The Community

American Health Information Community

April 24, 2007
8:00 a.m. - 1:15 p.m.

Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 800
Washington, DC 20201

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8:00 a.m. – 1:15 p.m. (EDT)

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

8:00 a.m.   **CALL TO ORDER** – *Secretary Leavitt*

8:05 a.m.   **Introductory Comments** – *Secretary Leavitt*

8:20 a.m.   **Comments** – *David Brailer*

8:25 a.m.   **Comments** – *Rob Kolodner*

8:45 a.m.   **Report on the First Year of the NHIN Initiative**
-   *John Loonsk, Office of the National Coordinator for Health Information Technology*
-   *Virginia Riehl, Gartner Consulting*

9:30 a.m.   **National Governors Association – State Alliance for e-Health**
-   *Jodi Daniel, Office of the National Coordinator for Health Information Technology*
-   *John Thomasian, National Governors Association*
-   *Kathleen Nolan, National Governors Association*

10:15 a.m.   **BREAK**

10:30 a.m.   **AHIC Successor**
-   *Secretary Leavitt*
-   *David Brailer*

11:15 a.m.   **Workgroup Recommendations:**
Electronic Health Records Workgroup
-   *Karen Bell, Office of the National Coordinator for Health Information Technology*
-   *Lillee Smith Gelinas, VHA, Inc., Co-Chair*

12:15 p.m.   **Personalized Healthcare Workgroup Update**
-   *Gregory Downing, HHS/Office of the Secretary*
-   *Douglas E. Henley, American Academy of Family Physicians, Co-Chair*
-   *John Glaser, Partners HealthCare Systems, Co-Chair*

1:00 p.m.   **Public Input**

1:15 p.m.   **Adjourn**

Meeting Report

American Health Information Committee
March 13, 2007

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 (EHRs) within 10 years, held its 12th meeting on March 13, 2007, at the Computer History Museum, 1401 N. Shoreline Boulevard, Mountain View, CA. Those Community members and other participants who were unable to attend the meeting in person participated via videoconference from Washington, DC, or via teleconference.

The purpose of the meeting was to bring together Community members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to the Department of Health and Human Services (HHS) 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's discussions focused on: (1) an update from the Certification Commission for Healthcare Information Technology (CCHIT), (2) AHIC Workgroup recommendations, (3) a privacy and security panel, and (4) an employer panel.

HHS Secretary Michael O. Leavitt chairs the Community; Dr. David Brailer serves as Vice Chair. 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 serve 2-year terms.

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

Call to Order

Joining Secretary Leavitt either in person or via videoconference/teleconference were:

David Brailer, MD, PhD, Vice Chairman, AHIC

Robert Kolodner, MD, Interim National Coordinator for Health Information Technology

Justine Handelman, Director of Federal Relations, Blue Cross Blue Shield Association (Ms. Handelman represented Scott Serota, President and CEO of the Blue Cross Blue Shield Association)

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

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

Charles N. (Chip) Kahn III, President of the Federation of American Hospitals (also represented by Howard Isenstein, Vice President, Public Affairs and Quality, Federation of American Hospitals)

Nancy Davenport-Ennis, founder of both the National Patient Advocate Foundation and the Patient Advocate Foundation (Gail McGrath, President and National Director of Government Affairs, National Patient Advocate Foundation, represented Ms. Davenport-Ennis for part of the meeting)

Kevin Hutchinson, CEO of SureScripts

Colin Evans, Director, Policy and Standards, Digital Health Group, Intel (Mr. Evans represented Craig Barrett, PhD, Chairman of the Board, Intel)

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

Tony Trenkle, Director of E-Health Standards and Services, Centers for Medicare and Medicaid Services (Mr. Trenkle represented Leslie Norwalk, Acting Administrator, Centers for Medicare and Medicaid Services)

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention (Dr. Gerberding was represented by Steven Solomon, MD, Director of the Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention, for part of the meeting)

Gail Graham, Director of Health Data and Informatics at the Department of Veterans Affairs, Veterans Health Administration

Steve Jones, DHA, Principal Deputy Assistant Secretary of Defense for Health Affairs (Dr. Jones represented William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs)

Dan Green, Deputy Associate Director, Center for Employee and Family Support Policy, Office of Personnel Management (Mr. Green represented Linda Springer, Director of the Office of Personnel Management)

Bettijoyce Lide, Scientific Advisor for Health Information Technology, National Institute of Standards and Technology (Ms. Lide represented Robert Cresanti, Under Secretary of Commerce for Technology, U.S. Department of Commerce)

Linda Dillman, Executive Vice President of Risk Management and Benefits Administration (Ms. Dillman represented John Menzer, Vice Chairman, Wal-Mart)

Introductory Comments

Secretary Leavitt welcomed participants, both those attending the meeting in person as well as those participating via videoconference and/or conference call. He also thanked staff at the Computer History Museum for hosting this AHIC meeting. Secretary Leavitt explained that almost 700 of the country's largest health care purchasers (which cover more than 82 million Americans) have committed their support to the principles of value-driven competition as expressed in the President's Executive Order (signed on August 22, 2006). He added that almost one-half of the largest 200 purchasers have made this commitment. These companies want change, and their success is being driven by AHIC activities focused on health information technology (HIT) adoption and transparency. The Community must continue to identify the interoperability standards that will allow HIT to reach its full potential while creating the ability for providers to measure and report on quality so that consumers can look for value in their health care.

As the second phase of work on the Nationwide Health Information Network (NHIN) begins, approaches to protecting privacy and ensuring security will be further developed. Secretary Leavitt emphasized that sensitive information must be appropriately protected. Additionally, creating a sustainable business model for producing those standards to encourage rather than impede innovation as technology advances over time is crucial.

Dr. Brailer also welcomed Community members to the meeting and introduced Gary Malone, a Trustee of the Computer History Museum. On behalf of the museum's staff, Board, and volunteers, Mr. Malone welcomed the Community, noting that part of the museum's mission is to understand the impact of the information age and its positive results on human society.

Approval of January 23, 2007, Meeting Minutes

Minutes from the January 23, 2007, AHIC meeting (which was held via teleconference) were distributed, reviewed by Community members, and approved unanimously with no changes.

Certification Commission for Healthcare Information Technology Update

Mark Leavitt, CCHIT Chair, explained that the Commission is an independent, non-profit organization, with the mission of accelerating the adoption of robust, interoperable HIT by creating an efficient, credible certification process. The CCHIT has the following four goals of certification: (1) reduce the risks of investing in HIT, (2) facilitate the interoperability of HIT products, (3) enhance the availability of adoption incentives and regulatory relief, and (4) ensure that the privacy of personal health information is protected. Mr. Leavitt briefly described CCHIT's role within HIT strategy, defining certification as a voluntary, market-based mechanism to accelerate the adoption of standards and interoperability.

In 2006, the CCHIT developed, pilot tested, and launched certification of ambulatory (office-based) EHRs. This year, the Commission is developing, pilot testing, and launching certification of inpatient (hospital) EHRs. In 2008, the CCHIT plans to develop, pilot test, and launch certification of networks through which EHRs interoperate. Mr. Leavitt commented that the CCHIT also will: (1) update certification criteria for each domain annually; (2) expand certification to address more specialized needs; and (3) transition to become an independent, self-sustaining organization by the end of the contract period (i.e., September 2008).

In terms of ambulatory EHR certification, which took 18 months and involved more 150 volunteers representing a wide variety of stakeholders, the proposed criteria were drafted and circulated for public comment (the CCHIT responded to more than 2,000 public comments). After pilot testing in February 2006, the certification program was launched in May of last year. Mr. Leavitt noted that the Commission also published a forward-looking roadmap that lists expected criteria one and two years in advance—this provides the Commission with a way to guide the marketplace without creating undo disruption. The CCHIT has been testing products for certification in quarterly batches, and has gone through three cycles to date. A total of 57 products have been certified over those 9 months; Mr. Leavitt estimated that certified vendors now represent more than 75 percent of the marketplace. After the final cycle of testing, it is expected that more than 80 products will be certified in this area.

Mr. Leavitt noted that most of the large professional associations associated with primary care have endorsed CCHIT's efforts. There are payer IT incentive programs keyed to EHR certification, and health information network pilots are relying on certification of EHRs to satisfy security requirements for participation. New criteria for 2007 include a mandatory ability to send electronic prescriptions and do electronics refills, as well as receiving electronic lab results; both based on standards. Mr. Leavitt commented that although the CCHIT has not started to certify networks, the Commission is having a positive impact on their work. For example, one Medicaid pilot project to share information with physicians caring for Medicaid patients is relying on certification to ensure that peripheral systems have sufficient security. A number of vendors have had to enhance their products to meet CCHIT's criteria; Mr. Leavitt commented that this process is raising the bar as it relates to security and privacy.

Mr. Leavitt also explained that one major issue facing the Commission is the worry that certification would favor large companies, "lock out" small vendors, or stifle innovation. To examine this, the CCHIT conducted an anonymous survey of its certified vendors in February 2007. Of the 30 respondents, only one-quarter have annual revenues of more than $10 million. More than one-half have annual revenues in the $1-$10 million range, and 17 percent have an annual revenue of less than $1 million (the Small Business Administration uses $23 million as the benchmark for a small business in the software vendor classification). Furthermore, the survey indicated that there is no bias against small practices when size of the practices served by these vendors was considered. Mr. Leavitt noted that instead of creating a barrier, certification has created a level playing field for a wide diversity of EHR companies to compete.

Mr. Leavitt provided the Community with an update on the Commission's status relative to certification development moving forward. The ambulatory criteria will go into effect on May 1, 2007. The second draft of the inpatient EHR certification was released on February 16, 2007; a pilot test is planned for April/May of this year and certification is expected to launch on August 1, 2007. The CCHIT also is working on network certification, and is in the preliminary, information-gathering stage. Formal work on the network certification development is anticipated to begin in May 2007.

In terms of certification expansion, the CCHIT has received feedback from stakeholders expressing the desire to have the Commission move faster, not slower, and to remain a consistent force in delivering certification. The CCHIT will refine certification criteria to address more specialized HIT needs, as represented by professional societies, additional care settings, and specific patient populations. The Commission has an objective process in place for prioritizing future areas to address through gathering environmental scan data and prioritizing based on the potential benefit of certification, readiness for certification, and effort required for development. A draft roadmap for expanding certification through the year 2010 has been developed and illustrates that the CCHIT will be addressing at least one topic in three areas: (1) Populations (e.g., Child Health, Behavioral Health Care): (2) Care Settings (e.g., Emergency Department, Long-Term Care, Home Care); and (3) Professional Specialties (e.g., Cardiovascular Medicine, Other Specialties).

Mr. Leavitt explained that the CCHIT has completed its governance transition—the Commission is now an independent, not-for-profit organization (501c3 status pending), with a formed and operational Board of Trustees as of January 2007. The Commission plans to become financially self-sustaining by the end of its HHS contract.

Discussion Highlights

"Is there a process underway to evaluate whether or not a certified electronic record delivers better outcomes, better results in the various dimensions of certifications in any other product, and when will we know what the real outcome measures of these technologies are?" – Dr. Brailer

"There are some outcomes that you can measure literally using the technology itself…[for example,] you can get a statistic out of computers that will tell you how much drug interactions they've caught…The bigger outcomes are the coupling of an EHR with the actions of people, and you need a more comprehensive study. I think that there is now the possibility for that research, and I think we're going to start to see data. It may be a year or two. We are going to do a study of the impact of our work, but we expect it may take some time before you are able to clearly measure clinical outcomes, like reduced hospitalizations or complications." – Mr. Leavitt

"HITSP is the organization that harmonizes standards. Standards are the substrate of our work. We need to certify against standards. And because the organizations started at different times, and they are separate, our schedules didn't automatically synchronize. So we have a joint Workgroup that's working on that…There is a slight difference in the perspective of the organizations, and that is a healthy one. We're very focused on the market and adoption of both the EHRs and also paying attention to

certification so people buy certified products. And their focus is more on this ultimate body of standards that works together in a comprehensive way." – Mr. Leavitt

"What are the rate limiters on your ability to accelerate?" – Secretary Leavitt

"Each marketplace has a speed. The vendors have what's called a 'product development cycle,' and in the small company they might be as short as three to six months, but any medium-to-large company, that's a one-year, 18 months, sometimes two-year cycle. You simply can't introduce a change and say 'we're going to require this next month,' and expect any vendors to be able to meet it. Especially when they don't do it now. So you have this natural 1-2 year cycle. You signal them two years ahead, get serious one year ahead, and then do it. I believe that's the natural rate-limiting step." – Mr. Leavitt

"I'm just curious about the process for accommodating changes in business and changes in technology as they occur. They can move pretty rapidly, and how do you bring that into the certification process and allow people, the early adopters, to move quickly?" – Ms. Dillman

"The certification criteria are intended to be kind of a floor on top of which the vendors innovate. We believe vendors will innovate with new ways to have humans interact with computers…Also, we actually use an expert juror process when we inspect the products…we build the flexibility in there, plus we have this 1-year update cycle, so we can advance the standards. We can also drop one that seems to be irrelevant or not working or change it." – Mr. Leavitt

"As you know, we just have quite an awesome nursing shortage in this country, and one of those issues is this amount of time registered nurses have to spend in documentation…an RN will spend 40 to 60 percent of their time just pushing paper. And I think consumers would be very, very surprised at that. So whatever the nursing community can do to help you get at this gnarly issue of the interaction between EHR and people, I think you'd have a tremendous amount of support." – Ms. Gelinas

"In the case of long-term care, as you are probably aware, between CMS and the states, we fund, together, almost all of that long-term care…And to say there is little nursing home EHR is an overstatement. There is none. I've never seen one. I've visited dozens of long-term care facilities across our state, and I've never seen one. There is no integration occurring, at least in our states, between what goes on in the inpatient environment and what goes on in the outpatient environment." – Mr. Roob

"When you look at mental health care, nothing is more integrated. I run mental health hospitals and most states run mental health hospitals. But the outpatient is all done by third-party vendors. That continuity of care is absolutely essential. Not to say it's not essential in other areas, but in mental health care, it's absolutely essential, that we move that data more effectively than we are today." – Mr. Roob

Workgroup Recommendations

Consumer Empowerment Workgroup Recommendations

Dr. Rose Marie Robertson of the American Heart Association thanked members of the Consumer Empowerment Workgroup for their efforts and reminded Community members that the Consumer Empowerment 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. Dr. Robertson also presented two broad charge issues to be addressed: (1) ideally, personal health data can be exchanged among PHRs and sources of personal health information (e.g., electronic medical records or pharmacy systems) under the control of the patient while preserving the meaning of the data; and (2) appropriate incentives to encourage consumer and provider adoption of PHRs should be identified and promoted.

Ms. Davenport-Ennis noted that a February 13, 2007, meeting of the Consumer Empowerment Workgroup included a presentation from the CCHIT to discuss basic questions about certification, such as: (1) What is certification? (2) How is certification actually going to be completed around a PHR? (3) What is the time involved for the certification process? (4) What will the cost be for those innovators that are trying to get into the PHR area? (5) How will the certification help to protect consumers? (6) What impact, if any, would certification have on innovation? As a result of these discussions, the majority of Consumer Empowerment Workgroup members feel that moving forward with certification is appropriate.

Dr. Robertson then presented the following Consumer Empowerment Workgroup recommendations, which were broken out into two categories:

Certification of Privacy, Security, and Interoperability

- **Recommendation 1:** HHS should support CCHIT and/or other certifying entities in identifying a pathway and timeline for voluntary certification of PHRs after adequate industry experience has been achieved in the market. Such certification should include: specifications for PHR privacy and security, interoperability between PHRs and personal health information data sources (including EHRs) consistent with HITSP-identified standards, and PHR portability. The certification criteria development process should take into account the best practices for security and privacy policies to be identified by the Consumer Empowerment Workgroup, the Confidentiality, Privacy, and Security Workgroup, and other relevant groups.

Incentives for Adoption

- **Recommendation 2:** HHS, through the Centers for Medicare and Medicaid Services and the Indian Health Service, and in collaboration with the Office of the National Coordinator for Health IT, should develop plans to offer portable PHRs with adequate privacy protections to their beneficiaries, and report back to the Community about their plans as available. The plans should take into account the results of the studies and best practices recommended by the Consumer Empowerment Workgroup on January 23, 2007, as they become available, and should build upon work already underway at the agencies.

David Lansky of the Markle Foundation presented a dissenting perspective (his comments also appear in a formal letter submitted to AHIC), noting that there is not consensus on this issue within the Consumer Empowerment Workgroup, and there is, across the industry, across health care, across the consumer sector, not yet enough experience or understanding to achieve a unified recommendation regarding how to proceed. He explained that not enough work has been done in the policy development area; in developing, marketing, and using these products; and in testing the relationship between those policies and those products to know exactly the best way to move toward implementing the policies. All parties involved share the same objective—building a trustworthy, reliable environment in which people share their health information and finding the appropriate mechanisms to develop the right policies and enforce those policies.

