The Community

American Health Information Community

March 13, 2007
8:00 a.m. - 12:45 p.m. (PST)

Computer History Museum
1401 N. Shoreline Boulevard
Mountain View, CA 94043

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

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

8:10 a.m. **Comments** – *David Brailer*

8:15 a.m. **Certification Commission for Healthcare Information Technology (CCHIT) Update**
- Mark Leavitt, Chair

8:45 a.m. **Workgroup Recommendations**
Consumer Empowerment Workgroup
- Nancy Davenport-Ennis, National Patient Advocate Foundation
- Rose Marie Robertson, American Heart Association
- David Lansky, Markle Foundation
Quality Workgroup
- Carolyn Clancy, HHS/Agency for Healthcare Research and Quality
Population Health/Clinical Care Connections Workgroup
- Charles Kahn, Federation of American Hospitals
- Steve Solomon, HHS, Centers for Disease Control and Prevention
- Kelly Cronin, HHS, Office of the National Coordinator
Confidentiality, Privacy and Security Workgroup
- Kirk Nahra, Wiley Rein LLP
- Jodi Daniel, HHS, Office of the National Coordinator

10:45 a.m. **Privacy and Security Panel**
- Jodi Daniel, Moderator, HHS, Office of the National Coordinator
- Sue McAndrew, HHS, Office for Civil Rights
Privacy and Security Solutions for Interoperable Health Information Exchange
- Linda Dimitropoulos, RTI
Health Information Security and Privacy Collaboration (HISPC)
- Rex Gantenbein, State of Wyoming
- William O'Byrne, State of New Jersey
- James Golden, State of Minnesota

11:45 a.m. **Employer Panel**

- *Andrew Croshaw, Moderator, HHS/Office of the Assistant Secretary for Planning and Evaluation (ASPE)*
- *Peter V. Lee, Pacific Business Group on Health*
- *Jeffrey Rideout, Cisco Systems, Inc.*
- *Chris Nohrden, IBM*

12:30 p.m. **Public Input**

12:45 p.m. **Adjourn**

Meeting Report

American Health Information Committee
January 23, 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 11th meeting on January 23, 2007, at the Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC, 20420.

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 (DHHS) on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting's discussions focused on: (1) state-level health information exchange (HIE) recommendations, (2) HIE business models, (3) AHIC priorities and 2007 use cases, (4) an announcement on a joint Department of Veterans Affairs (VA) Department of Defense (DoD) inpatient EHR, (5) Workgroup recommendations and updates, and (6) Nationwide Health Information Network (NHIN) prototype architecture demonstrations.

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

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

Call to Order

Joining Secretary Leavitt counterclockwise around the table were:

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

John Menzer, Vice Chairman, Wal-Mart

Scott Serota, President and CEO of the Blue Cross Blue Shield Association (Justine Handelman, Director of Federal Relations at the Blue Cross Blue Shield Association, represented Mr. Serota for part of the meeting)

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

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

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

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

Nada Eissa, Deputy Assistant Secretary, U.S. Treasury (Ms. Eissa was represented by Adele Morris, Senior Economist, U.S. Treasury, for part of the meeting)

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

Kevin Hutchinson, CEO of SureScripts

William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs (Dr. Winkenwerder was represented by Carl Hendricks, CIO of the Military Health System, for part of the meeting)

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)

Leslie Norwalk, Acting Administrator, Centers for Medicare and Medicaid Services (Ms. Norwalk was represented by Tony Trenkle, Director of E-Health Standards and Services, Centers for Medicare and Medicaid Services, for part of the meeting)

Craig Barrett, PhD, Chairman of the Board, Intel (Mr. Barrett was represented by Brian DeVore, Industry Affairs Manager, Intel Digital Health Group, for part of the meeting)

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

Bettijoyce Lide, Scientific Advisor for Health Information Technology in the National Institutes of Standards and Technology's Information Technology Laboratory (representing Robert Cresanti, Under Secretary of Commerce for Technology, U.S. Department of Commerce)

Steven Solomon, MD, Director of the Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention (representing Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention)

David Brailer, MD, PhD, Vice Chairman, AHIC, participated in the meeting via conference call.

Introductory Comments

Secretary Leavitt welcomed participants to the meeting and thanked the VA for hosting the meeting (this AHIC meeting was held at the VA instead of the DHHS to facilitate preparations for the President's State of the Union Address). The Secretary also thanked the VA for continuing to allow Dr. Kolodner to serve as the Interim National Coordinator for Health Information Technology (HIT). AHIC began its work just over 1 year ago. In that time, the Community has worked with urgency on a path that is producing results quickly. As an example of how AHIC's work is adding to the national landscape in HIT, Secretary Leavitt referred the Community to a recently released report entitled *Health Information Technology Initiative Major Accomplishments: 2004-2006*.

Secretary Leavitt outlined the day's agenda, and before moving forward, announced that he has officially accepted the Health Information Technology Standards Panel (HITSP) Interoperability Specifications as

recommended by AHIC in October 2006. Finally, Secretary Leavitt formally welcomed new AHIC member John Menzer, Vice Chairman of Wal-Mart, to the Community. Dr. Brailer participated in the meeting via conference call; therefore, Dr. Kolodner assisted Secretary Leavitt and served as Co-Chair of the proceedings.

Approval of December 12, 2006, Meeting Minutes

Minutes from the December 12, 2006, AHIC meeting (which was held via teleconference) were distributed, reviewed by Community members, and approved unanimously with no changes.

State-Level Health Information Exchange (HIE) Recommendations

State-Level HIE Steering Committee Recommendations

Ms. Linda Kloss, of the American Health Information Management Association (AHIMA) and the FORE Foundation, presented recommendations that have come forward from the State-Level HIE Project. As a representative of the Project's Steering Committee, Ms. Kloss reminded the Community that the Project has made two previous presentations at AHIC meetings to discuss progress made. In September 2006, the State-Level HIE Project presented its first phase of recommendations: (1) build mechanisms to promote strategic synergy among states and between state and federal efforts, (2) create salient financial models for sustainable HIE, (3) engage and leverage public and private payers, (4) advance the understanding of how state policymakers and government agencies should be involved, and (5) develop vehicles for support and knowledge-sharing among state-level HIE initiatives. During the December 2006 AHIC teleconference, recommendations in three of four major areas were presented (state-level HIE in coordination with major federal initiatives, HIE and coordination with quality and transparency initiatives, and Medicaid and HIE). Ms. Kloss explained that recommendations in the fourth area, financially sustainable HIE, would be presented following her remarks. The Project's first deliverable was a workbook entitled *Guide to Key Issues: Options and Strategies for State-Level Health Information Exchange*.

After completing its first two phases of work, the Project's Steering Committee has reviewed progress to date and developed four overarching strategy recommendations to the Community and to the Secretary for future action. These recommendations were developed with the intent of encouraging useful and healthy debate about how HIE transparency and transformation should fit together, and how states can be successful partners. The four recommendations are:

- **Recommendation 1: The federal government should consolidate oversight of HIT and quality/transparency initiatives under AHIC.**
    - 1.1 Create incentives for innovation and cost-effective coordination.
    - 1.2 Fund research on models for data capture, aggregation, and privacy.
    - 1.3 Appoint a representative of HIEs to quality workgroups and projects.
    - 1.4 Study sustainable business models for HIEs that supply aggregate data for quality measurement and reporting.

- **Recommendation 2: The Secretary should design the successor to AHIC and transition it to a public-private organization by 2008.**
  - 2.1 Charge a design group working in 2007 for implementation in 2008.
  - 2.2. Reintroduce the revised *2004 Framework for Strategic Action* that accounts for AHIC, state and local HIEs, and the NHIN.

- **Recommendation 3: Each state should establish or designate a consolidated, public-private health transformation governance mechanism that includes at least HIE and quality/transparency.**
  - 3.1 Build on work in the state-level HIE *Workbook* to describe models, authority, and core roles.
  - 3.2 Appoint a new State Workgroup for formal liaison to AHIC.
  - 3.3 Support a state-level learning community.
  - 3.4 Insert state perspective into the work of all AHIC Workgroups.

- **Recommendation 4: The federal government, to the degree possible under the statute, should fund transformation and provide strong leadership through CMS policy.**
  - 4.1 Develop a state workgroup to develop criteria and recommend mechanisms for funding.
  - 4.2 Provide leadership regarding Medicaid and Medicare support for state-level HIE and quality/transparency.
  - 4.3 Identify funding mechanisms.
  - 4.4. Establish a process for advancing the criteria.

Recommendation 1 Discussion Highlights

"When you talk about the Federal Government having a role, are you thinking that they should be the organizer of this, or are you thinking they are the long-term overseer?" – Secretary Leavitt

"We saw the Federal Government, and particularly AHIC, as convening some real discussion about how we go forward with less divergence, less opportunity for solutions that are going to need to be melded back together again…So we are looking for some convener to make sure we move at standardization." – Ms. Kloss

"There is a little bit of tension, there seems to me, between the idea of designating a successor to AHIC, as a public/private organization, and then the idea of federal funding and using it as an oversight." – Secretary Leavitt

"We do envision it being public/private, and that certainly there needs to be a strong role for the government in this. It's not completely private. So we didn't propose specific mechanisms, but we did propose that as a major payer, and a major purchaser of health care…there might be a role [for the Federal Government] for advancing the efforts in the states." – Ms. Kloss

"I really believe in HIT…we've got to have some connectivity, but I see that as the vehicle, not the substance, of collection of data, and aggregation of data for transparency, for accountability, for quality assurance…We haven't really figured out how to use IT to really make it effective for reporting, much less have it play the kind of role that it would play here." – Mr. Kahn

"I would ask you to look at these recommendations as not having not IT/technical underpinnings, but really governance and coordination underpinnings. So what is common across them is the notion that the work that state level health information exchange initiatives are doing is often disconnected from what quality and transparency efforts may be in the state." – Ms. Kloss

"I want to comment about [Recommendation] 1.1, and this notion of cost effective coordination...There has got to be a way [to have] cost-effective coordination between public and private sectors…And the idea of aggregating that data [in the VA's system] for quality and transparency seems to be fairly simple…This notion of the private/public partnership has got to be put on steroids if we're going to achieve the President's vision, as quickly as we can." – Ms. Gelinas

"Bringing these state activities into this coordination role, whether it's the Federal Government, as it's listed here playing that role, or whether it's really the public/private partnership playing that national coordination role, I think that's the only disconnect I have with the recommendation, because…if you look at the sub-bullets, it really is about this national partnership between public and private. And if we could modify that language, I think the recommendation is good, if it's a coordination role."
– Mr. Hutchinson

"I really question whether we want to bring quality and transparency initiatives, which already have an established protocol in process, together into this milieu, or whether we want to let them flourish in their own space. If we were to bring them in here…we would need a heavier clinical dose, if we're going to be venturing into approving and reviewing quality standards…So my advice would be to proceed with these recommendations, but, perhaps, back the quality and transparency piece of this, at least out for further discussion, and clarify precisely what's meant by those words, before we move forward." – Mr. Serota

"It would be nice if we could avoid duplicating things, and take advantage of what's already known. We stand ready to share on that front, and I know the VA does as well. I agree with Scott's comments about the role of this group being principally a convener, and a national coordinator…consolidation of oversight is a pretty strong pair of words, because it implies almost regulatory authority. And I'm not sure that's what we want to do here with this group." – Dr. Winkenwerder, Jr.

"From a policy and a directional standpoint, and encouraging sound information processes, we think that these two critical areas, health IT and HIE can't be disconnected…We're just supporting that need, and suggesting that that same kind of coordination needs to be occurring at the state level…Our focus is clarity in the role of states, and replicability of the vision that we've had at this group, to allow that to happen in the states." – Ms. Kloss

"At the Community level, the connection that we have to the quality and transparency initiatives that are occurring at the federal level, exist by virtue of the Workgroup that we have working on the quality standards…At the federal level, I think we've got that dealt with very well. I think what Linda has brought to the forefront is at the state level, that degree of connectivity between state related quality initiatives and HIT may not exist as well as it does at the federal level. And so is there a role for this body to encourage better coordination at the state level…I certainly would endorse that degree of coordination, but again, 'consolidation' and 'oversight' may be too strong terminology." – Dr. Henley

Recommendations 2 and 3 Discussion Highlights

"My vision on this has been from the beginning that we would see AHIC have a private/public successor. I clearly believe there needs to be a counterpart to AHIC at the state level, and we need to find a way to consolidate the efforts that are happening at states, and then coordinate what's happening among states with what's happening at AHIC. In my mind, I have envisioned that that would be a chartering model, where states formed their consolidated effort, and received some kind of charter from whatever the successor organization is." – Secretary Leavitt

"The question that's been raised today earlier is whether or not the quality effort, which frankly has a similar kind of vision, [has] a coordinated vision or a consolidated vision. I've noted that there is a

tension often between the people who manage the IT, and the people who manage the enterprises…While there is a tension, and often some duplication, having them separate is important." – Secretary Leavitt

"Tthe heads of the state HIEs that we've worked with here at the table would suggest that their vision of health information exchange, and its importance as a transformation mechanism, goes beyond IT. That is, when we look at the mission of these organizations, it's about quality, and it's about advancing change and improvement in health care. In some ways, it's one part of the flow." – Ms. Kloss

"As the head of a state-wide HIT operation, those comments are terrific, but we're trying to connect Indianapolis to Evansville, and the quality piece, we're not anywhere doing that yet…The states that I'm familiar with have…a much more practical view of what they need to achieve in the near term, because you can't get to the quality piece that you're talking about, until you get the connectivity that is still troublesome for many states." – Mr. Roob

"On Recommendation Two, I think obviously we're going to need to have that discussion, or a Workgroup that would look at this going forward. I just question the timing…Because I think we want to take advantage of all the learnings we possibly can, to lay out how this will go forward, and I think '07 could be a year where we'll see a lot of activity in this particular space that could have learnings that we would want to do to move that forward. Maybe end of '07 or early '08 is the right timing to look at the successor organization." – Mr. Hutchinson

"On Recommendation Number Three, I think the challenge, from a governance perspective, is…making sure that we're not squeezing off innovation. Because in many instances, what we've seen, from even the state level organizations, and the activities they've had in deploying HIT programs, is associated with being creative in their approach, being creative in incentivizing their positions, or being creative in how they're deploying." – Mr. Hutchinson

"Does AHIC, today, have a charter limit, a time limit?" – Dr. Winkenwerder, Jr.

"We have a 2-year limit, but it's renewable…The idea has been always to create a successor."
– Secretary Leavitt

Recommendation 4 Discussion Highlights

"We've not defined yet what needs to be a fairly broad role for the private sector. And I worry that if it's just about federal funding, that it creates a dependence; it creates a lack of involvement…The motto here ought to be 'create, fund, and spin out.' And it's not inconceivable to me at all, that in order to accomplish this, both the birthing of the successor, and the consolidation of the state counterparts, that we could use some federal money to provide seed capital…The condition of getting the seed capital ought to be the creation or an existence of an ongoing business model that will perpetuate it beyond that seed capital." – Secretary Leavitt

"It certainly is in line with [Recommendation] 4.1 where we reflect that work would need to be done to understand what the criteria would be for transformation entity, and that would be a precondition for any funding." – Ms. Kloss

"I think the seed capital concept, particularly subject to the criteria that you described, is very consistent with the direction we've gone. But it does raise the question about who sets those criteria, and I think the answer to that is very much embedded in the other three recommendations that Linda has raised; that today, regardless of whether we have a quote, governing, or an oversight mechanism, we don't even have a communication mechanism between the federal and state efforts, as they're beginning to form. And I

think establishing a means of communication between AHIC, or somebody like AHIC, and these efforts that are in the fledgling level in the states, can help us." – Dr. Brailer

"I think we should be cautious about our language with respect to successor. Remember that AHIC provides two important high-level functions. One is to provide a formal legal mechanism for advice into the government…The second value or function that AHIC provides is providing a mechanism for convening coordination and communication…These could move hand in hand." – Dr. Brailer

"The reason AHIC has the capacity to do this is first of all, as it's currently constituted, it is a group that advises the Secretary. The corollary to that is that the reason that has value is because of, essentially, the executive order, which says the Secretary will have the capacity to link the buying power of the Federal Government into it. Then we're adding to that by coordinating the buying power of the Federal Government with the buying power of many other organizations, both government and private."
– Secretary Leavitt

"Right now AHIC is a federal advisory committee. Its whole purpose is to advise, but if we're able to then create a successor, it can both continue to advise, and begin to act as the conduit to these state entities. I think that's the vision. And I see a complementary vision happening on the quality side. And it is, in my mind, very much an open question as to how those two interrelate." – Secretary Leavitt

"There is a body of research that would suggest, again, that implementation of certified EHRs, PHRs, etc. can bring huge cost savings to everybody, not just the Federal Government, but the private sector as well. And yet we can't get over this hurdle of thinking of everything as new money versus simply redistributing money that's already in the system. And we've got to somehow get over the present inefficient way of projecting those financial impacts, especially as it relates to the federal sector." – Dr. Henley

"I think if you look at Recommendation 4 as the Federal Government being a large payer, it might be, as opposed to a granter of money; and I would encourage Leslie and the other folks at CMS to articulate that vision to the states through the MMIS and MITA infrastructure…That's a missed opportunity, at least to date." – Mr. Roob

"That is addressed quite well in the task report on the Medicaid role in State-Level HIE, so I would recommend that you look at that specific set of recommendations." – Ms. Kloss

"I sort of had reticence in the first recommendation regarding the role that was envisioned there in the bold text regarding AHIC. I do think that we are at a point at which statute is needed to define these relationships, which is implied here…I'm concerned that it may not be lasting, because there is just nothing like law to make things happen, and obviously, to secure them over time." – Mr. Kahn

"I expect that at some point Congress will legislate on this…In the absence of legislation, we ought to be driving as hard and as fast as we can, not to outrun them, but to simply guide what would be prudent. What I believe our discussion leads us to today…would be recognition that the question of the interrelationship between quality and health IT is still an open question, and requires more thought. That we do intend to move forward with the creation of a public/private successor, and that our objective would be to accomplish that in advance of the 2-year authorization of this body." – Secretary Leavitt

"One of the first orders of business of that successor organization would be the creation of state counterparts, with the means of chartering, or some other link that would facilitate coordination and communication…A condition of that chartering would need to be a sustainable business model…it's possible, I suspect, that some federal component could be a piece…[but] it should not be viewed as simply a creature of federal appropriation." – Secretary Leavitt

"Is it fair to interpret that, that we're effectively saying 'yes' to Recommendation 2 as a precursor to considering any of the other recommendations?" – Mr. Barrett

"I think that's probably a fair statement, yes." – Secretary Leavitt

Health Information Exchange Business Models

Kelly Cronin, Office of the National Coordinator (ONC), opened this panel with a brief orientation on two mechanisms that have been utilized to fund exploratory work on business models for HIE. The first mechanism relates to the four NHIN consortia contracts. The consortia recently delivered to ONC their own cost and revenue models that are based on their ideas around what a viable business model would be for HIE from a service provider perspective. The second mechanism utilized to fund work on business models for HIE utilized funding from the State Health Information Exchange Project to review financially sustainable HIE services.

