appropriate filtering of data from ambulatory settings, emergency departments and laboraties, as well as hospital utilization data, needed to enable key public health functions as outlines above.

HITSP would identify the technical specifications for the these initial data requirements by 9/30/06. And CDC and others should provide HITSP with the public health expertise and funds necessary to perform these tasks.

And finally by 8/15/06, the data steering committee should identify the data sources and requirements necessary to allow for the collection of a limited set of data across a broader geographic area. So the key here is setting up a data steering committee, that working within the criteria I described, would come up with the minimal data set that would be most helpful to

public health particularly at the Secretarial and CDC level. And they would come up with a data set and then the other mechanisms would be developed as described here. So, Mr. Secretary, that's the Recommendation no. 1.

DR. BRAILER: Okay, with that let's open the floor for discussion for 1.0, 1.1, and 1.2, broadly or with respect to any particular. Robert?

MR. CRESANTI: Thank you. Just a very quick question. What -- this brings to mind a demonstration that I saw some time ago about four years ago by the Red Cross. They were using a geospatial map of the United States. I don't know if you engaged productively with them in conversation at all. But it reflected by city, by major Red Cross station in the city, the number of blankets they'd distributed, the number of meals that they -- gathering data on their daily operations. And it seemed to be fairly robust. And you could see live updates coming through, streaming as they showed this demonstration model.

Are we -- have we gone to school on some of those things that are already in the marketplace and that are being utilized at the moment, and are we working with organizations like Red Cross that aren't necessarily state or local governmental agencies but also one of the legs that we rely on in this country to handle disasters like Katrina and other things?

DR. GERBERDING: The short answer is, yes, we are.

MR. CRESANTI: Does that provide a model for us to build?

DR. GERBERDING: What we're talking about here are electronically enabled data that already exist and so we're basically multi-purposing existing information. The system that you're describing in particular, Red Cross require manual data entry and are, you know, a different premise. But the broader concept here for us as a response agency is the expectation that electronically enabled health records will be one opportunistic source of information that would have great utility for a variety of circumstances but it's not the only input that would be necessary to either detect or manage a particular incident. So, this is a subset of a broader set of information opportunities and needs.

MR. CRESANTI: Thank you.

SECRETARY LEAVITT: Dr. Gerberding, you and I have spent time talking at various points about an even closer integration of what has been happening at CDC on this subject for the last 2 or 3 years with this more short-term deliverable we're trying to produce. Any thoughts about how we can accelerate that?

DR. GERBERDING: I think that I would characterize it, and please correct me if I'm wrong, but I would characterize the vision for the product of this Workgroup as a very broad and shallow connectivity. But connectivity is probably the biggest value of what we're doing here in the short run, is getting systems to exchange any information is a giant leap frog ahead of where we are right now.

The CDC system, the bio-sensystem is a narrow and deep focus. It's not going to be able to come on-line on this time frame with the depth that we would ultimately like to have. But over time, these two systems should naturally become a merger where we have not just broad, but we have deep capability as we define our needs in a more mature and evaluative mode as we go forward. It would be impossible to try to get that depth of data integration across the network of sources in the short run. But ultimately we ought to be able to get there.

SECRETARY LEAVITT: I have defined in this group before, efforts like the one at CDC as the pure vision. And what we're trying to accomplish the immediately achievable. And I'm anxious, feeling the sense of urgency to create the immediately available.

One of the things I would like to commit myself to is to spend some time at CDC with the team that currently works on the pure vision to more closely link this immediately achievable up. I would like to do that in the fairly near future.

DR. GERBERDING: Thank you.

MALE SPEAKER: In the spirit of supporting this , and let me just endorse this, this suite of recommendations, both in terms of immediacy and breadth, as well as ultimately, depth as well, I think one of the important contributors to this information are federal partners, certainly, in VA, Department of Defense.

I just want to offer a friendly amendment here. It is appropriate that we add federal partners as well to the list of interested parties on the data steering committee and make our commitment to share data both with breadth initially and depth as we work together.

SECRETARY LEAVITT: I would assume that's a friendly amendment.

MALE SPEAKER: Let me ask a quick question. Maybe I don't know the answer to this question, but do your VA hospitals also -- do you share with local government and state government already? I don't know.

MALE SPEAKER: Yeah. Yes. The answer would be is that we would have the same sorts of relationships that any health care facility would have. Obviously there's another opportunity to complement that.