Mr. Lansky explained that in some ways, it is premature to move the certification process forward. For example, there is no standard definition of what constitutes a PHR. Additionally, evaluating and validating products in the consumer stage is a new challenge that has not yet been met. Also, Mr. Lansky explained, discussion of certification is premature until standards and policies in areas such as public trust and privacy have been established. He asked whether certification will enhance privacy, security, and trust in the public mind, and about the risk of impeding innovation in the consumer marketplace.

Mr. Lansky noted that there are areas of tremendous agreement across all of the AHIC Workgroups. He expressed the hope that significant progress will be made in moving forward in those areas of very strong

agreement. For example, there is overall consensus that more industry experience is needed in the real world with these products and services. Mr. Lansky appealed to the Community to defer the question of certification until those policies that must be enforced in this environment are understood. He indicated that if further work demonstrates that certification proves to be helpful, there likely will be a very strong consensus to support it.

Ms. Davenport-Ennis thanked Mr. Lansky and the Markle Foundation for their role in presenting the dissenting view, noting that the letter that was drafted and presented to the Community reflects the nature and scope of the discussions the Consumer Empowerment Workgroup had at its meeting on February 13, 2007. She added that the General Accounting Office has recommended a national strategy to ensure the privacy of medical records. HHS has reaffirmed that it currently has contracts in 33 states and Puerto Rico, where they are testing to assess organizational-level privacy and security related to the policy concerns and laws described by Mr. Lansky. In closing, she reminded Community members that consumers have four fundamental concerns regarding PHRs: (1) privacy, (2) security, (3) affordability, and (4) interoperability.

Recommendation 1 Discussion Highlights

"I do want to commend the process of the Consumer Empowerment Workgroup [in discussing] this issue, because there were a lot of concerns, and it was a very fair process…We do recognize, though, that this is a tiny issue, and we're happy that the recommendation letter does lay out certain steps that need to take place, standards and policies. And I just want to underscore what David had said, that we do need to work on those issues and I look forward to doing that moving forward." – Ms. Handelman

"Speaking for Markle, I think we have a great concern…that we don't yet understand what the policies are that will be helpful to create public trust in this new set of services. Any decision about what tool to use to enforce those policies or implement them, across an industry, must wait until we know what they are. Certification may or may not be an appropriate approach." – Mr. Lansky

"We do support…the recommendation of the Committee to go forward with certification of the PHRs…in looking at recent presentations of CCHIT, and their role of protecting the personal health information as associated with it, I do, in fact, feel that it is their role, and they do have the capacity to be able to do this. The limit to security, and confidentiality and interoperability, I think is very key for this recommendation…It is simply the underlying infrastructure of how levels of encryption, levels of password protection, associated with protecting personal health information, is associated with that."
– Mr. Hutchinson

"There may not be a sure definition of a PHR system that's out there, and I would agree with that, but there is such a wide variety of implementation of security features inside these products. It will only take one product that is broken into, and personal health information will shift there, much the same way electronic banking would run the same risk, if those products weren't secure, which is why that we would support the recommendation as well." – Mr. Hutchinson

"It's my understanding that PHRs exist in the Veterans Administration, and I would really want to have a little bit more information about that. But it would seem to me that we don't need a use case. The case is already out there, and it's how PHRs already exist in the Veterans Administration." – Ms. Gelinas

"[Use of PHRs] is a fairly new process for VA, and much recently in addition to the recording of veterans' own information, they have been able to add information from our electronic health record, which is the substantive part of this recommendation…The policies around this were as intricate as the technology around it…It was assurances to those whom you're providing this functionality…their highest level of concern is the confidentiality. So I agree that those are the most important things to tackle in the

beginning; these privacy, security policies. So from that perspective, I think it really reflects our experience and experience that was voiced by others." – Ms. Graham

"I'd like to know what percentage of the Workgroup was actually for this recommendation and what [percentage] was not…That would help inform comments going forward. And we just heard from CCHIT, details of success of certification, how it's sped the market adoption. And I would certainly hope that that would be considered, as we contemplate when we get down to the vote." – Ms. Gelinas

"Of the [approximately 21] Workgroup members, five signed the dissenting letter, and the rest are for the general recommendation." – Dr. Robertson

"Is this group heading towards consensus, or a problem?…It sort of appears to me that the comment of adequate industry experience, and the time required to get that, is critical to the recommendation. I find myself reading the recommendations, sort of agreeing with it, in a sense, but it seems to me there is a lot of work yet to be done, to get to what adequate industry experience would be, and what those agreements on policies would need to be for us to really believe that we could agree on certification of products and technology." – Mr. Evans

"I think the Workgroup has gotten input from multiple vendors. Everyone, that I have been present for the testimony of, has said that they would be in agreement with limited certification, not certification of all functionalities, but limited certification in and around privacy and security. That certainly is not true for all vendors, but it is true for many vendors." – Dr. Robertson

"I don't think the group is probably going to come closer together on this. I think we've had a lot of discussion. We've had many presentations, and I think we each have a slightly different view of this crystal ball of the future and what's the best way to do this." – Dr. Robertson

"Thinking about our employee needs, we hope there is an opportunity for a large amount of innovation in this. There are hundreds of different companies and ideas that we want to encourage to flourish in this area, that people use this data for; by the same token, there is also, as you say, a massive range of opinions about what adequate privacy is that varies both politically, as well as situationally, depending on how concerned you are about your data." – Mr. Evans

"I don't think there is so much variety about what privacy is. There is variability about how much people care about it." – Dr. Robertson

"There are profound disagreements, I think, across the Committee at this point, of the immature market state. With a year, or two, or three…we may find agreement in a yet unpredictable arena. But I do think there is great concern that certification is a strong intervention in a private marketplace, and for a federal advisory committee, or a federal agency to say that is a necessary step to influence this market, at this stage, is a very strong statement that we haven't seen evidence for yet." – Mr. Lansky

"I just wonder whether not moving towards certification is really letting the perfect be the enemy of the good here, and that if we're also moving towards interoperability, to not move towards certification here with all there is out there, I think would be problematic. So I personally think we ought to go ahead with the recommendations." – Mr. Kahn

"I, too, think we ought to move ahead with this recommendation…primarily because certification has already been considered an integral part of adoption for health information technology, overall…I think it flies in the face of general agreement that certification is going to drive the market, ultimately, for all aspects of HIT. I certainly think that one thing that hasn't been addressed is the idea of portability of EHRs, which I think is critical to the adoption of PHRs and consumer involvement…I simply don't see

what the harm is for moving forward now towards certification, at least the technical aspects of certification." – Mr. Green

"The consensus that we did have in the committee for advancing the recommendation to the Secretary within this letter was clearly a majority consensus among the CE Working Group members. I would also like to call the attention to the written recommendation, that has been proffered in the letter to Secretary Leavitt, that does identify that we are discussing voluntary certification. And I think that's a very important point to be considered today, as we're looking at this matter." – Ms. Davenport-Ennis

"On behalf of patients…certification is a very logical step for consumers who are used to being in a health care delivery system that has informed consent as a practical part of everyday life. And certification is another mechanism to ensure the consumer a fundamental safeguard is in place for them around PHRs."
– Ms. Davenport-Ennis

"Having been involved in building lots of systems and going through lots of certifications with various organizations, I believe in the certification process, and I would strongly encourage everyone to focus on interoperability first. If you want to drive adoption, that will do it. A concern I had is that there are a number of organizations today, that already exist, that have defined standards for privacy or security on consumer data. And I fear that this will become just one more that may or may not coexist with the other standards." – Ms. Dillman

"That's an excellent question, and was one we didn't address…The Confidentiality, Privacy and Security Workgroup would be an appropriate place to take that, and I think that's a very important issue to take forward. We certainly don't want to complicate the arena of privacy and security further."
– Dr. Robertson

"I read the report letter and the dissent letter with great interest…There are many parts to this puzzle we're trying to assemble. There is the adoption part of the puzzle. There is the interoperability part of the puzzle. There is the privacy part of the puzzle. These will not move forward in perfect symmetry. They will come together in different pieces. We'll get a corner piece, then we'll get a piece of the cover, then we'll start to build on it. We'll be assembling this in many different ways." – Secretary Leavitt

"AHIC will have more influence on interoperability than we will on adoption. Likewise, under privacy, it's very clear to me that there are policy debates that have to be ongoing, that we have not resolved yet…But frankly, our influence in AHIC will be greater on the technical side than it would be on the policy side, and that doesn't mean we don't keep working on both of them." – Secretary Leavitt

"From my view, PHRs would clearly play a major part [in solving] this puzzle. I agree that we don't know with exactness what they'll look like. We don't know with exactness, what part they will play. But…if you're going to have PHRs, ultimately you've got to have a way to populate them, independently of me putting in my information." – Secretary Leavitt

Following this discussion, Community members voted on Recommendation 1. The recommendation passed with no dissenting votes.

Recommendation 2 Discussion Highlights

"This is a recommendation that we brought back after further discussion with the various federal agencies affected by what we had recommended before." – Dr. Robertson

"I'd like to make just one slight modification and suggestion. Instead of 'offer,' [use the term] 'make available,' because I think what we're trying to do at CMS is make the PHRs available to our beneficiaries, but not create our own PHR. And I think there is a very important distinction. And when

you say 'offer,' it sounds like we're actually getting into the business of it ourselves. What we'd like to do is make sure we fully support PHRs, as they develop, and make our data available to ensure that the proper privacy and security protections are in place, but not offer a CMS-specific PHR." – Mr. Trenkle

"I would certainly accept that amendment. I don't think that there was a sense that we meant you had to build one." – Dr. Robertson

In the absence of dissenting discussion, Dr. Brailer declared Recommendation 2 approved by AHIC.

Quality Workgroup Recommendations

Dr. Carolyn Clancy, Co-Chair of the Quality Workgroup and Director of the Agency for Healthcare Research and Quality, explained that this Workgroup's guiding premise is that the quality enterprise should drive recommendations to the Community about how the capabilities of HIT can help make data capture for quality reporting more efficient, and help make improvements at the point where patients are receiving care. Dr. Clancy reminded the Community that the Quality Workgroup's broad and specific charges are as follows:

- **Broad Charge:** Make recommendations to the Community so that health IT can provide the data needed for the development and application of quality measures useful to patients and others in the health care industry, automate the measurement and reporting of a comprehensive current and future set of quality measures, and accelerate the use of clinical decision support that can improve performance on those quality measures. Also, make recommendations for how performance measures should align with the capabilities and limitations of health IT.

- **Specific Charge:** Make recommendations to AHIC that specify how certified health IT can capture, aggregate, and report data for a core set of ambulatory and inpatient quality measures.

To demonstrate a vision of the future from the patient's perspective, Dr. Clancy described an example using "Mr. Jones," who experiences typical symptoms of a heart attack and is rushed to the local emergency room where he was given aspirin by his nurse. The receipt of aspirin at the time of admission is one of the measures that hospitals have been reporting on for several years derives from very strong clinical evidence linking the use of aspirin to better outcomes. The clinician, "Dr. Smith," is prompted by an EHR that includes clinical decision support. That information also is transmitted to the hospital quality data store, or internal to that hospital repository; and ultimately, the performance information, not the patient data, is transmitted to a quality organization.

Dr. Smith reviews the EHR for Mr. Jones' past medical history, which, because of effective health information exchange (HIE), is available, even though he has moved a lot in the recent past. Dr. Smith also is prompted not to give this patient a beta blocker because he has asthma, one of the contraindications for beta blockers. Dr. Clancy noted that importantly, Mr. Jones is not included in the denominator when the hospital is reporting information on quality (i.e., a patient who is not eligible to receive this treatment should not be counted as someone who did not receive it). At the time of discharge planning, Dr. Smith answers questions electronically, gives his prescription information, and completes required fields in the discharge module.

When he gets home, Mr. Jones uses his PHR to understand what happened during his hospital stay; he also goes online to select a new doctor based on quality ratings and on what the physician charges. Mr. Smith selects "Dr. Thomas," who has access to what happened to Mr. Jones in the hospital. Dr. Thomas reviews Mr. Jones' EHR, and as he is getting ready to exit this review, Dr. Thomas is prompted by clinical decision support about whether he has counseled Mr. Jones about quitting smoking. Mr. Jones is now well on his way to becoming a much more active participant in managing his health and health care.

Following her description of this scenario, Dr. Clancy presented the recommendations of the Quality Workgroup, which were broken out into four categories:

Automate Data Capture and Reporting for Core Set of AQA/HQA Measures

- **Recommendation 1.1:** The Quality Alliance Steering Committee, with support from HHS and other relevant federal agencies, should convene an expert panel that would accelerate the current efforts to identify a set of common data elements to be standardized in order to enable automation of a prioritized set of AQA and HQA measures through electronic health records and health information exchange. The Quality Alliance Steering Committee, with support from HHS and other relevant federal agencies, should establish the priority order for the measures. This panel will build on work already done by NQF and others. The first group of recommendations from the expert panel should be shared with the Community by June 5, 2007.

- **Recommendation 1.2:** The Health Information Technology Standards Panel should use the work of the Quality Workgroup's expert panel recommended in 1.1 to identify the data standards to fill identified gaps for data elements required for automation of core sets of AQA and HQA quality measures.

- **Recommendation 1.3:** The Certification Commission for Health Information Technology should develop appropriate criteria necessary to support the reporting of core sets of AQA and HQA measures in the next round of criteria development.

Gather and Deliver Key Information to Providers To Help Drive Improved Care Outcomes

- **Recommendation 2.1:** The expert panel convened by the Quality Alliance Steering Committee in Recommendation 1.1 should gather, synthesize and refine clinical workflow maps, focusing on care processes related to care underlying the conditions targeted by the prioritized set of AQA and HQA measures. The Quality Alliance Steering Committee, with support from HHS and other relevant federal agencies, should establish the priority order for the measures. The panel should determine mechanisms and opportunities within these workflows for identifying patients who are eligible for inclusion in the AQA and HQA measure populations, for gathering performance measurement data, and for providing clinical decision support to optimize performance in targeted areas. In addition to a generic framework that could be used across many clinical conditions, the deliverable should include at least one scenario for how the workflows operate for AQA/HQA targeted conditions. Measure inclusion mechanisms must protect privacy and confidentiality. The results of this analysis should be reported to the Community by September 18, 2007.

Enable Data Aggregation To Allow Public Reporting of Quality Measures

- **Recommendation 3.1:** HHS, working with relevant public and private sector leaders and the BQI projects, should identify and articulate the key challenges associated with linking claims data from multiple sources (e.g. physician IDs, claims adjudication processes, data storage/purge policies), and the benefits and challenges of linking clinical data to other data sources, including claims. A report should be submitted to the Quality Workgroup by June 30, 2007.

- **Recommendation 3.2:** HHS should enable, through the NHIN contracting process and value exchanges, efforts to combine clinical and nonclinical electronic data for quality measurement and timely reporting of results.

Align Quality Measurement With the Capabilities and Limitations of HIT

- **Recommendation 4.1:** HHS, through the Centers for Medicare and Medicaid Services and the Agency for Healthcare Research and Quality, along with major measure developers, should identify opportunities to enhance measure development by considering the data needs at the time a measure is developed, especially for measures targeted for public reporting. This effort should also include clinical practice guideline developers and coordination of their role in developing performance measures.

- **Recommendation 4.2:** The National Quality Forum, through its endorsement process, should apply criteria that reinforce the use of standardized data elements in measures to allow quality measures to be embedded in EHRs. The NQF may do so by incorporating such criteria into its endorsement criteria for new measures.

