Meeting Report

American Health Information Community
May 16, 2006

The American Health Information Community (AHIC), a federally chartered commission formed to help advance President Bush's call for most Americans to have electronic health records within 10 years, held its fifth meeting on May 16, 2006, at the Department of Health and Human Services (DHHS), 200 Independence Avenue, SW, Washington, DC, 20201.

The purpose of the meeting was to bring together the Community's 17 members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to DHHS on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting focused on recommendations from the Electronic Health Records, Chronic Care, Consumer Empowerment, and Biosurveillance Workgroups as well as a presentation on progress made by the Certification Commission for Healthcare Information Technology (CCHIT).

DHHS Secretary Michael O. Leavitt chairs the Community. The remaining 16 members, selected by Secretary Leavitt, are key leaders in the public and private sectors who represent stakeholder interests in advancing the mission of the Community and who have strong peer support. Members will serve 2-year terms.

A summary of the discussion and events of that meeting follow.

Call to Order

Joining Secretary Leavitt counterclockwise around the table were:

David Brailer, MD, PhD, National Coordinator for Health Information Technology

Jonathan Perlin, MD, Under Secretary for Health, Department of Veterans Affairs and Veterans Health Administration

Lillee Gelinas, RN, MSN, Vice President of VHA, Inc.

William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs

Adele Morris, Senior Economist, U.S. Department of the Treasury (Ms. Morris represented Mark Warshawsky, PhD, Assistant Secretary for Economic Policy, U.S. Department of the Treasury)

Colin Evans, Director of the System Software Lab, Intel (Mr. Evans represented Craig Barrett, PhD, Chairman of the Board, Intel)

Mark McClellan, MD, PhD, Administrator of the Centers for Medicare and Medicaid Services (Dr. McClellan was represented by Mr. Tony Trenkle, Director, Office of E-Health Standards and Services, CMS, during portions of the meeting)

Mary Nell Lehnhard, Senior Vice President of the Blue Cross Blue Shield Association (Ms. Lehnhard represented Scott Serota, President and CEO of the Blue Cross Blue Shield Association, and was represented by Alissa Fox, Executive Director of the Blue Cross Blue Shield Association during portions of the meeting)

David Ayre, Senior Vice President, Compensation and Benefits, Pepsico, Inc. (Mr. Ayre was representing Steven Reinemund, CEO and Chairman of Pepsico, Inc.)

Linda Springer, Director of the Office of Personnel Management (during part of the meeting, Ms. Springer was represented by Dan Green, Deputy Associate Director, Center for Employee and Family Support Policy, Office of Personnel Management)

Nancy Davenport-Ennis, founder of both the National Patient Advocate Foundation and the Patient Advocate Foundation

Kevin Hutchinson, CEO of SureScripts

Douglas Henley, MD, Executive Vice President, American Academy of Family Physicians

Robert Cresanti, Under Secretary for Technology, U.S. Department of Commerce

E. Mitchell (Mitch) Roob, Secretary of the Indiana Family and Social Services Administration

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (Dr. Gerberding was represented by Ed Sondik, MD, Director of the National Center for Health Statistics, CDC, and by Laura Conn, Acting Director, Public Health Informatics Branch, CDC during portions of the meeting)

Charles N. (Chip) Kahn III, President of the Federation of American Hospitals

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Introductory Comments

Secretary Leavitt welcomed Community members and others to the meeting, noting that a great deal of progress has been made since the last AHIC meeting. With just under 1,000 days left in his tenure as DHHS Secretary, he described a sense of urgency related to continuing the progress made by the Community, indicating that the series of projects driving the priorities and vision of the Department are intimately linked to health information technology.

Secretary Leavitt announced the resignation of Dr. Brailer as the National Coordinator for Health Information Technology and recognized his tremendous contributions to the field. Dr. Brailer has agreed to serve on an ongoing basis as the Vice Chairman of AHIC and will continue to provide the Community with his counsel and advice. As the process of filling the role of National Coordinator for Health Information Technology begins, Dr. Karen Bell will lead the Office of the National Coordinator for Health Information Technology (ONCHIT) through what is hoped will be a relatively short transition period.

In other personnel-related news, Secretary Leavitt welcomed Robert Cresanti, Under Secretary for Technology at the U.S. Department of Commerce, who replaces Michelle O'Neill as a member of the Community. Secretary Leavitt thanked Ms. O'Neill, former Acting Under Secretary, for her work as a Community member. In closing his introductory remarks, Secretary Leavitt formally introduced Kathryn

Barr as the new AHIC Director. Ms. Barr comes to AHIC with a great deal of experience on Capitol Hill, including serving as a staff member for the Senate Committee on Health and Education, Labor, and Pensions, and working on the Senate Budget Committee.
Dr. Brailer expressed his appreciation for Secretary Leavitt's leadership in advancing health information technology. He noted that this meeting will involve laying out recommendations in a sequential basis for discussion, for action, and for potential further action. Some of these recommendations will be specific to certain Community workgroups; others will be more cross-cutting in nature and apply to all workgroups. Before moving forward with the day's agenda, Dr. Brailer reminded Community members that the next AHIC meeting is scheduled for June 13, 2006.

Approval of March 7, 2006, Meeting Minutes

Minutes from the March 7, 2006, AHIC meeting were distributed, reviewed by Community members, and approved unanimously with no changes.

Electronic Health Records Workgroup Recommendations

Dr. Perlin and Ms. Gelinas presented the Electronic Health Records Workgroup's recommendations. They reminded Community members that the Workgroup's broad charge is to make recommendations to the Community on ways to achieve widespread adoption of certified electronic health records (EHRs), minimizing gaps in adoption among providers. The Workgroup's specific charge is to make recommendations to the Community so that within 1 year, standardized, widely available, and secure solutions for accessing current and historical laboratory results and interpretations are deployed for clinical care by authorized parties.