SECRETARY LEAVITT: Any other comments about recommendations of 1.0, 1.1, 1.2?

MALE SPEAKER: Mr. Secretary, [unintelligible] and then the DOD's perspective of wanting to participate in the steering committee as well. Dr. Gerberding mentioned the Biosurveillance program, and you had mentioned the need for immediate response.

Just as a frame of reference, over the past 3 years under the Bio-sense program we've already transmitted 150 million records to CDC, electronic clinical records. So we think that as part of the committee we can contribute both experience as well as some detailed information to the group.

SECRETARY LEAVITT: Building on what you said and what Dr. Gerberding said, I think we get another clear glimpse of this. There is a pure vision out there that people have been working on for a long time that has been populated by data already in large measure from government facilities, government providers, and others, and I think our vision originally was -- continues to be -- that in the short run maybe we can capture a lot more data from many other sources that can be immediately available and get at least the immediately available operating as we work toward the pure vision. And I think that's what's represented here. And I think this is, I think, a good piece of work. Would there be any objection to the acceptance with the amendment made?

Hearing none, then, I will accept as consensus 1.0, 1 .1 and 1.2. And we'll now ask you to go to 2.0.

MALE SPEAKER: It was clear from the discussions that one, we need to develop the infrastructure and that needs to be based on an agreement and recommendation to envision the development of a memorandum of understanding between the CDC and the state, local entities that will cooperate in this effort to assure both that there's simultaneous reporting of that data that the data steering committee chooses to have as part of the initiative.

And second, that memorandum of understanding would clearly assure state and local entities that their traditional responsibilities and -- for both investigation and enforcement -- would not be impinged that was collected and provided to CDC, simultaneously with them for this initiative from health care providers primarily.

SECRETARY LEAVITT: Any comments here? As I read this, I will say, as I read through this recommendation and I believe the next one. Maybe it's the next one after that. Maybe it's just this one ... This is primarily what I would like to get into when I get -- when I meet with you, Dr. Gerberding at CDC.

Somehow we've got to take the resources being plowed into the pure vision and find a way to integrate it. And I think this might be the place to do that. I don't -- are there any other comments about this?

FEMALE SPEAKER: There's a practical issue here just in the interests of fairly representing my state and local colleague and that is that there is a debate about who should be the signatures to the memorandum of understanding. So for example, if we have an agreement with the DOD and the VA for data exchange and shared utilities, and we didn't go to 50 states to counter sign that agreement. So, when we're dealing with the source being a multi-jurisdictional entity, there have been concerns about not simultaneously getting the local and the state place where specific hospitals or clinics in that enterprise are located to similarly sign in.

So I think what we would like to do is to interpret this -- the intent of this is to assure state and local health agencies that we're not trumping their responsibilities or their source but that we are interested in having this work for everyone. But we need to do it in a way that's expeditious and respects the source as well as the jurisdiction.

MALE SPEAKER: My sense from the discussion at the Workgroup, though, was that ASTHO, and NAHCO could act as representatives for the public health community. And that may be the best way to facilitate this agreement being developed. And it will be voluntary. But hopefully all areas across the country would agree to take part.

SECRETARY LEAVITT: Dr. Brailer, do you have a comment?

DR. BRAILER: Well, this is a topic of a substantial amount of dialogue, which is not so much about the form of agreement is. And MOU directly between federal and state or local participants, or some other mediation but the content of it. What it is that's being agreed to do, who pays for it, and how this relates to not only the goals that are in scope of this current breakthrough discussion but of the broader breakthrough, that I think is posed before us now.

And I think one way of framing this discussion on the recommendation was how much can we bite off with respect to the narrow, specific charge, the one-year charge, and leaving untouched the broader charge, and how much of this should take into account the thinking that goes as part of the broader charge. Maybe what you call the pure vision. And so I think it's not a question of should it be done. This should be done, and I think we've heard consistently that it should be done.

The question is when in the life cycle of this effort should it be done? Now or some point soon hereafter when we're able to get better ideas of scope and how these mechanisms of relating to each other can come about. It's a judgment call.

SECRETARY LEAVITT: Any other discussion about this? Yes.

FEMALE: I'll maybe just ask the wicked question and that is if we just look at the main question here, it talks about traditional roles being protected. And I've struck with the amount of variation that exists at the state and local levels.