The NHIN Initiative Cost and Revenue Models

Dr. John Glaser, Vice President and CIO of Partners HealthCare, noted that the critical attribute of the NHIN is that it is financially sustainable (i.e., it provides services that are deemed to have value by stakeholders and willingness to pay on their part). The four NHIN contractors were requested to develop revenue and cost models to illustrate potential sustainability approaches; Dr. Glaser provided a summary of those analyses and provided his own observations. He reminded the Community that NHIN's intent is to foster widely available services that facilitate accurate, appropriate, timely, and secure exchange of health information that follows the consumer and supports clinical decisionmaking.

Dr. Glaser noted that the following shared assumptions and concepts guide this work: (1) the NHIN is envisioned as a "network of networks;" (2) the organizations that provide network services may take several forms; (3) there are some basic network services necessary for connecting health records, security, record look-up, and routing; and (4) many other network services ay be considered valuable in local settings. Dr. Glaser listed a number of NHIN services that could be provided, including secure data transport services; identification, authentication, and authorization services; participant registry and directory services; data mining and analysis services; etc.

Dr. Glaser commended the four contractors involved, noting that they faced some significant challenges in creating their models. For example, they were asked to define the business model (services, governance, pricing, and adoption) for a very complex IT infrastructure for which there is very little marketplace. They also were asked to define a model for which many of the base conditions may not be in place (e.g., extensive EHR adoption and quality-based financial incentives). Furthermore, they were basing the model on hundreds of variables and dozens of assumptions.

The revenue and cost models that were developed were based on very different business models and approaches. They differed in terms of the balance between NHIN services and sub-networks, NHIN governance structures, and revenue strategies and sources. All models were projected to reach a break-even point within 8 years, ranging from the very near term to about 7 years (not including the cost of EHR adoption by providers, hospitals, physicians, etc.). Dr. Glaser noted that reaching financial sustainability through any of these models will require progress on several NHIN conditions. All of the models require an active government role in terms of developing standards and certification, forming policy, providing initial capital, and/or serving as an employer/payer funder of NHIN services. In

addition, all models identified secondary uses of data as a critical contributor to sustainability (often accounting for more than 50% of revenue).

Dr. Glaser presented the following conditions for NHIN adoption:

- Financially viable participant networks and organizations
- Conformance of participant networks and organizations to necessary NHIN standards and policies
- Methods for addressing misaligned financial incentives and care improvement externalities
- Sufficient base of EHR adoption
- Broad adoption of standards
- Robust privacy and security policies and mechanisms
- Legal and policy approaches to anonymized, secondary uses of data.

In concluding his remarks, Dr. Glaser presented the following open questions/issues: (1) What else should government and the private sector do to facilitate progress on the conditions for NHIN adoption? (2) How well do we understand the business tradeoffs between services that support inter-network exchange and exchange within participant networks? (3) What are the differences in effectiveness of various revenue models? and (4) How viable is secondary uses of data as a source of NHIN revenue?

The Economic Proposition of Financially Sustainable HIE Services

Stephen Parente, of the University of Minnesota and HIS Network, LLC, provided an economic perspective on how to achieve financial sustainability for HIE. He noted that the opportunities to achieve sustainability in this field are favorable in two primary regards: (1) a return can be made on this, and (2) there are opportunities for public and private partnership (and the opportunities in the private sector are substantial). He explained that "sustainability" occurs when a firm, venture, or enterprise operates where it can break even at a certain point in the future and can grow to where marginal revenue equals marginal cost. Key factors include the size of the enterprise, time from start-up to sustainability, source of revenues, expected tenure/type of revenue sources, stakeholder expectations (profit sharing or other), barriers to entry/intellectual property rewards, technological opportunities/constraints, and rate of technological progress and redundancy threat.

In discussing the economics of information technology, Mr. Parente referenced the Applicable Conceptual Model developed by Erik Brynjolfsson and Lorin Hitt. The model touches on three different measures of IT value: (1) productivity, (2) profit, and (3) consumer welfare (which presents opportunities for public good creation). Mr. Parente then discussed sustainability benefits in terms of scale economies, scope economies, and network externalities. Economies of scale from single products include reductions in the average cost of a single product in the long run (e.g., clinical messaging) resulting from an expanded set of output (e.g., prevented clinical wait times and complications). In application, clinical messaging can yield reductions in medical errors and higher productivity. Higher productivity in turn yields additional revenue to more than offset the cost of the message fee or marginal cost of the messaging provider. These savings will be long-run savings and (ideally) increase over time (e.g., more aging baby boomers, more complications, better high-quality patient volume).

Mr. Parente explained that the concept of economies of scope for multiple products is similar to economies of scale, but economies of scope look at efficiencies from combining different types of products through changes in pricing, marketing, and distribution. In application, the bundle of products is worth more than the sum of the single products—for example, bundling clinical messaging, medication history, e-prescribing, and clinical data sharing on a common Web-based platform. This can be marketed to physicians with high broadband access (with the possibility of adding a diagnostic imaging component). High return on investment (ROI) (i.e., sustainable) single products can cross-subsidize lower ROI single products.

In terms of network externalities, externality-generating activities (e.g., a shared clinical database) raise the production or well-being of an externally affected party. Mr. Parente explained that positive externalities create the public good. Applications examples include: (1) shared clinical data services providing a national data repository to readily identify the high potential success of a vaccine for a future pandemic flu strain, and (2) KatrinaHealth results from prescribing utilizing a previous prescription exchange infrastructure that was tapped for a national emergency.

Mr. Parente offered three approaches to optimizing the public good:

- Support adoption of technologies that: (1) produce single products that optimize positive "scale" externalities, and (2) produce even greater "scope" positive externalities for product bundle combinations.

- Balance public/private investment to get the best network externality return on investment.

- If the private sector can profit and create a positive externality, identify whether the public sector can provide bridge financing or temporary exclusive property rights to mitigate the risk/reward.

A standard assumption is that IT cannot yield profits; it can only reduce costs. However, Mr. Parente emphasized that this assumption is not true if an industry has high barriers to entry. Health care has many barriers to entry, so providers and insurers should buy IT not just as a tool to control cost, but to profit as well. Mr. Parente discussed identifying sustainable revenues, noting that the best-case sustainable revenues include a per-transaction fee, substitutable "staple" commodity, subscription services with sustainable fixed base pricing and variable add-on pricing, the ability to be bundled as part of a software purchase/lease contract, and multi-year most favored trade partner status through opportunity cost savings. Less advantageous revenues for sustainability include grants for quality improvement/IT prototypes and venture capital without established revenue sources in start up.

Mr. Parente summarized by noting that to get the value of sustainability, one should:

- Seek long-run efficiencies (returns to scale).

- Have multiple revenue sources lined up and balance one's portfolio.

- Identify revenues that are expected to survive in the future and continuously renew and update.

- Look for bundling and channeling opportunities to get economies of scope.

- Be forward looking and either plan for redundancy or develop a new product to replace future lost revenues.

Financially Sustainable HIE Services

Victoria Prescott, General Counsel and Business Development Specialist at the Regenstrief Institute, Inc., presented the Community with the results of the ONC-sponsored study to identify and analyze HIE services that have achieved financial sustainability. At the onset of this project, her group defined the parameters for inclusion in the study. As part of that effort, they defined HIE, which is used as an umbrella term for several different types of specific exchanges of clinical and/or administrative data. HIE services were considered to involve the exchange of information between multiple stakeholders, and was not limited to an increase in use of EHRs or telemedicine. Financial sustainability was defined as having sufficient revenue for ongoing operations. Ms. Prescott noted that start-up costs were not included in some of their analyses because some of these data were not available. She provided a description analysis of five specific HIE services her group found to be useful: (1) clinical messaging, (2) medication history, (3) e-prescribing, (4) sharing patient clinical data at the point of care, and (5) quality measurement reporting.

Clinical messaging is defined as the delivery of delivery of electronic clinical results (such as lab test results, radiology reports, or transcribed reports) from the source system (e.g., lab, radiology center) to the intended recipients (e.g., ordering physician, primary care physician). The key rationale for this is that the ROI is easy to understand. It also establishes connections between clinical data providers and physician offices. A master patient index is not necessary, the clinical relevance of the data is important, and the physician receives the tests results faster than services provided today. Ms. Prescott noted that their study indicates that hospitals and/or labs would be willing to pay for this clinical messaging service.

Medication history involves electronically sharing a patient's medication history obtained from multiple sources with the clinician or institution treating the patient. This service is attractive to hospitals to help them comply with Joint Commission on Accreditation of Healthcare Organizations medication reconciliation requirements. It also is also useful because of the eligibility and formulary functions that are typically included in a medication history-type project; those can reduce drug costs for the patient, the payer, and also increase efficiencies. These data also are very relevant to clinical care. Ms. Prescott noted that as is the case for clinical messaging, their data indicate that hospitals are paying for this service based on the number of patients that were matched in the data.

Ms. Prescott explained that e-prescribing automates the process for the clinician to prescribe medications for patients by electronically delivering the prescription to the retail pharmacy or mail order service. This service reduces the physicians' and pharmacies' administrative expenses because it greatly increases the legibility of the prescription and processes refills. It also has a positive impact on many stakeholders (i.e., payers, doctors, patients, pharmacies). This service also could include a medication history component as well as the eligibility and formulary information, although this information would be needed before the doctor writes the prescription. Ms. Prescott described some implementation challenges associated with e-prescribing. For example, a critical mass of pharmacies will need to be covered, a critical mass of medication history needs to be available, physicians have to be willing to use the software, and there would be changes in workflow. She also noted that in their study, the e-prescribing delivery network actually paid for a portion of the HIE fees from the pharmacies.

Sharing patient clinical data a the point of care entails gathering and providing electronic clinical information (e.g., patient medication history, lab test results, diagnoses) from multiple sources on a patient when the patient presents for care. This has tremendous value to the treatment of a patient, avoids errors, reduces duplication of tests and procedures, and improves the continuity of care for the patient. A standardized repository of clinical data can also benefit other entities, such as public health, researchers, and the pharmaceutical industry. The addition of clinical decision support and reminders functionality can further enhance treatment and quality of care for patients. Implementation challenges to this service

include the fact that it is a very large-scale project, a sophisticated master patient index is necessary, it is difficult to project the value across different stakeholders and therefore there is a hesitancy to invest, and standardization of data is needed for this service to be of any real value. In terms of paying for this service, Ms. Prescott explained that the only example her group found was from Indiana, where a philanthropic foundation has provided long-term funding. She noted that some other HIEs are examining the feasibility of a subscription model.

Quality measurement reporting involves sharing health care information (clinical and claims) between multiple data sources for the purpose of quality measurement that can support provider quality initiatives and also serve as a basis for determining incentives to providers from payers. This service is beneficial in that it can result in a consistent set of quality measures. The payers recognize the improvements and efficiency in quality of care, and will have more influence by banding together to develop a set of standard quality measures. This also will allow providers to comply with only one set of measures (as opposed to many). Providers also will receive information on their own patients and incentives to help them improve. As quality increases, the patient receives better outcomes. The most significant implementation challenge to this service is the need for a critical mass of data and participation. Consensus on the quality metrics, standardization of the data, and the need for a master patient index represent additional challenges.

Ms. Prescott presented three major recommendations from the group, noting that the recommendations are generalizations, and that local circumstances and market conditions will dictate where HIE initiatives should focus their initial efforts:

- Leverage any infrastructure built and data collected (re-using data to build other services).
- Recommended initial services (less complex) are clinical messaging and medication history.
- Recommended later services (more complex) are e-prescribing, sharing patient clinical data at the point of care, and quality measurement.

Ms. Prescott concluded with some overall observations, noting that there is no single approach to reaching financial sustainability, as evidenced by the diverse projects studied. Market factors are not well understood (payer reimbursement incentives are helpful). Common challenges have been identified, and collaborations, a critical mass of participants, and a critical mass of data are necessary for many of these projects. The bottom line is that although they are few in number, there are sustainable models for HIE.

Discussion Highlights

"This is a very clinical presentation of the topic, and…it leaves out…the customer entirely. Even Southwest Airlines allows you to book a seat online. Why? Because the customer demands it. And the nature of the whole presentation is really, what is convenient for the service provider, not is what convenient for the customer or the patient. And if anything is going to drive this, I think it's going to be customer demand." – Mr. Barrett

"In our own assessment of the patient or the customer, their demands on us are not here today. We need to move them there, but if we're writing the checks in fiscal year '07, the major driver, at this point, is still the provider…Today I'm not sure that the customer is quite the voice that we might like them to be." – Dr. Glaser

"Probably the pressure from the customer has to come from the customer who pays the bill, which is either the employer, or the Federal Government. Neither of those voices have been particularly loud in

this instance…We're starting to see some momentum in those areas, [and] if that momentum grows, I think most of your analysis has to be kind of turned on its head, because it's going to be a customer-driven perspective, and not a provider-driven perspective." – Mr. Barrett

"Unfortunately, I think the individual customer-driven demand is held captive by the fact that his employer has an insurance provider, who has this administrative bureaucracy which throttles that demand and channels people in directions. But if the employer, for example, starts to say, 'I'm only going to do service with business who provide this capability,' then that's a much louder voice…It has to be an integrated voice, from my perspective." – Mr. Barrett

"What part of the items that Victoria talked about would have the best chance of having consumers just revolt, and demand that it be provided?" – Secretary Leavitt

"One of the things that we're seeing, certainly [in] the VA experience, is that personal health record where people start saying, 'You know, I want my own copies of my records' and…'by the way, if you're giving the laboratory [results] to my provider, how about if I have a copy, because the next provider, in another state when I'm traveling or something may not have it.'" – Dr. Kolodner

"People like making their medical appointments online...We are doing now about three-and-a half, four percent of all of our appointments. That's a low number, but to my knowledge, it's the highest of anybody, anywhere. People are making their appointments online. We have people in Iraq making appointments when they get back to the United States, online." – Dr. Winkenwerder, Jr.

"Patients are very much looking for the opportunity to have greater control over their health information. The knowledge that they gain from having access to the results of the information that we have about them, as providers, is something that they very much want." – Mr. Parente

"The thought of not always having to go sit in the waiting room at the +doctor's office for communication with the doctor, I think is a huge opportunity for the system for efficiency and customer service."
– Mr. Barrett

"Patients are clamoring to get their own information. We see that. So I think the demand is there. I think there is a lot of frustration, because once you're into the medical system with a health problem, it's very difficult to get your own information…Another issue that I didn't hear in the presentations, and I think it's certainly worth discussing, is who owns the data; and with this data, what stake does the consumer have in that?" – Ms. Graham

"Whether it's on the patient's side or on the provider's side, there is no money for clinical messaging. Doctors don't get paid if they get online. I have a great relationship with my doctor, but he is not going to give me his e-mail address, and we're not going to talk on e-mail, because that's time, and he doesn't get paid for it. Now, you can say, I could demand that of him, but how much can I really demand that of him when I'm insured?" – Mr. Kahn

"[E-prescribing] makes a lot of sense; but in terms of the workflow, it's so complicated for small physicians offices to do it, [to] transfer to it, and there's really nothing in it for them. Other than providing better service, there is no money there. The money is for the insurers if there is more ordering of generics." – Mr. Kahn

"At the end of the day, the consumer in health care tends to be passive; because the fact is they rely on a third party payer, and the customer doesn't have the same relationship with the provider that you do in other markets. I think it's a unique market, and either the money's got to flow differently, or something

has got to be shaken to really build these relationships. Otherwise, I think we're not going to make that much progress on these fronts." – Mr. Kahn

"I have to disagree with the money issue on e-prescribing…In my opinion, in knowing this space with respect to where the pharmacies are, where the payers are, where the physicians are, it is a disruption in workflow, initially, in implementing these systems, without a doubt. But when they see the value of getting these refill requests in a physician's office in an automated fashion, it does save them time, which brings in more money." – Mr. Hutchinson

"I'll call everyone's attention to a really, very interesting Zogby poll that was published, a poll of Texans. And so if we take the risk of generalizing from Texans to the U.S., notwithstanding, the two highest ranked preferences that this sample that was done last week reported; number one was 73 percent of the respondents wanted e-prescribing…Second was virtual visits to the doctor, 42 percent." – Dr. Brailer

"I think there can be a big impact on educating the patient, and then the patient on their ROI…And as you know, last year, Wal-Mart introduced the $4 generic drug program. And our theme was to put price back in the equation, price for the customer. And we received tremendous response. We've had a dramatic change in behavior, not only in the customers, but in the industry. So I think working back to the patient and the customer can have dramatic results, and it can move very, very quickly." – Mr. Menzer

"We are tremendously underestimating the capability of the doctors in the United States, if we don't think that they can put routine, everyday…technology into their offices. Frankly, if my doctor can't put that into his office, I have no interest in visiting that doctor." – Mr. Barrett

"My colleagues in family in medicine, we're approaching 35 percent adoption of EHRs in the absence of financial incentives to do so. So that is occurring…Chip is correct in the sense that the way that we pay for health care in this country needs to change. That's not asking for new dollars in the system. It's a redistribution of the dollars that are already there. There is abundant research that shows, if you connect individuals to a medical home, that quality goes up, and costs go down." – Dr. Henley

AHIC Priorities and 2007 Use Cases

Dr. Kolodner introduced this panel by reminding Community members that Secretary Leavitt accepted AHIC's October 2006 recommendations for round one of the standards development effort. He explained that the current panel would discuss the development and identification of primary focus areas for round two. Dr. John Loonsk, ONC, explained that use cases are descriptions of events that detail what a system (or systems) needs to do to achieve a specific mission or stakeholder goals. They convey how individuals and organizations (actors) interact with the involved systems and strive to provide enough detail and context for follow-up activities to occur. Generally, the follow-up from a use case is work that leads to the development or implementation of a specific software system. He explained that ONC has been using high-level use cases based on priorities expressed by the AHIC Workgroups that strive to provide enough detail and context for standards harmonization, architecture specification, certification consideration, and detailed policy discussions to advance the national HIT agenda. The high-level use cases focus on the exchange of information between organizations and systems rather than the internal activities of a particular organization or system.

For 2007, AHIC Workgroups have identified more than 120 priorities and issues for consideration. ONC has clustered like priorities and issues among the different Workgroups and organized them so that as many can be attended to as possible, and that there are opportunities to reuse existing use case efforts.