Discussion Highlights

"We're talking about quality measurement and reporting, but what we really want is value; and how will we link the cost information to the quality information, in terms of a set of measures that we can really get ourselves around…Because that's where the evidence faces, that's what we know, that's where we can develop our scientific expertise. Fundamentally, what we really want is the best value for our patients."
– Dr. Gerberding

"When we think about quality traditionally, we're thinking about either something that happens to the patient at an encounter, or set of encounters, provided by a team of health care providers in an organization or set of organizations, but ultimately, we're so networked now that it's really the quality of the system, and who owns that. And I'd like to say that it's probably the public health department who owns it. Others might say it's the payer who owns it. But somebody ultimately has to be accountable for the help within that whole set of networked organizations and entities." – Dr. Gerberding

"Ultimately, the real test for the quality enterprise is going to be [whether they] can develop measures and implement them that actually speak to misuse and inappropriate use. We're starting to see some of this in work on patients…but I'd have to say it's not an area that's terribly well developed right now."
– Dr. Clancy

"I want to make sure that I understand the sequence here. You're proposing that by June, you would identify [a prioritized set of measures from the Workgroup] and then by September, a criteria to support reporting. This is on the ambulatory side of the house. What I hear you saying is that inpatient it's going to take longer, because we're not as far as long with that. So if that occurs on schedule, we're out creating value exchanges [that] are hopefully going to have the capacity ultimately to bring that data…perhaps a year after June?" – Secretary Leavitt

"June is the perfect time for input to the Workgroups on the '08 cycle, for what will be available in May, what will go on the standards for 2008, the criteria. They may decide the market is ready enough to include it, literally, so we would require it for the 2008 criteria for May, or they may say it's a little too far beyond where people are to put it on their road map, which means it would be required one year beyond. But that doesn't mean it doesn't encourage vendors to include it when it's on the road map. It just doesn't force them to have it on for certification until it actually becomes [a criterion]" – Mr. Leavitt

"This will happen in one system at a time, but theoretically, in June you would have data standards and criteria to support its collection. It would go into a certification that would begin to happen at the end of that year…And then theoretically, people would begin to buy systems that would be certified to that, and the doctors could get their one-and-a-half percent by buying them, and they would start to collect the data. And the data, then, would be a way that ultimately could begin to form a value exchange where the information could begin to be assembled. And that's where it would connect, at least in my mind…with the price." – Secretary Leavitt

"So if you allow a year for that to begin to mature, for the system to be populating with data, you're really looking at something like maybe the year 2010 before you'd start to see automated collection of data connecting into or being aggregated with the value exchange and ultimately, some kind of product falling out the end of the pipe." – Secretary Leavitt

"You've coupled that one-and-a-half percent reimbursement [which] looks much easier for the vendors, when their customers are going to recognize extra reimbursement, so I think that's a very good accelerating factor." – Mr. Leavitt

"We're more than happy to participate in value exchanges and make them work in terms of being change agents and providing information to people. But at the end of the day, what's implicit in these recommendations is that somehow data is going to be collected locally, and at least on the hospital side, not only is it a nonstarter, it is completely different from what's happening today with the Iowa QIO, collecting the information, and being reported on a CMS Web site. I think that we can improve what's happening today, but it can't be local. The information can, of course, be used locally, but I think implicit in here is policy that is counter to current practice and is problematic, if we go down that road."
– Mr. Kahn

"I'm all for efficiency measures, and those efficiency measures can be connected to length of stay, to other kinds of activities. But if you want to connect those on the hospital side to the monetary side, or even on the physician side connecting it, you've got tremendous technical issues that go way beyond records." – Mr. Kahn

"We are dealing with issues that can ultimately be worked out, but tying these payment issues to reporting of measurements, I think, is problematic. And I think when we look into efficiency, we're going to find activities within the episode of illness, rather than connection to cost data that's going to be most useful, because we don't know the cost data in the same timeframe, however you calculate it, as we would the clinical side or the experience side, even for a whole episode of illness." – Mr. Kahn

"Value exchanges are not going to be doing data aggregation themselves. There will be a central contractor that does that for them, and they will be buying those services to aggregate data from private payers and from Medicare. And they will be hopefully using data about local hospitals and data about local physicians. So people begin to get a sense of this picture, but that's still several steps removed from the future vision that we're showing you." – Dr. Clancy

"You can use the network to do the reporting, but I think this is not going to be done on a local basis. At least [in] the near future." – Mr. Kahn

"It's the local hospital that's the foundation piece of it, and that in many respects, the intellectual firepower behind it and so forth. And it's also clear to me, when I talk to physicians, that they don't want CMS or the government to be the place where this data gets publicly disclosed. They want to have it on a local basis, where they can get a hold of the people and say, 'This is wrong. There is something going on here.'" – Secretary Leavitt

"At least in terms of the clinical data, just having the data from a hospital isn't really sufficient. You need to be able to compare that hospital to all other hospitals across the country. And you need to have comparable data, collected in the same way, with all the same standards, in the same timeframes. And in a sense, with Hospital Compare, that's what we have now…I don't think it's user friendly for consumers, but for those who are professionals, it actually is a fairly useful database to make comparisons."
– Mr. Kahn

"One of the things that's a well-documented outcome is medication adherence and compliance…The MMA recognized the value of medication therapy management services in putting medication therapy management within the MMA. This is something where data is available today, to be exchanged with physicians as well, and I'd ask that we…also recognize the role of the pharmacist in that process, not only as a healthcare services provider, but also as a point of information in data exchange, to be able to share that medication and history information." – Mr. Hutchinson

"Oftentimes the pharmacist is the only point of information about the fact that a patient has tried to refill an inhaler, for example, 12 times in the past month; which tells you something about either they're losing them a lot or that their disease severity has increased dramatically and so forth." – Dr. Clancy

"[In terms of] Recommendation One, I'm certain that you would be including a patient consumer on the expert panel, but as I represent those within the AHIC, I would just like to call this out so that it can be a matter of public record that we are recommending that they, indeed, are included on the expert panel."
– Ms. Davenport-Ennis

"As we are looking at cost and collecting cost, and trying to define the value that's being received for the cost, I think it is also an ideal time for us to look at collecting the cost that the consumer and the patient is investing, in order to access the public health networks in this country, and the hospitals and the clinics in the country. That information is going to be available at the time that you are capturing the costs that are cited here." – Ms. Davenport-Ennis

"In Recommendation Three, there is going to be such a concentrated effort to collect the data, and I would simply call out for a matter of public record that [this] information will be of particular interest to the consumer, once it is reported out to them, as they're defining value." – Ms. Davenport-Ennis

"The progress that we've made [in Indiana], and I think that you'll find here in California, would not have been made…had we waited for CMS to create the singular national model. You couldn't have gotten off the ground, both in Indiana and other places, with the speed and robustness in which we were able to do. We will be able to report data, beginning at the next contracting cycle, as a result of that. And I think other value exchanges will, as well, in terms of copying that performance to contracting." – Mr. Roob

"[It is] very difficult to equate cost to this when you have as many uninsured Americas as we have today, and that, when you're layering the cost of other people's care into your care, it's very difficult to find what a real cost number is, on a counter basis. So we've got work on quality, I think, here, and work on the cost issue, once we give more Americans a real opportunity to purchase affordable health care products." – Mr. Roob

"The real attraction is where local hospitals are working with local groups to report this information. They're far more enthusiastic about reporting to a local group than they are in sending it off to CMS. They get paid for sending it to CMS, but they're paying to send it to their local organization. And somehow we've got to streamline that process, and certify into the collection records, so that people can do it automatically." – Secretary Leavitt

In the absence of dissenting discussion, Dr. Brailer declared Recommendations 1.1, 1.2, 1.3, 2.1, 3,1, 4.1, and 4.2 approved by AHIC. Community members voted on Recommendation 3.2. The recommendation passed with no dissenting votes.

Population Health/Clinical Care Connections Workgroup Recommendations

Population Health/Clinical Care Connections Workgroup Co-Chair and Community member Mr. Charles (Chip) Kahn noted that this presentation marks the first time this Workgroup is presenting to AHIC under its new name following its transition from the Biosurveillance Workgroup.

Ms. Cronin, Office of the National Coordinator, explained that the Workgroup includes representation from all levels of public health as well as clinical care. Recently, membership from a Health Information Exchange was added to help ensure a comprehensive and diverse set of expertise at the table as Workgroup members debate the many different issues that apply to how HIT can more broadly enable the many goals shared by all for improving population health. She reminded Community members that the Population Health/Clinical Care Connections Workgroup's broad charge is to make recommendations to the Community that facilitate the flow of reliable health information among population health and clinical care systems necessary to protect and improve the public's health.

In recent months, the Workgroup has focused on two of its key priorities—case reporting and bi-directional communication. Two emerging themes have arisen in the Workgroup's deliberations: (1) public health agencies, across the country at all levels, are largely not connected (e.g., they do not share the same standards and do not have systems that can interoperate or share information with each other on a seamless level); and (2) there is a need to develop the business case for public health, so that public health entities can participate in the emerging NHIN and share data with each other, as well as benefit from the data that are going to be coming from health care, so there can be a bi-directional flow, as needed.

Dr. Steven Solomon of CDC and Mr. Kahn then presented the following Population Health/Clinical Care Connections Workgroup recommendations, which were broken out into three areas:

Overarching

- **Recommendation 1.0:** The State Alliance for e-Health, in collaboration with state and local governmental public health agencies and clinical care partners, and in consultation with HHS, should develop a business case for data/information exchange between public health and clinical care as well as develop a communications plan to improve the understanding of the need for this exchange.

- **Recommendation 1.1:** By June 30, 2007, HHS, in collaboration with federal, state, and local governmental public health agencies, should develop an approach, including identification of possible resources within public health, to support the HITSP process to ensure there is capacity to harmonize standards for AHIC population health use cases.

- **Recommendation 1.2:** By June 30, 2007, HHS, in collaboration with state and local governmental public health agencies, should engage or consult with CCHIT to establish an open, participatory process for certification of public health information systems for functionality, security, and interoperability that is coordinated with the certification of clinical care and health network systems.

- **Recommendation 1.3:** By June 30, 2007, HHS, in collaboration with the Association of State and Territorial Health Officials (ASTHO), National Association of County and City Health Officials (NACCHO), and other appropriate organizations, should support the establishment of a proof-of-concept demonstrating the added value of sharing data from clinical care to public health through health information exchanges.

- **Recommendation 1.4:** By June 30, 2008, HHS, in collaboration with ASTHO, NACCHO, the State Alliance for e-Health, and other appropriate organizations, should develop a plan to encourage the integration of state funded public health surveillance programs and health information exchanges.

- **Recommendation 1.5:** In 2007, HHS and all its agencies shall communicate internally and with all funding recipients that interoperability standards were accepted by the Secretary of Health and Human Services in December 2006 and will be recognized in December 2007. This recommendation

acknowledges that the time between acceptance of interoperability standards in December 2006 and recognition of these standards in December 2007 will be used for planning and programming to incorporate these standards.

- **Recommendation 1.6:** Beginning January 1, 2008, HHS and all its agencies shall ensure that internal programs, as well as externally funded programs, implement relevant HHS-recognized interoperability standards. This requirement applies to the implementation, acquisition and upgrade of health information technology systems that support public or population health consistent with Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs (http://www.whitehouse.gov/news/releases/2006/08/20060822-2.html).

- **Recommendation 1.7:** By June 2007, HHS should identify a process to establish and manage an authoritative Web site to share recognized standards as well as provide a collaborative space for the sharing of standards being tested or used that are not yet recognized.

Case Reporting

- **Recommendation 2.0:** By April 30, 2007, the Council of State and Territorial Epidemiologists (CSTE), in collaboration with CDC, should define an ongoing process to be used in establishing a common list of nationally notifiable conditions to be reported to all levels of public health and their associated standardized case definitions including the data elements to be reported.

- **Recommendation 2.1:** By August 1, 2007, CSTE, in collaboration with CDC, should provide to HHS the common list of nationally notifiable conditions and the first set of case definitions including the list of common and disease-specific data elements to be reported. Subsequent sets of case definitions will be delivered on a scheduled basis as defined by the process resulting from Recommendation 2.0 above.

- **Recommendation 2.2:** HHS should ensure the harmonization of data, technical, and interoperability standards for notifiable disease case reporting based on the availability of resources resulting from Recommendation 1.1 above.

- **Recommendation 2.3:** The CCHIT should include requirements for flexibility in and certification criteria for automated case reporting of nationally notifiable conditions in electronic health records by 2009.

- **Recommendation 2.4:** HHS should convene a meeting to determine a process for defining requirements and implementation criteria for supporting automated case reporting from electronic health records or other clinical care information systems. The meeting should include industry vendors as well as state and local public health officials. The requirements and criteria that result from this process should be used to inform Recommendations 2.2 and 2.3 above.

- **Recommendation 2.5:** HHS, in collaboration with ASTHO, NACCHO, provider organizations, vendor organizations and other appropriate organizations, should develop a business case for automated electronic case reporting. The business case should articulate the burden associated with manual reporting and the benefits and limitations of automating reporting.

Bi-Directional Reporting

- **Recommendation 3.0:** HHS should ensure the harmonization of standards for formatting the structure of health alerts, including broad categories of content and metadata about the content based

on the availability of resources resulting from recommendation 1.1 above. These standards should be considered for e-mail and Web-based alerting, but should not impede risk communications needs to optimize alert content or content presentation.

- **Recommendation 3.1:** HHS should ensure the harmonization of standards for exchanging public health and clinician directory information (contact information categorized by person, roles, organization, organization type, and jurisdiction) based on the availability of resources resulting from recommendation 1.1 above.

- **Recommendation 3.2:** By June 30, 2007, HHS, in collaboration with ASTHO, NACCHO and other appropriate organizations, should support the establishment of a proof-of-concept demonstrating the added value of sharing information through bi-directional communications among clinical care and public health.

Discussion Highlights

"What these recommendations do is really bring the public health system closer to the clinical care system in ways that not only allow the public health sector to do its job better, but also contribute to the future of the meaningful health system, where we can begin to even talk about the value of the health system, not just the value of the health care delivery system." – Dr. Gerberding

"The first step…is about, first of all, measuring the health of the status in the community, reporting that to the community, but also understanding, what are we investing, and what is the value of that investment to the community…By bringing this set of recommendations forward, I really see it as the first step towards actualizing a future state, where we really are talking about the same sides of the coin, and that we really can get to a value-based public health system that will be very complementary to a value-based health care delivery system." – Dr. Gerberding

In the absence of dissenting discussion, Dr. Brailer declared Recommendations all of the Population Health/Clinical Care Connections Workgroup recommendations approved by AHIC.

Confidentiality, Privacy, and Security Workgroup Recommendations

Mr. Kirk Nahra, Chair of the Confidentiality, Privacy, and Security Workgroup, noted this Workgroup's broad charge is to make recommendations to the Community regarding the protection of personal health information in order to secure trust, and support appropriate interoperable electronic health information exchange. The Workgroup's broad charge is to make actionable confidentiality, privacy, and security recommendations to the Community on specific policies that best balance the needs between appropriate information protection and access to support, and accelerate the implementation of the consumer empowerment, chronic care, and electronic health record-related breakthroughs.

Mr. Nahra informed the Community that the Workgroup's sole recommendation for this meeting relates to the identity-proofing recommendations presented at the January 23, 2007, AHIC meeting. The Confidentiality, Privacy, and Security Workgroup's recommendation for this meeting is as follows:

- CCHIT should be made aware of the identity proofing recommendations accepted by the AHIC on January 23, 2007, and where possible security criteria it develops should support these recommendations.

Jodi Daniel, Office of the National Coordinator, explained that at the last AHIC meeting, concerns were voiced related to whether or not the Workgroup was suggesting that CCHIT should be setting criteria for business processes. She clarified that to the extent that there are criteria for the technology that can be addressed to support the identity-proofing recommendations, the Workgroup is encouraging CCHIT to do

that, as they develop criteria. It may be appropriate for AHIC to discuss, at a future meeting, the issue of business processes and how best to implement those.

In the absence of dissenting discussion, Dr. Brailer declared the Confidentiality, Privacy, and Security Workgroup Recommendation approved by AHIC.

Privacy and Security Panel

Privacy and Security Framework

Ms. Daniel explained that exciting results are beginning to emerge from privacy and security solutions work at the state level, where a contract with RTI has created the Health Information Security and Privacy Collaboration across 34 states and territories. Susan McAndrew, Deputy Director for Health Information Privacy at the Office of Civil Rights, stated that addressing the privacy and security of information issues found in the health care world are critical for moving AHIC's mission forward. Balancing these issues with policy decisions is a difficult, complicated undertaking. Ms. McAndrew noted that her office is available to provide its expertise and experience in creating and achieving the balances that exist within the Health Insurance Portability and Accountability Act (HIPAA) privacy rule. Discussions at a recent National Meeting of the States indicated that the privacy rule can be seen as a way of facilitating uniformity in terms of state issues and state business practices to the point where it has created a baseline on which uniform practices can build on.

Ms. McAndrew explained that the new e-health initiatives represent many new risks to information, raise consumer concerns about information exposure, and provide opportunities to get the consumer more involved and give them more opportunities with respect to controlling their data and having access to it. She added that the HIPAA privacy rule has helped establish a common ground for many policy issues. Her office has received requests from AHIC's Consumer Empowerment Workgroup to provide clarifications about how the privacy rule operates with respect to PHRs and in general, how the rules operate within some of these exchanges.

Ms. Daniel then noted that privacy and security are integral to AHIC efforts in terms of policy, technology, and many other areas through partnerships at federal, state, and organizational levels. She emphasized that technology and policy solutions are interdependent and need to be developed in concert. Policy development will be most effective when it is based on an understanding of the environment and how people interact with the technology. Technology development will be most effective when technology's implications on use are considered and when ways to incorporate the policies effectively are considered.

Ms. Daniel presented a number of collaborative activities underway to advance privacy and security, including:

- Privacy and security solutions for interoperable HIE (34 states and territories have identified variations in privacy and security policies and practices; solutions and implementation plans are being developed to address these variations).

- The National Committee on Vital and Health Statistics has submitted privacy and security recommendations for the NHIN.

- Identity-proofing recommendations from AHIC have been submitted to the HHS.

- NHIN prototype security architectures are being developed.

- CCHIT security criteria are being developed.

In addition, Ms. Daniel discussed a number of planned collaborative activities to advance privacy and security, such as final deliverables from the Privacy and Security Solutions Contract, the State Alliance's Health Information Protection Task Force, and HIPAA guidance on exchanging data with PHRs. She closed her presentation by describing how different phases of privacy and security activities feed into each other while accounting for federal, state, and local legislation. For example, the Privacy and Security Solutions Contract will be feeding the state privacy and security implementations, the State Alliance for e-Health, and federal policy development.