As a practical matter, if there were a true disaster, that was multi-state, does this mean that the local and the state interventions are first at bat, so-to-speak? At one point, where's the glue that ties it all together?

MALE SPEAKER: This is -- my sense of this is that we're talking about information here. That there are all kinds of agreements and ways of operating between the federal level and the state and local level in terms of actual events. And this would not affect those.

However, the agencies perform generally -- would be how they perform. This is simply providing the information to the secretary. And actually if you cross over into that area you're talking about then you get tremendous controversy. But I think if you keep this simply as, this is the radar for the secretary and CDC and then when something requires response they respond in a way that they've already -- there's a long tradition and they have agreements to respond.

FEMALE SPEAKER: The difference is that in the past there would be time gaps between each element in the network knowing that something was going on. Now if we're in an environment

where there's simultaneous knowledge, there is the opportunity for a push from the top-down, so to speak, as opposed to waiting until the bottom up brings something to our attention. That's the desire, is to shorten the time frame to recognition and response.

But until we get reassurances, it's a point of concern. And I think we can't address that until we can demonstrate we're trustworthy in that regard, there will be ongoing need to be thoughtful about how we proceed.

SECRETARY LEAVITT: David, you indicated that the question was how much now. Are we prepared to accept this or should this be the subject of more discussion?

DR. BRAILER: Well, I think this is certainly could be accepted at this point. It's in a relatively immature state. We don't know at this level what we want to agree to. So if we have urgency, it can be accepted. This is something though, that the passage of some time, even if we hold this over to the June meeting and have the Workgroup do more of their dialogue, have your visits, we certainly could then be in a position to have much more specificity here.

Julie is right that the ultimate question is one of how do we preserve the traditional roles of state and local public health, while we're building a near simultaneous response infrastructure. And that causes a need for a lot of debate, that won't be resolved even in these memoranda. So I think it's either now or the June meeting.

And that would be the frame, otherwise we lose the urgency. We will get a lot more information between now and then, on the other hand, we'll lose essentially, a month of clock time in terms of progress.

The question, ultimately, I think you want to deal with is one of how much, again, does the scope of this narrow charge touch the broader charge in terms of how much do you want to bring back into this? So there's one set of memoranda that go out for one broader set of purposes as opposed for this specific purpose.

SECRETARY LEAVITT: This is federalism in a networked world. It's a very complex…

DR. GERBERDING: I would say that we also already have memorandums of understanding that have been effective with various organizations. We are implementing connectivity in a variety, and growing list of medical context and local and state jurisdictional issues have been resolved. I think we have models that can work.

SECRETARY LEAVITT: I'd be inclined, I think, to ask you to consider accepting this with the understanding we may want to bring it back. I'd like to spend more time at CDC understanding how we can do this. Would the group feel all right about that? Let's just have the minutes reflect the fact we'll likely bring this back.

MALE SPEAKER: Mr. Secretary, if I could just add, just from my experience with this -- which is brief -- there's a great panel that makes up this Workgroup. But at the end of the day you have all of the governance issues we just discussed. But you before you even get to the

governance issues, you have these issues of what is the "it"? And this data committee that was in the early recommendations is really key to that. And although some of the people on the body of the Workgroup would sit on that, there would be a host of other people that would sit on that.

And let me suggest I really think that needs to get going so that the "it" can be defined, which I'm not sure the Workgroup is the right entity to decide. And once that's defined then that could fit -- may fit right into all of the agreements and work that's already done at CDC on other matters, bio-sense and other matters.

I think you should -- My recommendation would be to get that going because that's sort of the beginning. If you put that off a month or two months, then it's going to be that much longer before those same people have to get together and answer those questions.

SECRETARY LEAVITT: I think we should clearly get that moving. One of the things that I'm feeling a little bit impatient about is we have been working at the pure vision for 3 years now, or 4 years now. Or some number of years. How long has it been?

DR. GERBERDING: Well, bio-sense for 2 years. But the broader and standards and so forth for 4 years, 5 years.

SECRETARY LEAVITT: And we -- I guess what I want to say is, I want to drive this hard, but I want to make sure that we're integrating it closely. The fact is the federal government pays through grants to health departments, the vast majority of what happens. Mitch, tell me if I'm wrong about this but we're paying for most of this. And I understand from my days as a governor and my card-carrying federalist instincts why this discussion has to be held. But we are, in fact, reinventing federalism in a networked world here. This is a classic example of how you create new checks and balances and you honor the respective sovereign roles of different players in a networked world.