The President has endorsed the widespread adoption of interoperable EHRs. Despite the benefits linked to EHR use, only 17% of physicians have adopted their use. Barriers identified that contribute to this low adoption include the high cost to purchase and implement EHRs and costly custom interfaces to the most needed systems such as laboratory information systems. Because laboratory results are a component in 70% of clinical decisions, timely and easy access to comprehensive laboratory information is of high value to clinicians. The accuracy, efficiency, and lower overall cost of EHR use was emphasized.

The following recommendations were presented, with highlights of discussion following each recommendation:

- **Recommendation 1.0:** *How can lab results be shared to meet provider and patient needs?* DHHS should take immediate steps to facilitate the adoption and use of endorsed standards and incentives needed for interoperability of laboratory results within the current provider-centric environment. ONCHIT shall work with multiple stakeholders to develop a detailed workplan to achieve patient-centric information flow of laboratory data by March 31, 2007.

"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." – Ms. Gelinas

"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…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…How are we going to deal with that?" – Dr. Henley

"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 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'." – Dr. Perlin

"In VA, just as an example…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 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'." – Dr. Perlin

"We suggest 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." – Dr. Perlin

"This issue of the 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 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." – Dr. Brailer

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendation 1.0.

- **Recommendation 2.0:** *How can standards be identified?* The Healthcare Information Technology Standards Panel (HITSP) should identify and endorse vocabulary, messaging, and implementation standards for reporting the most commonly used laboratory test results by September 30, 2006, so as to be included in the CCHIT interoperability criteria for March 2007 certification. HITSP should consider the Clinical Laboratory Improvement Amendments (CLIA) and the Health Insurance Portability and Accountability Act (HIPAA) regulatory requirements as appropriate.

"How close are you to resolving the vocabulary issues? Do you think that's a major stumbling issue in laboratory results or have you passed that threshold?" – Mr. Roob

"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...This recommendation speaks to making sure that our standards-naming bodies formally say, 'the discussion is over and this is the standard'." – Dr. Brailer

"It's not the standard itself that has been the biggest issue. I'd like to 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 time to take it through the HITSP organization." – Mr. Hutchinson

"The big challenge…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." – Mr. Hutchinson

"As you move forward with the identification of the implementation standards, the standards should be sensitive to the patient-centric model because ultimately, we want to be certain that that implementation allows for easy transference to the patient." – Ms. Davenport-Ennis

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendation 2.0.

- **Recommendation 2.1:** *How can standards be put into use?* Federal healthcare delivery systems (those which provide direct patient care) should develop a plan to adopt the HITSP-endorsed standards for laboratory data interoperability by December 31, 2006.

"A reasonable timeframe is an important thing to consider here. We certainly endorse moving in this direction and getting there as quickly as possible, it's important that the standards be built for information exchange, not to rebuild our whole systems. We're a little concerned about the time and the cost if we're 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 that technical people ought best to work out, but we endorse it, we just – it's with a little bit of caution." – Dr. Winkenwerder

"What I hear you [Dr. Winkenwerder] saying is, 'we're all for it as a policy matter, as a practical matter, we need to talk about what it means.'" – Secretary Leavitt

"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." – Mr. Trenkle

"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 what we're doing and move toward this as a standard." – Dr. Perlin

"I'd like to make clear that adopting it is important. I think ultimately to 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 left in this administration. And I have a strongly held view that we have got to have demonstrated progress and commitment long before those days have run out or we will not have succeeded here." – Secretary Leavitt

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendation 2.1.

- **Recommendation 2.2:** *How can standards be put into use?* Federal agencies and departments with health lines of business should include/incentivize the use of HITSP-approved standards in their contracting vehicles where applicable.

"Here it is even more important from our perspective to proceed with some caution…Imposing those standards through our contracted health plans could be a cost prohibitive thing. We'd like to start with our direct care system…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…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." – Dr. Winkenwerder

"Yeah, I would agree with Bill. I think we 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 to incentivize and include the language as we do

that." – Mr. Trenkle

"We have strong incentives in our contracts right now for electronic claim submission, for example, and for items to be done digitally…We endorse it and our proposal would be that we work with the VA and others that are in the direct care business to sort of build a platform that then could be used to extent of the contracted purchase care partners for the federal government." – Dr. Winkenwerder

"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. We anticipate moving promptly on this." – Mr. Green

"While I indeed concur with the recommendation…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…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 this recommendations?" – Ms. Davenport-Ennis

"The implementation here in the discussion was envisioned so that one wouldn't disrupt current activities. Those would sunset, but as new contracting vehicles came into place, these standards would be expected as well." – Dr. Perlin

"Well first of all, let me say I'm very much in favor of these recommendations. But I'm confused and maybe a bit concerned about a few points. As I understand it, we're adopting standards or we want HITSP to adopt standards that relate to the certification process for the private vendor community. In essence we are 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 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 period 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." – Dr. Henley

"I 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 create the back pressure that we have the capacity as payers to create." – Secretary Leavitt

"Laboratory results and the interoperability and transmission of those are really crucial…In terms of the dates, 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. CDC is building a system that actually can help translate from one laboratory system to another laboratory system…that may be an option here that would help to sort of bridge between one standard and another." – Dr. Sondik

"It is important that we move forward with this, but I think you are leaving an enormous number of dollars 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, engaging Medicaid is an effective way of doing that." – Mr. Roob