This clustering has led to three high-level categories of use cases—Consumer, Provider, and Population—as well as several options for immediate action in each category. Dr. Loonsk explained that Community members are being asked to prioritize the possible use cases in each high-level category. He reminded Community members that each high-level use case category has existing use cases (i.e., Consumer = Consumer Empowerment, Registration and Medication History; Provider = Electronic Health Records-Labs, Emergency Responder EHRs; Population = Biosurveillance). He also noted that as of January 21, 2007, 13 AHIC members responded and ranked the options to provide input on the use case development schedule. Consumer Access to Clinical Information (Consumer Use Case), Medications Management (Provider Use Case), and Quality (Population Use Case) are ranked first in their respective use cases.

Overview of Consumer Use Case Choices

Dr. Rose Marie Robertson of the American Heart Association commented that all of the Consumer use case choices presented focus on ways to improve the health of the public. Key to all three of them is having adequate privacy and security safeguards. Dr. Robertson then presented the following three potential uses cases in the Consumer category:

- ***Remote Monitoring.*** Providers in chronic care management would benefit from automated remote monitoring of patient physiological indicators recorded on home medical devices, which are then transmitted to the provider for inclusion in the patient's EHR. Examples of indicators could include weight, blood pressure, heart rate and rhythm, pulse oximetry, other vital signs, as well as other data from home medical devises such as glucose readings.

- ***Remote Consultation.*** Based on the information provided through remote monitoring and other sources, consumers could consult with their health care providers remotely. This could occur through secure e-mail as well as real-time online consultations. Patients could also benefit from reminders initiated by clinicians that would be delivered via e-mail or other means to remind patients of events and activities that are important to maintain their level of health.

- ***Consumer Access to Clinical Information.*** Consumers will benefit from the ability to access important health care data stored within their EHR to assist them in making decisions regarding care and healthy lifestyles. Accessible information could include registration information, medication history, lab results, current and previous health conditions, allergies, summaries of health care encounters, and diagnoses. Consumers would be able to incorporate this information from their EHRs into personal health records and share the information with designated individuals as needed. The PHR should describe medical terminology into layman's terms for the consumer. PHRs should be portable between vendors, so consumers can transfer the information as required.

Overview of Provider Use Case Choices

Dr. Blackford Middleton, Corporate Director for Clinical Informatics Research and Development at Partners HealthCare, noted that EMR adoption in the United States is at best approximately 24 percent in primary care. This percentage varies greatly between small office environments and large office environments, and between specialty and subspecialty care. He explained that there are significant market barriers or market asymmetries facing adoption that must be considered. For example, physicians often are asked to be the purchasers of health care IT, but research analyzing the value of HIT use in ambulatory care practice environments suggests that up to 89 percent of the benefit goes to the public or private payer. Dr. Middleton noted that other data indicate that EHR advanced computerized provider order entry capabilities could save the country about $44 billion. Furthermore, if those EMRs are able to communicate with each other, the value of that HIE would be about $78 billion. He presented the following two potential use cases in the Provider category:

- ***Medications Management.*** Consumers and providers would both benefit from electronic prescribing of medications, which would include transmittal of prescriptions to pharmacies by clinicians. Providers would be able to receive real-time feedback regarding potential adverse interactions and verify medication compliance by the consumer. Pharmacy benefits management entities would be able to interact with providers and consumers during the medications prescribing and fulfillment activities. Consumers would also be able to request prescription refills, view their prescription histories, verify insurance eligibility and coverage, view formulary information, and incorporate all of this information into their personal health records.

- ***Referrals and Transfer of Care.*** Providers would benefit from the ability to transfer care information to and from other medical providers. Transfer of care occurs in many circumstances, ranging from emergency care to acute care and longer-term care management. For example, providers issue patient referrals to specialists, who would benefit from receiving summary health information about the patient. This summary record could include clinical information about patient lab results, problem lists, vital signs, immunizations, and other data. Effectively communicating summary information during transfer of care will require appropriate methods of unambiguously identifying patients and matching them to their data.

Overview of Population Use Case Choices

Dr. Carolyn Clancy, Director of the Agency for Healthcare Research and Quality (AHRQ), noted that much of the content presented in the Consumer and the Provider use case choices focuses on quality of care. The challenge is to determine how best to take advantage of HIT applications to make reporting on quality of care transparent to consumers, and at the same time, help providers get a view not only of how they are doing, but actually give them information in something close to real-time. Dr. Clancy presented the following potential use case in the Population category:

- ***Quality.*** Providers would benefit from the collection and dissemination of health care quality data such as Hospital Quality Alliance (HQA) quality indicators for inpatient care and Ambulatory Care Quality Alliance (AQA) quality indicators for ambulatory care, particularly if this information can be integrated into EHR systems within the providers workflows. Clinicians could benefit from receiving real-time or near real-time feedback regarding relevant quality indicators and contraindications for specific patients. Additionally, quality data across multiple providers and entities could be aggregated for the purpose of public reporting.

Dr. John Lumpkin of the Robert Wood Johnson Foundation presented two additional potential use cases in the Population category. He commented that in his opinion, of these two use cases, the one that provides the most opportunity to explore and advance key issues related to future HIT, is the Public Health Case Reporting use case.

- ***Public Health Case Reporting.*** Public health effectiveness could be enhanced through electronic case reporting to state, local, and federal public health authorities. By incorporating case reporting criteria into laboratory information systems and EHR systems, providers can be alerted to the need to report a case based on lab results. Upon provider authorization, a minimum interoperable data set per jurisdictional guidelines could be generated and automatically transmitted to the appropriate public health authority.

- ***Response Management.*** During public health emergencies, coordinating response, and managing available medical resources will be important. Providers and public health authorities should be able to exchange information regarding the availability of hospital beds, medications, and medical

personnel, among other resources. Immunization response could include the ability to track and manage the administration of countermeasures and integrate information from the commercial sector countermeasure supply chain. An immunization registry could inform public health entities about which individuals have been immunized within a given period of time utilizing a specific vaccine. Information about the immunization status of health care providers would assist in planning the threat response.

Discussion Highlights

General Discussion

"What we've tried to do is to titrate in appropriate amounts of priorities, as associated with what can be done in an extension, what can be done in an entirely new use case, and with the target of coming out with four, in total, for the next round [including the Emergency Responder EHR use case]." – Dr. Loonsk

"We have created an on-deck circle, and I would like to ask the Office of National Coordinator to begin leaning forward to the next priorities expressed. That isn't to say we take them on, but I think the third crank will be the most difficult to get within the timeframe." – Secretary Leavitt

"We're also going to be…going to go through a transition. We're contemplating a transition to a successor group, and there will be some need for us to be especially well prepared for that third crank. This has been particularly useful, in that I think it has created a tentative agenda for us on an ongoing basis." – Secretary Leavitt

Consumer Use Case

"I ranked Remote Monitoring first…because I thought of it in a much more broader context…This country, over the last 20 or 25 years, has evolved from a three generational structure of families to four and five generations, because of advancing life span and things of that nature. And it's that third generation, the middle generation predominantly populated or controlled by women in their mid-40s to mid-50s, where not only are they caring for their children, but they are caring for their parents…They are the caregiver for the family unit. They are not accounted for in any of these scenarios." – Dr. Henley

"Sometimes a friend or colleague or a paid care worker lives in the home, but usually a family member. So I think we need to look forward to that, and I think for the consumer perspective, that remote monitoring becomes critical, because the caregiver, often the family member, cannot be in the home, most of the time…Remote monitoring also includes remote consultation, also includes the transfer of clinical information among that triangle, not just between two points but three points. And if we don't anticipate that, we're going to wear that middle generation out…And so I vote for Remote Monitoring, but in a much broader context." – Dr. Henley

"In thinking about consumer access, indeed, access, it did include providing that access to others, perhaps, you know, mom in Kansas, when the patient is somewhere else or the daughter is somewhere else. So the technology was inclusive of that. The broader increasing technology of having mom's blood pressure be an icon on the screen that you can monitor has a little ways to go yet in some circumstances, but providing access didn't just mean the patients, themselves." – Dr. Robertson

Following this discussion, Secretary Leavitt declared a consensus on the matter of having Consumer Access as the first priority of the Consumer use case choices.

Provider Use Case

"Better medication management reduces medical error. But I think abundant research also shows that what produces the most medical errors is hand-off of patients from A to B to C…So, again, I think referrals and transfer of care in that context, to me, was why I ranked it much higher than the first one, simply because it's that hand-off. Again, the more people that touch the patient, the greater number of errors you get and the lesser the degree of quality…It's that hand-off that's critical, and I think that's why transfer of care, to me, is far more important." – Dr. Henley

"This goes actually toward the consumer access to clinical information and the medications management. One missing item, I saw, in the write up of the detail of it, was around authentication identification of the end users; that I think we need to make sure that we include [this]. I assume we're not speaking of manually entered information here on medications management, as well as clinical consumer access to information. And the original identification of that user is who they say they are, and then the authentication of each time they log in is critical, if we're going to be delivering information from live EHR systems, or pharmacies, or payer databases." – Mr. Hutchinson

"There will actually be some recommendations later this afternoon that start down that road of identifying from an identity proving standpoint." – Dr. Loonsk

Following this discussion, Secretary Leavitt declared a consensus on the matter of having Medications Management as the first priority of the Provider use case choices.

Population Use Case

There was no discussion on this use case; Secretary Leavitt declared a consensus on the matter of having Quality as the first priority of the Population use case choices.

Comments From the Secretary, DHHS

Secretary Leavitt noted that the meeting thus far had resulted in three important accomplishments for AHIC. First, the Community has created an assumption for AHIC's conclusion and transition, as well as its need to connect with state counterparts in a way that has continuity, coordination, and communication. This important conclusion hopefully will be reached at the next AHIC meeting. Second, AHIC has better prepared itself for making some important decisions on the NHIN. Although this task remains complicated, Secretary Leavitt expressed optimism that there is a "light at the end of the tunnel." He commented that there are sustainable business models that are being pursued through a course that will bear results. Third, AHIC has established priorities for the near term, and potentially for the medium term, on use cases.

The Secretary also reported that a major factor driving AHIC is the commitment on the part of large payers and providers to implement work coming out of the Community. In addition to the public payers that have come behind this effort in the Executive Order through the federal government, firm written commitments from almost 50 of the largest 200 payers in the country have been obtained. Recently, a large union joined that number, and another union has pledged its support as well. It is anticipated that by spring, the goal of having 60 percent of the health care payer's system participating will have been exceeded.

Announcement of a Joint VA-DoD Inpatient EHR

VA Secretary Nicholson thanked Secretary Leavitt and the Community for their extraordinary efforts, commitment, and leadership in guiding these important efforts. He affirmed the President's goal of assuring EHRs for most Americans within 10 years and the support of the VA in helping to achieve this. In building on the President's and Secretary Leavitt's imperative for action, Secretary Nicholson announced a joint VA-DoD program that will reshape health care for America. The VA and DoD have agreed to make the vision of having a joint inpatient EHR a reality. This groundbreaking event will have benefits that extend beyond the military and the veteran communities. This agreement has the potential to change the future of electronic health care records nationwide, possibly worldwide. The joint VA-DoD inpatient EHR will result in significant savings for taxpayers, making inpatient medical records instantly accessible to doctors and other clinicians in both Departments. It will help the VA and DoD share medical data more seamlessly, and will help provide better care to their patients.

The first step toward achieving this joint inpatient EHR will be an examination of the clinical and business processes of both Departments, and a determination of the means and methods to achieve cost effectiveness. Secretary Nicholson commented that once the groundwork has been laid for the development of this joint inpatient record, the doors of opportunity for other health care systems, both public and private, will begin to swing open, and may result in the model for other large providers in this country to emulate. He added that the potential that this joint effort holds for the nation's health care community is probably immeasurable. A successful, vibrant, and dynamic VA-DoD model can be synthesized and reproduced in health care systems, both large and small. Both Departments are committed to finding every opportunity to work together, to provide top-notch care to their patients.

Secretary Nicholson stated that this announcement marks an important step toward honoring this country's patriots by relieving them of a burden that they have shouldered for too long. In so doing, it moves closer to realizing the President's call for better health care technologies for all Americans by improving it for the U.S. military and its veterans. Secretary Nicholson then introduced Dr. Winkenwerder, who provided additional comments from DoD's perspective.

Dr. Winkenwerder thanked Secretary Leavitt and Secretary Nicholson for their leadership and noted that both the DoD and VA are excited about this common, mutually beneficial solution to their inpatient needs. He noted that AHLTA, DoD's outpatient record system, has been a great success. The system is in place at 140 locations around the world, and almost 40 million patient visits have been recorded, resulting in a huge central data repository. On the inpatient side, the DoD does have some inpatient electronic medical record capability working with certain private entities, and the VA already has proven its ability to do this, and was looking to upgrade its platform. Dr. Winkenwerder explained that through this confluence of events, it made sense for the Departments to proceed together and jointly adopt the system to be developed.

The DoD and VA will be examining a feasibility study over the next few weeks, and the Departments hope to make another announcement in the near future that will provide information on how they plan to proceed. Dr. Winkenwerder commented that this effort may not have happened without much of the work that has been done and is being done by the Community.

Secretary Leavitt expressed congratulations to both Departments, noting that this is a monumental event—the integration of these two remarkable and renowned systems, both committed to migrate toward AHIC standards, constitutes an important step forward.

Workgroup Recommendations and Updates

Before this panel began, Secretary Leavitt excused himself from the proceedings. Dr. Kolodner took over as Chair of the meeting

Confidentiality, Privacy, and Security Workgroup Recommendations

Jodi Daniel, ONC, represented Kirk Nahra, Co-Chair of the Confidentiality, Privacy, and Security Workgroup, and reminded Community members that this Workgroup was formed in response to requests from the Consumer Empowerment, Chronic Care, and Electronic Health Record Workgroups, all of which have been addressing privacy and security issues independently. Each of these three Workgroups noted that it would be more advantageous to have a specific Workgroup focused on confidentiality, privacy, and security issues so that these issues could be discussed in one forum, and so that appropriate privacy and security expertise could be brought to bear on those issues. She also reminded AHIC members of the Workgroup's broad and specific charges, which are as follows:

Broad Charge: 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.

Specific Charge: 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.

Ms. Daniel explained that the Workgroup first addressed issues related to identity proofing and user authentication, and that today's recommendations would focus on patient identity proofing.

Paul Feldman of The Health Privacy Project provided some general statements regarding the patient identity-proofing recommendations. He explained that patient identity proofing is defined as the process of providing sufficient information to correctly and accurately establish and verify a patient's identity to be used in an electronic environment. The purpose of these recommendations is to advance the specific charges of the Chronic Care, EHR, and Consumer Empowerment Workgroups. More widespread application of these recommendations may necessitate further review. All data included in secure messaging, EHRs, and PHRs should be considered sensitive. Appropriate policies and supporting security measures must be in place to mitigate the risks of unauthorized or unintended data disclosure. Patient identity proofing is just one part of an overall process (e.g., validation, revocation) for issuing and maintaining electronic identity credentials. All parts of the process are interdependent and, if they do not achieve comparable levels of security, the overall strength of the electronic identity credential may not be adequate.

Ms. Daniel noted that the Confidentiality, Privacy, and Security Workgroup suggests that the recommendations be used for adoption as DHHS policy regarding current and future activity. The Workgroup also expressed hope that these recommendations apply more broadly, and that the public and private-sector organizations would parallel DHHS in following these recommendations. Mr. Feldman then described the following patient identity-proofing recommendations:

- ***Recommendation 1:*** Entities that offer health care consumers or their authorized proxy(ies) electronic access to data and services through secure messaging, PHRs, or EHRs should perform, or rely upon, identity proofing performed by the entity or an accountable trusted third party that meets or exceeds one of the following options:
  - ***1.1:*** When it is practical and feasible for a health care consumer or his/her authorized proxy to present themselves in person, in-person identity proofing should be performed by the health care entity. Identity proofing can be achieved by using, at a minimum a valid, government-issued picture ID to verify identity. Examples of such documents include a passport, driver's license or state-issued ID, permanent resident card, or military ID.
  - ***1.2:*** When the health care consumer or his/her authorized proxy has an established and durable relationship (e.g., long-standing, trusted) with an entity, this relationship could be used to confirm the consumer or proxy's identity on the basis of that relationship. Examples of confirmation may include in-person or telephonic dialog where confirmation occurs at the time of request (i.e., a voicemail message left for the entity to confirm at a later time would not be acceptable).
  - ***1.3:*** When the health care consumer or his her/authorized proxy is unable to meet the criteria necessary to satisfy 1.1, and the entity determines that 1.2 is not viable, and a relationship exists between the consumer or proxy and the entity, identity proofing should consist of a method that verifies a person's identity based on information they know or can produce about themselves when asked. The entity or trusted third party should: (1) request basic identity data (e.g., name, address, date of birth, etc.); and (2) require the individual to provide some personal information specific to that relationship (e.g., last prescription, electronic device).

- ***Recommendation 2:*** For the purposes of secure messaging and accessing data through a PHR or EHR, document(s) and the information therein or other information used solely for purposes of identity proofing a health care consumer or their authorized proxy(ies), if kept, should be securely maintained separate from the health care consumer's clinical data.

- ***Recommendation 3:*** Converting from a paper-based health care practice to one that uses EHRs does not require a health care entity to identity proof their patients. Where this conversion also provides patients with access to data within the EHR (such as via flash drive, Internet, or remote access), health care providers should follow the identity proofing recommendation schema noted in Recommendation 1.

- ***Recommendation 4:*** Entities that provide patient access to personal health information via secure messaging or a PHR (such as via a flash drive, populating data records stored on the Internet, or remote access), should follow the identity proofing recommendation schema noted in Recommendation 1.

- ***Recommendation 5:*** Where applicable, the Certification Commission for Healthcare Information Technology (CCHIT) should develop certification criteria for the systems and networks they certify to support the identity proofing practices in these recommendations.

Ms. Daniel explained that the Workgroup is considering a number of topics as candidates for a future round of recommendations. For example, there has been some preliminary discussion on identity proofing in instances where no prior relationship exists. Mr. Feldman described some additional potential future topics for consideration, including: (1) identification and analysis of the differences between the current HIT environment and the Health Insurance Portability and Accountability Act (HIPAA) (activities of non-covered entities, with respect to EHRs, PHRs, and health information exchanges); (2) privacy protections for information held by non-covered entities in collaboration with the Consumer

Empowerment Workgroup per their recommendation 2.1; and (3) an analysis of the effects consumer choice and control could have on the benefits of electronic HIE.

Discussion Highlights

There was minimal discussion on Recommendations 1 through 4.