Privacy and Security Solutions for Interoperable Health Information Exchange

Linda Dimitropoulos of RTI International, serves as Project Director on the Privacy and Security Solutions Contract. She explained that when the Community was last given a status report (June 2006), the state teams had just signed their subcontracts and were forming steering committees and workgroups. In August and September of last year, the state teams worked on their assessments of variation; in October and November, a series of 10 regional meetings were held at which the state teams came together to share information. A total of 43 states participated in these meetings. In November, January, and February, the states submitted interim assessments through three reports: (1) an interim assessment variation, (2) an interim analysis of solutions, and (3) an interim implementation plan. Final reports are due at the end of March 2006. A national meeting was held earlier in March 2006 that included more than 300 participants, roughly half were from the state subcontract teams. This meeting, which was open to the public, included a great deal of interaction among the states and between the states and various experts and members of the public.

Ms. Dimitropoulos described some of the high-level sources of variation that the states identified. Not surprisingly, stakeholders in different states and businesses apply the HIPAA rules differently, creating a wide variety of organization-level business practices across the nation. Some of the variation is due to the flexibility built into the rules, and some is due to misunderstanding of how and when the rules apply. In addition, some of the variation is caused by the use of differing terms in the different regulations. Many states have laws that require patient consent, and even where there is no state law, many, if not most organizations, require patient consent anyway. There also is broad variation among stakeholders as to what is required legally, what is appropriate for risk management purposes, what constitutes the best public policy, and what is feasible from an implication perspective.

Another source of variation related to HIPAA is the term "minimum necessary." The HIPAA privacy rule states that a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use disclosure or request. HIPAA requires that uses and disclosures of personal health information for anything other than treatment be subjected to minimum necessary use review, so that no more than the minimum necessary amount of information is used or disclosed in each situation. One of the issues surrounding the term "minimum necessary" is the widespread belief that it applies to disclosures to providers for treatment purposes, even though the HIPAA privacy rule explicitly exempts a specific purpose from the minimum necessary requirement. Many business practices documented by the states show that "minimum necessary" was applied to such disclosures, even in emergency-related transfers of records, creating inappropriate barriers to otherwise necessary HIE. The state reports indicated that in many cases, the existing technology cannot limit disclosures to the minimum necessary, so processes that could be electronic must be manual, which can be time consuming and prone to error. In terms of the HIPAA security rule, stakeholders expressed confusion regarding the different types of security required and misunderstandings regarding what was currently technically available and scalable.

Ms. Dimitropoulos also noted that there clearly is a variation in understanding of 42 CFR Part 2 by treatment facilities, physicians, and integrated delivery systems; there also is variation in the way that stakeholders understand the relation of 42 CFR Part 2 to HIPAA, and how each is applied. Additionally, there is a great deal of variation related to the state privacy laws, partly due to the fact that many state privacy laws are fragmented, scattered through many chapters of law, and when states identify them, they often are in conflict with each other. Many states have additional privacy laws that in some cases predate HIPAA. These antiquated laws do not apply sensibly to electronic information exchange, because they were developed for paper-based information flows.

Ms. Dimitropoulos commented that trust is an overarching issue, and mistrust between organizations often is created by variation. For example, the state teams reported that the lack of a common method for authenticating individuals creates mistrust between organizations, and reduces their comfort level with other organizations. A number of states have reported that concern about liability for incidental or inappropriate disclosures causes many stakeholder organizations to take a conservative approach to developing practice and policy, which then creates a mistrust of what the other organizations are doing. Stakeholders are concerned about policies that will govern rights to access control and management of health information whenever data exchange occurs. A key question is whether and how much access patients should have to their health information. The state teams have raised the issue of the tension between healthcare providers, hospitals, and patients concerning who controls the data.

A summary of the interim analysis reports that the states provided to RTI is underway—this effort includes summarizing approximately, 7,000 pages of analysis and information from the states. Interim solutions have emerged in four major categories: (1) practice and policy solutions, (2) legal and regulatory solutions, (3) technology and data standards, and (4) education and outreach. The states also are pushing out multi-state recommendations. Ms. Dimitropoulos explained that the implementation plans will document practical approaches and actionable steps for implementing solutions. Next steps include conducting a final assessment of variation and analysis of solutions reports, creating the final implementation plans, and developing a nationwide summary.

Health Information Security and Privacy Collaboration (HISPC)

State of Wyoming

Rex Gantenbein commented that in Wyoming, variations were identified through small workgroups and individual conversations with a variety of stakeholders. Solutions were proposed by stakeholders after reviewing the variations report. There was a focus on incremental steps that would reform business practices at the state level, and stakeholders were adamant that the project should lead to action and not "another report on the shelf." Mr. Gantenbein noted that the implementation plans were developed at a core stakeholders meeting and will be vetted at a statewide security and privacy symposium in late March. Three main variations were identified in Wyoming:

- Inconsistent and incorrect interpretation of HIPAA. No authoritative interpreting body exists, smaller facilities lack resources to interpret law, and the fear of legal reprisal for wrongful disclosure engenders conservative practices.

- A lack of existing electronic health information infrastructure. EHRs exist, but are not interoperable; concerns over security, privacy, cost, and complexity deter many providers and consumers from HIT adoption; and most providers resist centralized or mandated systems.

- Outdated state statutes inhibit the exchange of health information. Recently passed "credit freeze" laws protect financial information, but do not specifically address health information, and existing health privacy laws only apply to inpatient facilities.

Mr. Gantenbein described some proposed solutions. In terms of HIPAA and other policy issues, there are plans to establish a regional policy coordinating center for HIE in Wyoming that will analyze, clarify, and communicate legal and technical issues as well as provide education and training. With regard to the lack of existing health information infrastructure, Wyoming will create an HIE pilot project to: (1) develop an interface mechanism for information exchange among disparate systems, and (2) demonstrate the benefits and trustworthiness of HIE to providers and consumers. To address issues related to outdated state statutes, Wyoming will generate changes in state law to extend protection and notification laws to health records, review and update several statutes to assure consistency, and address other specific needs such as high-risk juveniles.

State of New Jersey

William O'Byrne explained that New Jersey has a health information technology law, the Health Information Electronic Data Interchange Technology Act (HINT), that has allowed the state to incorporate a wide range of stakeholders into the process, including traditional health care payers, New Jersey's Medicaid office, automobile personal injury protection insurers, workman's compensation insurers, state veteran facilities, inmates, and committed patient facilities. HINT allows for the adoption of rules and regulations not only for EHRs, but also for HIT. Mr. O'Byrne explained that they have a great deal of authority over many of the players at the state level, which provides a tactical and strategic advantage to play an active role in the development of EHRs in New Jersey. He commented that in New Jersey, they view themselves as facilitators at the local level of what is developed at the national scale. New Jersey plans to pass the significant development and implementation costs on to all of those who will share in the efficiencies and the savings that will be realized from the deployment of these systems.

Mr. O'Byrne noted that one of the issues they have been struggling with has been patient identification, which comes up repeatedly in terms of privacy and security (i.e., how does one authenticate that the patient and the person that one is dealing with is, in fact, the right person?). He explained that absent a federal master patient index (MPI), New Jersey will construct its own MPI, or if possible, will join with other willing states to form a regional MPI. This MPI will be a unique identifier, which will permit access to and from patients' EHRs, with the goal of reliably linking a patient to their health information. Recently, the states of New York and New Jersey formed the basis of an agreement to handle the MPI between the two states (millions of people travel between the two states). The next goal is to include Pennsylvania.

New Jersey also is considering using bar coding and electronic strips on health care identification cards to eliminate misdirected and misrecorded information, with the idea of increasing reliability and verification of detail at the absolute lowest level. Mr. O'Byrne commented that states can play a meaningful role in these types of projects. He noted that moving records from state to state can be problematic. Privacy and security application is normally different from state to state, and problems arise when individuals go across state lines when looking for medical care. Efforts are underway to try to regionalize some of the agreements that may exist, so that documents signed in New Jersey will be recognized and valid in Pennsylvania or New York.

New Jersey also plans to create a federated model in the form of a public service-type entity that will be the custodian and gateway for access to EHRs. Mr. O'Byrne explained that this body will be akin to a credit-reporting agency that will hold access to highly private medical information with extreme privacy and security protections. When a claim for payment for a medical test is submitted, access to the medical test will be given to this public entity custodian in the nature of a regional health information organization (RHIO). New Jersey also intends to establish a Web portal for ordering medical tests, constructed in such a way as to prompt the ordering physician to use existing electronic test results, if still valid, rather than ordering a duplicate or unnecessary test. This will save money and give the provider immediate access to critical data when they are needed. Much like a credit-reporting agency, Mr. O'Byrne explained that payers, providers, and others would pay a subscription rate, based on the volume of usage, so this public-

entity RHIO would be self-sufficient and self-sustaining. He concluded his remarks by noting that patients would have access to see and view their records. They would have some control over the more sensitive aspects of their records, and model it much the same as the bill of rights that people have in their credit reports.

State of Minnesota

Dr. James Golden explained that when Minnesota began examining the privacy barriers to the electronic exchange of health information, two issues were identified as being most significant and in need of attention: (1) incorporating Minnesota's patient consent requirements into the electronic exchange of information; and (2) developing security measures around authorizing and authenticating individuals that access information, setting appropriate access controls for those individuals, and then auditing those individuals' access to data. Dr. Golden also explained that in discussing patient consent as a barrier, he is referring to how to make those consent requirements integrated into whatever electronic exchange is developed in the state. Generally speaking in Minnesota, patient consent is required for the disclosure of any health information for any purpose, including for treatment purposes. Those consents need to be written and generally expire within 1 year. There are a few exceptions (e.g., medical emergencies), and some special consents that do not expire (e.g., consents for disclosures to other providers when they are being consulted, or to payers for payment).

Minnesota law places all liability for inappropriate disclosures on the disclosing providers. A violation of patient consent requirements may be grounds for disciplinary action against a provider by the appropriate licensing board or agency. A person who negligently or intentionally releases a health record is liable to the patient for compensatory damages caused by an unauthorized release, plus costs and reasonable attorney's fees. As a result, providers are very cautious in disclosing data and respond to privacy/security concerns by not disclosing patient data. Dr. Golden noted that Minnesota's patient consent requirements cause a barrier to the electronic exchange of health information because: (1) health care providers cannot agree on when and how patients are required to exchange their health information; and (2) Minnesota's requirements were designed for paper-based exchanges and are not conducive to a real-time, automated electronic exchange.

Dr. Golden described three primary causes of patient consent barriers in Minnesota:

- Undefined terms and ambiguous concepts that are used in Minnesota Statutes § 144.335 – patient consent requirements.

- Difficulties in determining the appropriate application of consent requirements to new concepts in the electronic exchange of health information that do not have an analogous concept in a paper-based exchange.

- The need to update consent requirements to allow mechanisms that facilitate the electronic exchange of patients' information while respecting the patients' ability and wishes for controlling their information.

Dr. Golden explained that a workgroup of industry representatives and privacy advocates did not reach consensus on a set of best solutions. They did, however, identify options, document advantages and disadvantages for each option, and connect related options. The Minnesota Department of Health developed criteria for evaluating each of these options, for example, whether the option maintains or strengthens patients' privacy or control over their health records, whether it improves patient care, etc. A number of legislative solutions are being pursued. For example, efforts are underway to clarify undefined terms and ambiguous concepts such as "health record," "medical emergency," "related health care entity," and "current treatment." Consent requirements will be applied to new concepts (e.g., introducing and defining the terms "record locator service" and "identifying information"). In addition, mechanisms that

facilitate electronic exchange will be updated, and Minnesota's patient consent statutes will be recodified to make the requirements easier to understand for patients and health care providers.

Discussion Highlights

"This is a very broad and complex area that has many stakeholders, and many levels of precedent established in state and federal areas. I think you can see why this is not only a project that's been very long in fruition, but was, in fact, I think the single largest contract issued by ONC in the past couple of years. We have to evaluate this on the foundation that it needs." – Dr. Brailer

"To what extent is there an urgency among the states to begin to harmonize this, and is that [national meeting] going to become a center of gravity to do it, and if not, where will it be?" – Secretary Leavitt

"The energy and the urgency around this has been demonstrated clearly by the states…it was an aggressive schedule to begin with. And for the states to pull together the range of stakeholders that they were able to muster, very much of the work is done on volunteer time, on cost sharing, people not billing for their hours because the issue is so important to them. So the states are moving forward at an incredible pace. I think the national meeting went a long way to catalyzing this. There is a recognition that they share common problems, and each of the states may be at a different point in the process…as it all raises up it will patchwork together a really comprehensive picture of what is needed nationwide."
– Ms. Dimitropoulos

"There has got to be some collection of where are we…And then the next step is somebody has got to take charge of beginning to drive an agenda of harmonization. Did anything like that come out of the meeting? I'm looking to see, now that we're beginning to assemble the information and we know where we are, and have everybody's attention, what's the governance process to drive this forward?"
– Secretary Leavitt

"I know in New Jersey, I can assemble a lot of different players in the arena, but that's not the same as it is in other states. They tend to rely on their Department of Health, and not the Department of Banking and Insurance, so you don't always have the same players at the table, and the mix of governance probably will have to change in each state. That doesn't mean that the information that moves back and forth has to be different." – Mr. O'Byrne

"I fully acknowledge what you're saying is true, every state will be different…Somehow we've got to connect this up to a broader driver. There has got to be a central coordination and local control. What I hear you saying is 'we've got to have a local control,' and I completely concur with that. Somehow we've got to figure out a way to begin driving the agenda among the states." – Secretary Leavitt

"The State Alliance for e-Health…does have this one task force called the Health Information Protection Task Force. They are looking at these cost-cutting state privacy and security issues, and will take some of the inputs from this process to try to think across the states how best to harmonize state laws, if that's appropriate, to come up with approaches that states should look at, so that they're acting in a coordinated way." – Ms. Daniel

"We are going to be looking at opportunities for funding some of the implementation plans, and one of the things that we're looking at is trying to promote those implementation strategies that provide coordinated efforts across states and regions. So that while there is a lot of important work going on state by state, we want to promote that collaboration across the states, as they're looking at implementing some of these solutions, and we hope to do that in the next phases of our work in this area." – Ms. Daniel

"The work you've done is extraordinary, and obviously a lot of thinking going on in each state. And I would just summarize my own views that we now need to begin to think through how we can put this into a coordinated agenda that somebody wakes up every morning thinking about." – Secretary Leavitt

Employer Panel

Andrew Croshaw, Office of the Assistant Secretary for Planning and Evaluation, HHS, explained that the movement to bring value to health care transcends greatly upon AHIC's work. He noted that the purpose of this panel was to share with the Community how the four cornerstones of value-driven health care are being addressed and moved forward through the payer community. There is a clear and definite role for employers to play, along with the other stakeholders in health care.

Pacific Business Group on Health

Peter Lee of Pacific Business Group on Health (PBGH) discussed the fact that employers and purchasers have been seeking to promote value for many years, both collectively and as individual employers. He described the PBGH as a collective of large employers anchored in California that has a national presence. One of the first cornerstones of value-driven health care is quality transparency. Collectively, employers have been driving to create standards, and using national quality forum standards, HQA and AQA standards for measurement. Mr. Lee noted that today, every national health plan has hospital chooser tools, while none of them did five years ago. Employers are now demanding that of their plans.

The second cornerstone is price transparency. Consumers, like employers, care about quality, but they also care about what it is going to cost them—it is a value equation that brings together information about quality with price and cost. Many of the PBGH members have started this effort by looking at plan chooser tools, getting information to consumers, based on their health status, what their health care is going to cost them over the next year. Mr. Lee used Wells Fargo as an example, noting that one of their members uses the plan chooser tool that has about 60 percent of their enrollees every year to relook at which plan they are going to choose. This tool is being used based on what their financial exposure is going to be, but also what the quality is of the plans they are going to choose. Those same tools are needed at the physician and hospital levels.

The third area is incentives for better performance; employers are looking at benefit design to encourage consumers to make better choices, and at incentives for the providers. A key element is rewarding both sides, the provider and the consumer.

The fourth cornerstone is promoting HIT. Mr. Lee highlighted a California project of the Integrated Healthcare Association, which is a pay-for-performance initiative and a multi-stakeholder collaborative. The purchasers have been key drivers in this initiative. Over the last three years, hundreds of millions of dollars have been paid out on a performance-based basis, using common measures as well as some non-common measures. Medical groups in California are getting rewarded for data integration for population management, electronic clinical decision support, and care management tools. Mr. Lee concluded that changing the payment system to reward IT is what it will to take to actually get ramped up more quickly.

Cisco Systems, Inc.

Jeffrey Rideout of Cisco Systems, Inc., noted that the company has more than 20,000 employees in the Silicon Valley alone, giving it some unique opportunities to work with peers, local medical groups, and hospitals. Cisco's employee base is young, at an average age of 38 years. The company is getting younger, and does not have a large burden of disease, resulting in some unique challenges and opportunities. As is the case with many young physicians and other clinicians, Cisco's employees expect everything to be available on the Web through Internet tools, and they do not want to use paper. Mr.

Rideout explained that Cisco has tried to promote, through its health benefits activities, an environment that meets these expectations.

More than one-half of Cisco's costs for its employees in terms of health and wellness is associated with presenteeism (work that they are not able to do, while they are at the work site, because they are suffering under some disability related to a typically health or medical condition). Mr. Rideout noted that Cisco is trying to get in front of health issues that its employees are experiencing. This effort involves modifying their health conditions so that rampant cost increases in future years are avoided.