"I think there's a vendor side of it which without some 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 to know what the technology vendors on the committee thought about these recommendations and whether they thought they were clear enough for them to invest their money as well." – Mr. Evans

"Having technology vendors in 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." – Ms. Gelinas

"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…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…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." – Secretary Leavitt

"Whenever the cycle begins, one should, in fact, be including this in the contracts…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." – Dr. Sondik

"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."
– Mr. Hutchinson

"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 [the June AHIC meeting]." – Dr. Winkenwerder

"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." – Secretary Leavitt

"We'll work with the appropriate people at CMS and come up with a timeline and…see how that fits in with your timeline as well." – Mr. Trenkle

"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." – Mr. Green

"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." – Secretary Leavitt

"I would suggest that the EHR work group develop by the June 13th Community meeting, a timetable for the implementation for this recommendation." – Dr. Brailer

"One of the things we have to do is work on the development of a proposal that I can then drive through the policy process." – Secretary Leavitt

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendation 2.2, with the understanding that the Electronic Health Records Workgroup will

develop a timetable for implementation of this recommendation. This timetable will be presented at the June AHIC meeting.

- **Recommendation 3.0:** *How can regulatory barriers be removed?* By September 30, 2006, ONCHIT 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/or statute change.

"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." – Dr. Winkenwerder

"In addition to being technically complicated, this is an area that's transformational…This recommendation is a least common denominator…to 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." – Dr. Brailer

"Maybe there's two aspects of this: to make use of available guidance and other mechanisms to offer things that remove these barriers 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." – Dr. Brailer

"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." – Dr. Perlin

"I think you're going to have to work within…CLIA and HIPAA to try and solve the problems. It's going to be difficult to get any kind of legislative change." – Mr. Kahn

"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." – Mr. Trenkle

"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." – Ms. Gelinas

Following this discussion, Secretary Leavitt declared a consensus on a modified version of Recommendation 3.0: By September 30, 2006, HHS shall issue guidance on how to achieve patient-centric flow of lab results under current CLIA and HIPAA regulations. HHS 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.

- **Recommendation 3.1:** *How can regulatory barriers be removed?* Based on the findings from Recommendation 3.0, by December 31, 2006, ONCHIT 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 laboratories seeking to define access rights to electronic laboratory data.

There was no discussion on Recommendation 3.1. Secretary Leavitt declared a consensus and accepted Recommendation 3.1.

- **Recommendation 4.0:** *How can privacy protections be designed?* The Community should create a Consumer Empowerment Subgroup comprised of privacy, security, clinical, and technology experts from each Community Workgroup. 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 key stakeholders. The recommendations developed should establish an initial policy framework and address issues including, but not limited to: (1) methods of patient identification, (2) methods of authentication, (3) mechanisms to ensure data integrity, (4) methods for controlling access to personal health information, (5) policies for breaches of personal health information confidentiality, (6) guidelines and processes to determine appropriate secondary uses of data, and (7) a scope of work for a long-term independent advisory body on privacy and security policies.

"One of the things I believe we've been good at is focusing on the breakthrough projects. I'm wondering how the group would feel about focusing on these issues as they relate to our breakthroughs, not looking at them as a general subject." – Secretary Leavitt

"I think that would really provide focus and make it a manageable segment. I think that would be a very good recommendation." – Dr. Perlin

"Maybe there are some cases where 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." – Mr. Evans

"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…using 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 are certain things within this group that we can do, and then there are other forums that bring a better technical expertise to the table to address in a public fashion many of these issues." – Mr. Hutchinson

"There is a significant overlap of privacy professionals on the NCVHS Privacy Subcommittee and on each of the workgroups…[Recommendation 4.0's] 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." – Secretary Leavitt

"There seems to be general agreement that we ought to pursue this recommendation, but we ought to ask them to narrow their focus on the breakthroughs, and come back with solutions in those categories on our breakthroughs." – Secretary Leavitt

"Well, let me bring up a side point here, which is coming in from left field…this is the cross-cutting issue which we talked about two meetings ago, which is measurement reporting. I just wanted to make the suggestion or the offer that the Federation and Booz Allen are doing a paper on measurement and reporting. If we could just have space on the next meeting's agenda, I'd appreciate it. If we don't build in the measurement and reporting aspect of this, then we're going to miss a bet in terms of quality improvement." – Mr. Kahn

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendation 4.0.

- **Recommendation 5.0:** *How can adoption be advanced?* 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.

"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…there might be some negative business cases." – Ms. Morris

"There's both a clinical and an economic business case that needs to be made." – Ms. Gelinas

"I'm a little uncomfortable with government's identifying the business case. It suggests who ought to be the winner and who ought to be the loser…The group could identify the economic, generally speaking, and clinical case…Having said that, there will be winners and losers, as there are in any set of business transactions across an industry." – Dr. Winkenwerder

"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...Some of this becomes a dissemination and education exercise as well as this discovery. 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." – Dr. Brailer

"I think the role for government in this instance is through the provision of information…I also think there's a role to articulate the case for the federal government engaging in this effort as a society…I don't think it is the role of government to necessarily provide business strategies for individual providers and try to make assessments about what returns on investments are going to be." – Ms. Morris

"I do think that there's a role for education. The mere collection of case studies or examples, both within government and outside of government, the costs that are associated, the benefits…there is an emerging set of information about what the experience has been. And some of it is very positive."
– Dr. Winkenwerder

"The bottom line here is 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…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." – Mr. Kahn

"What I would like to see the United States do through Secretary Leavitt's leadership is 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." – Ms. Davenport-Ennis

"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." – Mr. Hutchinson

"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 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." – Dr. Henley

Following this discussion, Secretary Leavitt declared consensus on tabling Recommendation 5.0.