Dr. Kolodner declared a consensus for AHIC unanimously accepting the Confidentiality, Privacy, and Security Workgroup Recommendations 1, 1.1, 1.2, 1.3, 2, 3, and 4.

Highlights from discussions on Recommendation 5 follow:

"Recommendation 5 talks about the process for CCHIT to develop certification criteria for the systems, but I'm curious if we focused on the data requirements of the process. For instance, I know we can use last prescription and other things like that, but are we looking at other even more readily available information like credit reports are used in the financial industry?" – Mr. Hutchinson

"I think that's exactly the intention, understanding that there is a variety of potential data sources that would be useful here, and to let CCHIT dig into that." – Mr. Feldman

"In-person identity proofing could be either directly or through a third party. And so it could be that there is a trusted third party that would use another mechanism where there is a relationship for identity proofing. And then again, where there isn't a relationship, that's where the Workgroup said that they wanted to talk about that more, and to think through what, for instance, the financial industry is doing." – Ms. Daniel

"How do you build into a certification process a mechanism that says, 'okay, this product or this system is good because somebody has checked somebody's ID'…How do you build that into a system? Am I missing something? Isn't there a step in between these two things?" – Mr. Green

"Absolutely. If you noticed, the first two words in this recommendation [are] 'where applicable,' so if it is based on an existing relationship, where the provider just has had a longstanding 10-year relationship with a particular patient, and is willing to verify the identity based on that longstanding relationship, the system would have no criteria in it for identity proofing. However, where, for instance, there is the recommendation to keep the information separate, there could be a review of the system to make sure that there is a way of keeping that information separate, in order to meet that requirement." – Ms. Daniel

"I think we ought to give CCHIT a chance to evaluate, based upon the work that they are doing, where this fits in that work…efore we put the requirement on them to do that. So I was hedging on the first two words, the 'where applicable,' quite a bit, on the recommendation. So I'm assuming that this 'where applicable' would go over to CCHIT, and they would get to decide." – Mr. Hutchinson

"We just wanted to make sure that one, that CCHIT wasn't doing something inconsistent with these recommendations, and wanted to put forth that as a priority, and where there might be an opportunity in order to help support these, to do so. And that was sort of the intent of this. And that's why we put the 'where applicable,' because all of these recommendations won't be a perfect fit with certification criteria." – Ms. Daniel

"I suggest that the recommendation be revised a little bit to include some of those ideas. When you have words like 'CCHIT should develop certification criteria for systems,' it sort of is like a foregone conclusion before you've had that dialogue." – Mr. Green

Following these comments, Dr. Kolodner declared consensus on tabling Recommendation 5 so that the Workgroup can reword the recommendation and bring it back to the Community for consideration at a later time.

Consumer Empowerment Workgroup Recommendations

AHIC member Nancy Davenport-Ennis 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 that is easy to use, portable, longitudinal, affordable, and consumer centered. A number of broad charge issues must be addressed. Ideally, personal health data can be exchanged among PHRs and sources of personal health information (e.g., electronic medical records, payer or pharmacy systems) under the control of the patient while preserving the meaning of the data. Privacy protection and security safeguards are paramount, and timely access for all consumers to their personal health information should be ensured. Appropriate incentives to encourage consumer and provider adoption of PHRs should be identified and promoted. Research on effective messaging from consumers and providers should guide broad educational efforts to engage them.

Ms. Robertson then presented the recommendations of the Consumer Empowerment Workgroup.

Interoperability and Portability Recommendations:

- ***Recommendation 1.1:*** DHHS should promote consumer access to their personal health information in the trial implementations of the NHIN.

- ***Recommendation 1.2:*** Ms. Davenport-Ennis noted that Recommendation 1.2 will be presented at the next AHIC meeting, to allow for more time to further tease out this recommendation.

Privacy and Security Recommendations:

- ***Recommendation 2.1:*** The AHIC Confidentiality, Privacy, and Security Workgroup, in collaboration with the Consumer Empowerment Workgroup, should develop principles and identify best practices for privacy policies for consumers' PHR data that are interoperable (i.e., protections that follow the consumer as his or her data move or are shared). These recommendations should apply to all individuals and entities, including both covered and non-covered entities under HIPAA.

- ***Recommendation 2.2:*** The DHHS Office for Civil Rights should provide guidance to clarify the protections provided under HIPAA regarding the rights of consumers and their proxies to timely access to their electronic personal health information requested from covered entities.

- ***Recommendation 2.3:*** CMS, in collaboration with the DHHS Office for Civil Rights and other interested agencies, should develop policies and guidelines for HIPAA-covered entities and business associates for authorization of data release to and from PHRs, including the development of HIPAA-compliant standardized authorization language, no later than December 28, 2007.

- ***Recommendation 2.4:*** The State Alliance for e-Health should consider exploring issues relative to state privacy laws and PHRs and share their findings with the Community and DHHS. The Consumer Empowerment Workgroup intends to provide the State Alliance for e-Health with background information and a detailed explanation for this request.

Incentives for Adoption Recommendations:

- ***Recommendation 3.1:*** DHHS, through AHRQ, and in collaboration with the Indian Health Service, CMS, the VA, and the Office of Personnel Management, should develop an evaluation framework that can assist in the systematic assessment of PHR offerings to federal employees and beneficiaries, by December 28, 2007. Evaluation criteria may include the effect of PHR services on health outcomes, level of consumer engagement in their health care, economic impact, data security, and other measures.

- ***Recommendation 3.2:*** In 2007, DHHS, through AHRQ when appropriate, should conduct evaluations that will provide useful information needed to develop the evaluation framework for assessing PHRs specified in Recommendation 3.1. Specific study topics include the impact of data sharing through HIE, the comparative value of various data sources, and the impact of various architectural models.
  - ***3.2.1:*** DHHS should assess how the sharing of personal health information with consumers through the use of PHRs impacts health care quality and patient satisfaction, including the results of private-sector efforts as available.
  - ***3.2.2:*** DHHS, through AHRQ, should conduct a study to assess the comparative value of and challenges related to using data on diagnoses and medication derived from claims, administrative, clinical, laboratory, pharmacy, and consumer-based sources to populate and maintain PHRs, including evaluations of the current availability of each source of data and of consumer and clinician reactions to and decisions based on the use of these data. Because of the low rate of EHR adoption by providers, the study should begin with an examination of experiences with currently available PHRs based on claims and administrative data as well as consumer-based sources, then move to clinical and other data over time, with interim results reported back to the Community by December 28, 2007, and final results reported back by June 30, 2008.
  - ***3.2.3:*** DHHS, through AHRQ, should fund evaluations of the impact on health care quality and patient satisfaction of various architectural models of PHRs (e.g., stand-alone, integrated, networked) and delivery methods (e.g., Web-based, compact disc, flash drive).

- ***Recommendation 3.3:*** The VA should conduct an evaluation of the benefits of their My Health*e*Vet PHR in the 2007 calendar year, and report back to the Community about the status and results to date no later than December 28, 2007. Based on the evaluation, the VA should communicate the value of their PHR to veterans and stakeholders to encourage adoption.

- ***Recommendation 3.4:*** DHHS, through CMS and the Indian Health Service, should develop plans to offer portable PHRs with 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 form Recommendations 2.1 and 3.2, as they become available.

- ***Recommendation 3.5:*** In 2007, the Consumer Empowerment Workgroup should identify a range of incentives intended to increase adoption of PHRs, and report on their findings to the Community. These incentives may include financial benefits accruing to patients and consumers, or other forms of economic benefit of established effectiveness (e.g., employee productivity, customer loyalty). The Consumer Empowerment Workgroup should include in its report any available evidence documenting the effectiveness of each type of incentive and how that incentive might best be deployed to encourage PHR adoption.

Education and Outreach Recommendation:

- ***Recommendation 4.1:*** In 2007, the Consumer Empowerment Workgroup should continue to study public and private sector activities to increase consumer awareness of PHRs, including the convening of an expert panel on consumer engagement and social marketing, and report on their findings to the Community.

Recommendation 1.1 Discussion Highlights

"I think that the Consumer Empowerment Working Group felt that we needed to put a placeholder out to say that as we are implementing these various trials, we need, within that process, to be sensitive to creating processes so that consumers can have access to their information." – Ms. Davenport-Ennis

"There will be a spectrum of things that will be encouraged, not required. There will be a set of requirements for all of the applicants, but then in terms of the spectrum of what might be done in any particular trial implementation, what I'm hearing you say, is at least encourage that some of them will include access by the consumer." – Dr. Kolodner

"If you want to encourage adoption of these, if you have Medicaid fund it, at the 90/10 rate, you will encourage states to do it, particularly in the disabled populations, which is a terrific trial opportunity." – Mr. Roob

"That's the broader impact, as opposed to this one being focused just on the trial implementations for the NHIN." – Dr. Kolodner

"I think overall, what the Consumer Empowerment Workgroup is saying is a lot of work needs to be done on PHRs around privacy, security, adoption…One of the things that already has been trialed, as part of the original NHIN deployment…has been the sharing of information between the personal health record, which is, in this case, the CapMed solution as part of the IBM contract, with respect to the National Health Information Network and pharmacy information." – Mr. Hutchinson

"In circumstances where people have used these and found them useful, they have sometimes found them really transformative…being able to see your data graphed out in terms of laboratory values can have a tremendous impact." – Dr. Robertson

After these comments, Dr. Kolodner declared a consensus on AHIC's acceptance of Recommendation 1.1.

Recommendations 2.1 - 2.4 Discussion Highlights

"On [Recommendation] 2.3…it should read the opposite. It should be the Office of Civil Rights, because CMS is not responsible for HIPAA privacy. It's the Office of Civil Rights that has the lead, government-wide. CMS can't develop the policies…the Office of Civil Rights would be the ones who would have the overall responsibility for that." – Mr. Trenkle

"So what we would like to do is to try to make the language reversal, with the understanding that the CMS representatives, that have been working with us on this particular matter, are certainly invited to have further discussions with us." – Ms. Davenport-Ennis

"Right, I think that's fine, but not driving it." – Mr. Trenkle

"As HIPAA applies to covered entities, and at this time, to my knowledge, patients aren't themselves, a covered entity. And maybe it's a philosophical question, because in the case of VA, for example, once the information is in My HealtheVet, it belongs to the patient. So I'm just grappling with, are you asking for them to have language that applies to the patient?" – Ms. Graham

"No. I think we're asking them to have language that applies to data release to PHRs from the covered entities. Now, that data may come back from a PHR to a covered entity, and then be sent elsewhere, and then it would, again, come under the covered entity issue." – Dr. Robertson

"I would just maybe ask that in your recommendation, you make that more clear." – Ms. Graham

After this discussion, Dr. Kolodner declared a consensus on the Community accepting Recommendations 2.1 through 2.4, with the understanding that the language in Recommendation 2.3 will be amended to read as follows: "DHHS Office for Civil Rights, in collaboration with CMS and other interested agencies, should develop policies and guidelines for HIPAA-covered entities and business associates for authorization of data release to and from PHRs, including the development of HIPAA-compliant standardized authorization language, no later than December 28, 2007."

Recommendations 3.1 - 3.5 Discussion Highlights

"Why [is] December 28th is the magic date to have reports back? Every time we hear the Secretary, there is a sense of urgency of getting things done. MyHealtheVet has been out there, and it would seem to me that VA personnel could do an evaluation and have a report back to us. It doesn't take a year. So I'm just curious what the timeframes were." – Ms. Gelinas

"We just released the patients' direct access to the clinical data. While the portal's been up, and there has been a contingent of about 1,500 of them that have had access, actually the release for the broad Community just happened at the end of December. So while we could confer about moving the date up, it isn't data we have readily available today." – Ms. Graham

"We did pick that date as a date that seemed feasible, given that we knew that this release was happening. We could discuss it further." – Dr. Robertson

"I think that we would also be accurate in saying that if any of this were going to be accelerated, when it is initiated, certainly it can be delivered prior to December the 28th, but we wanted to make certain that by December the 28th, it was completed." – Ms. Davenport-Ennis

"I just know that in seeing the demonstrations at the VA Medical Center, and talking to the veteran that was actually doing the demo, you just heard directly, empowerment, taking control of his own health. The minute he did the remote monitoring, he knew his weight went up and his blood pressure went up, and, you know, the quality of care and patient satisfaction issues should really come roaring out at us." – Ms. Gelinas

"Maybe this belongs more with [Recommendation] 4.1, but I'm looking at a lot of these evaluations that are occurring, and then [Recommendation] 4.1 talks about convening an expert panel to report on findings of informational consumer engagement. It seems to me like a lot of this information you get out of these evaluations should feed right into [Recommendation] 4.1. And it seems to me they should be linked more closely together than they are now, because it almost sounds like separate activities, but one should feed the other." – Mr. Trenkle

"We separated them, really, because of the importance of using these for education and outreach, not because of how they would come into the Workgroup. But…you're right." – Dr. Robertson

"[Regarding Recommendation 3.4] I think it's probably a fair assessment that perhaps within the plan, there could be a section that would address adoption, or promotion, or integration within a system, that would, then, allow us to have a talking point to move forward and address things like, what is the funding going to be, and what will the implementation schedule be." – Ms. Davenport-Ennis

"It's very important, because we're in a funding situation now that's very tight, and I think if the Community could send a signal that's a little stronger than says 'develop any plan,' I think it would certainly help us in terms of getting additional funding for activities related to PHRs." – Mr. Trenkle

"We certainly could make it a more robust recommendation." – Ms. Davenport-Ennis

Following these discussions, Dr. Kolodner declared a consensus on AHIC's acceptance of recommendations 3.1, 3.2, 3.3, and 3.5. Recommendation 3.4 was tabled until a future meeting so that the Workgroup can develop a recommendation with stronger language.

Recommendation 4.1 Discussion Highlights

There was no discussion on Recommendation 4.1. Dr. Kolodner declared a consensus on AHIC's acceptance of this recommendation.

Quality Workgroup Update

Dr. Clancy began her presentation by asking Community members to send the Quality Workgroup any comments they might have, particularly in terms of visioning and the consumer perspective. She then presented the Workgroup's broad charge:

- Make recommendations to the American Health Information Community so that health IT can provide the data needed for the development of quality measures that are 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.

Dr. Clancy provided some comments on the current state, noting that there is no unified, national quality agenda; reporting is manual, expensive, and time consuming; the focus is on reporting measures that are widely available, as opposed to high priority; and most measures lack detailed data specifications, limiting the potential for automation or easy data capture. Furthermore, multiple stakeholders retain relevant data with minimal data exchange, and varied (often proprietary) data formats and poor data quality hamper data aggregation efforts. Clinical decision support has limited penetration and is not closely aligned with quality reporting. Public reporting is fractured, inconsistent, and infrequently used to support a choice of providers. There has been extensive innovation in the private sector with pay-for-performance, but this is not yet broadly scaled. Privacy and security policy gaps exist for non-covered HIPAA entities' use of electronic health information.

Dr. Clancy explained that in the vision for the future, quality is integral to all aspects of health care. Every citizen expects consistently high-quality, safe, and efficient care. Performance information is

timely, comprehensive, and trusted as an accurate measure of the nation's ability to address high-priority gaps in quality and safety. Information technology and information sharing support consumers' information needs and assist providers in delivering evidence-based care. The national quality agenda promotes these activities, and is: (1) aligned with state and regional health care reform policies, (2) reinforced by public reporting on metrics, and (3) supported b a payment framework that aligns expectations with resources.

The envisioned end state includes widespread awareness of the national quality agenda, and a significantly reduced administrative burden of performance measurement due to adoption of national consensus metrics and unified data stewardship. Needs for data to support measurement and quality improvement will be largely met by EHRs, PHRs, and other network technologies. Common services will allow small practices to participate more effectively. A rapid diffusion of new guidelines, metrics, and best practices into EHRs will be facilitated by harmonized standards and distribution services. In addition, clinical decision support will be routinely available and will support improved quality of care. Also as part of this end state, reporting and feedback will be provided in near real-time. Data collection will be a natural by-product of care, and data quality will be high. Consumers will routinely use provider performance information to help make health care provider decisions, and providers will begin to differentiate on safety, quality, and cost. More health care spending can be performance-based due to better reliability and availability of quality improvement metrics and tools. A national framework for the secondary use of health data for multiple purposes will provide for appropriate privacy and security protections.

Dr. Clancy explained that before this end state can be achieved, a mid-state will need to be reached, possibly within the next 4-6 years. As part of this mid-state, the National Quality Forum and measure developers will have established consensus around national goals for quality and a common measures framework for development and maintenance of measures. A body governed by multiple stakeholders (data steward) will establish uniform operating rules and standards for sharing and aggregating public and private sector data on quality and efficiency. Quality reporting will be largely supported by existing HIT. EHRs will increasingly support data capture and reporting for consensus measures, using interoperable platforms. Quality metric development organizations will have developed an expanded, basic set of metrics, and data standards will exist for common data elements required for quality reporting. Also part of this mid-state, standardization of clinical decision support methodologies is complete, with certification requirements for robust use of clinical decision support in EHR systems. Consumer engagement strategies will be more mature and tied to transparency of price and quality. There will be an increased alignment of reimbursement and quality, and state, regional, and national privacy and security policies will enable appropriate secondary uses of clinical data for quality management (and other applications or purposes).

Dr. Clancy discussed a number of key enablers for reaching this mid-state, including:

- Quality alliances producing uniform standards for sharing, aggregating, and reporting data and metrics.

- Measures that span care delivery.

- NHIN/regional health information organization collaboration on quality measurement initiatives.

- Quality use case guiding standards harmonization and inpatient and ambulatory EHR certification criteria in 2007.

- Quality use case guiding NHIN contracts.

- Scalable open source software development to reduce costs of multiple approaches to data aggregation.

- Availability of knowledge management repository in public domain.

- Clarification of the role of a national health data stewardship entity to oversee appropriate use of data.

- Additional pilot projects for a national framework to link public and private data sets and to assess clinical quality, cost of care, and patient experience.

Dr. Clancy then closed her presentation by noting that the Quality Workgroup will be addressing the following near-term needs: (1) automate data capture and reporting to support core sets of AQA clinician-focused and HQA inpatient quality measures; (2) provide feedback to providers in real or near-real-time; (3) enable data aggregation to allow public reporting of quality measures based on comprehensive clinical data that are pooled across providers and merged, as appropriate, with other data sources; and (4) align performance measurement with the capabilities and limitations of HIT. Dr. Clancy noted that the Quality Workgroup likely will be presenting formal recommendations at the next Community meeting.