Mr. Rideout highlighted some programs related to these activities. For example, the IHA program is an HIT-driven, pay-for-performance program that involves taking some leading medical groups and some area employers, and driving an advancement in a program for an earlier and more advanced adoption of HIT in a short period of time. This effort includes Cisco, Intel, and Oracle, as well as seven medical groups. Cisco also has doubled the number of physicians who are qualified under the National Committee for Quality Assurance's Physician Practice Connections Program to more than 1,800 in Cisco's program alone. The company also has a Bridge to Excellence Program. Cisco also has shown, working with a number of medical groups, a five-point return on investment for secure messaging adoption. Cisco is paying for this by either supporting subscription services or paying for Web visits. The company also is in the final design phases of constructing a state-of-the-art health and wellness clinic on site at the Cisco campus, so that the company can become an additional provider of care. This health and wellness clinic will be paired with Cisco's state-of-the art fitness center. Mr. Rideout concluded by commenting that one of the biggest challenges is addressing what can be done by individual employers or a limited number of employers versus what should be done through larger collaboratives.

In response to a question from Secretary Leavitt, Mr. Rideout explained that Cisco participates in a program in which several area medical groups have adopted an electronic health system that has the ability to do online transactions and services; Cisco is promoting this program through its employees. Part of the challenge associated with this program is that there are three different business models driving how the overall system is organized.

IBM

Chris Nohrden of IBM explained that activities centered on promoting value-driven health care involve engaging employees in the dialogue, getting them to understand how they are spending their health care dollars, because they are really spending IBM's dollars as a self-insured company. IBM provides PHRs to its U.S. employees. About 80 percent of IBM's 500,000 employees in the U.S. have subscribed to put their personal information in a Web MD-type format for their PHR. Employees who input their data, complete a health risk assessment, take action on one of their major identified health risks, and investigate the quality of hospitals in their community, are rewarded with a $150 dollar payment. IBM is beginning to integrate some of the pharmacy data, as well as some of the episodes of care from their providers through claims data, to start building toward the concept of discrete episodes of care. As a result, IBM employees will be able to see where they are spending dollars on their care.

In terms of patient-centric primary care, Mr. Nohrden explained that there is a tremendous opportunity to re-engage IBM employees with a primary care focus in their overall health care experiences. IBM plans to partner with the American Academy of Family Physicians, the American College of Physicians, and a large multi-specialty clinic in the Texas area that will also have a primary care focus. It is planned to help that clinic transform its ways of delivering health care to IBM employees by redefining the experience so that there is technology enablement with e-mail visits. There are open access calendaring and clinical decision support tools available. Mr. Nohrden also noted that there also is a need to address the issue of how IBM pays for that type of care. He concluded his remarks by explaining that PHRs, patients' central primary care, and information transparency, are key to IBM. The company wants its employees to have

that information at their fingertips, as they select their plans and providers, so that the are doing the best they can to avail themselves of that information and make the best use of it.

Safeway

Kevin Herglotz of Safeway noted that the company is beginning to see measurable success in terms of getting its employees more involved and more active in their health care decisionmaking. Safeway has taken a model with about 30,000 of its employees throughout the country that brings this value into their plans, particularly as it relates to more responsibility and preventive care. It is hoped to expand the program to the company's entire workforce of 200,000 over time. As part of the program, employees complete a health risk questionnaire to establish a baseline. The company does not see any of this information, and incentives such as a reduction in premiums, are used encourage participation in the program. The program pays 100 percent of all preventive care (e.g., breast exams, prostate cancer tests, annual physicals, etc.). The program even pays for employees to stop smoking, and is based on an incentive structure to help Safeway employees make better decisions and take more control of the decision-making.

Mr. Herglotz noted that the program is proving to be extremely successful, and Safeway's employees like the plan. In roughly two years, Safeway has been able to provide these discounts and reduce health care costs not only for the company, but also for its employees. Employees who are participating in this plan have seen a 22-32 percent decrease in their annual health care costs. Safeway also has been able to expand these employees' benefits by providing a lot of the preventive care. In addition, the company decided that instead of adding cost savings to its bottom line, it would share these savings with participating employees.

Safeway is looking to continue to expand this program in the next several years, working with other large companies like Cisco, with the goal of eventually having participation from 90-100 percent of employees. Mr. Herglotz explained that this program is a way for companies to show how using market forces and corporate programs designed for employees can actually make a difference and flatten double digit increases in health care costs. Because Safeway is a retailer with millions of customers coming into its stores each day, the company is able to share this information and conduct a strong preventive health and wellness program inside its stores, using the Internet, customer communications, a stronger emphasis on health and wellness, and foods to help customers make better health-related choices and drive the preventive health agenda.

Discussion Highlights

"It's very clear to me that the effort that AHIC has undertaken is, in lots of respects, following what you are pioneering, and trying to figure out how we can take what you're doing, and implement it over a much broader construct of society. At the same time, it's clear to me that to get to what you aspire and envision, you're going to need to have the output of just mind-numbing detail that has to go into building the infrastructure that we have been discussing today." – Secretary Leavitt

"This whole effort to bring employers behind the four cornerstones has been to create the necessary weight to drive through the resistance that naturally exists. There is a very high probability, in my mind, that we'll get to 60 percent of the entire marketplace, but before we get to the '08 policy year, that we'll be behind in some way, in some form, pushing in these four broad categories. That is the pressure that continues to drive this forward." – Secretary Leavitt

"Every year that clicks off the calendar, we're getting closer and closer to this vision of a system that is integrated, connected, and based on value." – Secretary Leavitt

Public Input Session

Speaker Number 1 – Al Kinel, Director of Alliance Health Group at Eastman Kodak, commended AHIC on the progress that has been made. He noted that there is an opportunity for improvement in terms of completing the EHR. Mr. Kinel explained that medical imaging is a critical part of the health record, and there are many reasons why it can and should be part of the agenda, whether it's as a use case, as a Workgroup, or whether it is simply part of the EHR community. The cost of medical imaging is increasing at a tremendous rate—it is now the second fastest growing component of health care in this regard. In addition, access to imaging for quality and clinical care can improve lives, improve care, and reduce costs significantly. He asked the Community when and how this issue should be addressed.

Secretary Leavitt agreed that the cost of medical imaging is becoming a large factor, and one that could be subject to competition based on value. He commented that this is an area where a competitive environment should be able to be developed much more quickly than in some of the other more complicated conditions and procedures.

Speaker Number 2 – Mimi Grant, President of the Adopted Business Leaders Organization, commended the Community for their efforts.

Closing Remarks

Dr. Brailer thanked everyone for their participation and adjourned the 12th AHIC meeting.

Nationwide Health Information Network

Report on 2006 – "Prototype Architectures" and
Plans for 2007 – "Trial Implementations"

John W. Loonsk, ONC

Virginia Reihl, Gartner Consulting

The Nationwide Health Information Network

Agenda

- Update on the NHIN status

- Gartner report on the 2006 "prototype architectures" and common services

- 2007 "trial implementations" plans

The Nationwide Health Information Network

From the National HIT Agenda:

…foster widely available services that facilitate the accurate, appropriate, timely, and secure exchange of health information

…information that follows the consumer and supports clinical decision making
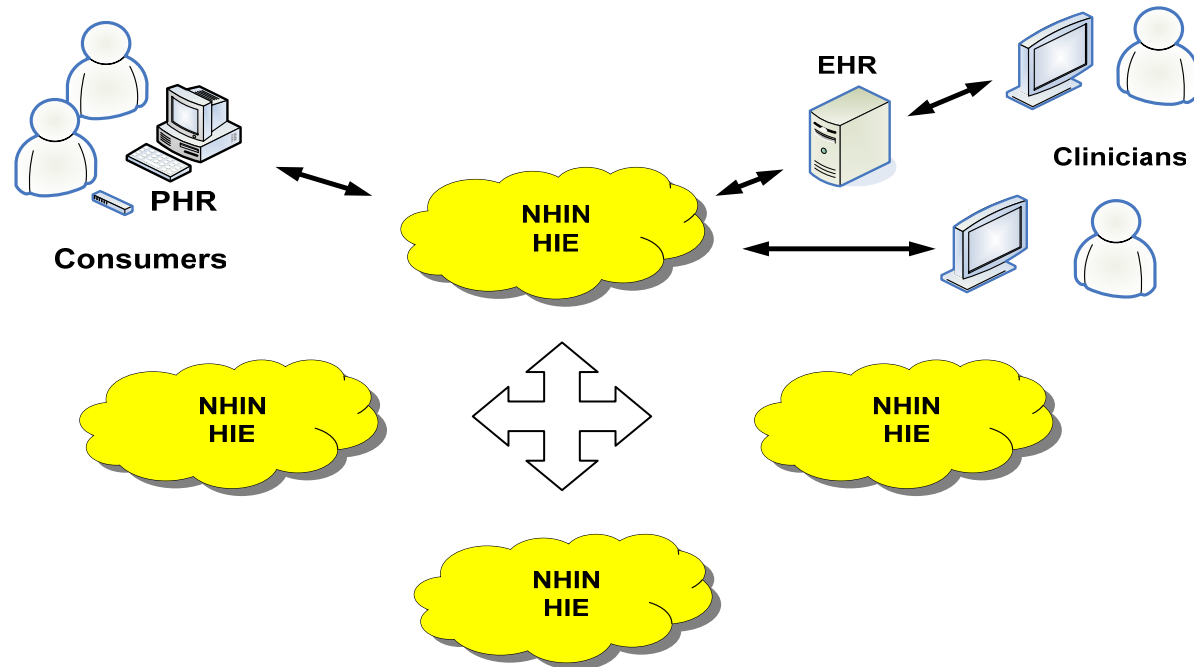
The Nationwide Health Information Network

NHIN Working Assumptions

- a 'network of networks'

- securely connects consumers, providers and others who have, or use, health-related data

- no national data store or centralized systems at the national level

- no national patient identifier

- shared architecture (standards, services, and requirements), processes and procedures

The Nationwide Health Information Network

- **Health Information Exchange (HIE)** – A multi-stakeholder entity that enables the movement of health-related data within state, regional or non-jurisdictional participant groups.

- **NHIN Health Information Exchange (NHIE)** – An HIE that implements the NHIN architecture (services, standards and requirements), processes and procedures, and participates in the NHIN Cooperative.

The Nationwide Health Information Network

- NHIN – moves data when a patient moves, but more critically, ensures secure data movement wherever appropriate

- Eventually the NHIN Cooperative may include specialty networks as well as NHIEs

The Nationwide Health Information Network

Products of 2006 are guidance for 2007 trial implementations:

- Seven AHIC use cases
- HITSP standards
- NHIN functional requirements (with NCVHS)
- Public input from fora
- Privacy and security work (CPS, NCVHS)
- Prototype architectures
- Core services and capabilities for an NHIE
- Report on service interfaces

Gartner Summary Findings

Architecture

- NHIN as comprised of NHIEs rather than a central database or network hub

- NHIEs exchange information among themselves in a fully standardized fashion

- NHIEs help bridge standardized implementations of EHRs and PHRs to full standards compliance

Providing Data for Secondary Use

- NHIE routes data to public health, researchers, and other secondary users

- NHIEs may play an important role in anonymizing and de-identifying data.

Common NHIE and cross-NHIE services

NHIN Core Services

- Key Data Services
  - Data delivery
  - Patient look-up in an NHIE and between NHIE's
  - Supporting access to data for secondary uses

- Key User and Identity Management Services
  - User identity proofing, authentication and authorization, or attest for connected organizations
  - Identity adjudication between NHIEs

- Key Management Services
  - System and trusted user protection
  - Emergency access (individual and community)

NHIN Core Services

Key Consumer Services

- Identify a personal health record home
- Be supported in getting data there
- Search for other places where data about them exists
- Control who can access their personal health records
- View who has accessed their PHRs or made NHIE look-ups and how their data may have been disclosed
- Send change requests to data providers when they think the data are wrong
- Choose to *not* use network services

2007 – "Trial Implementations"

- 2006 architecture products
- State and regional health information exchanges
- Focus on services and interfaces
- A cooperative of awardees who will interoperate
- Roughly 22 million in 7 - 10 contracts
- Two sites for each breakthrough / use case if possible
- Release RFC – May

American Health Information Community

State Alliance for e-Health

Jodi Daniel
HHS/Office of the National Coordinator
for Health Information Technology

John Thomasian and Kathleen Nolan
National Governors Association Center for Best Practices

April 24, 2007

State Alliance for e-Health

State Alliance

- Contract with the National Governors Association
- Comprised of Governors and high-level executives of US states and territories
- Charge
  - Identify, assess, and, through consensus solutions, map ways to resolve state health IT issues that affect multiple states and pose challenges to interoperable electronic health information exchange

  - Provide a forum in which states may collaborate to increase the efficiency and effectiveness of the health IT initiatives that they develop
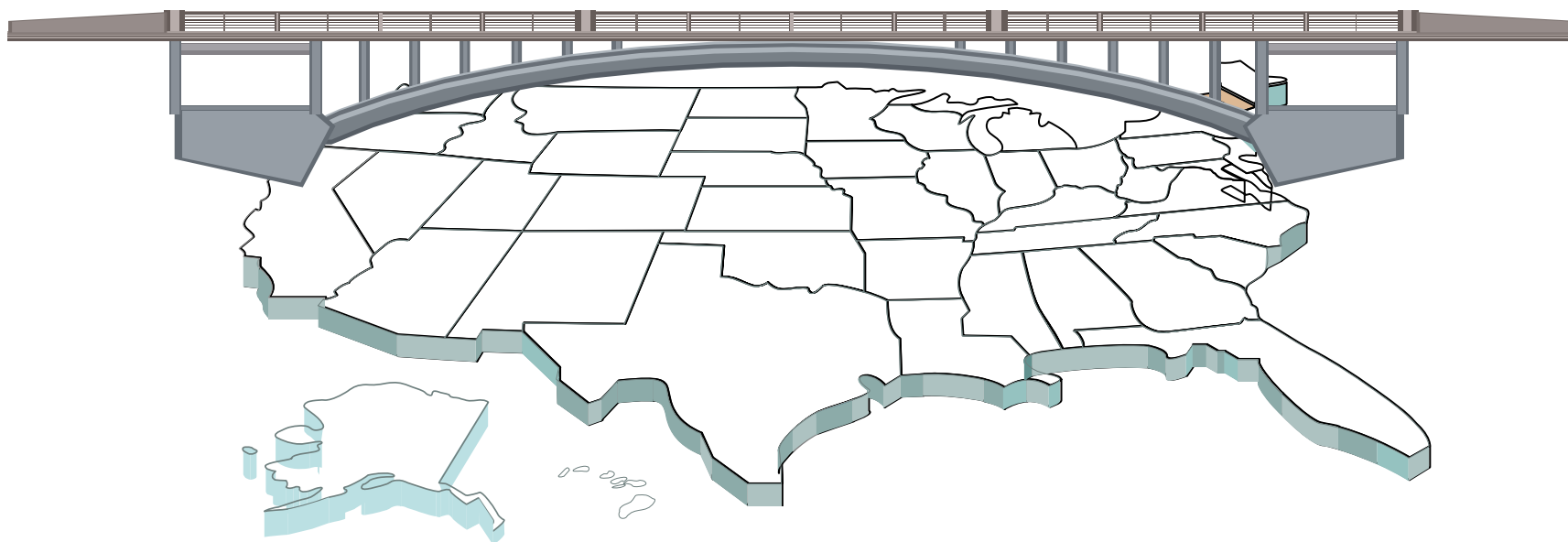
State Alliance for e-Health

State Activities
HISPC
State Level HIE

State Alliance

State Government
Consensus Building

Federal Activities
HITSP   AHIC
CCHIT   NHIN

State-level Activities

	State Alliance	**State Level HIE**	**HISPC**
Focus	State Government roles	State-level HIE practices	State, territory, and organizational privacy and security practices and laws
Composition	Governors, legislators, and high-level state officials and technical experts	State-level HIE leaders (public/private sector)	State/territory HIE stakeholders (public/private sector)
Products	Action-oriented recommendations to state government to spur HIE adoption within and across states	Best practices for HIE • Governance • Funding • Data exchange practices	Assessments of organizational practices and state law and implementation plans to enable HIE while preserving privacy

Why a State Alliance for e-Health?

- Relevant state roles for Health IT adoption
  - Regulate the insurance market
  - License and oversee health professionals and facilities
  - Purchase and fund health care services and coverage under Medicaid and other programs
  - Provide legal protections for consumers and others
  - Set the regulatory and legal environment on health record privacy and other relevant issues
  - Provide direct funding for public good

- States are experienced in reform
  - They are practically focused
  - Experiences in interstate coordination
  - Very interested and actively engaged on health issues

Major State Activity on HIE

- Twenty executive orders have been issued by governors calling for HIT and HIE, seven in 2007 alone.

- Legislatively in 2005 and 2006:
  - 121 bills were introduced in 38 state legislatures that specifically focus on HIT, 37 bills were passed in 24 state legislatures.