Recommendations 6.0 and 6.1 from the Electronic Health Records Workgroup were discussed simultaneously by Community members.

Recommendation 6.0: *How do we learn from early adopters*? By March 31, 2007, AHRQ, 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.

Recommendation 6.1: How *do we learn from early adopters?* By December 31, 2007, AHRQ, 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.

"I'm…starting to wonder if there's a need for us to have a workgroup on education or some group that…falls outside of the development of standards. I want to keep this group focused on developing standards." – Secretary Leavitt

"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 electronic health records and we could support it. But maybe it's a task that could be taken on by the private sector." – Dr. Winkenwerder

Following this discussion, Secretary Leavitt declared consensus on tabling Recommendations 6.0 and 6.1.

Dr. Perlin noted that Secretary Leavitt had given the Electronic Health Records Working Group an additional charge to assist insuring that first responders serving at a disaster or emergency situation can obtain the critical health information that they need electronically. Four data elements have been identified as being broadly useful in an emergency situation: (1) medications that a patient is taking, (2) allergies, (3) diagnoses, and (4) advanced directives. The Electronic Health Records Workgroup has begun receiving additional modifying input on this, and as a next step, will coordinate with AHIC's Consumer Empowerment Workgroup and coordinate with other federal efforts related to emergency response preparedness. One goal is to take the knowledge of what the most critical pieces of information are and develop a consensus document that identifies them and serves as a template for a patient, family, or an individual to list their allergies, their medications, their main diagnoses, their advanced directives, and some individuals who might be contacted in an emergency.

Chronic Care Workgroup Recommendations

Dr. McClellan and Mr. Evans presented the Chronic Care Workgroup's recommendations. They reminded Community members that the Workgroup's broad charge is to make recommendations to the Community to deploy widely available, secure technology solutions for remote monitoring and assessment of patients and for communication between clinicians about patients. The Workgroup's specific charge is to make recommendations to the Community so that within 1 year, widespread use of secure messaging, as appropriate, is fostered as a means of communication between clinicians and patients about care delivery.

At present, approximately 50 million Americans live stably with a chronic condition; most have more than one. About 80% of chronic care management takes place outside of the practitioner's office in home, work, and school environments. Secure messaging between patients and clinicians allows patients to receive clinical guidance outside of the office setting, at the time that it is needed. Secure patient-clinician messaging refers to communications between patients and the individual clinicians who have explicit responsibility for their care. Early studies and experience in staff model environments associated with secure messaging demonstrate improved quality and patient satisfaction while reducing utilization and costs. Secure messaging is reimbursed by multiple national and local payers. Key issues facing the Chronic Care Workgroup include: (1) reimbursement, (2) medical liability and licensure, (3) standards for secure patient-clinician messaging and supporting systems, (4) consumer and clinician access, and (5) privacy and security.

The following recommendations were presented, with highlights of discussion following each recommendation:

- **Recommendation 1.0:** *What is the justification for reimbursement?* HHS should develop and regularly update the evidence base for informed reimbursement policies with respect to secure messaging between clinicians and their patients. This should include monitoring and reporting the effect of secure messaging on cost, quality of care, patient and caregiver satisfaction, and medico-legal issues.

There was no discussion on Recommendation 1. Secretary Leavitt declared a consensus and accepted Recommendation 1.0.

- **Recommendation 1.1:** *What are the best methods of reimbursement?* HHS should compile and assess the effect of various reimbursement methodologies for secure messaging on clinician workflow in various care models, and report on best practices.

There was no discussion on Recommendation 1.1. Secretary Leavitt declared a consensus and accepted Recommendation 1.1.

- **Recommendation 1.2:** *What can be done to expand reimbursement?* Public and private payers, including CMS, should contribute to the evidence for and 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.

"From a CMS standpoint, the caveat that we'd add here 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." – Dr. McClellan

"We have about 10 plans, Blue Cross/Blue Shield plans, across the country that are doing various forms of secure messaging…It's premature to look at the actual reimbursement of it on a widespread 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." – Ms. Fox

"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." – Dr. Henley

"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 want, which is better quality." – Secretary Leavitt

"CMS clearly has some authority to support the development and effect adoption of standards; we've just mostly done it in the context of getting to a particular goal like better quality care at a lower cost." – Dr. McClellan

"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." – Secretary Leavitt

"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…We would love to join in with CMS and others to do the pilot studies." – Dr. Winkenwerder

"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." – Secretary Leavitt

"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 secure messaging systems. In looking at studies, I think we should bear that in mind as we go along." – Mr. Evans

"Is there any recommendation on a timeline for these pilots? Or what agencies should be tasked with doing this, or private payers? Who is committing you to sign up to do this and by when?" – Dr. Winkenwerder

"We might want to make this relate to Recommendations 3 and 4…particularly the recommendations related to standards for secure messaging. 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 widespread use in physician workflow." – Dr. McClellan

"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…I would at least at this point say we have reasonable confidence of." – Dr. Brailer

"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?" – Secretary Leavitt

"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 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." – Dr. Brailer

Following this discussion, Recommendation 1.2 was reworded as follows:

- **Public and private payers should implement secure messaging pilots or demonstration projects based on HITSP-approved standards that evaluate: (1) possible forms of reimbursement for secure messaging, (2) integration of secure messaging into physician workflow, and (3) impact of secure messaging on patient involvement in their care.**

Secretary Leavitt declared a consensus and accepted Recommendation 1.2 as rewritten.