And I'm anxious to drive this one hard and I would like to ask for your acceptance. We will assume it's approved as a consensus. And then I would like to bring it back and we'll get started on the data -- what did we call it? The data steering committee right away. Good. Let's go on.

MALE SPEAKER: The next two recommendations: 3 and 3.1 have to do with confidentiality and patient privacy. Let me stress to begin that HIPAA does allow for public health agencies to communicate with each other, but the notion in our discussions was that the information that would be brought up to the federal level through in this program would be anonymous, at least by name.

The notion was under the recommendation by 8/30/06, HHS should develop a sample data use agreements to facilitate the sharing of data from health care providers to local, state, and federal public health agencies. HHS would also offer practical implementation guidance to data providers and state and local public health agencies to address HIPAA concerns about transmitting the data.

The next item - 3.1: In the discussions about privacy and confidentiality, the issue was raised, since public health has a protection under HIPAA. Clearly, this kind of function is protected, but the group felt that it was important to inform those whose information might be used that it was being collected. And so recommendation 3.1 would have HHS, in collaboration with private experts, state and local governmental public health agencies, and clinical care partners, develop public communication materials to educate the general public about the information which is used for biosurveillance, including the benefits, the public's health, improved national security and the protection of patient confidentiality by 9/30/06. So that's the package sort of in response to the privacy and confidentiality issues.

SECRETARY LEAVITT: And there is a crosscutting -- this is part of the crosscutting issues we've been discussing. Any conversation here or are we prepared to move forward with acceptance? Kevin?

MR. HUTCHINSON: I think my only comment would be timing of September 30th, '06, is that understand we have a lot of issues in the public eye right now around phone numbers and other things going on. Is this the right time to start talking about health information that's also being collected? And my concern with that is that what if a patient wants to opt out of that information? Do we have an answer to that question?

SECRETARY LEAVITT: If it's anonymous data, can you opt out of anonymous data?

MR. HUTCHINSON: Even at a state and local level?

MALE SPEAKER: I mean, I -- my response to that is that health officials, you'll get to. You don't -- if you present in an emergency room with the plague --

MR. HUTCHINSON: I agree with that. I'm totally agreeing with you. [laughter] I'm not fighting that.

MALE SPEAKER: Okay. So that's exactly the point, though, why I think it's important from folks who are -- who know far more about the -- who have spent a lot of time worrying about this, is they view this as the Achilles heel of electronic records, which is that unless we -- because this effort will move more -- perhaps more quickly, right, and potentially has more media coverage than the rest of the breakouts that we're doing that it's very important that we articulate the general welfare component of transmitting this data quickly and anonymously. And that making sure people know that it's happening and at least gain to acceptance of that.

And so I think, actually -- Kevin, to your point -- that the importance of doing that -- it's even more important now that they don't discover that this data transmission is occurring by reading or hearing it on Fox News or CNN, that we do it very overtly in a way that's sensitive and that has broad and bipartisan support.

MR. HUTCHINSON: I just highlight it because this is no small issue because --

SECRETARY LEAVITT: And I'd like to make clear, NSA is not part of this panel. [laughter] That we know of.

MALE SPEAKER: As far as you know.

SECRETARY LEAVITT: As far as I know. [laughter]

FEMALE SPEAKER: I'd just like to, you know, make sure that we also put this into context because the exact same data have been coming to the federal government for about 50 years under the notifiable diseases capabilities. The only difference is that we're bringing them in electronically as opposed to paper records, so the information exchange is not changing. It is the speed and the volume that's changing.

MALE SPEAKER: I 100% agree with [inaudible]. I think that the -- and the reason I highlight it is because of the effort to create a plan. If we're going to do public education, which is, as I understand, 3.1 to be around what is actually occurring, this is a huge task to answer those questions that will come up about a patient's rights to that information or lack thereof.

SECRETARY LEAVITT: I would recommend that we ask at our June meeting for an update on progress and evaluate the 9/30 deadline based on progress. But that we accept the recommendation as it's offered and proceed forward with no objections. Good.

MALE SPEAKER: Finally, in the fourth set of recommendations, have to do with program evaluation and sustaining the dynamism of the program. Because obviously, over time, the number of data collected may increase, and also, the data that's important at a given time may change. So you might want to change the date you ask for from providers.