Biosurveillance Workgroup Update

Mr. Kahn reminded Community members that the AHIC approved the Biosurveillance Workgroup in November 2005. The Workgroup originally was intended to bring information in the biosurveillance area to the Secretary's attention as quickly as possible. The DHHS Health Information Technology Policy Council recognized a gap in population health needs across AHIC Workgroups, and the Biosurveillance Workgroup appeared to be a natural home for these efforts within the Community, considering the expertise of the Workgroup members and the fact that the Workgroup was looking broadly at how populations would be affected by HIT. The Workgroup presented population health needs at the October 2006 AHIC meeting; AHIC has since asked the Biosurveillance Workgroup to expand its scope.

The Workgroup, in a sense, is the center for the populations, although there certainly are areas of overlap with other AHIC Workgroups. Mr. Kahn presented a diagram of population health and HIT constructs, with five main areas of emphasis centered around tools and organizations such as EHRs, NHIN, PHRs, registries, repositories, automated survey tools, etc. Mr. Kahn emphasized the need to avoid duplicative efforts with other AHIC Workgroups, particularly the Quality Workgroup.

Dr. Lumpkin then discussed in detail the following five main areas of population health that the Biosurveillance Workgroup plans to pursue:

- ***Public Health Surveillance and Response:*** Ongoing systematic collection, analysis, and interpretation of public health data essential to the planning, implementation, and evaluation of public health practice closely integrated with the timely dissemination of these data to those responsible for prevention and control, and management of the appropriate response.

- ***Health Status/Disease Monitoring:*** Accurate, periodic assessment of community and patient-level health status.

- ***Population-Based Clinical Care:*** Health and functional status for populations of people (e.g., income-based, ethnicity based, age-based, gender-based, others defined as needed).

- ***Population-Based Research:*** Research for new insights and innovative solutions to health problems on a population level.

- ***Health Communications/Health Education:*** Inform, educate, and empower providers, consumers, and others about health and wellness issues.

Mr. Kahn explained that in light of this expanded scope for the Biosurveillance Workgroup, the Workgroup is proposing to change its name to the Population Health and Clinical Care Connections (PH/CCC) Workgroup, with the following proposed broad charge: 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.

Discussion Highlights

"To get work done, you have to have focus. And there was great intent on why the Workgroup was called Biosurveillance in the beginning, to focus on a very critical area. And this seems like a much broader agenda. How will you maintain focus? Will you come back to us with what the agenda of work is going to be?" – Ms. Gelinas

"The simple answer is yes. And in tandem with this, we also were working on a letter with a set of recommendations as to the areas we should specifically address that was comparable to the earlier Workgroups, but our feeling was that one, we wanted to present this proposition to you first, and two, that we wanted to go through the priority setting process to sort of see how that played out before we came back to you with specific recommendations and use cases. But we will be ready to do that at the March meeting." – Mr. Kahn

"I know that part of the name change was in response to a prior meeting where we said, 'consider the name change.' I think the other context is that at times, I hear some members talking about are the Workgroup task forces that should be formed and then disbanded, or that they should have a longer life because there are some broad areas that need to be moved forward, and you can't do that in a piecemeal fashion." – Dr. Kolodner

"One of the things that we went through, in sort of our historical development was beyond the sort of immediate biosurveillance function, or target that we had; we also did a review of all the areas in public health that might be affected by changing electronic possibilities. And so even prior to the discussions about population health at the AHIC level, we were exploring the various functions of public health that needed to be covered, in some way, by the AHIC." – Mr. Kahn

"I'm confident that, from our discussions, we are talking about a functional area that albeit having some overlap with…other Workgroups, it is a very distinct set of functions, and ones that can't be ignored." – Mr. Kahn

"We, at the last meeting, presented a series of priority areas, many of which are reflected in the use cases that you discussed today. And so we will continue to flesh those out, and begin to move those forward as we do our work. But it begins to set a longer term agenda." – Dr. Lumpkin

"There are some collaborative opportunities between the various different Workgroups. This seems to also scream for the need of cooperation with the EHR Workgroup, to some degree. And so with CCHIT,

if there is going to be need for additional capabilities inside of electronic health records, to support population health, as an example, I'm just curious if you gave any thought with those two areas."
– Mr. Hutchinson

"The overarching concern that I have is that in order to communicate with the public health, within the population dimension, people who are designing electronic health records need to think about that function…things that are currently required to be reported ought to be things that people who design electronic health records are thinking about. The process by which we begin to move to that would be CCHIT. And the harmonization, which we're all committed to, would be through HITSP."
– Dr. Lumpkin

"This is another opportunity to engage the private sector or health care providers, and to integrate them within the system, and to encourage their adoption into the EHR and the PHR world, because by collecting that additional data from those sources, again, you have more opportunities to track and to see trends that are happening in the country that have direct relationship to public health."
– Ms. Davenport-Ennis

Following this discussion, Dr. Kolodner declared a consensus on the Biosurveillance Workgroup changing its name to the Population Health and Clinical Care Connections Workgroup based on its expanded scope.

NHIN Prototype Architecture Demonstrations

Dr. Kolodner introduced this final set of presentations by noting that they represent the culmination of the work being done in the NHIN over the past year. Dr. Loonsk explained that the presenters, representatives for the four consortia, would be demonstrating some aspects of the NHIN. Each of the NHIN consortia was asked to work on the same breakthroughs advanced by AHIC last year, and the presentations focused on components of the NHIN efforts related to consumer empowerment and EHRs. He emphasized that these demonstrations represent software implementations of prototype architectures. The NHIN is intended to be a network of networks—these demonstrations are a presentation of the way these applications would connect to it. Dr. Loonsk noted that the full demonstrations that each of these prototype architectures, a discussion of their architectures, and a discussion of the full software implementations would be presented at the Third NHIN Forum, held January 25-26, 2007, in Washington, DC.

The demonstrations all focused on a scenario involving an 89-year old female patient, Patricia Walker, with diabetes who recently had total knee replacement surgery. She moved in with her daughter, Lois Parker (in a different state), to get help with her rehabilitation. The woman now has a new primary care physician (Dr. Douglas), will also visit a specialist (Dr. Cooper), and has a personal health record.

Consumer Empowerment

In terms of consumer empowerment, three scenarios were demonstrated by IBM and Northrop Grumman: (1) the consumer views and updates registration and medication history information, (2) the consumer establishes provider permissions to view data, and (3) the provider retrieves registration and medication history data. Dr. Loonsk noted that there are some key issues borne out through the demonstrations related to consumer empowerment, including:

- Connection of commercial and "tethered" PHRs to the NHIN
- Opportunities for consumer management of PHR data
- Consideration for how consumers could influence the exchange of data on the NHIN
- Needs for tracking providers associated with patients.

IBM Demonstration

Ginny Wagner of IBM noted that their architecture is open standards based, and adheres to the standards recommended by HITSP. Theirs is a hybrid model, with functionality driven totally by the needs of the health care community. A full-federated model, a centralized architecture, or a combination of the two can be accommodated. The model utilizes a registry, but data are not stored centrally—metadata are stored at the community hub level. The metadata are utilized to provide additional insight into the data, such as the document type, the service date, the source information, and in the future, document types. This will allow for tagging the data, which will be critical for aggregating the data, and using them in a secondary manner in the future.

Ms. Wagner explained that for the purposes of this demonstration, Patricia Walker has been pre-registered to the CapMed PHR, the NHIN, and Surescripts. Dr. Douglas, his office manager, and Lois Parker have been invited to access Patricia's PHR online. A registration summary has been uploaded to the NHIN for consumption by an EMR product. Ms. Wagner demonstrated navigation through the CapMed PHR log-on screen and how Patricia Wagner would go into her PHR to manage her information. Ms. Wagner demonstrated how Patricia Walker would update her address; download information through the NHIN; select, preview, and import information from a hospital discharge summary report; import, review, and update a current list of medications. Other functionalities, such as adding comments, uploading information through the NHIN, and sending information directly to a doctor, also were demonstrated.

Ms. Wagner also demonstrated how Patricia Walker would establish provider permissions to view the data by adding a provider, establishing permissions for the provider, and integrating the registration information into the physician's EMR at the data element level. She noted that IBM's system includes a wizard to assist the patient in inviting a doctor(s) to view the PHR and selecting the extent of the access the doctor(s) and their office staff will have. Ms. Wagner added that this access could be set up for family members, as well. Finally, Ms. Wagner demonstrated how the physician's office manager can integrate the continuity of care document into an EMR.

Northrop Grumman Demonstration

Dr. Robert Cothren of Northrop Grumman began his demonstration with Patricia Walker already logged in to her PHR, which for this demonstration was a simple model of a Web-based application that can be used to manage an online store of personal health information and access NHIN services. Patricia Walker's PHR already includes her updated information, her address, previous provider of care, etc., and one medication—her Type II diabetes medication that she was taking before her knee replacement surgery.

The first component of the demonstration focused on Patricia Walker updating her medications using NHIN services, providing access to them, and then adding Dr. Douglas to her access list. Dr. Cothren noted that in performing a query to retrieve medication history, a number of different sources could respond—for the purposes of this demonstration, RxHub was used. After the medications are imported,

Patricia Walker can decide whether to share information on each medication by checking a box (they are not shared by default). Northrop Grumman's architecture supports controls for the exchange of health information, through a mechanism in NHIN, called the permissions registry. This registry is implemented as an NHIN service, and allows or restricts exchange of health information. Dr. Cothren demonstrated how Patricia Walker would add Dr. Douglas to her permissions registry so that he can retrieve information on her, including information from her PHR.

Using the login screen for University Hospitals in Cleveland and the First Gateway's product that University Hospitals currently uses as their EHR system, Dr. Cothren demonstrated how Patricia Walker is registered as a new patient for Dr. Douglas. Dr. Cothren noted that one of the key goals of NHIN services is the ability for Dr. Douglas to get information on Patricia without having to access her PHR—instead, he can use his EHR system and NHIN services. Dr. Cothren demonstrated how this is accomplished for a new patient such as Patricia Walker (i.e., Dr. Douglas' EHR system reaches out to NHIN and performs a query for information on Patricia Walker). Only information that Patricia Walker chooses to share is available to Dr. Douglas. NHIN services take the information that is appropriate, formats it, and translates it into the form that's expected by Dr. Douglas' EHR system. Dr. Cothren emphasized that Dr. Douglas did not have to learn anything new or perform anything new, demonstrating how the NHIN can keep from getting in the way of the normal work flow of a physician.

Consumer Empowerment Discussion Highlights

"Note that both Accenture and CSC, Connecting for Health, have implemented the same consumer empowerment use case in the context of the work that they've been doing as well." – Dr. Loonsk

"What was accomplished was a consumer viewing and updating the registration and medication history. The consumer establishing provider permissions. And you'll see the connections between the patients to identify providers, and the providers to identify patients. And the provider retrieving registration and medication history data, and you saw that through in EHR. The use case also asks for it through a PHR, as well." – Dr. Loonsk

"When you looked at the new physician, you didn't have a procedure on that. Was there a reason why the procedure wouldn't have been loaded?" – Mr. Roob

"Patricia's PHR system didn't happen to include procedures, as part of the data that it manages. It could have easily included that data as well, and it could have been imported, but that's simply something that wasn't included in Patricia's PHR, in the example of the PHR that we presented here." – Dr. Cothren

"It's heartening to see you come this far, when in October 2005, I don't think we were anywhere near. In nursing, we're having just a real challenge with implementing electronic health records with baby boomer nurses, and the fonts are so small. We're getting enormous complaints from medical and nursing staff, as we have spent millions on computers, and they can't see the fonts. And it is really creating quite a workplace issue, either by lighting or by font…You're certainly dealing with an elderly population, in many respects…Did you consider that aspect when you were designing the screens and the fields that consumers would actually have to utilize?" – Ms. Gelinas

"What's really easy to do is to focus on the end applications here rather than the flow of information, and it's really the flow of information that we were asked to concentrate on during the course of the last year. Now, that all said, the PHR industry is very new. It's very young, it's very immature, and I think there is going to be a lot that still needs to be developed in PHRs to really address some of those issues, and strike the balance between the type of information that could be provided to the consumer versus their ability to deal with that level of information." – Dr. Cothren

"I think the real message needs to be communicated to all the end applications, and the screens that we demonstrated here today, while I think that's an excellent product, I have no problem with that, but that's a message we certainly can communicate back. That is something that the CCHIT maybe wants to communicate back to the vendors they're working with." – Ms. Wagner

"In terms of being on the network and finding information, Ginny, you mentioned that there is, I think, a record of where some information is located. So if a patient had a psychiatric condition, is there a storage of that information, that they were seen at a particular institution, in sort of a locator, or is the architecture such that it goes out and can poll entities so that there isn't that revelation?" – Dr. Kolodner

"Right. In our architecture, that is controlled by the local community of what will be published, and at what level it will be published out there. And then it goes out to a registry, and it only publishes the URL from where the data is located, and you must have the appropriate level of access to get access back, controlled by the local community." – Ms. Wagner

"You actually saw two different versions of how that might be handled here in these two examples, and there are other examples the other contactors are going through. In our architecture, there is no registry, and no publishing of information, so it's handled strictly through a query. And, for instance, NHIN services don't know what types of data may even be stored at certain facilities. Plus the permissions registry allows the consumer the ability to block that information so that it isn't carried on NHIN as well. So there are different answers to those questions that all have pluses and minuses to them." – Dr. Cothren

"When you look at our approach, it's very similar to some of the methods that have been previously described. The key is that the local community can set the parameters for what type of data gets shared, under what circumstances; and that can be also impacted by how the patient feels about that particular data." – Dr. Kelly

Electronic Health Records

In terms of EHRs, three scenarios were demonstrated by Computer Sciences Corporation (CSC) and Accenture: (1) the ordering physician receives lab test results, (2) the physician receives historical results, and (3) a non-ordering clinician receives lab test results or notification. Key issues borne out through the demonstrations related to EHRs, included:

- Routing of lab data to the appropriate EHR
- Portal- and EHR-based retrieval of historical lab results
- Notifications of when new lab data are available
- Lab result routing to "non-ordering" providers of care
- Comparability of data across provider sites.

Computer Sciences Corporation Demonstration

Dr. Marc Overhage of CSC noted that the NHIN is envisioned to be a network of networks; those component networks are referred to as Sub Network Organizations (SNOs). SNOs can be national in scope (e.g., Surescripts, RxHub, or the VA) or regional in scope (e.g., the Mendocino RHE, or the Indiana Health Information Exchange). In either case, they consist of a collection of care delivery organizations

that have specific trust relationships, and may represent a wide diversity of how they move information within their community. They also may have different approaches to what information is shared and exactly how that is controlled. In CSC's model, the SNOs can implement two important pieces of technology: (1) the InterSNO Bridge (ISB), which is the SNOs' window to the NHIN; and (2) a record locator service (RLS), which is the mechanism by which a request for information can be directed to the appropriate care delivery organizations where the patient has received care in the past.

Dr. Overhage emphasized that the separation of clinical and demographic data is a critical issue for architectural design that helps ensure that the patient's privacy is always being protected under the agreements that the local environment may have. Dr. Overhage characterized CSC's prototype of an NHIN as the sum of its parts. There are no central structures or central services; just the two key pieces of technology, the ISB and the RLS, that have to be implemented within a particular network or SNO that enable these diverse SNOs to share clinical data. Dr. Overhage demonstrated how Patricia Walker, seen by Dr. John Watson in Mendocino County, CA, has her lab tests ordered and reviewed using live applications currently being used by providers (e.g., i2i MediTracks). The test results are imported and incorporated into Patricia Walker's electronic medical record. Dr. Overhage noted that research indicates that 14 percent of lab results either don't make it to the outpatient physician or get there later than would have been optimal for patient care. The lab test results also are made available to the ordering physician using his EMR system.

In a second scenario, Dr. Overhage demonstrated how Dr. Watson would receive historical test results for Patricia Walker to provide a clinical context. Because Patricia Walker is a new patient, Dr. Watson authenticates himself to the open HRE, a browser-based application that enables him to access the Mendocino health record exchange. This request is sent to the Mendocino HRE through the ISB. It then is distributed to an HIE in Indianapolis, IN, and in both of those markets, the RLS is consulted to find out where the patient has received care previously. A second-level query then is sent to that care delivery organization to retrieve the data. The data are formatted in a standardized, consistent format, and returned to the Mendocino HRE, after being aggregated in Indianapolis. Those data from Indianapolis then are aggregated with the data from Mendocino, and returned back to the provider.

Dr. Overhage noted that the NHIN is not a health care application; rather, it is a set of capabilities for data transfer in a structured standardized format built on policies, and the trust that has to underlie that, as well as the process. He concluded by noting that this very thin set of NHIN functionalities approach accommodates the diversity that we seen in the current healthcare environment in these different SNOs with different infrastructures for exchanging data, and that it will enable creation of a health care system that will become much more efficient and deliver higher quality and safer care.

Accenture Demonstration

Dr. Brian Kelly discussed some of the underlying principles of Accenture's architecture. One of the fundamental premises is that normalizing data, as they are extracted from provider organizations and brought up to the NHIN to facilitate sharing, is a critical enabler and a critical blocking and tackling piece that has to be addressed to achieve true health care interoperability. Accenture's architecture is based on a flexible hybrid model that allows local communities to determine where health care data are stored. It uses a service-oriented approach consistent with best application designed methodologies. The architecture is designed to sit alongside and leverage the large investments in local provider EMR, laboratory, and medication systems. The model aggregates data at the distinct health care level so that a more complete view of a patient is available to caregivers and patients. These data can be supplemented with information from remote health care settings using the NHIN. Accenture's philosophy and approach is based on the premise that most health care is a local phenomena, and that providing a critical core dataset at the regional level that can be supplemented by additional data from remote locations will be of

great value to patients and providers. Accenture's three distinct health care markets did not have pre-existing regional information exchanges. Therefore, their prototype not only demonstrates that an NHIN can be built quickly, but that in less than 12 months, the infrastructure for three regional health care organizations can be established.

Dr. Kelly also explained that to truly support interoperability and realize the benefits of secondary use, it is critical to address the problem of normalizing data to Federal Health Architecture (FHA) standards. He noted that in less than 1 year, Accenture's prototype successfully interfaced with 31 different provider systems at 15 provider organizations, to extract demographic, lab, and medication data, and convert them to FHA standards.

Dr. Kelly began the demonstration with the ordering physician logging in through one of the regional exchanges after ordering a lab test for Patricia Walker (the physician has been granted permission to access this record). The physician can access a compilation of demographic, medication, allergy, and social history data. These data can be populated through messages from the local provider organizations, from data entered by the provider, and/or by data entered into the patient's personal health record. The physician can view the test results, and in the demonstration, found an abnormal result. Therefore, the physician queries the NHIN, and in so doing, imports additional information from other distinct health care markets—previous lab results can be retrieved in this manner and viewed individually or cumulatively. Information can be put into chart form, with the ability to trend information and show norms. Accenture's architecture provides the capability to map medication, lab test, and demographic data pulled from all of its 15 provider organizations and map them to FHA standards. This allows for capabilities in terms of biosurveillance and aggregation of data sets.