- **Recommendation 2.0:** *How can state-level barriers be removed?* HHS should convene the appropriate state agencies and professional societies to develop and adopt new licensing alternatives which will address the ability to provide electronic care delivery across state boundaries while still ensuring compatibility with individual state requirements.

"I would also add that this will get much more play from the states when you tie it to…Medicaid funding…To really motivate the state folks to move more quickly, tying it 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." – Mr. Roob

Following this discussion, Secretary Leavitt declared consensus and accepted Recommendation 2.0.

- **Recommendation 3.0:** *How can standards be identified?* ONCHIT should direct HTSP to define standards for secure patient-clinician messaging transactions so that they may be interoperable with electronic health records.

"Recommendation 3.0 is very focused on patient/clinician messaging and I think from my understanding that's the specific charge, but looking at the benefits that accrued from broader messaging, I'm just wondering about the prospect for further standards for both the clinician/clinician messaging and messaging where the physician is at a remote site and is interacting with an EHR." – Adele Morris

"Recommendation 3.0 is so important because it's one of the building blocks…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." – Dr. Perlin

"We really see this as a fundamentally important recommendation…it is a component that feeds into the broader health record but also supports other sorts of communication…it's one of the set of tools that builds the more powerful usefulness of health records." – Dr. Perlin

"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." – Dr. Winkenwerder

"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." – Dr. Brailer

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendation 3.0.

- **Recommendation 3.1:** *How can secure messaging be integrated in the EHR?* ONCHIT should direct CCHIT to establish certification criteria for system interoperability with patient-clinician secure messaging.

There was no discussion on Recommendation 3.1. Secretary Leavitt declared a consensus and accepted Recommendation 3.1.

- **Recommendation 4.0:** *How can equal access to secure messaging be enabled?* AHRQ should conduct a synthesis of current knowledge from existing studies of health information technology use by elderly, ill, and underserved populations including an analysis of barriers and drivers. The barrier and driver analysis should elucidate for which subpopulations barriers can be overcome and how.

There was no discussion on Recommendation 4.0. Secretary Leavitt declared a consensus and accepted Recommendation 4.0.

- **Recommendation 4.1:** *How can equal access to secure messaging be enabled?* 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 securing messaging available uniformly.

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

"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." – Dr. Brailer

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendation 4.1.

- **Recommendation 5.0:** *How can privacy protections be designed?* Recommendation 5.0: The Community should create a Consumer Empowerment Subgroup comprised of privacy, security, clinical, and technology experts from each Community workgroup. 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 key stakeholders. The recommendations developed should establish an initial policy framework and address issues including, but not limited to: (1) methods of patient identification, (2) methods of authentication, (3) mechanisms to ensure data integrity, (4) methods for controlling access to personal

health information, (5) policies for breaches of personal health information confidentiality, (6) guidelines and processes to determine appropriate secondary uses of data, and (7) a scope of work for a long-term independent advisory body on privacy and security policies.

There was no discussion on Recommendation 5.0. Secretary Leavitt declared a consensus and accepted Recommendation 5.0 with the understanding that it is limited to this breakthrough.

Secretary Leavitt excused himself from the meeting following the discussion of the Chronic Care Workgroup recommendations. Dr. Brailer chaired the meeting in Secretary Leavitt's absence.

Consumer Empowerment Workgroup Recommendations

Ms. Davenport-Ennis and Ms. Springer presented the Consumer Empowerment Workgroup's recommendations. They reminded Community members that the Workgroup's broad charge is to make recommendations to the Community to gain widespread adoption of a personal health record (PHR) that is easy to use, portable, longitudinal, affordable, and consumer centered. The Consumer Empowerment Workgroup's specific charge is to make recommendations to the Community so that within 1 year, a prepopulated, consumer-directed, and secure electronic registration summary is available to targeted populations. In addition, the Workgroup is to make additional recommendations to the Community so that within 1 year, a widely available, prepopulated medication history linked to the registration summary is deployed.

Consumer involvement in self-care and care management could be encouraged with the successful deployment of some form of easily accessible personal health information. Consumer commitment to PHRs could increase efficiency in the health care system, lower overall costs, and improve access to health care information. Making a medication history and registration summary widely available to targeted patient populations is an incremental step to realize progress in the short term.

Five key issues face the Consumer Empowerment Workgroup: (1) privacy and security safeguards and consumer control of personal health information need to be established and enforced, (2) there is no widely accepted standard definition or functional specification for the features of a PHR, (3) there are no standards or functional specifications for populating PHRs, (4) appropriate incentives for consumer and provider use of PHRs must be identified and supported, and (5) generally, consumers are unaware of the availability and value of medication histories and electronic registration summaries.

The following recommendations were presented, with highlights of discussion following each recommendation:

- **Recommendation 1.0:** *How can standards be identified?* HITSP should identify the technical and data standards to enable the availability of a core registration dataset and medication history (with comprehensive review of recommendations for registration and medication history provided to HITSP by the Workgroup), including vocabularies, messaging, authentication, security standards, and appropriate documentation, by September 30, 2006.

"We recommend approving Recommendation 1.0, 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…with HITSP to develop the standards for personal health record, and we should have that done this fall."
– Ms. Fox

"I'm just looking ahead to our various recommendations. I'm trying to remember with great clarity the problem we're trying to solve...and my best recollection was that the primary function of this data was to help eliminate the clipboard in the doctor's office…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." – Ms. Morris

"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." – Dr. Brailer

"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." – Dr. Brailer

Following this discussion, Dr. Brailer declared a consensus and accepted Recommendation 1.0.