The first part of this recommendation is the CDC, state and local governmental public health agencies, and clinical care partners with first-hand experience in managing the ongoing biosurveillance program should design and conduct evaluations of the biosurveillance breakthrough. These parties should establish goals, develop outcome measures, and establish metrics for evaluation by 9/30/06.

And second, recommendation 4.1, the data steering committee will monitor the progress, continuously interpret the results of program evaluations, and assess the value of the data. The committee will use the results of program evaluations, taking into account the minimum data necessary for public health purposes to inform recommendations for modifications to the program. The committee should consider a large-scale limitation and suggest modifications to the collection when sufficient evidence exists that demonstrates the value of the information derived or lack thereof. The committee should monitor adherence to the protection of patient confidentiality.

Obviously, any issues that arise will be brought back to the committee. So that would be the final recommendation, and so it begins with the committee setting up the program and ends with the committee evaluating the progress of the program.

SECRETARY LEAVITT: Any comments? Any objections? Hearing none, we would accept that as a consensus. Declare a consensus, and thank you very much for the good work that you have done. I believe that concludes what -- oh, that's right. We have a very important one that -- anxious to have so --

MALE SPEAKER: Okay. Thank you all very much. At this point, we are about a half hour ahead of schedule and we will now turn to the Certification Commission for Health Information Technology presentation from Mark Leavitt, the chair of the commission. Mark, thank you for being with us.

MR. LEAVITT: Thank you. Thank you, Mr. Secretary, Dr. Brailer, and members of the community. I'll be brief because I know you've had a long day. If you think I'm going too slow, just let your lids sag a little bit and I'll take that as another speed-up signal.

If you we could go to the next slide. What I want to do is just introduce you briefly to CCHIT. Most of you have heard about it, so that will be very brief. The essence of my report is some recent events. Mr. Secretary, you've talked about your sense of urgency and wanting to see tangible results. We actually have a tangible result. So, we'll talk about that. We have released Criteria for Certification of Ambulatory Electronic Health Records. We'll talk about that, and then I'll give you an overview of the criteria. I won't go into details and talk about next steps and save plenty of time for questions.

Go to the next slide. Thank you. CCHIT is a voluntary consensus-based initiative. We were founded in the private sector by three health IT associations. We broadened our funding base further in June of 2005, and then we were awarded the contract from HHS for compliance certification, and in doing that, we work alongside the other HHS health IT contractors.

Our goal is pretty simple, with a mission of accelerating the adoption of robust interoperable health IT, we try to do four things: Reduce the risk of health IT investment by providers; facilitate the interoperability of the systems they're investing in with the emerging network; enhance the availability of incentives and/or regulatory relief; and while doing all of this, make sure that the privacy of personal health information is not compromised as we move from a paper to a digital world.

Recent events: On May 1st, we published our final 2006 Certification Criteria for Ambulatory Electronic Health Records. And I'll talk about how we arrived there. It was an arduous, 18-month long process. Then two days later, we launched our certification program. We started taking applications from the vendor community and this was kind of one of those cases of: If you build it, will they come? And we waited anxiously during the 10-day window, and we're very gratified to see a very positive response from the IT vendor community. We had more than two-dozen applications.

And the other good news is that it represented a very good spread over the marketplace. There was some concern: Would it be only vendors that served the large clinics and the high end of the market that could afford certification in money or in time? And that doesn't seem to be the case. We've got vendors that serve the smaller offices, mid-size and the large clinics.

So we're pleased by that, and we are actually now in the midst of our compliance inspection process, and we expect to have our first announcement around July 10th. We're making the date approximate because we'd like to get through testing all the products in the batch and not disadvantage any of those, and there was no way to predict exactly.

But I believe we can do that because I wanted to just also tell you we've had a terrific response from the community in terms of willingness to serve and work with us. In developing the criteria, you know, we had probably more than 100 volunteers and probably hundreds of people besides that that participated by commenting or providing input.

Well, when we put out a call for jurors -- and this is not a fun job. This is eight hours in front of a computer screen observing a demo for 250 tests. Not fun. We had more than 175 volunteers. About 80% were practicing physicians who see patients willing to -- and then they said -- we said, "Are you available Monday, Tuesday, Wednesday, Thursday, or Friday?" And some came back and said, "What about Saturdays?"