- In 2007 so far:
  - 68 bills have been introduced in 30 states that specifically focus on HIT.

- Quality, patient safety, and rising costs are the primary drivers for state interest in health information technology and exchange.

Note: Data from presentation at March 30 Alliance meeting, presented by Gerry Hinkley Davis Wright Tremaine LLP

Goals of the Alliance

- **Build consensus among states, and among the different players within states for health IT solutions.**
- **Provide states with realistic, timely, and well-researched options.**
- **Allow for input of experts and practitioners working on health IT endeavors to inform state policymaking.**

- Proposed as a 3-year contract, initiated 9/06.
- Working in partnership with partner organizations including NCSL, NAAG, and NAIC.

Membership

- **<u>Voting Members(12)</u>**
  - Governor Phil Bredesen, TN (Co-Chair)
  - Governor Jim Douglas, VT (Co-Chair)
  - 2 Attorneys General
  - 2 State Insurance Commissioners
  - 4 State Legislators
  - 2 Former Governors

- **<u>Non-Voting members (Advisory group-8)</u>**
  - State health government representatives (3)
  - Relevant private sector members
  - Technical experts

Timeline and Access

- The Alliance is being conducted in a transparent fashion with input from states (nominations, testimony, comment on outputs)
- All meetings open to the public and available via webcast
- Inaugural meeting—January 26, 2007
- Alliance is meeting quarterly
  - 2nd meeting March 30
  - 3rd meeting scheduled for July/August
- August meeting: 1st recommendations to states expected

Alliance Taskforces

- Three Taskforces
  - Health Information Protection
  - Health Care Practice
  - Health Information Communication and Data Exchange
- Each Taskforce is composed of public and private sector representatives from major sectors including:
  - Public health and Medicaid
  - Health systems and plans
  - Health providers (physicians, nurses, pharmacists, labs)
  - Employers, academics, and other private sector voices
- Role of Taskforces for the Alliance
  - Charges from Alliance
  - Report to Alliance and provide recommendations on actions
  - Free-standing outputs from the taskforces possible

Taskforce: Health Information Protection

- Charge: *Support the State Alliance for e-Health on policy options around protection of consumer health information.*

- Focus topics include privacy and security, as well as further development of solutions identified in HISPC.

The initial taskforce work product is an analysis that:
  a) examines the rationale behind the major state health privacy protection laws that affect the sharing of health information across entities (whether paper-based or electronic);
  b) discusses the applicability of each kind of protection, with an emphasis on an individual's health in an electronic HIE environment; and
  c) provides recommendations for addressing issues arising from such protections.

Taskforce: Health Care Practice

- Charge: *Support the State Alliance on policy options regarding the regulatory, legal, and professional standards that impact the practice of medicine and interoperable, electronic HIE.*

- Focus topics include: licensure issues, state laboratory laws and regulation, and liability concerns.

Three work products have been identified:

1. Examine state licensure laws and describe how such laws, rules and procedures permit or hinder the exchange of electronic health information (including telehealth). Suggest solutions to permit the interstate transaction of health information and services.

2. Conduct a study of case law and opinion concerning liability issues arising from the exchange of electronic health information and produce an assessment that identifies current practices that may result in malpractice challenges.

3. Conduct an analysis of malpractice insurance coverage for e-health across states that identifies the availability of and options for coverage. As part of the analysis, identify coverage issues that impair the electronic exchange of health information across state lines. Suggest solutions to expand the availability of coverage.

Taskforce: Health Information Communication and Data Exchange

- Charge: *Support the State Alliance on the appropriate roles for publicly funded health programs in HIE, including ways states can enhance Medicaid, SCHIP, employee health benefits, and public health through HIE activities.*

- Focus issues: Opportunities for publicly funded programs to participate and contribute to HIEs in relation to data sharing and protection requirements, core mission support, governance, and funding.

Two work products have been identified by the Alliance:

1. Conduct an analysis of state coverage programs and identify opportunities within these programs to further electronic HIE.

2. Provide an overview of the landscape of current state action to support the creation and operation of electronic HIE networks.

Near-term Issues for the Alliance

- Increase knowledge of business models and sustainability issues (e.g., in the context of public health, public utility options, and potential government oversight needs)
- Recommendations for action from the Taskforces' work products expected by the 3rd meeting (August 2007)
  - Licensure
  - Privacy recommendations for special information classes
  - Priority opportunities for publicly funded programs
- Continuing to find ways to support standardization and interoperability

American Health Information Community

Planning for Long Term Succession and Sustainability

Secretary Leavitt, Chair, AHIC
David Brailer, MD, PhD, Vice Chair, AHIC

April 24, 2007

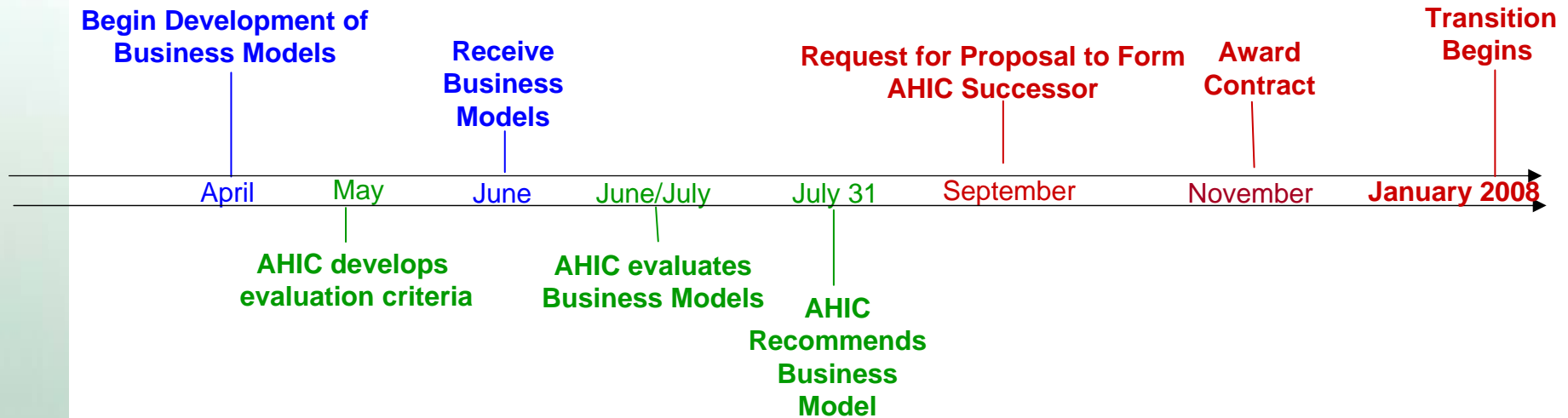# AHIC Charter

- A public-private collaborative functioning as a Federal Advisory Committee

- Two primary functions:

  1) advise the Secretary and recommend specific actions to achieve a common interoperability framework for health IT; and

  2) serve as a forum for participation from a broad range of stakeholders to provide input on achieving widespread adoption of interoperable health IT.

Potential Roles For An AHIC Successor

- Operate as a public-private entity in the private sector with voluntary membership representing all stakeholders in health care
- Set priorities for national standards harmonization and adoption
- Maintain a trustworthy and effective governance model on a national level
- Establish guidelines for data stewardship based on consensus
- Develop and maintain principles for data sharing policies
- Advise ONC on the roadmap for NIHN implementation
- Evaluate market trends and economic models to support interoperability, Health Information Exchange, and EHR adoption
- Coordinate federal and state relationships and governance activities

Work Process for Developing the AHIC Successor

Begin Development of Business Models

Receive Business Models

Request for Proposal to Form AHIC Successor

Award Contract

Transition Begins

April — May — June — June/July — July 31 — September — November — **January 2008**

AHIC develops evaluation criteria

AHIC evaluates Business Models

AHIC Recommends Business Model

Note – items in Blue relate to the Business Model Contracts; Red items are Successor procurement-related, Green items are AHIC activities.

Determining the Business Model

- Three contractors will describe potential business models based on a delineation of responsibilities between the successor and existing Federal entities, including:
  - The appropriate role of government
  - Short, mid- and long-term goals of the entity
  - Mechanisms to ensure diverse and voluntary membership representing all stakeholders in health care
  - A transition plan
  - A path to sustainability
- Informed by case studies of other governance entities and guiding principles

AHIC's Role in Planning the Successor

- Develop and gain consensus on evaluation criteria for proposed business models
- Form a subgroup of AHIC chaired by the Secretary to evaluate the proposed business models
- Propose recommendations to the Secretary on July 31st that address:
  - A governance structure and business model
  - The role of government
  - A transition plan
  - A path to sustainability

American Health Information Community

Electronic Health Records Workgroup
Recommendations

Lillee Smith Gelinas, RN, MSN, FAAN
VHA, Inc., Co-Chair
Jonathan Perlin, MD, PhD, MSHA, FACP
HCA, Inc., Co-Chair

April 24, 2007

Workgroup Member List

Co-Chairs:

- Lillee Smith Gelinas   VHA, Inc.
- Jonathan Perlin   HCA, Inc.

Members:

- Jason Bonander   Centers for Disease Control and Prevention
- Susan Christensen   Agency for Healthcare Research and Quality
- Jodi Daniel   HHS/Office of the National Coordinator for Health IT
- Lorraine Doo   Centers for Medicare and Medicaid Services
- Carolyn Clancy   Agency for Healthcare Research and Quality
- Bart Harmon   Department of Defense
- John Houston   NCVHS
- Charles Kahn   Federation of American Hospitals
- Mark Lewis   EMC Corporation
- George Lynn   American Hospital Association
- Alan Mertz   American Clinical Lab Association
- Blackford Middleton   HIMSS
- Pam Pure   McKesson
- Robert Smith   Department of Veterans Affairs
- Barry Straube   Centers for Medicare and Medicaid Services
- John Tooker   American College of Physicians

Office of the National Coordinator:

- Karen Bell

2

Electronic Health Records Workgroup Overview

Broad Charge:

To make recommendations to the Community on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers.

Specific Charge:

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 is deployed for clinical care by authorized parties.

May 2006 Recommendations from EHR Workgroup

- **HITSP interoperability standards for exchange of lab results**
    - Presented to AHIC, October 2006
- **CCHIT to incorporate HITSP standards in certification criteria**
    - On implementation roadmap for 2007
- **Federal Delivery Systems to develop workplans to incorporate interoperability standards**
    - 100% commitment from DoD, VA, Indian Health Service
- **Federal Contracts to include language to support use of HITSP standards**
    - Planning for next contract cycles in place

- **CLIA review with respect to sharing information with multiple providers and patients with recommendations for guidance or regulatory changes**
    - In process of developing guidance
- **Cross-cutting workgroup to address privacy and security issues**
    - Formed in May 2006 and first set of recommendations presented
- **Develop interoperable First Responder EHR**
    - Use case developed and provided to HITSP, CCHIT, others

4

Five Key Areas of Focus

- **Business case alignment**

- **Workflow and cultural concerns**

- **Medical-Legal issues**

- **Privacy and security**

- **State of the technology**

Business Case Alignment

Recommendation 1.0:

As the Federal Government develops language in its contracts with health plans and insurers to support the widespread adoption of HITSP interoperability standards, this language should foster the use of Pay for Performance programs for physicians that include structural measures to incent the adoption and effective utilization of certified EHRs. This emphasis on structural measures may be limited to a specific time frame with the ultimate goal of using process and outcome measures to assess performance

☐ **Accept**   ☐ **Table**   ☐ **Reject**

Business Case Alignment

Recommendation 1.1:

Recommendation 1.1: These pay for performance programs should use reliable, standardized and validated tools which are currently available to assess structural measures as defined by the Medicare Payment Advisory Commission (MedPAC), such as the NCQA's Physician's Practice Connections or CMS' publicly available Office System Survey. This emphasis on structural measures may be limited to a specific time frame with the ultimate goal of using process and outcome measures to assess performance.

☐ Accept   ☐ Table   ☐ Reject

Workflow and Cultural

Recommendation 2.0:

HHS should provide continued support to DOQ-IT U for new module development, upgrades, maintenance, and CME credit management beyond the 8th SOW funded by CMS. The program should be supported by a learning management system that is user friendly, has search functionality, and provides links to other key sites.

☐ **Accept**   ☐ **Table**   ☐ **Reject**

Medical-Legal

HHS should work with the CCHIT to obtain medico-legal counsel to assure that its functional criteria include documentation, security, and other approaches that will mitigate malpractice risk.

☐ **Accept**   ☐ **Table**   ☐ **Reject**

Medical-Legal

Recommendation 3.1

HHS should meet with malpractice insurers throughout the country to encourage premium reductions for those physicians who have adopted certified EHRs.

☐ **Accept** ☐ **Table** ☐ **Reject**

Overarching

Recommendation 4.0:

HHS should develop a schedule for implementing differential reimbursement to Medicare physicians for use or non-use of EHRs. While we would defer to Departmental expertise, we note that this might be achieved by paying full Medicare rates and market-basket updates (and possibly an "EHR premium") to physicians using certified EHRs, while physicians using paper-based records are paid at discounted rates achieved by non-qualification for full market basket updates or other measures.

☐ **Accept**   ☐ **Table**   ☐ **Reject**

April 24, 2007

The Honorable Michael O. Leavitt
Chairman
American Health Information Community
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Chairman:

The Electronic Health Records (EHR) Workgroup was formed on January 17, 2006 to address both the broad and specific charges formulated by the AHIC:

> **Broad Charge for the EHR Workgroup:** Make recommendations to the Community on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers.

> **Specific Charge for the EHR Workgroup:** 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.

The initial effort of its fourteen members focused on the specific charge.   After much deliberation and public testimony, the workgroup presented on May 16, 2006 a number of recommendations to the AHIC which led to your acceptance of the following:

- HITSP should identify and endorse interoperability standards for the exchange of laboratory results
- CCHIT should incorporate these HITSP standards in its certification criteria
- Federal delivery systems should develop workplans to incorporate these lab interoperability standards in their own health information technology (HIT) systems
- Federal contracts should include language to incentivize and support the use of HITSP approved standards
- CLIA should be reviewed with regards to facilitate how laboratories may share information with multiple physicians, patients, and other treatment-related entities for recommendations on guidance or changes
- A cross-cutting workgroup should be formed to initially address privacy and security issues related to patient identification, patient linkage, authorization, and authentication
- An additional workgroup charge of a First Responder EHR, to ensure that first responders responding to a disaster or emergency situation can obtain the critical health information they need electronically

We are pleased that you have been able to move forward on all of these. We note that the HITSP standards for lab interoperability were presented to the AHIC in October 2006

and the CCHIT process will include these standards in their 2007 certification criteria. Additionally, the August 22, 2006 Executive Order: *"Promoting Quality and Efficient Health care in Federal Government Administered or Sponsored Health Care Programs"*, requires federal delivery systems and contracts to incorporate interoperability standards in new implementations and major HIT system upgrades. CLIA guidance is being developed by ONC, CMS, and the CDC. The Confidentiality, Privacy, and Security (CPS) workgroup was formed in May, 2006, and its first set of recommendations have already been discussed in detail by the AHIC and presented to you. Under the leadership of the Federal Health Architecture (FHA) program within ONC, an emergency responder use case was developed and released to HITSP for standards harmonization in December, 2006.

Since last May, the EHR workgroup has widened its scope of activity to encompass the Broad Charge and has continued to be heavily engaged in hearing and synthesizing testimony about barriers to and enablers of widespread adoption of EHRs within the physician community. In July, 2006, we heard the results of work done by GWU and Harvard under contract with ONC which standardized the methodology for measuring adoption of EHRs in physician offices and defined the 2006 adoption rate among physicians as 10%. This report was presented by the Robert Wood Johnson Foundation, and represents those physicians using an EHR for a minimal set of functions. The report also described the five key areas that must be addressed for more widespread adoption to occur:

- Business case alignment
- Workflow/ cultural concerns
- Medico-legal issues
- Privacy and Security
- State of theTechnology

The EHR workgroup structured its effort along those five key areas, and will continue to do so as it continues to refine further recommendations in the physician office setting and develops future recommendations in the hospital and other health care settings.

RECOMMENDATIONS

I. Business Case Alignment

There are many stakeholders in healthcare: consumers and patients; employers; health insurers (public and private); large delivery systems, individual physicians, hospitals, laboratories, nursing homes; and a myriad of other clinicians and clinical settings. In addition, there are researchers, public health entities, pharmaceutical and device manufacturers, HIT developers and vendors, companies that provide care/disease management services, data managers, and others too numerous to mention here. All will benefit from efficient electronic access to reliable clinical information. Some will benefit far more than others, and some will bear the costs of HIT adoptions far more than

others. Unfortunately, those who benefit the most, and those who bear most of the costs, are not the same stakeholders.

This misalignment of the business case is clearly one of the major barriers to widespread EHR adoption. While some physician offices have been able to capture some financial return on their investment (ROI) from better charge capture and more efficient record keeping and management, this ROI is often not sufficient to justify EHR adoption. Additionally, the majority of small physician offices cannot afford either the capital outlay to implement the EHR software and supporting hardware nor the loss of productivity that accompanies this transition for about a year.