- **Recommendation 2.0:** *How can access to and value of medication history and registration summary be demonstrated?* HHS, through CMS, AHRQ, 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 organizations should strive to implement pilot programs that meet all the objectives identified by the workgroup no later than December 31, 2006, and an evaluation of the initial results should be reported to the Community by June 30, 2007.

"To get a pilot up, start it, evaluate it, and so forth, in a year's time is going to be a pretty ambitious task." – Dr. Winkenwerder

"We can move forward with this with the caveat that we might have to revisit this if we find fatal issues." – Dr. Brailer

"I have to do a little bit exploring but I would also expand the comments both to Recommendations 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 I am absolutely supportive." – Dr. Perlin

"We talked to our Medicare beneficiary…folks and they feel that we can support something of 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." – Mr. Trenkle

"I am 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, etc. So I think we should look demonstrating the value a bit more broadly than just to patients when we speak about PHRs." – Dr. Henley

Following this discussion, Dr. Brailer declared a consensus and accepted Recommendation 2.0 with the caveat that it be slightly reworded so that the first sentence reads as follows: "HHS, through CMS, AHRQ, 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 and their physicians or clinicians."

- **Recommendation 2.1:** *How can consumers be made aware of the breakthrough?* In the next 6 months, HHS agencies sponsoring pilots for an electronic registration summary and medication history should work with appropriate private-sector health organizations, such as patient advocacy organizations and medical professional societies, to promote provider and consumer participation in a breakthrough project through a targeted outreach initiative.

"We'll substitute the word 'federal' for 'HHS' on line 1." – Dr. Brailer

"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." – Ms. Morris

"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 correct, then it's all about putting it in." – Mr. Ayre

"Remember, we adopted a recommendation 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 the patient's information doesn't have to be re-keyed, it will be interoperable with the HER, 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. Henley

"I think the big challenge everybody faces in maintaining good and accurate and up-to-date registration information is the constant movement of individuals in society. Their addresses, phone numbers, contact information, just changes all the time. Whatever is done here ought to highly focus upon something that is individual directed or consumer directed with the ability to update from that point…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. Winkenwerder

"The other party here that's highly motivated for the potential efficiency benefits that come from this are employers…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." – Mr. Evans

Following this discussion, Dr. Brailer declared a consensus and accepted Recommendation 2.1 with the understanding that the term "federal" will replace the term "HHS."

- **Recommendation 3.0:** *How can privacy protections be designed?* The Community should create a Consumer Empowerment Subgroup comprised of privacy, security, clinical, and technology experts from each Community workgroup. 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 key stakeholders. The recommendations developed should establish an initial policy framework and address issues

including, but not limited to: (1) methods of patient identification, (2) methods of authentication, (3) mechanisms to ensure data integrity, (4) methods for controlling access to personal health information, (5) policies for breaches of personal health information confidentiality, (6) guidelines and processes to determine appropriate secondary uses of data, and (7) a scope of work for a long-term independent advisory body on privacy and security policies.

There was no discussion on Recommendation 3.0. Dr. Brailer declared a consensus and accepted Recommendation 3.0 with the understanding that it is limited to this breakthrough.

Ms. Springer noted that the Consumer Empowerment Workgroup recognizes that consumers are among the last stakeholders to become engaged in these important discussions on PHRs and there are many key policy issues/barriers to be addressed to assure the general public that a personal health record can be developed that will provide for the privacy and security of consumer information. The Workgroup further recognizes that its recommendations will be subject to periodic review and possible revision as work continues on both the broad and specific charges issued by the Community. Some questions to be addressed include the following: (1) Should the market be left alone for innovation or could vendors compete around a minimum criteria set for PHRs? (2) Would a minimum set of PHR elements ensure that consumers have the features and options most important to them when choosing a PHR to manage their medication history or registration summary? and (3) Who should identify the most important elements of a PHR?

Ms. Davenport-Ennis raised the following issues related to certification:

- Some think certification of PHRs would be a positive voluntary market-based mechanism to ensure privacy and security of personal health information and interoperability.

- Some don't think enough is known about what consumers want to develop requirements for PHR certification.

- Would certification of PHRs advance the specific and 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?

- Should the Consumer Empowerment Workgroup's recommendations in this area include a definition, process, and measurement system that would support the best treatment at the best place and at the best time?

Community members then participated in a brief discussion, the highlights of which appear on the following page:

"Clearly the personal health record is several years behind the electronic health record in terms of technical sophistication, the user need, our experience with it, the technical definitions." – Dr. Brailer

"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…start with the 20% that are ready, that are electronic savvy, that want it to happen." – Ms. Gelinas

"The 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." – Ms. Davenport-Ennis

"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. 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…is much more mature." – Dr. Henley

"I do agree that 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." – Mr. Trenkle

"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." – Dr. Brailer

"We'd be happy to share the experiences we've had—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." – Ms. Fox

Biosurveillance Workgroup Recommendations

Dr. Gerberding, Mr. Kahn, and Mr. Roob presented the Consumer Empowerment Workgroup's recommendations. They reminded Community members that the Workgroup's broad charge is to make recommendations to the Community to implement the informational tools and business operation to support real-time nationwide public health event monitoring and rapid response management across public health and care delivery communities and other authorized government agencies. The Biosurveillance Workgroup's specific charge is to make recommendations to the Community so that within 1 year, essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems can be transmitted in standardized and anonymized format to authorized public health agencies within 24 hours.

Scenarios considered by the Workgroup include environmental signals, suspect illnesses, intelligence warning, monitoring ongoing events, and ascertaining size and rate of spread. Biosurveillance functions to be supported with advanced, enhanced, or real-time transmission of electronic health data include: (1) initial event detection, (2) situational awareness, (3) outbreak management, and (4) response management.