So I think the providers are interested in this, and I was gratified. So we think we can ramp up and get all the products tested in the first batch, and then we'll continue quarterly inspections.

To the next slide. A little bit about how we came up with the criteria. We realized this could be a powerful force in the marketplace. It could change the fortunes of companies that do millions of dollars of business, so we take the responsibility very seriously.

We engaged diverse stakeholders in the participation from providers, vendors, providers, payers. We have both the public and the private sector involved. From the public sector: Whether on our commission or our Workgroups or giving comments. We heard from, obviously, HHS, ONC, CMS, the Veteran's Administration, CDC, NIST, and others.

And we also followed processes to try to guarantee openness and transparency. Even though we're in the private sector, we tried to follow the governmental guidelines in terms of that, publishing all of our work products, having three cycles of public comment -- by the way, received nearly 2,000 public comments that we read and responded to in the course of that -- multiple town halls and events to make sure that everyone had the chance to get engaged and provide feedback.

Then the next slide. Oh, if we could -- I skipped something. I wanted to mention that after developing the criteria -- we first published the proposed final criteria in November -- we took it through a pilot test, and we solicited participation. More than 30 vendors offered. We picked six randomly and basically ran the test in pilot form, and evaluated whether the criteria were valid and whether the inspection process was repeatable and reliable.

So now, moving forward. We have released the criteria. As I said before, it's focused on ambulatory electronic health records. There are three sets of criteria. I brought them with me on paper here. There are about 250 functionality criteria, about 25 in interoperability, and about 50 in security.

And besides the criteria, every item includes a road map saying at what year we will require this in-certification. So we're signaling the industry what will be inspected and when. And the road map gives us an excellent opportunity to support the breakthroughs you're working on. We simply put it on our road map and say at which point -- now, we can't put it in at any given quarter, 'cause we have an annual cycle of updating. But we can basically take new needs that we hear about strategically and plug them into that road map and carry them forward.

The next document is just to show you what these look like. I won't go through them in detail, but just to point out: It lists the criteria; it lists the evidence-base, which is the priority of those criteria among the stakeholders; the availability in the marketplace, that's reference to the standards that we're certifying against; and then the road map, which says which year we're going to require that criteria in our inspection.

There are -- about 10% of the criteria this year are provisional, meaning, like on the college boards, there are these questions that you take and they don't participate in your score. They're being evaluated to see if they're good questions, and they're not secret. They're highlighted so that everyone participating knows that those are under evaluation. That's going to be a good way for us to develop the new criteria and make sure that they're appropriate as we move forward. So, those documents are on our web site if you want to see the actual material.

Then, just the next slide. I'll just wrap up with next steps. We'll announce the first results in July, probably around the middle of July. And then we'll launch quarterly cycles, about a 10-day window of applications, testing for two and a half months, and then a release an announcement of the certified products at the end of that quarter.

For next year, we will be doing two things: We will be updating the ambulatory criteria, and we will be developing the new criteria for certification of inpatient electronic health records. Our contract calls for that. We, in our third year in spring of 2008, are supposed to begin certifying the networks. That's a lot fuzzier right now, as you might expect, exactly what certification will be like, but we will begin thinking about that later this year and starting to gather input. As our fellow contractors, the National Health Information Network prototype contractors, start to report out, we'll be listening very carefully to that and also talking to them.

So I'd just like to wrap up by saying that we're really proud to be part of this strategy, to work collaboratively with the community and our fellow contractors. And I also want to take a moment to really thank everyone that's supported our work. I get to sit up here and give this talk, but it's really hundreds of people putting in hundreds and hundreds, even thousands, of hours, and they all really share in any credit for this work. Thank you very much, and I would be happy to answer questions.

SECRETARY LEAVITT: Thank you. Any questions?

MALE SPEAKER: You said that there were over two-dozen applications received. How many do you think -- out of how big a population do you think you might have received, and did those who didn't apply give you any reasons as to why not?

MR. LEAVITT: Yes. Good question. People who have surveyed the marketplace believe that there are on the order of 200 vendors that will show up commercially, although some speculate there are 1,000 or more when you count doctors that wrote a program for themselves and sold it to their neighbor.

MALE SPEAKER: You know someone who --

MR. LEAVITT: I was one of those 30 years ago. [laughter] So I'm sympathetic. But about 200 that are active commercially, so actually -- and it's not a bell-shaped curve because probably the dozen with the largest market share make up two-thirds or three-quarters of the market. And then there's this long, long tail of ones that are -- have very small market share. So actually, we thought we would get 12-15. So getting more than two-dozen was a healthy number.