Dr. Kelly demonstrated how Patricia Walker's primary care physician can log into his portal to check on his patient views. In this demonstration, the physician receives an alert that there is a new lab test on Patricia Walker, and he can click on that alert, which takes him to Patricia Walker's home page, where the results can be viewed and analyzed. Dr. Kelly also demonstrated how the primary care physician's staff would log in and view these results, noting that one of the features of Accenture's system is that it requires providers to verify that they have a relationship with the patient before accessing their information.

Electronic Health Records Discussion Highlights

"I just would like to compliment the entire consortia on the work that you have done, and seeing you demonstrate particularly the ability to pull the test, and to exchange medical information, provider to provider. There is, indeed, a great opportunity to reduce medical errors and to ensure that consumers are going to have a more comprehensive, timely set of medical decisionmaking tools in the hands of the doctors that are working with them today." – Ms. Davenport-Ennis

"It also highlights another important topic around the sharing of information, while respecting patients' rights to share information and not share information. It also could introduce significant issues with respect to the quality of care that can be delivered, if physicians feel that they are looking at a complete record of information when, in fact, certain levels of information have been hidden at the patient's request. We ran into the same issues with Katrinahealth.org, when sharing that information, making sure that there are alerts, letting the physician know that not a complete record is being shown. We have to find that balance in making sure that patients know when you are taking information away from the eyes of the physician, of your care provider, that you are increasing the risk of the quality of care that could be delivered." – Mr. Hutchinson

"Not only do we have to identify there is missing information, but I would encourage that we have to identify at least the type, the universal type of information. It's different if there is one field of one prescription missing as opposed to an entire diagnosis that is missing." – Ms. Davenport-Ennis

"I think the Workgroups will be mulling this over, and bringing some things back. Because on the other hand, right now the consumer, in a non-electronic world, has the right to keep that information away and not have it revealed, that there is information being held back. And so the question is, do they lose that right, just because it's electronic? But what is that correct balance? Because there certainly is increased risk when information is missing. We happen, right now, to deliver care in a world where there is always missing information, but we kind of know that, whereas if we move into the electronic world, there is often the assumption that it's now a complete set. So finding that balance is, I think, going to be something that is a very important discussion, and will be probably an ongoing one for the Community for a period of time." – Dr. Kolodner

"I'm sure that there were some enablers that helped you get the job done, and you identified some barriers along the way. And having those visible to us, in our Workgroups, could really help us, because at the end of the day we're all about trying to adopt technology…If we were able to distill out the enabling top 10, the barriers top 10…it would really inform our work a great deal. But I don't want to burden you with that, knowing what went into it so far. But you're just sitting on a wealth of knowledge that we don't have." – Ms. Gelinas

Public Input Session

Speaker Number 1 – Kathryn Serkes, representing the American Association of Physicians and Surgeons (AAPS), commended the AHIC Workgroups for taking an incentive-based approach in formulating their recommendations. She noted that the AAPS has unanimously passed a resolution supporting the voluntary adoption of HIT. The resolution also indicates that adoption of HIT, or an EHR, should not be a requirement for participation in a government program for either the provider or the patient. Ms. Serkes added that the American Legislative Exchange Council, a nonpartisan association of state legislators, is working to develop a set of principles for HIT adoption; these draft principles promote an incentive-based or voluntary-based approach as well.

Ms. Serkes noted that the issue of HIPAA non-covered entities has surfaced with the Consumer Empowerment Workgroup recommendations presented at the meeting. She explained that AAPS believes that it would be valuable to suggest best practices for non-covered entities, but the organization would oppose any efforts to extend HIPAA regulations to non-covered entities. Many AAPS members have elected to remain non-covered entities. HIPAA does not require patient consent for disclosure of records, but merely the advisement of how the records may be used, and there is the provision for the non-binding request for specific restrictions. Some of the patients who choose to utilize non-covered entities as providers do so to protect their ability to consent to disclosure. The privacy issue is one of the reasons that patients go to non-covered entities.

Ms. Serkes summarized by stating that the AAPS believes that patients should be empowered as consumers, and that consumer empowerment means greater and better choices. The Association also believes that one of those choices should be the choice of refusal—patients should be able to refuse treatments and/or participation in an HIT or NHIN system. She noted that it is promising that the demonstrations given at the meeting included multiple opt-out points for patients. Ms. Serkes concluded her comments by thanking AHIC and the presenters at this meeting for all of their efforts.

Closing Remarks

Before adjourning the 11th AHIC meeting, Dr. Kolodner reminded participants that the next meeting, previously scheduled for March 6, 2007, has been moved to March 13, 2007. This meeting is expected to include a focus on confidentiality, privacy, and security issues, with updates from a number of groups, including recommendations from several of the Workgroups that did not make recommendations at this meeting. Dr. Kolodner then thanked everyone in attendance, and adjourned the meeting.

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Certification Commission for Healthcare Information Technology (CCHIT) Update

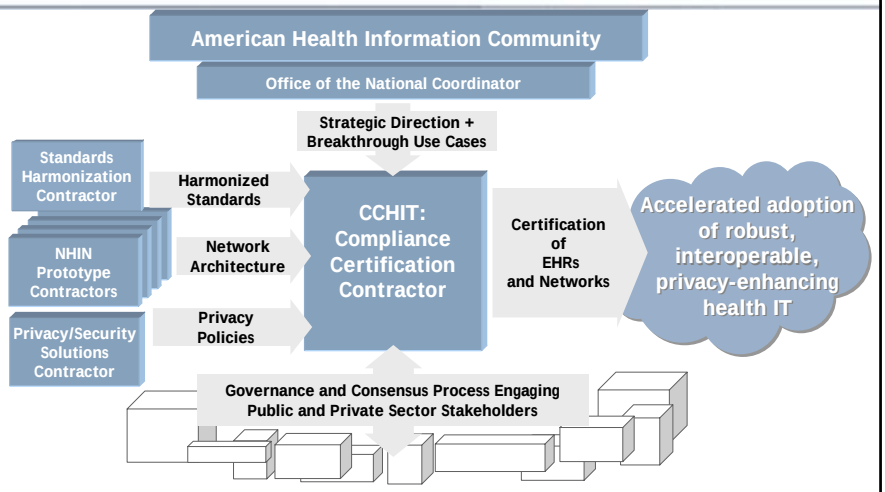
Mark Leavitt
Chair, CCHIT

March 13, 2007

Overview of CCHIT

- Mission: accelerate the adoption of robust, interoperable health IT by creating an efficient, credible certification process
- Goals of Certification:
  - Reduce the risks of investing in health IT
  - Facilitate interoperability of health IT products
  - Enhance availability of adoption incentives and regulatory relief
  - Ensure that the privacy of personal health information is protected

CCHIT's Role within the Health IT Strategy



Certification is a voluntary, market-based mechanism to accelerate the adoption of standards and interoperability

Scope of Work for CCHIT

- 2006: Develop, pilot test, and launch certification of ambulatory (office-based) EHRs
- 2007: Develop, pilot test, and launch certification of inpatient (hospital) EHRs
- 2008: Develop, pilot test, and launch certification of networks through which EHRs interoperate
- Update certification criteria for each domain annually
- Expand certification to address more specialized needs
- Transition to become an independent, self-sustaining organization by the end of the contract period

Progress Report: Ambulatory EHR Certification

- Attributes of the EHR system that are certified:
  - Functionality
  - Interoperability
  - Security
- Criteria development process
  - 18 months
  - Transparent, consensus-based process
  - Received and responded to over 2,000 public comments
  - Pilot tested criteria and inspection process, February 2006
  - Published Final Criteria and Inspection Process, March 2006
  - Certification program launched, May 2006

Ambulatory EHR Certification Program Status

Certification Year	Certification Quarter	Application Window	Announcement
2006 Ambulatory EHRs	1st	May 3-12, 2006	22 Certifications Announced
	2nd	Aug 1-14, 2006	11 Certifications Announced
	3rd	Nov 1-14, 2006	18 Certifications Announced
	4th	Feb 1-14, 2007 35 applications	Apr 19, 2007
2007 Ambulatory EHRs	Continual	Opens May 1, 2007	Continual

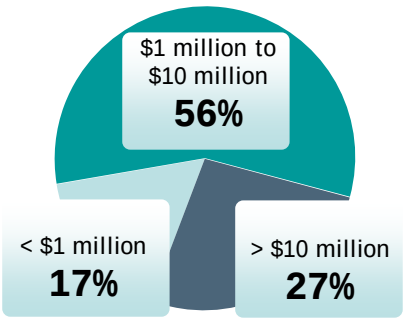
Note: Total number of products now certified is 57 – including additional private-labeled versions of certified products.

Evidence of Certification's Positive Impact

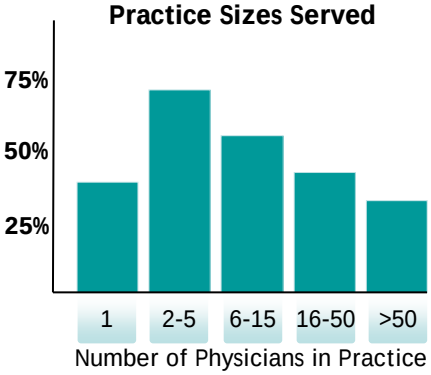
- Endorsement by professional societies:
  - American Academy of Family Physicians
  - American Academy of Pediatrics
  - American College of Physicians
  - Association of Emergency Physicians
  - Medical Group Management Association
  - Physicians' Foundations for Health Systems Excellence
- Payer IT incentive programs keyed to EHR certification
- Health information network pilots relying on certification of EHRs to satisfy security requirements for participation
- HHS acceptance of criteria and of CCHIT as a Recognized Certifying Body

Profile of Certified Vendors

Annual Revenue



Practice Sizes Served



Certification has created a "level playing field" for a wide diversity of EHR companies to compete

Data from anonymous survey of certified vendors as of February 2007; N=30; response rate 55%.

Current Status of Certification Development

- Ambulatory EHR certification update for 2007
  - Pilot Test completed January 30, 2007
  - Proposed Final Criteria published February 14, 2007
  - Certification against 2007 Criteria will launch May 1, 2007
- Inpatient EHR certification – new for 2007
  - First Draft Criteria released September 25, 2006
  - Reviewed and responded to over 800 public comments
  - Second Draft Criteria released February 16, 2007
  - Pilot test planned April/May 2007
  - Certification launch planned August 1, 2007
- Network certification
  - Currently in preliminary information-gathering stage

Expanding Certification to Address More Specialized Needs

- Refine certification criteria to address more specialized health IT needs, as represented by:
  - Professional specialties
  - Additional care settings
  - Specific patient populations
- Objective process for prioritizing areas to address
  - Gather environmental scan data
  - Prioritize based on:
    - Potential benefit of certification
    - Readiness for certification
    - Effort required for development

Draft Roadmap for Expanding Certification

Specialized Area	1H 2007	2H 2007	2008	2009	2010
Populations					
Child Health	Begin development	---------->	Launch - May 2008		
Behavioral Healthcare		Begin development	Possible launch	Possible launch	
Care Settings					
Emergency Department	Begin development	---------->	Possible launch	Possible launch	
Long Term Care	Further discussions	Begin development	---------->	Possible launch	Possible launch
Home Care		Further discussions			
Professional Specialties					
Cardiovascular Medicine	Begin development	---------->	Possible launch	Possible launch	
Other specialties	Further discussions	Set priorities, create roadmap	Begin development in selected specialties	Possible launch	Possible launch

Progress Report: Becoming an Independent, Self-Sustaining Organization

- Organizational transition:
  - Board of Trustees formed and operational as of January 2007
  - CCHIT is now an independent nonprofit organization (501c3 status pending)
- Financial transition:
  - Plan for becoming financially self-sustaining by end of HHS contract has been outlined
  - Results are currently on track with plan

Thank you!
Q & A

For more information, please visit:
www.cchit.org

Dissenting Statement on
PHR Certification Process

March 13, 2007

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

Dear Mr. Chairman and the American Health Information Community:

We, the undersigned members of the AHIC Consumer Empowerment Workgroup, dissent from the Workgroup Recommendation 1 that HHS encourage a certification process for electronic personal health records (PHRs.)

We acknowledge a need for federal governmental leadership that accelerates the potential of PHRs to empower the consumer. However, certification should not be a governmental focus at this time. The risks outweigh any potential benefits. If this recommendation goes forward, it will create momentum for certification that is likely to ignore a broad range of critical policies and, as well, stifle innovation by prematurely locking in current approaches to PHRs and deterring new entrants in a field that is newly developing. For the reasons outlined below, a premature process for certification — even if it begins as voluntary and attempts to limit itself to privacy, security and interoperability — risks undermining opportunities to empower consumers and improve the quality of care.

The PHR landscape is immature in several ways. First, we cannot yet define which features or requirements will prove to be most valuable to American patients and families. Innovative models for a wide range of services for consumers have not been explored. Second, the policies that might potentially be fulfilled by certification have not been developed. Third, the technology and data standards — including those recommended by HITSP to support the AHIC use cases — also remain largely untested in real-world settings. Each of these gaps is acknowledged in the Consumer Empowerment Workgroup's findings and recommendation.

Certification will not drive a marketplace for PHRs, and thinking about the issue as one of creating a marketplace is misguided. Rather, a more appropriate focus would be to collaborate broadly to develop policies that establish consumer confidence in the accuracy, confidentiality and limitations on secondary use of their records, and on how to make PHRs useful to consumers. If these two things can be achieved, they are far more likely than certification to drive consumer adoption.

We believe the primary focus today should be on developing recommended privacy and security policies for the use in PHR services with trusted exchange of personal health data. This is consistent with Recommendation 2.1 made by the Consumer

Empowerment Workgroup at the AHIC meeting on Jan. 23, 2007. Once we have identified a set of policies and practices for PHRs, it will be appropriate to determine what kind of enforcement process is best suited to each type of policy. We should consider a full range of enforcement mechanisms to achieve robust privacy protection and interoperability. This spectrum includes regulatory enforcement, contractual agreements, procurement, self-certification with validation, third-party certification, and statute.

We recognize that the Consumer Empowerment Workgroup is not explicitly recommending certification of product features and functions at this time. However, we submit that for HHS to encourage a process for certification of standards and interoperability implies a certain level of functionality. We also note that the workgroup does not recommend that the government require its vendors to use certified PHRs or that it make certification a prerequisite for federal funding. This demonstrates our point that it is too early to adopt this recommendation.

We have the following specific concerns about any focus on PHR certification at this time:

- **PHRs are different from EHRs:** Proponents of PHR certification point to the launch of CCHIT's certification of EHRs. We believe the two domains are dramatically different — and not only because EHRs are more mature by nearly a decade. High initial capital outlays and significant financial exposure are barriers to physician adoption of EHR products, and market stabilization is therefore considered vital. By contrast, access to PHR applications is free or of minimal cost, switching costs are low, and therefore the proposed advantages of certification of EHRs do not apply to PHRs.

  In addition, we note that at most only 24 percent of U.S. physicians are using some form of EHR products.[1] Indeed, the adoption rate is closer to 9 percent for EHR systems most likely to have data of high value to consumers.[2] It is likely that PHRs will develop with many approaches to data acquisition and sharing, including self-population, use of claims data, direct access to pharmacy, laboratory, and monitoring data, scanned documents, and community-derived content. We see no reason to pick any one class of data as deserving special and limiting attention at this time.

- **Software certification does not necessarily assure privacy or security protections:** Proponents of PHR certification cite a need to provide assurance

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[1] Blumenthal D, DesRoches C, Donelan K, Ferris T, Jha A, Kaushal R, Rao Sowmya, Rosenbaum S. Health Information Technology in the United States: The Information Base for Progress. Available at: http://hitadoption.org/downloads/annual_report_2006.pdf

[2] National Center for Health Statistics. National Ambulatory Medical Care Survey. Available at: http://www.cdc.gov/nchs/products/pubs/pubd/hestats/electronic/electronic.htm

to consumers about privacy in order to increase adoption of (presumably) certified PHR products. However, we submit that privacy practices are not primarily software product attributes. Instead, they depend on behavioral conformance to a broad set of policies that bear upon the data source, the sponsor of the PHR, the hosting service of the PHR, and its users. We are not aware of circumstances where "privacy" has been certified for a software product. Indeed, certification of PHR applications alone will be inadequate because true privacy and security protection must exist throughout an entire chain of handoffs between data sources and the end-user application. Further, we have seen no published research suggesting that certification will adequately address public concerns about privacy or encourage greater adoption and use of PHRs. Moreover, certification provides no redress for breaches of personal health information or inappropriate secondary uses. It can create false assurances for the public. We therefore believe that the potential harm of a voluntary privacy and security certification at this time outweighs any potential benefits.

- **Early "winners" can deprive consumers:** We do not yet know which approaches to PHRs will prove valuable to consumers. Any certification at this time effectively declares "early winners" and prescribes a required path for market success. This will be true regardless of whether certification begins as "voluntary." If federal agencies were required, for example, only to procure certified PHR products, it is likely that many innovative approaches to empowering patients and families would be unavailable to federally sponsored populations. Certification "locks in" a definition of systems around today's dominant product offerings, which are based on our experience of yesterday. Relying on yesterday's technology experience almost invariably leads to systems that fail to meet tomorrow's needs. Over time, certification can reward mediocrity, encourage an industry of legacy systems, and increase the costs of switching to new and better approaches.

- **Certification can freeze out innovators:** The administrative and financial burdens of conforming to a certification process fall hardest on smaller players (from which new innovations often spring). These burdens are not simply the cost of a certification review, but the very substantial operating costs of conforming to the third-party review process.

- **Given their inherent inflexibility, certification criteria are difficult to get right.** If the bar is set too low, then too wide a range of applications will be certified. The result will be meaningless to consumers or, worse, give them false expectations about protections to their data. If the bar is set too high, then new innovators will be blocked and the consumer will be deprived of improved services. This problem of setting optimal criteria exists in any market, but it is particularly resonant in an immature one. If, at some future time, PHRs require certification, we would need a careful consideration of what criteria, due process, and skill set would be suitable. We believe that

there needs to be a thorough discussion about the pros and cons of various certification entities and a process to allow for competition among possible certification services.