The Association of State and Territorial Health Officials conducted a survey and collected responses from 29 states, 3 territories, and the District of Columbia. Results indicate that the majority of state public health agencies have the capacity and the need to participate in biosurveillance efforts. This finding emphasizes the need for public health to be actively engaged in this area. Approximately 82% of state

public health agencies are receiving, or plan to receive within 6 months, electronic data from clinical care settings for one or more biosurveillance capabilities. As of April 2006, 89% of these agencies have an active relationship with some clinical partners to develop the capacity for electronic exchange and use of data for notifiable disease reporting or biosurveillance efforts. Primary obstacles to participation cited by the agencies were lack of funding (82%) and lack of trained personnel (70%).

In a similar survey of 93 large local public health agencies, the National Association of County and City Health Officials found that the majority of local public health agencies have the capacity and the need to participate in biosurveillance efforts. In this survey, 68% of local public health agencies reporting receiving, or planning to receive, electronic data from clinical care settings for one or more biosurveillance capabilities. Approximately 98% of agencies have an active relationship with clinical partners for local preparedness planning. In terms of primary obstacles for participation, 68% cited lack of funding and 51% cited lack of technology infrastructure.

The Biosurveillance Workgroup considered the following four key issues: (1) the data and technical specifications needed to support key public health functions; (2) sharing data in a way that supports all levels of public health; (3) protecting patient confidentiality; and (4) defining clear goals, metrics, and rigorous program evaluation. The following recommendations were presented, with highlights of discussion following the recommendations (during discussion of these recommendations, Secretary Leavitt returned and resumed his role as Chair of the meeting):

- **Recommendation 1.0:** *How can data needed for biosurveillance be defined?* By June 30, 2006, HHS, in collaboration with state and local governmental public health agencies and clinical care partners, should establish, convene, and oversee a data steering committed to carrying out the activities described in the recommendations that follow.

- **Recommendation 1.1:** *What data should be captured?* The Data Steering Committee will identify the data elements and the appropriate filtering of data from ambulatory care settings, emergency departments, and laboratories; as well as hospital utilization data needed to enable the key public health functions as outlined above. HITSP should identify the technical specifications for these initial data requirements by September 30, 2006. CDC and others should provide HITSP with the public health expertise and funds needed to perform this task.

- **Recommendation 1.2:** *What data could enable broader geographic coverage?* By August 15, 2006, the Data Steering Committee should identify the data sources and requirements necessary to allow for the collection of a more limited set of data across a broader geographic area.

"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?" – Mr. Cresanti

"The short answer is, yes, we are. What we're talking about here are electronically enabled data that already exist and so we're basically multi-purposing existing information. 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. This is a subset of a broader set of information opportunities and needs." – Dr. Gerberding

"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,

getting systems to exchange any information is a giant leap ahead of where we are right now." – Dr. Gerberding

"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…I would like to do that in the fairly near future." – Secretary Leavitt

"In the spirit of supporting this…suite of recommendations, both in terms of immediacy and breadth, as well as ultimately, depth…important contributors to this information are federal partners, certainly the VA, Department of Defense…It is appropriate that we add federal partners 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." – Dr. Perlin

"Just as a frame of reference, over the past 3 years under the BioSense 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." – Dr. Winkenwerder

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendations 1.0, 1.1, and 1.2, with an amendment to Recommendation 1.0 indicating that federal partners will be included in the Data Steering Committee.

- **Recommendation 2.0:** *How are the traditional roles of local, state, and federal public health agencies protected?* For the purposes of the Biosurveillance Breakthrough Initiative, the CDC should establish memoranda of understanding to enable simultaneous data flow from data providers to local, state, and federal public health entities while preserving traditional investigation roles at local and state public health levels whereby local and state jurisdictions continue to have lead roles in public health investigations. State and local public health agencies should ensure such memoranda of understanding are put into place and supported.

"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." – Secretary Leavitt

"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." – Dr. Gerberding

"My sense from the discussion at the workgroup, though, was that ASTHO, and NAACHO 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." – Mr. Kahn

"It's not a question of should it be done. This 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." – Dr. Brailer

"If we hold this over to the June meeting and have the workgroup do more of their dialog…we certainly could then be in a position to have much more specificity here. 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." – Dr. Brailer

"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 contexts and local and state jurisdictional issues have been resolved. I think we have models that can work." – Dr. Gerberding

"I'd be inclined…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." – Secretary Leavitt

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendation 2.0, with the understanding that it may come back to the Community for further consideration as additional information becomes available.

- **Recommendation 3.0:** *How can patient confidentiality be protected?* By August 30, 2006, HHS should develop sample data use agreements to facilitate the sharing of data from health care providers to local, state, and federal public health agencies. HHS should also offer practical implementation guidance to data providers and state and local public health agencies to address HIPAA concerns about transmitting data (with obvious identifiers removed) for public health purposes.

- **Recommendation 3.1:** *How can patient confidentiality be protected?* HHS, in collaboration with privacy experts, state and local governmental public health agencies and clinical care partners, should develop public communication materials to educate the general public about the information that is used for biosurveillance, including the benefits to the public's health, improved national security, and the protection of patient confidentiality by September 30, 2006.

"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?" – Mr. Hutchinson

"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…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. Roob

"I'd just like to 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." – Dr. Gerberding

"I would recommend that we ask at our June meeting for an update on progress and evaluate the 9/30 deadline based on progress." – Secretary Leavitt

Following this discussion, Secretary Leavitt declared a consensus and accepted Recommendations 3.0 and 3.1, with the understanding that an update on progress will be given at the June AHIC meeting and that the September 30 deadline in Recommendation 3.1 will be re-evaluated.