We can't say how many we'll see, but there will be some cut points. For example, without naming any names, we got an email from a doctor. He said he's developed in the HR. His revenues are $100,000 a year. How can he pay $28,000 for certification? And then they have to say, "Well, how will you develop biosurveillance interface? How will you develop personal health record interface?" I didn't answer that way. I simply said, "Well, this is the -- we've made it as efficient and economical as we can. There is a minimum level of investment to keep the data secure, to improve patient's safety and interface with the rest of the world." So there may be some number that aren't going to apply. That doesn't apply, by the way, to the inpatient world, which is different.

MALE SPEAKER: Yeah, right. So were the two-dozen [unintelligible] in the fat end of the bell -- of the curve, or --

MALE SPEAKER: Yeah. Yes, I think you'll see when the certifications come out, we're getting that end of the curve as well as some smaller ones.

SECRETARY LEAVITT: For those of you who -- most of you will have followed this, but let me just restate it in this context. Recently, we've put forward a proposed rule on a Stark exception, which means an exception to the Stark amendment, which restricted the capacity of clinics or of hospitals, rather, the medical provider organizations to supply systems in the broad sense to physicians and clinics and other providers.

The Medicare Modernization Act provided a requirement that we create an exception so as to begin to further adoption of those systems. In the proposed rule, we conditioned the providing of any system upon meeting this criteria. It's a very important part of the way we hope to move toward interoperability. So today, as we conclude and adopt this, we will have taken a very important step forward in terms of the use of that exception, and I believe created substantial momentum to the point that a large number of those 200 systems will ultimately see it in their interest to achieve certification. The market will demand it.

And I think a great example of a way we can utilize the payer power, if you will, at this table and emerged with the various interests that it can bring wisdom to it. I think that's why this was such an important undertaking. So, Mark, thank you.

MR. LEAVITT: Thank you.

SECRETARY LEAVITT: Any other comments? Yes, Kevin?

MR. HUTCHINSON: Mark, could you just, for clarification purposes, share with the group the interoperability between HITSP and the CCHIT, because for example, vocabulary. Does that fall under standards work to try to standardize vocabulary, or is that something that you're looking at a requirement within -- once we have a standardized vocabulary within the certification process?

MR. LEAVITT: Yes. Well, we don't do -- of course, we don't develop any standards or vocabularies. We just test products to see that they're compliant with the standards. HITSP comes into it when it becomes necessary to understand what standard is applicable and what vocabulary is applicable, especially if there's two conflicting standards and that needs to be resolved.

So we work very closely together, and then of course, we can provide feedback, which is valuable to a standards organization. When we validate, we already had it happen. We're validating the pilot test. You know, this standard isn't clear to anyone, so look at that again. Maybe the wording needs to be a little clearer. In this case, it had to do with functionality. So, there's a symbiotic relationship between the two organizations.

Timing is also interesting with -- HITSP directed this year to deliver their results in September, at least, many of their results. We're kind of pushing it -- pushing the pedal to the metal to get those standards into our criteria that we start testing in May, 'cause we'll literally be piloting it in October, November, and vendors need some time. If the standards have arrived anew, that isn't enough time for a vendor to incorporate it in their product.

So we have to kind of look case by case. In many cases, they're addressing a standard that was already out there being used and you can move faster. In cases where that's a new standard -- people were talking about PHRs and new areas, there's going to be more of a lag time between getting the standard approved, vendors being able to put it in their products so that we can certify and make sure it's there.

SECRETARY LEAVITT: Okay. Any other comment? Mark, you and your colleagues have done remarkable work here, and this is an important moment, at least for HHS. I'd like to know if there is any disagreement to the recommendation to the Secretary that we adopt this -- the CCHIT standards as a criteria standard. Hearing none, I'm going to declare a consensus on that point. Dr. Brailer?

DR. BRAILER: This concludes the recommendation component of the meeting. We do have one other item of business, which is the chance for public input. We do have microphones in the center aisle [unintelligible] for anyone that is either listening or in the building elsewhere. We'll ask that any comment you make be devoid of any commercial content or any advocacy for certain products or solutions that are offered on the market. Other than that, we're open to your comments. Please.