In summary, we agree that solutions to privacy, security, and interoperability problems are needed to advance PHR adoption in this country. However, it is not warranted to assume that PHR certification is going to solve these issues or enhance consumer trust in PHRs. Credibility with consumers is a far different matter than credibility with vendors. Government encouragement of PHRs requires a public process that builds consumer understanding of the benefits of PHRs and confidence in the policies that underpin them. This requires a robust public debate on how privacy will be protected and secondary use controlled, and sustained public exposure to the benefits of PHRs and their role in their health and health care. What is needed now is for that discussion to take place, including a broader set of consumer representatives and industry experts, for a full exploration of these issues as well as the potential benefits, costs and risks of certification and its many alternatives. **For the reasons stated above, we believe it is premature for AHIC to adopt a recommendation on certification of PHRs and urge the Community to reject this recommendation.**

Sincerely,

Stephen Downs, The Robert Wood Johnson Foundation

David Lansky, Markle Foundation

JP Little, RxHub

Steve Shihadeh, Microsoft

Myrl Weinberg, National Health Council

March 13, 2007

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

Dear Mr. Chairman:

The American Health Information Community has given the following broad charge to the Consumer Empowerment Workgroup:

> **Broad Charge for the Workgroup:** To make recommendations to the Community to gain widespread adoption of personal health records (PHRs) that are easy to use, portable, longitudinal, affordable, and consumer-centered.

The Workgroup's deliberations have highlighted a number of key issues regarding the broad charge, including the following:

1. Ideally, personal health data can be exchanged among PHRs and sources of personal health information (e.g., electronic medical records, payer, or pharmacy systems) under the control of the patient while preserving the meaning of the data.
2. Appropriate incentives to encourage consumer and provider adoption of PHRs should be identified and promoted.

This letter provides both context and recommendations for how these issues can be addressed in 2007.

FINDINGS

Empowering consumers to take an active role in managing their health through engaged management of their personal health information has been the overarching goal for this Workgroup. Certification of PHRs may be a useful tool for addressing some of the main challenges of the PHR marketplace and may offer better protection for the consumer. The Consumer Empowerment Workgroup has had extensive discussions about the potential benefits of certifying PHRs and of encouraging connectivity of electronic health records (EHRs) to PHRs. The Workgroup has also discussed the challenges related to achieving a meaningful certification process that supports consumers in making informed choices about PHRs. Our recommendations and comments here reflect the majority opinion of the Workgroup. There was, however, a significant dissenting opinion regarding the usefulness of working toward the certification of PHRs at this time given the evolving PHR marketplace. We believe this alternate viewpoint is critical to the deliberations of the Community and offer the dissenting opinion in a separate document.

One area where certification could fill a current gap in the marketplace relates to PHR privacy and security policies. An analysis of privacy and security policies for PHRs estimates that, while nearly all of the PHR vendors surveyed stated they had these in place, only half of these PHR vendors are sharing these policies with consumers (Altarum, 2006). Another privacy concern is that many PHR vendors and service providers are not considered to be covered entities or business associates under the Health Insurance Portability and Accountability Act (HIPAA), so the protections provided under HIPAA does not extend to the consumers of these products. Certification of PHRs for security could potentially enhance the protections afforded to the consumer's personal health information.

A second area where certification could fill a gap in the marketplace is that of interoperability between EHRs and PHRs. Currently, few incentives exist to motivate the sharing of information between systems, but it is in the best interest of the consumer that they be able to access their personal health information stored in an EHR or other system and be able to populate their PHR with these data. Several vendors and payers have testified that minimum certification of EHRs and PHRs for interoperability would improve data liquidity and increase trust in the products, thereby encouraging adoption of PHRs.

There are at least two major prerequisites to creating a meaningful certification process for PHRs that empowers consumers rather than stifles innovation. First is the establishment of standards and specifications against which a vendor's PHR could be assessed. Second is the development of adequate industry experience in real-world settings to ensure the standards and specifications are sufficiently mature as to warrant certification. The Workgroup notes that, for example, while HITSP recently approved an interoperability specification for the exchange of patient medication history and registration summary information, there is limited industry experience with adopting the specification.

Even more work is required to establish privacy and security policies that could be used as benchmarks for certification. The Consumer Empowerment Workgroup has discussed the need for the establishment of standards, specifications, and privacy policies before market implementation of certification. The Workgroup concluded that testing of standards and specifications in the marketplace was also necessary before they are included in a certification process. The deliverables of the Privacy and Security Solutions for Interoperable Health Information Exchange contract funded by the Department of Health and Human Services may provide valuable input into Workgroup deliberations on these issues. In addition, the Consumer Empowerment Workgroup is working with the Confidentiality, Privacy, and Security Workgroup to address the issue of privacy policies.

While the Workgroup acknowledges that there are risks associated with certification, the Workgroup believes that the benefits outweigh the risks. Although there is a risk of impeding innovation in the PHR market if rigid certification requirements are established, the Workgroup believes that this risk can be mitigated through the development of a voluntary certification process that is sufficiently responsive to advancements in the market. On the other hand, the Workgroup believes that the risk of PHR data being inappropriately accessed or misused is far greater without these protections. We believe that certification is a method of reassuring consumers and providers that certified PHR products meet at least some minimum security

requirements. The Certification Commission for Healthcare Information Technology (CCHIT) and others have testified that a lack of certification will result in what is being experienced in the EHR marketplace today: proprietary solutions of narrow scope with little interoperability. CCHIT believes that a voluntary certification process will not interfere with the market's development because if certification does not prove to be useful, it will simply be ignored by the offerers and purchasers of PHRs. CCHIT has stated that the funding model for certification of PHRs may differ from that of EHRs, so that small developers in the early PHR market will not face prohibitively high application fees. Based on its experience in the ambulatory EHR market, CCHIT has found that certification helps to create a level playing field while allowing a wide diversity of vendors to compete.

There are many different organizations capable of certifying PHRs, with CCHIT being one of them. The Workgroup notes that the mission and charter of CCHIT are consistent with the goal of certifying PHRs as the health care system moves from being provider-centric to being more consumer-centric. While there is no requirement that CCHIT be the institution providing this certification and other groups may have a suitable role in this process given their experiences in the consumer marketplace, CCHIT may serve as a logical resource to consider as a future certifier of PHRs.

The recommendations below identify initial strategic steps that could leverage ongoing activities and address prioritized challenges to address this Workgroup's charge of gaining widespread adoption of a personal health record that is easy to use, portable, longitudinal, affordable, and consumer-centered. We suggest that these recommendations, if accepted by the AHIC, be considered by the Department of Health and Human Services (HHS) for adoption as HHS policy regarding current and future activities, including appropriate federal contracts, pilot and demonstration projects as they relate to the Workgroup's charge. We urge caution, however, when considering certification as a prerequisite for federal funding before adequate industry experience has proven the appropriateness of the standards and policies on which the certification is based.

Furthermore, it is the Workgroup's intention that these recommendations apply more broadly to the health care system, and that public and private sector organizations would parallel HHS in their implementations. While their roles are different, the public and private sectors each play important parts in the new and emerging PHR marketplace. The federal government role is to create policies that address public concerns and increase data liquidity. The private sector is focused on understanding the value proposition and innovating to meet the needs of consumers. Both sectors need to collaborate in order to realize the vision of widespread adoption of PHRs.

RECOMMENDATIONS

The Workgroup identified the following actionable recommendations that could be initiated in 2007 to begin to address the broad charge.

1. Certification of Privacy, Security, and Interoperability

Previously, most PHR products were standalone products having little connectivity with electronic data sources. Currently, new PHR products have established connectivity with at least one electronic data source, e.g., a provider system or health plan. However, when a consumer's PHR is tethered to an entity such as a health plan or a provider group, in the absence of interoperability standards, the data typically cannot be transferred to a different PHR if the consumer switches to another health plan or provider. If the consumer wishes to share the data with another provider or a new health plan, there is currently no consistent way for this data exchange to occur, and there has not been consensus on the data elements or information to be collected, maintained, and shared in a PHR. Certification of PHR products is an important tool for encouraging increased security, interoperability, and portability for PHRs.

> **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.**

2. Incentives for Adoption

Currently, there is a lack of incentives for PHR adoption and utilization by consumers. Enabling federal employees and beneficiaries to become early adopters in government-sponsored PHR pilot programs could encourage adoption while providing valuable feedback and lessons learned about how to implement a PHR and about the benefits such a tool provides. The PHRs may be offered directly by the agencies to their beneficiaries, through contracts with health care providers or plans, or through incentives that encourage individuals to gain access to PHRs on their own. Government agencies, such as the Department of Veterans Affairs, the Indian Health Service, Office of Personnel Management, and the Centers for Medicare & Medicaid Services (CMS), are also working on projects that could provide valuable information for future PHR implementations.

> **Recommendation 2: HHS, through the Centers for Medicare & 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 HHS should 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.**

These recommendations are supported by information obtained through research and testimony to the Consumer Empowerment Workgroup which is contained in the supporting documents available at http://www.hhs.gov/healthit/.

Thank you for giving us the opportunity to submit these recommendations. We look forward to discussing these recommendations with you and the members of the American Health Information Community.

Sincerely yours,

Rose Marie Robertson
Co-chair, Consumer Empowerment Workgroup

Sincerely yours,

Nancy Davenport-Ennis
Co-chair, Consumer Empowerment Workgroup

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Consumer Empowerment Workgroup
Recommendations

Nancy Davenport-Ennis
National Patient Advocate Foundation
Rose Marie Robertson
American Heart Association
David Lansky
Markle Foundation

March 13, 2007

Workgroup Member List

Co-Chairs:

– Nancy Davenport-Ennis	National Patient Advocate Foundation
– Rose Marie Robertson	American Heart Association

Members:

– Jason Bonander	Centers for Disease Control and Prevention
– Susan Christensen	Agency for Healthcare Research and Quality
– Jodi Daniel	DHHS/Office of the National Coordinator for Health IT
– Lorraine Doo	Centers for Medicare and Medicaid Services
– Stephen Downs	Robert Wood Johnson Foundation
– Kevin Hutchinson	Surescripts
– David Lansky	Markle Foundation
– JP Little	RxHub
– Ross Martin	Pfizer
– Susan McAndrew	DHHS/Office for Civil Rights
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– Kim Nazi	Department of Veterans Affairs
– Nancy Nielsen	American Medical Association
– Jayne Orthwein	National Institute of Standards and Technology
– Charles Safran	American Medical Informatics Association
– Scott Serota	Blue Cross Blue Shield Association
– Steve Shihadeh	Microsoft
– Linda Springer	Office of Personnel Management
– Paul Tang	Palo Alto Medical Foundation
– Robert Tennant	Medical Group Management Association
– Myrl Weinberg	National Health Council

Office of the National Coordinator:
– Kelly Cronin

Broad Charge: What are we trying to accomplish?

Make recommendations to the Community to gain widespread adoption of a personal health record that is easy-to-use, portable, longitudinal, affordable, and consumer-centered.

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, payer, or pharmacy systems) under the control of the patient while preserving the meaning of the data.

2. Appropriate incentives to encourage consumer and provider adoption of PHRs should be identified and promoted.

1. 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.

☐ **Accept** ☐ **Table** ☐ **Reject**

2. Incentives for Adoption

Recommendation 2: HHS, through the Centers for Medicare & 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.

☐ **Accept** ☐ **Table** ☐ **Reject**

March 13, 2007

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

Dear Mr. Chairman:

The American Health Information Community has identified and prioritized several health information technology applications, or "breakthroughs," that could produce a specific tangible value to health care consumers. To address one of these breakthrough areas, the Quality Workgroup was formed and given the following broad and specific charges:

> **Broad Charge for the Workgroup:** Make recommendations to the American Health Information Community so that breakthroughs in HIT can provide the data needed for the development of quality measures that are 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 HIT.
>
> **Specific Charge for the Workgroup:** Make recommendations to the American Health Information Community that specify how certified health information technology should support the capture, aggregation, and reporting of data for a core set of ambulatory and inpatient quality measures.

This Workgroup is one of many efforts focused on improving the quality of health care and plays an important role within the context of broader efforts. As the Workgroup strives to meet both its broad and specific charges, it has undertaken an iterative approach to integrating quality and health information technology which leverages the collective wisdom of industry experts in the public and private sectors and supports integrated and aligned efforts across the national quality enterprise. The Workgroup values and supports the development of a common framework aligned with a variety of organizations, to ensure that scalable approaches to quality measurement, reporting, and improvement are adopted. To the extent possible, this Workgroup will consider common data needs that may overlap with other Workgroups, as data needs for quality are not entirely separate from data needs for other secondary uses of data. Given advances in technology coupled with increased pressure for quality improvement and growing demand for relevant and accurate health care information, there is both urgency and an opportunity today to meet the broad charge of the Workgroup.

Success of the Workgroup will be measured by how health information technology enables both informing consumers' health care decisions as well as improving the quality of care delivery. Examples of success might include consumer engagement through information based on a nationally accepted set of quality metrics that informs their decisions about what treatments they

want and who they want to provide them, and clinicians who routinely use clinical decision support and electronic health records to bring all needed patient data and medical knowledge into shared decision-making with patients to achieve optimal outcomes.

Our Approach to Date

Consensus on quality metrics is a fundamental precursor to realizing the Workgroup's high-level vision presented to the Community on January 23, 2007. Therefore, it was important for the Workgroup to first define what "core set" of inpatient and ambulatory measures should be addressed first. The Workgroup agreed that the consensus process is critical to convergence on a core set and that the measures selected by AQA and Hospital Quality Alliance (HQA) represent the current national consensus. Both AQA and HQA are multi-stakeholder alliances that prioritize the implementation of measures endorsed by the National Quality Forum (NQF).

Through testimony and the development of the vision, the Workgroup has identified critical barriers and enablers for its near-term priorities that also impact long term priorities.

1. Security and privacy concerns must be addressed.
2. The provider business case for automating quality measurement must be developed in concert with the incentives for EHR adoption and the sharing of clinical data. The business model for value-driven health care will be dependent on the use of a robust set of quality and efficiency measures.
3. In order to produce data for quality metrics, multiple sources must be accessed and aggregated. Therefore, data aggregation strategies are needed to support public reporting of clinical care at a regional, state, and/or national level.
4. Business process and workflow changes will likely be required to ensure optimized capture of data.
5. Consensus is required on the ways in which patients will be uniquely identified through data, both within a subset as well as across institutions that will support quality measurement and reporting while protecting confidentiality.
6. Translating quality measurement and reporting into improved results for patients requires much greater use of effective clinical decision support, as well as rapid development and evolution of market competition and collaboration across multiple stakeholder groups.

The Workgroup's deliberations to date have highlighted a number of key needs that must be addressed in the near-term to meet the group's specific charge, including the following:

1. Automate data capture and reporting to support core sets of AQA clinician-focused and HQA inpatient quality measures.
2. Create a common framework of workflow activities that underpin performance measurement, and improvement with clinical decision support, so that these inter-related activities can occur seamlessly within care delivery.
3. Enable data aggregation to allow public reporting of quality measures based on comprehensive clinical data that is pooled across providers and merged, as appropriate, with other data sources.

4. Align performance measurement with the capabilities and limitations of health information technology.

This letter provides both context and recommendations for how these issues can be addressed so that health information technology can enable and accelerate the consistent delivery of high-quality, safe, and efficient care.

Relevant Organizations and Projects

The following organizations and projects can provide leadership and examples for efforts to encourage quality measurement to improve health care quality and patient safety.

The AQA was formed to improve health care quality and patient safety through a collaborative process in which key stakeholders agree on a strategy for measuring performance at the physician or group level; collecting and aggregating data in the least burdensome way; and reporting meaningful information to consumers, physicians, and other stakeholders to inform choices and improve outcomes.[1] The AQA has developed a consensus around a starter set of 26 measures of physician quality and has recently adopted an additional 83 measures. However, the AQA measures are not widely deployed due to adaptive challenges related to collecting data and technical challenges related to aggregating physician data from multiple sources to allow for meaningful comparisons.

The HQA is a public-private collaboration to improve the quality of care provided by the nation's hospitals by measuring and publicly reporting on that care. The ultimate goal of the HQA is to identify a set of quality measures that would be reported by all hospitals, and accepted by all purchasers, oversight and accrediting entities, payers, and providers. The twenty-one measures currently reported on www.hospitalcompare.hhs.gov reflect recommended treatments for heart attack, heart failure, pneumonia, and surgical care improvement/surgical infection prevention.[2] The vast majority of the data required to support HQA measures is collected manually, even among hospitals with electronic medical records. A major barrier to electronic collection of the data required to measure quality, and therefore a barrier to the rapid expansion of measurement requirements, is the lack of standards for documentation, storage, and transmission of such data.

The Quality Alliance Steering Committee is a collaboration between the AQA and the HQA. The goal of the committee is to better coordinate the promotion of quality measurement, transparency, and improvement in care by considering how best to expand the scope, speed, and adoption of the work of AQA and HQA.

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[1] www.aqaalliance.org; George Isham, American Journal of Managed Care

[2] Under Section 5001 (a) of the Deficit Reduction Act (DRA) of 2005 (P.L. 109-171), hospitals who choose not to voluntarily report data to CMS for display on Hospital Compare lose 2% of their market basket adjustment for Fiscal Year 2007. Furthermore, the DRA lays the foundation for a nationwide Medicare hospital value based purchasing (VBP) program. Section 5001(b) of the DRA mandates that CMS propose a plan for a VBP-program for Medicare hospital services that could commence in FY 2009. The HQA measures are expected to be strongly considered for that program.

The National Quality Forum is a voluntary consensus organization which reviews and endorses quality measures and is a critical actor in helping to identify a set of common data elements across measure sets. Through their work with the Quality Alliance Steering Committee, the NQF has led efforts to harmonize measure definitions across settings and developers. Through its endorsement process, NQF also can apply criteria that reinforce the use of standardized data elements in measures to allow quality measures to be embedded in EHRs.

Value Exchanges are an expansion of current AQA pilot sites focused on facilitating use of quality data and promoting local quality improvement efforts.

The Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) Project is part of HHS' Value-driven Health Care Initiative which is based on the following four cornerstones announced in President Bush's Executive Order issued in August 2006: interoperable health information technology (health IT); transparency of price information; transparency of quality information; and the use of incentives to promote high-quality and cost-efficient health care. The Executive Order directs federal agencies, to the extent permitted by law, to share information with beneficiaries on the quality of services provided by doctors, hospitals, and other health care providers.

Recommendations

The Workgroup identified the following actionable recommendations to meet the specific charge.

1. **Automate data capture and reporting from electronic health records to support a core set of AQA clinician-focused and HQA quality measures.**

The Quality Workgroup sees opportunities to advance the use of the AQA and HQA measures and to lower the burden associated with manual data collection by accelerating the use of electronic health records to capture and transmit the data required to support the measures and by standardizing the claims data that can be used as a proxy for electronic health records data.

> **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 (HITSP) 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 (CCHIT) should develop appropriate criteria necessary to support the reporting of core sets of AQA and HQA measures in the next round of criteria development.