- **Recommendation 4.0:** *How can the breakthrough be evaluated?* The CDC, state, and local governmental public health agencies, and clinical care partners with firsthand experience in managing ongoing biosurveillance programs should design and conduct evaluations of the biosurveillance breakthrough. These parties should establish goals, develop outcome measures, and establish metrics for evaluation of the breakthrough by September 30, 2006.

- **Recommendation 4.1:** *How can lessons learned steer future direction?* 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 large scale implementations and suggest modifications to data 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.

There was no discussion on these Recommendations. Secretary Leavitt declared a consensus and accepted Recommendations 4.0 and 4.1.

CCHIT Progress Report

Dr. Mark Leavitt, Chair of the CCHIT, described the organization as a voluntary, consensus-based initiative. Founded in 2004 in the private sector by three health information technology associations, CCHIT's funding base was broadened in June 2005, and the HHS Compliance Certification contract was signed in September of 2005. CCHIT accelerates the adoption of robust, interoperable health information technology, with the goals of: (1) reducing the risk of health information technology investment, (2) facilitating interoperability with emerging networks, (3) enhancing the availability of incentives/regulatory relief, and (4) protecting the privacy of personal health information.

On May 1, 2006, CCHIT published the final 2006 Certification Criteria for Ambulatory Electronic Health Records. The certification program was launched May 3-May 12 with more than 24 applications received. Compliance inspections began May 12 and will extend to July 10, with the first announcement of certified products expected at that time. The CCHIT promotes a consensus-driven process that includes broad participation by diverse stakeholders from both the private and public sectors, with provider, vendor, and payer representatives. Policies and processes were set to ensure fairness, transparency, and credibility. There were three cycles of public comment with multiple channels of communication and feedback—almost 2,000 public comments were collected. The criteria were validated through pilot testing with six randomly selected vendors out of a pool of more than 30 volunteer entities.

The criteria, focused on ambulatory electronic health records, can be categorized into three groups. There are 250 functionality criteria, about 25 interoperability criteria, and approximately 50 security criteria. Besides the criteria, every item includes a roadmap indicating at what year it will be required in certification, signaling to the industry what will be inspected and when. The roadmap also provides an opportunity to support the breakthroughs identified by AHIC. New needs can be strategically inserted into CCHIT's roadmap and carried forward.

Dr. Leavitt presented a sample document showing functionality criteria, listing the criteria, the evidence base, the availability in the marketplace, and the road map. About 10% of the criteria this year are provisional; they are currently under evaluation.

In terms of next steps, the first results of this certification program will be announced in July, at which time quarterly repeat application/inspection cycles will begin. Ambulatory HER criteria will be updated, incorporating AHIC breakthrough use cases and preparing criteria for the 2007 certification year. Next year, the CCHIT will be developing new criteria for certification of inpatient electronic health records. In the spring of 2008, CCHIT plans to begin certifying the networks.

After Dr. Leavitt's presentation, a brief discussion session ensued, with the following highlights:

"People who have surveyed the marketplace believe that there are on the order of 200 vendors that will show up commercially…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." – Dr. Leavitt

"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. 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." – Secretary Leavitt

"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." – Secretary Leavitt

"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." – Dr. Leavitt

Following this discussion, Secretary Leavitt declared a consensus and the Community adopted the CCHIT standards as a criteria standard.

Public Input Session

Speaker Number 1 – Dr. Carol Bickford, American Nurses Association. Dr. Bickford asked that the language in Recommendation 1.2 from the Chronic Care Workgroup be amended, changing the word "physician" to "clinician, " to ensure that all clinicians are engaged.

Speaker Number 2 – Tom Leary, Healthcare Information and Management Systems Society. With regard to the Electronic Health Record Workgroup's recommendation on federal agencies and the purchase or the requirement of having integrated standards efforts, Mr. Leary recommended that the Workgroup examine efforts that have been ongoing in other countries. Canada, several countries in Europe, and a few in the Asia-Pacific Rim have incorporated specific language in their contracting requirements in this area.

Mr. Leary also noted that June 5-8 is National Health IT Week. A total of 31 cosponsoring organizations and 11 partnering organizations will be coming together to meet in Washington, DC, that week. Three federal agencies are heavily involved in this effort, and many organizations whose representatives attend AHIC meetings are participating.

Dr. Brailer noted that he recently joined his peers from other countries in a 2-day summit at which the issue of standards collaboration and how to bring them together and enforce them through contracts was the dominant theme of discussion. There will be follow-up actions that the United States will take with England, Australia, and Canada to explore how global development of standards can be promoted as the health information technology market globalizes and how these countries can learn from each other through this collaborative process.

Speaker Number 3 – Hugh Zettle, GE Healthcare. Mr. Zettle serves on the HER vendor association on the Executive Committee and is one of the many individuals who helped participate in CCHIT's efforts to create certified EHRs. Mr. Zettle emphasized the importance of supporting efforts to develop codified standards to get laboratory results to physician customers. There is concern whether a laboratory test ordered from three different facilities would return with the same coded laboratory results. There are thousands of laboratory systems, and there will be orders of magnitude more EHRs. Reconciling the laboratory results should be done at the source, not at the level of the EHR that receives it.

GE Healthcare provided feedback to CCHIT relative to the roadmap of its activities asking that the commercial timeframes to implement these standards are taken into consideration. His organization would encourage the use of roadmap exercises between CCHIT, HITSP, and the AHIC.

Closing Remarks

Before adjourning the meeting, Secretary Leavitt thanked all members of the Community and those who provided public comments.