The workgroup heard testimony on various EHR models and their relative costs, purchasing collaboratives, loan programs, grant programs, and approaches to minimize loss of revenue during implementations. Reimbursement strategies such as increased payments for services rendered by users of certified EHRs were also discussed.   It is anticipated that various "Pay for Performance" programs may also ultimately offset the costs of investment and continued upgrades for physicians adopting EHRs.   Those programs, however, that offer reward for improved outcomes may actually widen the gap between large and small practices in that these programs differentially reward those practices that have had EHRs in place for at least three years, the earliest time frame necessary to actually demonstrate improvement in outcomes after EHR implementation. Practices that have already been able to manage capital cost because their larger size allowed for economy of scale savings are those that will benefit from the pay for outcomes programs.   Smaller practices that need upfront capital are less likely to be rewarded.

Both Bridges to Excellence and the Pacific Business Group on Health (PBGH) in conjunction with the Integrated Healthcare Association (IHA) have both offered health plans and insurers an alternative that is more likely to spur increased adoption equitably among all types of practices. These are programs that pay for structure, process, and outcomes – and do so in a way that is weighted towards moving practices along the path toward better outcomes.   Initial payments are weighted toward HIT adoption and use, subsequent payments are weighted toward process measures, and payment for outcomes is emphasized for practices with mature EHR systems that have been in place for several years.   The concept of paying for performance using structural measures was described by the March 2005, Medicare Payment Advisory Commission's (MedPAC) *Report to the Congress*: *Medicare Payment Policy*. Incorporating the MedPAC findings, H.R. 6111, *The Tax Relief and Health Care Act of 2006,* which became Public Law No: 109-432 on 12/20/2006, recognizes the use of structural measures in 2008. Such structural measures can be assessed by using either the National Committee for Quality Assurance's (NCQA) proprietary Physician Practice Connections (PPC) assessment tool or using the publicly available Office Systems Survey (OSS) developed by CMS for use by its Quality Improvement Organization (QIO) community.

At this time, the EHR workgroup, having discussed many different approaches, finds that the Pay for Performance model developed by BTE, PBGH, and others is one that has

proven its value in the market and one that could be more widely used to support adoption and narrow the widening adoption gap of EHRs in the physician community. We therefore proposed the following recommendation in this key area:

Recommendation 1.0:   As the Federal Government develops language in its contracts with health plans and insurers to support the widespread adoption of HITSP interoperability standards, this language should foster the use of Pay for Performance programs for physicians that include structural measures to incent the adoption and effective utilization of certified EHRs. This emphasis on structural measures may be limited to a specific time frame with the ultimate goal of using process and outcome measures to assess performance.

Recommendation 1.1: These pay for performance programs should use reliable, standardized and validated tools which are currently available to assess structural measures as defined by the Medicare Payment Advisory Commission (MedPAC), such as the NCQA's Physician's Practice Connections or CMS' publicly available Office System Survey. This emphasis on structural measures may be limited to a specific time frame with the ultimate goal of using process and outcome measures to assess performance.

2. Workflow and Culture

Physician offices must reorganize their workflow processes, redirect their employees, and minimize disruption in patient care during the EHR implementation process. This poses an additional and unique challenge when assisting small practices with limited resources. Several efforts, such as the American Medical Informatics Association's (AMIA) 10 x 10 program and AHRQ's National Resource Center for Health IT, have been launched to address the workforce need for healthcare professionals to be educated and trained in informatics principles as they champion HIT adoption and implementation.

Through its 8th Scope of Work, CMS has directed its QIO programs to develop and directly provide consultative support for a limited number of small physician practices as they embark on the adoption process. One of the results of this program has been the creation of Doctor's Office Quality-Information Technology University (DOQ-IT U), a publicly available CME supported web based set of learning modules that can guide a clinician's office through the steps necessary to successfully and efficiently choose, contract for, and implement an EHR that best meets the needs of that office. Funding for this program is currently limited to the QIO 8th SOW, which ends in 2008 and is specific to a web learning environment of limited capability.   There is a need for ongoing funding to support maintenance, upgrades, module development consistent with new learning, and CME credit management. The Workgroup therefore recommends:

Recommendation 2.0: **HHS should provide continued support to DOQ-IT U for new module development; upgrades; maintenance; and CME credit management beyond the 8th SOW funded by CMS. The program should be supported by a**

learning management system that is user friendly, has search functionality, and provides links to other key sites.

3. Medico-legal concerns

Physicians are concerned about the accuracy of information coming from other sources, responsibility for large amounts of electronic health information that they had not anticipated, and the increasing demands for personal health information that they maintain for specific patients being made available for secondary purposes, not related to direct patient care (e.g. quality reporting, research, etc.).

The workgroup heard testimony about these concerns, legal testimony about how they might be addressed, and testimony from malpractice carriers with regards to risks and benefits of EHR adoption and use. The workgroup will continue to hear more testimony on this topic in the future as it turns its focus to adoption of EHRs in the hospital setting. At this time, however, it is clear that a critical facet of mitigating medico-legal risk is documentation of clinical activity and how it is presented. <u>Clear, focused, easy to find documentation of health information decreases overall cost of claims paid by malpractice coverage entities, and some have therefore decreased premium rates for those physicians with specific (CCHIT certified) EHRs</u>. The workgroup is therefore recommending at this time:

Recommendation 3.0: HHS should work with the CCHIT to obtain medico-legal counsel to assure that its functional criteria include documentation, security, and other approaches that will mitigate malpractice risk.

Recommendation 3.1: HHS should meet with malpractice insurers throughout the country to encourage premium reductions for those physicians who have adopted certified EHRs.

OVERARCHING RECOMMENDATION:

Mr. Chairman, the final recommendation is one that we arrived at after considerable discussion and debate. As noted above, the "Broad Charge" to the EHR Workgroup is to, "make recommendations to the Community on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers." While this recommendation reflects the workgroup's focus on the small physician office in particular, we note that the recommendation should be applicable to a much broader group in time. This goal reflects our shared commitment to assure all Americans health care that is safe, timely, effective, efficient and patient-centered – attributes endorsed by the Institute of Medicine, and strikingly unattainable with paper-based tools. We would like to highlight the need for continued investigation and demonstration projects that address potential reimbursement strategies which support the adoption and effective utilization of HIT.

We believe that there is no more effective means to achieve this laudable goal than by using the appropriate leverage of the nation's largest healthcare payer and insurance program, Medicare, to create incentives for adoption of certified electronic health records.

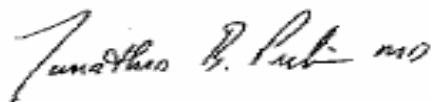The workgroup is therefore recommending for consideration of the AHIC:

Recommendation 4.0: HHS should develop a schedule for implementing differential reimbursement to Medicare physicians for use or non-use of EHRs. While we would defer to Departmental expertise, we note that this might be achieved by paying full Medicare rates and market-basket updates (and possibly an "EHR premium") to physicians using certified EHRs, while physicians using paper-based records are paid at discounted rates achieved by non-qualification for full market basket updates or other measures.

Mr. Chairman, we believe that Recommendation 4.0 has merit because it not only has the capacity to advance adoption of interoperable electronic health records, but it supports providers and vendors in exercising their free-market prerogatives most appropriate to their circumstances.

In addition to these key areas, the workgroup addressed issues in the areas of both privacy and security, and technology. It intends to work directly with the leadership of other workgroups on privacy and security, which is the heart of widespread adoption of HIT. The technical aspects of interoperability were also discussed at length and the workgroup contributed to the Use Case process presented at the AHIC in January of this year. The workgroup believes that the market place will continue to address issues of usability with respect to EHR products. Given our previous recommendations and current coordination with other AHIC workgroups on cross-cutting issues, we are therefore not making any recommendations to the AHIC at this time in the two key areas of privacy and security or technology. These recommendations are supported by information obtained through research and testimony to the Electronic Health Records Workgroup, which is contained in the supporting documents available at: http://www.hhs.gov/healthit/ahic/healthrecords/ehr_archive.html

Thank you for the opportunity to submit this second set of recommendations that begin to address the broad charge of widespread EHR adoption. We look forward to discussing them with you and the members of the American Health Information Community.

Sincerely yours,   Sincerely yours,

Jonathan B. Perlin, M.D., Ph.D.   Lillee Smith Gelinas, R.N., M.S.N., FAAN
Co-chair, Electronic Health   Co-chair, Electronic Health
Records Workgroup   Records Workgroup

American Health Information Community

Personalized Health Care Workgroup Update: Vision and Priorities

Douglas E. Henley
American Academy of Family Physicians, Co-Chair

John Glaser
Partners HealthCare Systems, Co-Chair

April 24, 2007

Workgroup Member List

- **Co-Chairs:**
  - John Glaser   Partners HealthCare
  - Douglas Henley   American Academy of Family Physicians

- **Staff Co-Chair:**
  - Gregory Downing   Office of the Secretary, HHS

- **Members:**
  - Carolyn Clancy   Agency for Healthcare Research and Quality
  - Beryl Crossley   American Clinical Laboratory, Quest
  - Paul Cusenza   23andMe
  - Andrea Ferriera-Gonzalez   Virginia Commonwealth University
  - Becky Fisher   Patient Advocate
  - Felix Frueh   Food and Drug Administration
  - Alan Guttmacher   National Institutes of Health/NHGRI
  - Kathy Hudson   Genetics and Public Policy Center
  - Betsy Humphreys   National Institutes of Health/NLM
  - Charles Kennedy   Wellpoint
  - Joel Kupersmith   Department of Veteran Affairs
  - Stephen Matteson   Pfizer
  - Deven McGraw   National Partnership for Women and Families
  - Amy McGuire   Baylor College of Medicine
  - Rhonda Ozanian   Department of Defense
  - Mark Rothstein   University of Louisville
  - Steve Teutsch   Merck
  - Janet Warrington   Affymetrix
  - Andrew Wiesenthal   Permanente Federation
  - Marc S. Williams   Intermountain Health

What Are We Trying to Accomplish?

Broad Charge:

Make recommendations to the Community for a process to foster a broad, community-based approach to establish a common pathway based on common data standards to facilitate the incorporation of interoperable, clinically useful genetic/genomic information and analytical tools into electronic health records to support clinical decision-making for the clinician and consumer.

Specific Charge:

Make recommendations to the Community to consider means to establish standards for reporting and incorporation of common medical genetic/genomic tests and family medical history data into electronic health records, and provide incentives for adoption across the country including federal government agencies.

Vision for Personalized Health Care

- Visioning session for the Workgroup was held on March 12, 2007
- Four perspectives were identified as important to the vision
  - Consumer
  - Clinician
  - Researcher
  - Health Plan/Payer

- Personalized Health Care is a consumer-centric system in which clinicians customize diagnostic, treatment, and management plans

- Takes into account a variety of factors, including culture, personal behavior, preferences, family medical history, and the individual's unique genetic/genomic makeup

- Based on the confluence of advances in health information technology and improved understanding of the relationships between health, disease, genetics/genomics, and treatment options

Vision: Consumer Perspective

- **Current Status**
  - Health care practices are rarely based on family history or a person's genetic makeup
  - Fragmented health care sector
  - Emphasis on treatment and acute care rather than on prevention
  - Lack of easy access to information about genetic/genomic tests and their utility
- **Desired Future**
  - Complete, organized, and quality consumer information, including family medical history, captured in Personal Health Record
  - Easy access to information about genetic/genomic-based risks and treatment options
  - Personalization of diagnosis and treatment using genetic/genomic information leads to higher quality care with greater value

Vision: Clinician Perspective

- **Current Status**
  - Challenge to stay current with medical breakthroughs
  - Insufficient background in clinical genetics/genomics
  - Lack tools to bring evidence to the point of care
  - Limited risk analysis and prevention messages for specific disease
  - Appropriate selection of genetic/genomic tests hampered by lack of information

- **Desired Future**
  - Combination of genetic/genomic tests results with family medical history
  - More preemptive medical practice
  - Robust genetics/genomics-based clinical decision support tools in the EHR

Vision: Researcher Perspective

- **Current Status**
  - Limited translation of basic research into relevant clinical knowledge
  - Minimal access to datasets of patient information
  - Limited post-marketing surveillance of treatment and diagnostic options

- **Desired Future**
  - Improved understanding of the genetic basis of disease
  - Research resources from federally funded genetics/genomics studies made widely available
  - Translation of information both from 'bench to bedside' and 'bedside to bench'

Vision: Health Plan/Payer Perspective

- **Current Status**
  - Data on care patterns and treatment efficacy limited to financial and business transactions
  - Insufficient reimbursement strategies for the use of genetic/genomic tests

- **Desired Future**
  - New reimbursement strategies and other incentives to encourage appropriate use of genetic/genomic tests
  - Focus disease prevention and health maintenance based on genetic/genomic test results
  - Use of genetic/genomic information in benefit design and disease management

Priorities in the Near Term

- **Genetic/Genomic Tests**
  - Inclusion of relevant genetic/genomic test results in the EHR
  - Information to describe analytical validity, clinical validity, and clinical utility of genetic/genomic tests
  - Incentives for development and evaluation of new genetic/genomic tests
  - Consumer education about the potential benefits and risks associated with genetic/genomic tests
  - Harmonization of standards for submission of clinical pharmacogenomics data and state-mandated newborn screens

Priorities in the Near Term (cont.)

- **Family Medical History**
  - Consumer and clinician entry of family medical history information in the interoperable PHR and EHR
  - Support clinician use of consumer entered family medical history information
  - Standardization of nomenclature for family relationship and other data
  - Characterization of the validity and utility of use of family medical history in making clinical decisions

Priorities in the Longer Term

- **Clinical Decision Support**
  - Development of approaches to informing the clinician of the clinical utility of test results
  - Development and assessment of genetics/genomics predictive algorithms
  - Development and assessment of genetics/genomics-based CDS to guide treatment and medication dosing decisions
  - Incentives for development and incorporation of clinical decision support tools in EHRs

Priorities in the Longer Term (cont.)

- **Confidentiality, Privacy, and Security**
  - Technical solutions and policy considerations to ensure that genetic/genomic information will be used appropriately
  - Capabilities to link large datasets to generate large-scale, individual-level genetic/genomic data with sufficient protections and limits for use
  - Balancing the desires of the research community to have secure and consented access to clinical databases with the privacy and confidentiality rights of the consumer and clinician
  - Understanding the risks associated with certain types of genetic/genomic information:
    - Contextual access criteria limits to necessary information
    - Ensuring privacy and confidentiality rules apply to all collection/exchange of health information
    - Research to assess CPS of the NHIN and consumer confidence

Next Steps

- **Short Term**
  - Two subgroups
    - Genetic/Genomic Tests
    - Family Medical History
  - Recommendations to the AHIC for July 31 meeting

- **Longer Term**
  - PHC-CPS Subgroup
    - Coordinate activities with AHIC Confidentiality, Privacy, and Security Workgroup
  - CDS Ad-hoc Workgroup
    - Coordinate activities across AHIC Electronic Health Records, Personalized Health Care, Population Health and Clinical Care Connections, and Quality Workgroups

In response to the American Health Information Community (the Community), the Personalized Health Care (PHC) Workgroup prepared the following document to assist the Community in its deliberations on recommendations it will make to the Secretary to address the needs and expectations of health care stakeholders by the year 2014[1]. The concepts and statements in this document are directed to the Community and subject to further deliberation by the Community. The Workgroup's vision is predicated on the idea that PHC is a consumer-centric system in which clinicians customize diagnostic, treatment, and management plans based on a variety of factors, including culture, personal behaviors, preferences, family medical history, and the individual's unique genetic/genomic makeup. This vision also embraces the notion that consumers are provided more information about their individualized options and actively participate in the management of their health care practices.

Underpinning this vision is the confluence of two powerful forces, the development of Health Information Technology (HIT), and the rapid advances in the basic understanding of the relationships between health, disease, genetics/genomics, and treatment options. Knowledge of an individual's genetic/genomic makeup appears to have an exceptionally powerful ability to assist with disease prediction, diagnostic accuracy, targeted treatments, medication dosing, and health management.

For the purposes of this document, the vision will be presented primarily from four perspectives: the consumer, the clinician, the researcher, and the health plan/payer.

The Vision for the Desired Future

Consumers will have access to communication tools such as electronic newsletters, personalized weekly health updates, Personal Health Records (PHRs), as well as interactive systems that allow them to make informed health decisions. With these resources, consumers will become more health literate, knowledgeable about health care practices and choices, and embrace their own health care management. As a consequence, consumers should experience safer, more effective treatments that empower their individual health care decisions. If achieved, personalized health care will result in a system that achieves high quality care and greater value.