FEMALE SPEAKER: [inaudible] American Nurses Association. I'd like to speak to the chronic care initiative, the 1.2 of the newly edited document, the statement was posed. I would ask that you change the language from physician to clinician to ensure that all clinicians are engaged in the consideration that is chronic care initiative 1.2.

SECRETARY LEAVITT: Okay. Thank you. Any other comments?

MALE SPEAKER: One for Dr. Brailer. Tom Herring [spelled phonetically] with Healthcare Information and Management Systems Society. I just wanted to highlight for the EHR Workgroup recommendation regarding federal agencies and the purchase of -- excuse me -- the purchase or the requirement of having integrated standards efforts. Would recommend that you look at efforts that have been ongoing in other countries. They may have some -- you know, they may have had to address certain issues that you've addressed today in your conversation. We point to Canada, several countries in Europe, and a few in the Asia Pacific rim that have incorporated specific language in their contracting requirements. And I'll -- happy to provide more information through the channels.

The other thing is, June 5-8 is the National Health IT Week. We have 31 cosponsoring organizations and 11 partnering organizations that will be coming together in Washington. We have three federal agencies that are very much involved. A lot of the organizations that are here in the crowd are participating. So, for those that are -- that know about it, continue to advocate for it.

I ask the AHIC to consider: One, we have a concurrent resolution before the Congress declaring June 5-8 National Health IT Week, and we're working with the White House with respect to a national proclamation by the President. Finally, it's through Dr. Brailer and his two years of effort that I think that we have all this momentum, and we have 42 organizations coming together in June. So I personally want to extend my thanks to him for all his efforts these last two years. Thank you. [applause]

DR. BRAILER: Thank you. And I would note that that last comment came very close to a commercial endorsement. [laughter] I would say to your earlier comment that, actually, about two weeks ago, I joined my peers from other countries in a two-day summit. And the issue of standards collaboration and how we go about bringing those together and enforcing them through our contracts was the dominant theme of discussion. There will be follow-up actions that the United States will take with England and Australia and Canada to explore how we can not only support global development of standards as the health IT market does globalize, but how we can each learn from each other in that collaborative process. Thank you. Any other public comments?

MALE SPEAKER: I'm Hugh Zettle [spelled phonetically] from G.E. Healthcare, and I'm also proud to serve on the EHR vendor association on the executive committee. And I'm one of many of the thousands of person hours that helped participate in the certification commission's efforts to create certified EHRs.

Just a comment on the EHR lab process, and I'd like to see if we can get a clarification. It's important, and we've -- support the efforts to get codified standards to get lab results into the hands of our physician customers. And I think one of the concerns we have is we would anticipate that if I ordered a lab from three different lab facilities, that I would expect to get the same coded lab results back. And I think that's one of the challenges we face, is it's not entirely clear that -- because I embrace and use either HL7 or some other standard for the lab and LOINK [spelled phonetically] for the coding, that I get the lab result back the same from three different lab providers. So I think that's one thing that we'd like to see for clarification, that when those standards are implemented that the lab results are actually coded at the source. Many times, that has to fall on the hands of the physician, EHR systems.

So, you think of thousands of lab systems. There's going to be orders of magnitude -- more EHRs that are going to be in the family physician practices. So getting that reconciliation of the lab result should be done at the source and not at the EHR that receives it.

And then my second comment is relative to the time frame it takes to develop and implement some of these standards. We provided feedback to CCHIT relative to the road map of its activities that we make sure that we take into consideration the commercial timeframes to implement these standards, and we would encourage the use of road map exercises between CCHIT, HITSP, and the AHIC to make sure we can cross-coordinate the road map activities to see where there's synergies of different areas between the different Workgroups so that we can make sure that the time frames are realistic to what the commercial marketplace can both implement and our consumers can absorb.

SECRETARY LEAVITT: Thank you, and we'll ask the Workgroups to take up your comments as well as others as they continue their work at implementing these recommendations. Are there any other public comments?

MALE SPEAKER: With that, Mr. Secretary, we've concluded our business.

SECRETARY LEAVITT: Thank you. Still a lot of work to do. Let's -- I will look forward to our June meeting, where we will have made even more progress. I'm sure it's evident to everyone who's here that while this meeting is about reporting primarily, there is a lot of work that goes underneath it and we thank you all, and all those who participate who don't sit at this table. Thank you. Meeting adjourned.

[End of Transcript]