Where once clinicians had to practice medicine much like an art form, using macroscopic tools to alleviate symptoms, PHC will provide them the molecular tools to refine their art through science and evidence. Making use of genetic/genomic profiling tests, large databases of predisposing factors, family medical history information, and interoperable Electronic Health Records (EHRs), clinicians will be enabled to promote health, prevent disease, predict outcome, and help patients heal faster. With better screening and risk factor profiling tools, medicine will shift from a disease-focused, crisis-reaction orientation toward a health-

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[1] This date references President Bush's call for most Americans to have access to an interoperable electronic health record by 2014, in his 2004 Technology Agenda, Promoting Innovation and Competitiveness. It is recognized that the implementation of personalized health care for comprehensive deployment of personalized health care may take many years to achieve.

focused, proactive approach that embraces health promotion and disease prevention. Management of health information through the use of EHRs will reduce the need for redundant health care data gathering, and so save time and reduce cost as well as improve the quality of information. Advanced Clinical Decision Support (CDS) tools and systems will help the clinician keep up-to-date with the latest medical discoveries and use advanced algorithms for more accurate diagnostic and treatment decisions. These tools will also enable "just-in-time" education for consumers and clinicians, which has been shown to be the most effective tool to change behavior. Development of a more collaborative environment will allow clinicians to share experiences and incorporate new medical information into clinical practice.

Research and public health will be advanced through improved access to the vast amounts of standardized information that is readily accessible at clinics and hospitals. Overall, the uneven and linear translation of information from the 'bench to the bedside' will become a circular channel through the return of information from 'the bedside to the bench'. Medical research activities will be improved through better understanding of phenotype-genotype relationships. Advances in health information technology and education will improve the translation of research results to clinical care. Post-marketing surveillance of the safety and effectiveness of medical product interventions will be used to continually refine best-practice guidelines.

Health plans/payers will be able to develop new models that incorporate the use of genetic/genomic information into benefit design, disease management programs, and testing and treatment reimbursement strategies. Health care costs should be reduced and health care quality improved by more accurate diagnosis and more effective treatment decisions.

Current Status

Currently, consumers, clinicians, and other stakeholders are presented with a fragmented health care system, where the emphasis of primary care is on treatment of acute and chronic care rather than on prevention. Consumers have little interaction with the health care setting outside of visits to their clinicians. They are fearful that their health information may be used against them for insurance and employment decisions, and concerned that their information may be used without their consent. While PHRs are being offered by a growing number of health plans, employers, HIT vendors, and a few select EHR-enabled clinician offices, overall adoption is very limited. In general, consumers cannot easily access their personal health information or populate a PHR with their health history. Compounding this issue, Confidentiality, Privacy, and Security (CPS) issues may not be clearly understood or addressed by many of the PHR vendors and users.

Clinicians are challenged to keep up with medical breakthroughs, have insufficient education about genetics/genomics in medicine, and lack tools to bring evidence to the point of care. The use of genetic/genomic information, either in the form of family medical history or genetic/genomic tests, is not integrated into medical practice. Family medical history is currently collected in many different formats, multiple times, by the many different clinicians a consumer interacts with through his or her life. CDS and related analytical tools in EHRs

have not advanced beyond simple messaging and reminders. While currently over 1,000 genetic/genomic tests are available for a variety of diseases, there is no widely accepted process for vetting and determining the analytical validity, clinical validity, and clinical utility of genetic/genomic tests. Reimbursement strategies for the use of genetic/genomic information are generally insufficient to encourage appropriate adoption in clinical practice.

The sequencing of the human genome, combined with the power of genomic analysis techniques, tools, and databases, facilitated by the HapMap Project, and Genome-Wide Association Studies (GWAS) are rapidly advancing the basic understanding of disease processes. However, translation of this information into knowledge that can guide an individual consumer's health care is occurring on a very limited basis. EHRs that enable knowledge delivery to physicians and other clinicians are limited in breadth and depth. Researchers are hindered by the paucity of systems that support the integration of genotype-phenotype data and perform post-marketing surveillance of treatment and diagnostics options. Currently, a foundation exists for privacy, security, and confidentiality protections, but these may be insufficient to maintain public trust in information sharing as technology advances and interoperability amongst data sources grows.

Defining Characteristics of the Health Care System in the Context of Personalized Health Care

The various characteristics of the current status and the future vision of PHC are described below.

Consumer's Perspective

Consumers have little interaction with the health care sector outside of visits with their clinicians. A consumer's health care experience can be improved by engaging the consumer through a PHR. A PHR enables a partnership with clinicians that can reduce or eliminate duplicate procedures or processes, save health care dollars, and save time for the consumer and the clinician. The PHR should display complete, organized, and quality patient information, including genetic/genomic and environmental risk and exposure data, and the relevant educational tools to encourage health promotion and disease prevention. Consistent privacy protections, the ability to view, annotate, and, in appropriate circumstances, amend information, and role-based access control of consumer information should be integral in the development of PHR systems. Through the PHR, the consumer will have the ability to input family medical history information for review by the clinician. Algorithms that take into account current medical information, environmental information, and family medical history should generate personalized prevention messages.

Clinician's Perspective

Despite the availability of a growing number of genetic/genomic tests, lack of clinical practice guidelines or systematic information on the evidence base, including analytical validity, clinical validity, and clinical utility, hinders appropriate selection by the clinician making diagnostic and treatment decisions. Clinicians will remain hesitant about embracing these

new tests if they lack confidence in the utility of the tests or their ability to effectively respond to the test results. It is possible that in the future the inexpensive availability of entire genomic sequence information for the individual consumer will negate the use of individual tests. However, the evidence development and treatment guidelines to respond to emerging information will always be required. Combining the power of genetic/genomic testing information with family medical history information, when collected in a systematic fashion in the EHR, will enable improvements in medical decisions and the transition to a more preemptive clinical practice. Robust CDS systems using validated algorithms based on basic scientific, outcomes, and effectiveness research will be available. These should be incorporated in the EHR, where messages are ranked to maximize use of the clinician's time, and further information about the evidence supporting the messages can be easily accessed to increase clinicians' confidence in these systems.

Researcher's Perspective

Development and evaluation of genetic/genomic testing continues to be a major focus of basic and applied biomedical research. Improved understanding of the genetic/genomic basis of disease and identification of new biomarkers for disease are driven by large projects that are evaluating the relationships between genes, environment, human health, treatment response, and disease. Translation of these discoveries into health care interventions should be supported by robust evidence development. Research resources from federally funded genetics/genomics studies should be made widely available, with the appropriate protections in place. An integrated system of health information that captures routine clinical interactions and outcomes information from different health care delivery systems should be built based on common data standards and definitions. Appropriate access to this network by public health and other researchers could support evidence development, safety assessment, post-market surveillance, and outcomes research. This requires that reassurances are made to the consumer and the clinician, through the development of technical and policy solutions, that personal health information will be used appropriately, with their knowledge, and for the benefit of health research.

Health Plan/Payer's Perspective

As the health care system focuses on health promotion, disease prevention, and preemption through personalized approaches based on risk assessments, these advances will drive a need for new reimbursement strategies and other incentives. Health Plans/Payers will need to construct new models that incorporate the use of genetic/genomic information in benefit design, health maintenance, prevention, and disease management. This could lead to a reduction in overall health care costs by encouraging early detection and preemption to minimize costly interventions associated with the advanced progression of disease. Consumers may select benefit packages that are more specifically targeted to their health and disease profiles. Disease management strategies can be tailored to the individual based on that person's likelihood of responding to traditional treatments. Reimbursement should be established for genetic/genomic tests that have a demonstrated ability to lead to more effective treatment.

Building Blocks for Change: Personalized Health Care Requirements

To support the vision of PHC, a number of enablers and barriers that transcend any single stakeholder perspective are described below.

Confidentiality, Privacy, and Security

The introduction of powerful genetic/genomic tests into the health marketplace has the ability to positively impact individuals and society. Genomic information has the potential to identify and predict the health outcomes of individuals and their families. Maintaining the public's trust in the use of their personal health and genetic/genomic information, by developing technical and policy guidelines to ensure the security of their EHR and PHR data, is key to maximizing utility and health benefits of new medical genetic/genomic tests. Improved understanding of the risks associated with certain types of genetic/genomic information, as well as the risks associated with the development of interoperable EHRs, needs to be taken into consideration. Innovation in new security and privacy methods and policies should be encouraged to prevent misuse of genetic/genomic information and ensure privacy and confidentiality rules apply to all collection and exchange of health information. Appropriate technical and policy solutions need to be developed to address the inherent ability to re-associate an individual with their de-identified genetic/genomic information through data aggregation, cross-referencing with publicly available databases, and potentially through phenotype prediction.

In parallel to these advances in personal health management, large registries of phenotypic and genotypic information are fueling the advances in the basic scientific understanding of diseases. To ensure continued participation in important clinical studies, the public needs reassurance that their personal health information will be used appropriately and for the benefit of science. Potential participants in clinical studies should undergo thorough education and understandable consenting procedures. This would clearly establish how their information will be used for the study and future potential studies, and inform them of the risks and benefits associated with the release of their genetic/genomic information. Transparent policies need to be formulated to manage access to research information. An individual's genetic/genomic information should only be used to guide treatment and decision making, and should not be used as the basis for employment, insurance coverage, and unauthorized marketing or law enforcement practices.

Health Information Exchange

While innovation in technology to collect information is a key step, data collection alone will not support personalized health care. As technological capabilities develop across the health care system, better information based on individual differences will aid in future medical product evaluations and post-marketing assessments of safety and efficacy. Exchange of information between the PHR and the EHR will build the partnership between the consumer and the clinician, and the development and exchange of quality information will allow clinicians to compare practices. Integration of the research enterprise into the clinical enterprise will provide the basis for significant acceleration of medical discoveries. Such

integration requires the development of technologies to ensure privacy and security, the development of contextual access criteria limits, and the policies to enforce the appropriate use of these technologies. Regional Health Information Organizations (RHIOs) have the capacity to serve as local sources of health information; however, the lack of general oversight and their differential development in various geographical areas could result in variations in health care delivery and practices.

Knowledge Development

There is an increasing need for integrated data sets and higher quality information regarding efficacy and safety outcomes. Using integrated databases, the ability to assimilate and relate experiences will enable incredible predictive power regarding disease progression and treatment effectiveness. Until now, this could only be modeled at a population level. Personalized health care should equate not only to an emphasis on more effective health outcomes but improved prevention and safer health interventions as well. As new knowledge is developed, transparency of the evidence base and research methods should be highlighted to ensure the propagation of clinically valid information.

New and Innovative Relationships

New approaches to medical product review, market entry, and product safety monitoring will require improvements in the integration of government and industry roles and responsibilities. Many genetic/genomic tests are based on rapidly developing information, and a flexible regulatory environment will be necessary to accommodate such rapid change. Development and dissemination of information about the analytical validity, clinical validity, and clinical utility of these tests will be required to guide their appropriate use in care provision. The relationship of industry and academia in basic R&D will continue to undergo change in funding methods and intellectual property management. Currently, the high cost associated with carrying out many clinical studies limits the types of investigations that can be conducted on diseases and treatments. New models built on targeted studies with extensive post-market surveillance and modification of treatment protocols based on real-time clinical information could decrease cost while broadening the scope of medical investigations. Additionally, new relationships may emerge in employer/employee relationships in supporting personalized health care programs through incentives and web-based information tools.

Personalized Health Care (PHC) is conceptualized as a future consumer-centric system in which clinicians customize diagnostic, treatment, and management plans based on a variety of factors, including culture, personal behaviors, preferences, family medical history, and their unique genetic/genomic makeup. This vision is based on the confluence of two powerful forces, the development of Health Information Technology (HIT), and the rapid advances in the basic understanding of the relationships between health, disease, and genetics. The priority areas described here focus on the inclusion of useful genetic/genomic information and analytical tools in the Electronic Health Record (EHR)[1] to support clinical decision making by the consumer and the clinician in the age of a genome-enabled electronic health record.

The PHC Workgroup has identified four priority areas. All are important if consumers, clinicians, the research community, and health plans/payers are to realize the potential benefits of interoperable health information technology. In each priority area there are components that can be advanced in the *near term* to support interoperability across the health care enterprise, thereby providing a strong foundation for future efforts. The priority areas are:

- **Genetic/Genomic Tests** – Inclusion of genetic/genomic test results and other genetic/genomic information in the EHR or Personal Health Record (PHR)[2] could enable the personalization of health care decisions through avoidance of adverse reactions, selection of optimal interventions, and beginning the transition of the health care sector from a reactionary to a predictive enterprise. The Genetic/Genomic Tests priority area includes:

  - Electronic recording of laboratory data associated with genetic/genomic testing analyses
  - Inclusion of relevant genetic/genomic test results in the EHR
  - Harmonization of standards for submission of clinical pharmacogenomics data
  - Harmonization of standard state-mandated newborn metabolic and genetic/genomic screens
  - Inclusion of information that describes the analytical validity, clinical validity, and clinical utility of genetic/genomic tests in the EHR
  - Incentives for the development and evaluation of new genetic/genomic tests and their incorporation into routine clinical practice
  - Consumer education about the potential benefits and risks associated with genetic/genomic tests

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[1] The Electronic Health Record (EHR) is a secure, real-time, point-of-care, patient-centric information resource for clinicians. The EHR aids clinicians' decision-making by providing access to patient health record information when they need it and incorporating evidence-based decision support. The EHR automates and streamlines the clinician's workflow, ensuring all clinical information is communicated and ameliorates delays in response that result in delays or gaps in care. The EHR also supports the collection of data for uses other than clinical care, such as billing, quality management, outcomes reporting, and public health disease surveillance and reporting. http://www.providersedge.com/ehdocs/ehr_articles/HIMSS_EMR_Definition_Model_v1-0.pdf *Electronic Health Record HIMSS Definitional Model*

[2] Personal health records are broadly considered as a means by which an individual's personal health information can be collected, stored, and used for diverse health management purposes. However, NCVHS found that there is no uniform definition of "personal health record" in industry or government, and the concept continues to evolve. http://www.ncvhs.hhs.gov/0602nhiirpt.pdf *Personal Health Records and Personal Health Record Systems*

- **Family Medical History** – Clinicians already use a basic and important genetic/genomic tool in everyday practice: family medical history. Combined with the power of genetic/genomic testing results, family medical history adds value and provides useful predictive information that can lead to preemptive actions and earlier detection of disease. The Family Medical History priority area includes:

    o Consumer and clinician entry of family medical history information in the PHR and EHR
    o Infrastructure and incentives to use PHRs to improve consumer-clinician communication
    o Communication of family medical history information between the PHR and the EHR
    o Clinician use of consumer entered family medical history information
    o Standardization of family relationship nomenclature and other critical items to capture related to family medical history
    o Characterization of the validity and utility of use of family medical history in making clinical decisions

- **Clinical Decision Support[3]** – Currently there is no systematic process for the development, dissemination, and uptake of evidence-based practice information and other science based information concerning disease and medication management to the clinician community. As a consequence, important clinical guidelines often take years to develop and incorporate into daily clinical care practices. Use of genetic/genomic information in many areas of clinical practice is a relatively new development. Many clinicians commonly indicate their lack of sufficient training, education, and time to make the transition to including this information in practice. Development and deployment of clinical decision support tools should take into consideration the usability, workflow, and practice environment of the clinician. The Clinical Decision Support priority area includes:

    o Development of evidence and accompanying information for clinicians and consumers related to genetic/genomic information that facilitates evidence-based decisions
    o Development and assessment of risk analysis algorithms, predictive tools, and prevention messages based on genetic/genomic test results and family medical history information
    o Development of sophisticated algorithms and support tools to aid in treatment and clinical decision making with deployment into critical functions of the EHR

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[3] Clinical Decision Support: Providing clinicians, patients, or individuals with knowledge and person-specific or population information, intelligently filtered or presented at appropriate times, to foster better health processes, better individual patient care, and better population health. CDS interventions include alerts, reminders, and order sets, as well as other techniques for knowledge delivery including reference information and education (delivered with or without context sensitivity), health/clinical protocol and workflow orchestration support, display off context-relevant data, topic-oriented documentation forms, and others. http://www.amia.org/inside/initiatives/cds/ *A Roadmap for National Action on Clinical Decision Support*

- Incentives for development and incorporation of clinical decision support tools in EHRs
- Health information exchange to support clinical decision making

- **Confidentiality, Privacy, and Security** – Consumers today are concerned that their health information may be for unintended purposes or without their authorization in insurance and employment decisions. Compounding this concern are the limited understanding of new genetic/genomic tests, the immutability of this information across the consumer's entire lifetime, the predictive abilities attributed to genetic/genomic information, and the potential harm that could come to their relatives because of a common genetic/genomic background. Technical solutions and policy considerations should be developed to address these concerns. To ensure acceptance of genetic/genomic tests in health care, the consumer and clinician need to be assured that the relative risks and benefits of this information have been assessed. The Confidentiality, Privacy, and Security (CPS) priority area includes:

  - Technical solutions and policy considerations to ensure that genetic/genomic information will be used appropriately, with consumer consent, and for the benefit of their health
  - Sufficient confidentiality and security measures to protect consumer genetic/genomic information as it is electronically recorded in the EHR and PHR
  - Capabilities to link large datasets to generate large-scale, individual-level genomic data with sufficient protections for use
  - Balancing the desires of the research community to have secure and consented access to clinical databases with the privacy and confidentiality rights of the consumer and clinician
  - Understanding the risks associated with certain types of genetic/genomic information:
    - Contextual access criteria limits to necessary information
    - Ensuring privacy and confidentiality rules apply to all collection/exchange of health information
    - Reducing harm of discriminatory use of health information
    - Research to assess CPS of the Nationwide Health Information Network and consumer confidence