2. **Establish a unified framework and enhanced collaborations around gathering key data from care processes and delivering key information to providers to help drive improved care outcomes.**

Clinical decision support (CDS) and quality measurement are fundamentally interconnected and draw from the same evidence base. The former is a systematic process for ensuring that the right information gets to the right persons in the right manner to support optimal decisions and outcomes, and the latter is an assessment of the extent to which those outcomes are achieved. Today's clinical decision support tools are hampered by similar challenges as quality measurement; for example, the lack of standardized approaches for delivering key information into, and abstracting it from, the clinical workflows through which patient care is delivered.

The Quality Workgroup recognizes opportunities to approach performance measurement and improvement in a more integrated and effective fashion. For example, work is beginning in several initiatives to identify specific opportunities for delivering CDS into specific provider workflows to support improved performance in areas such as those targeted by AQA and HQA measures. These efforts could be accelerated, expanded, and coordinated to produce frameworks for determining how best to gather the data needed to determine which patients are eligible for specific care targeted by quality metrics.

These same frameworks could simultaneously be used to identify optimal strategies for helping providers know precisely what they need to do (and for whom) to ensure the highest quality care. Furthermore, shared models of clinical workflows underpinning concurrent performance measurement and CDS can help accelerate collaboration and results across a variety of performance measurement and improvement initiatives focused on targets such as AQA/HQA measures.

Recommendation 2.1: The expert panel convened by the Quality Alliance Steering Committee in Recommendation 1 should gather, synthesize and refine clinical workflow maps, focusing on care processes related to the 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.

3. **Enable data aggregation as needed to allow public reporting of quality measures based on comprehensive health care data that are pooled across payers and providers and merged, as appropriate, with other data sources while protecting privacy.**

Many measures require that data be collected from multiple sources to provide an accurate picture of performance. Data aggregation would support the measurement of care across episodes, and would help reduce the burden of reporting by capitalizing on comprehensive reporting of data one time, to then be used for multiple purposes. Data aggregation is required to support the uniform measure of quality across providers, and to provide consumers with useful information with which to make decisions.

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 non-clinical electronic data for quality measurement and timely reporting of results.

4. **Align quality measurement with the capabilities and limitations of health information technology.**

Development of quality measures and health information technology development are currently pursued independently of each other, yet the efficient and effective implementation of quality measurement and reporting systems is reliant upon the effective use of health information technology. The Quality Workgroup recognizes an opportunity to reduce the future burden of data collection for quality measurement purposes through increased collaboration and communication between developers of quality measures and health information technology vendors. The communication channels outlined in the following recommendations should be leveraged to ensure that HIT vendors are attuned to the data requirements of emerging quality measures, so that these data needs can be considered in subsequent systems development.

Recommendation 4.1: HHS, through the Centers for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ), 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 should coordinate 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.

These recommendations are supported by information obtained through research and testimony to the Quality Workgroup, which is contained in the supporting documents available at http://www.hhs.gov/healthit/.

Thank you for giving us the opportunity to submit these recommendations. We look forward to discussing these recommendations with you and the members of the American Health Information Community.

Sincerely yours,

Carolyn Clancy
Co-chair, Quality Workgroup

Sincerely yours,

Richard Stephens
Co-chair, Quality Workgroup

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Quality Workgroup
Recommendations

Carolyn Clancy
HHS/Agency for Healthcare Research and Quality

March 13, 2007

Workgroup Member List

Co-Chairs:

– Carolyn Clancy	HHS/Agency for Healthcare Research and Quality
– Richard Stephens	The Boeing Company

Members:

– Abby Block	HHS/Centers for Medicare and Medicaid Services
– Janet Corrigan	National Quality Forum
– Helen Darling	National Business Group on Health
– Anne Easton	U.S. Office of Personnel Management
– Nancy Foster	American Hospital Association
– George Isham	HealthPartners and AQA alliance
– Jane Metzger	First Consulting Group
– Susan Postal	Hospital Corporation of America
– Gerald Shea	AFL-CIO
– Barry Straube	HHS/Centers for Medicare and Medicaid Services
– Jonathan Teich	Brigham & Women's Hospital
– Phyllis Torda	National Committee for Quality Assurance
– Reed V. Tuckson	United Health Group
– Charlene Underwood	Siemens Medical Solutions and HIMSS EHR Vendor Association
– Margaret van Amringe	The Joint Commission
– Josie Williams	Quality and Patient Safety Initiatives

Office of the National Coordinator:
– Kelly Cronin

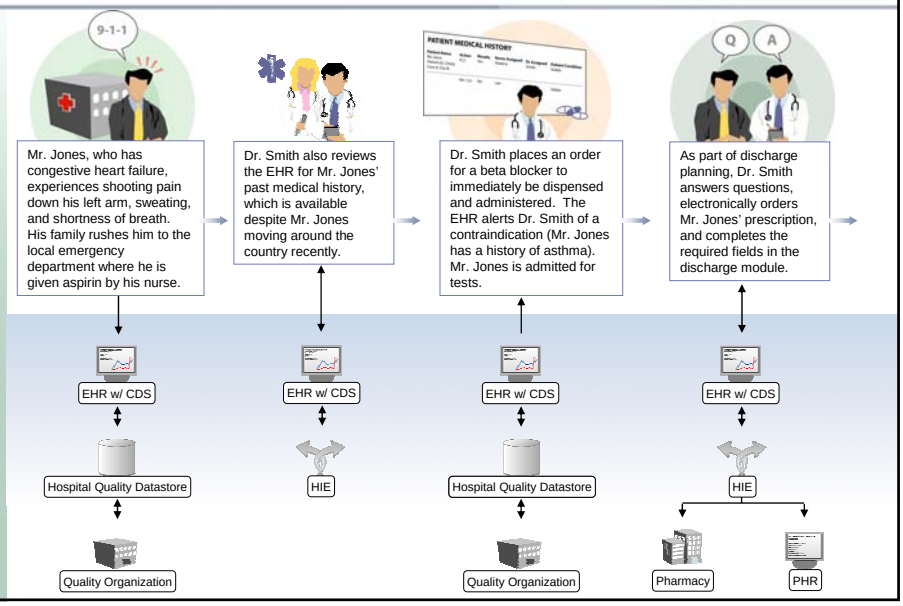
Broad Charge: What are we trying to accomplish?

Make recommendations to the American Health Information Community so that health IT can provide the data needed for the development of quality measures that are 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.

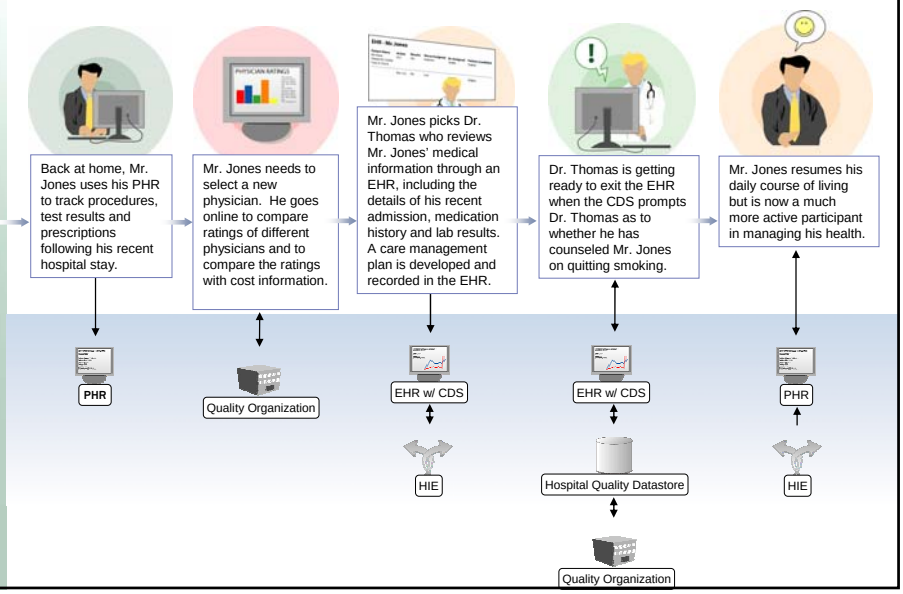
Specific Charge: What are we trying to accomplish?

Make recommendations to the American Health Information Community that specify how certified health information technology should capture, aggregate, and report data for a core set of ambulatory and inpatient quality measures.

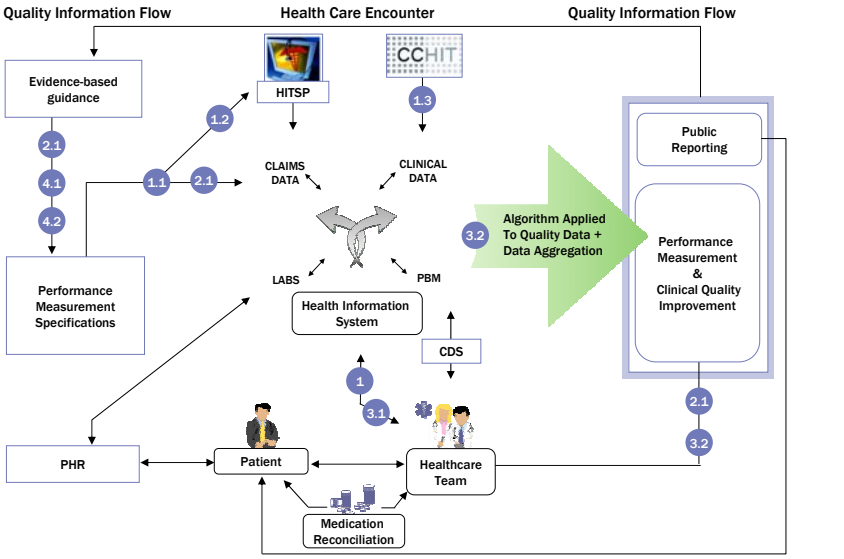
A Vision of the Future: A Patient's Perspective



A Vision of the Future: A Patient's Perspective



Flow of Quality Information



1. Automate data capture and reporting for core set of AQA/HQA measures

- **<u>Recommendation 1.1:</u>** 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.

1. Automate data capture and reporting for core set of AQA/HQA measures

- **Recommendation 1.2:** The Health Information Technology Standards Panel (HITSP) 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 (CCHIT) should develop appropriate criteria necessary to support the reporting of core sets of AQA and HQA measures in the next round of criteria development.

☐ **Accept** ☐ **Table** ☐ **Reject**

2. 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 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.

☐ **Accept** ☐ **Table** ☐ **Reject**

3. 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.

☐ **Accept** ☐ **Table** ☐ **Reject**

3. Enable data aggregation to allow public reporting of quality measures

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

☐ **Accept** ☐ **Table** ☐ **Reject**

4. Align quality measurement with the capabilities and limitations of HIT

- **Recommendation 4.1:** HHS, through the Centers for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ), 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.

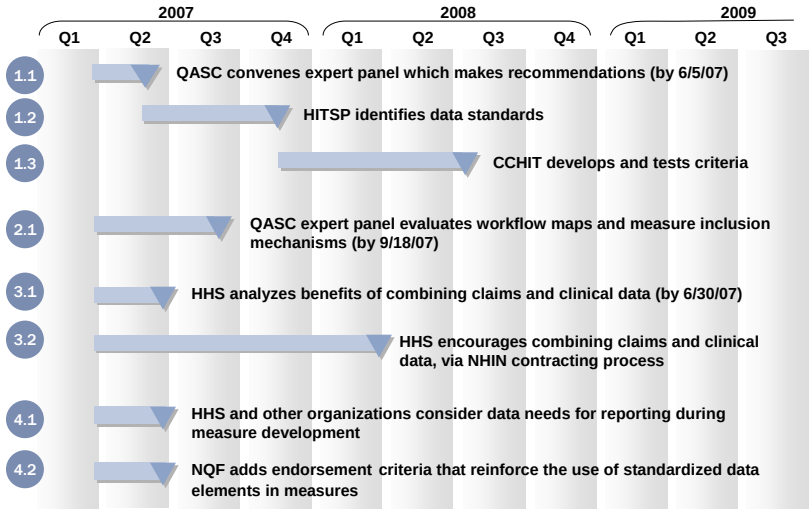
☐ **Accept** ☐ **Table** ☐ **Reject**

4. Align quality measurement with the capabilities and limitations of HIT

- **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.

☐ **Accept** ☐ **Table** ☐ **Reject**

Timeline of Quality Workgroup Recommendations



A Vision of the Future: A Patient's Experience

Mr. Jones, who has congestive heart failure, is having dinner with his family when he experiences shooting pain down his left arm, sweating, and shortness of breath. His family rushes him to the local emergency department. Immediately after triage, Mr. Jones receives an aspirin, as indicated by a nationally-endorsed inpatient clinical measure. Following triage, Mr. Jones is evaluated by Dr. Smith who records findings such as vital signs into a certified inpatient EHR. Updates to prescription medications are already included in the EHR through data exchanges with Mr. Jones' pharmacy. The EHR, which includes a robust Clinical Decision Support (CDS) system, prompts Dr. Smith as he continues with the patient's history and physical. The EHR highlights details of Mr. Jones's medical history, including a history of smoking, high cholesterol and asthma. Even though Mr. Jones has lived in several locations around the country over the past few years, Dr. Smith is able to view Mr. Jones' care and treatment history, including his medication management, because of an interoperable health information network. Dr. Smith places an order for a beta blocker to immediately be dispensed and administered. The computer quickly informs Dr. Smith that because of the patient's history of asthma, he is not an ideal candidate for beta blocker treatment.

The results from an electrocardiogram suggest that Mr. Jones suffered a mild heart attack, and Dr. Smith admits him to the hospital for observation and treatment. While Mr. Jones is being admitted, his daughter uses a computer located in the hospital's computer lab to educate herself on how this particular hospital and Dr. Smith have historically performed when treating heart attack patients. The information is presented in a clear and consumer-friendly format. The daughter is relieved that both the hospital and Dr. Smith have received high scores on standardized quality measures over the past several years. Information on cost is also available, and she is able to find out how much her father's tests and daily hospital stay will cost (assuming no additional complications).

After being properly admitted, Mr. Jones undergoes a series of diagnostic procedures, including laboratory tests and radiology tests, but is expected to be released the following afternoon. Before each test is administered, a resident working closely with Dr. Smith walks through the tests with Mr. Jones, explains why the test is being administered, what will happen, and how long it will take to receive the results. Mr. Smith has lingering questions and engages in an open dialogue with the physician who pulls up a picture of a heart on the computer next to Mr. Smith's bed and walks him through a variety of diagrams. Mr. Smith

feels much more comfortable now that he has a clear understanding of what happened to his heart.

The next morning, before going to the hospital to pick up her husband and meet with Dr. Smith, Mrs. Jones visits an endorsed web site for consumer information on cardiovascular disease. The web site is easily navigated and is full of valuable information including visual images. Mrs. Smith spends about one hour on the site, writing down questions that she has for Dr. Smith.

Upon arriving at the hospital, Mrs. Jones joins her husband in his hospital room. They talk about the tests he received. Mr. Jones relays the information he learned from the physician yesterday, and Mrs. Jones talks about the information she learned on the web site. Dr. Smith arrives, and reviews Mr. Jones' test results with him. Mr. Jones did in fact suffer a mild heart attack and has early signs of Coronary Artery Disease. Dr. Smith explains the treatment plan while entering it in the EHR system. He then asks the Jones' if they have any questions, and Mrs. Jones walks through her list. Dr. Smith spends some time answering the questions and officially discharges Mr. Jones. Dr. Smith electronically orders Mr. Jones' prescriptions, which will be ready for the Joneses to pick up at the pharmacy on the drive home. Mr. Jones is also instructed to schedule a follow-up appointment with a physician within the next two weeks.

Back at home, Mr. Jones uses a personal health record (PHR) to track the procedures, tests, results and medications following his recent experience. Before scheduling his follow-up appointment, Mr. Jones needs to select a new physician. He goes online to compare ratings of different physicians, especially scores on standardized performance measures on care and treatment of heart attacks. He also compares the ratings with cost information.

Mr. Jones goes for his follow-up visit with Dr. Thomas, who is part of a small physician practice. Although he has already reviewed the patient's medical information available through an EHR, Dr. Thomas takes the time to walk through Mr. Jones' electronic health record, including details of his recent admission, medication history and lab results to ensure the patient understands his diagnosis. He walks through the short-term treatment plan that Dr. Thomas prescribed and explains to Mr. Jones his recommended care management plan. The care management plan is developed and recorded in the EHR. Mr. Jones points out that he has been suffering from a few side effects from the medications he was prescribed upon his hospital discharge. Dr. Thomas looks up additional medication options on the computer, chooses one, and submits the order to Mr. Jones' pharmacy. In addition to changing Mr. Jones' medication, Dr. Thomas instructs him to focus more attention on his diet and exercise regime. Dr. Thomas also recommends a nutritionist and personal trainer, both of whom work closely

with his medical group. Dr. Thomas is getting ready to exit the electronic health record when it prompts him on whether he has counseled Mr. Jones on smoking cessation. Dr. Thomas provides education on smoking cessation and refines the care management plan accordingly.

Following his appointment with Dr. Thomas, Mr. Jones updates his PHR. Mr. Jones resumes his daily activities, feeling motivated to make some positive changes and fully engaged as an active participant in managing his health.

Mar 13, 2007

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

Dear Secretary Leavitt:

The American Health Information Community (The "Community"/AHIC), at the October, 2006 Community meeting, recommended that the scope of the Biosurveillance Workgroup be expanded to encompass the broader perspective of population health, and a corresponding name change to the "Population Health and Clinical Care Connections Workgroup" (PH/CCC). Population health is described using five interrelated domains: Public Health Surveillance and Response; Health Status and Disease Monitoring; Population Based Research; Population Based Clinical Care; and Health Communications/Education.

The recommendations in this document follow from the work of the Biosurveillance Workgroup and fall predominantly under the domains of Public Health Surveillance and Response, and Health Communications/Education. Future recommendations will be required to better address the remaining three domains. The Population Health and Clinical Care Connections Workgroup (PH/CCC) has the following broad charge:

Broad Charge for the Workgroup: 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.

The Workgroup's deliberations highlighted a number of key issues with respect to the broad charge:

- Public health agencies are not interconnected:
  - Only a small proportion can receive electronic data from clinical care or public health partners.
  - "Silos" of data exist in clinical and public health systems.
- The business case for data/information exchange between public health and clinical care is not well articulated and requires improvement.
- Public health programs are separated from information technology support in most states. This is at times compounded by a lack of emphasis on information systems to support public health activities.

This letter provides both context and recommendations for how these issues can be addressed to implement informational tools and business operations to support real-time nationwide public health event monitoring and rapid response management.

BACKGROUND AND DISCUSSION

The threat of significant naturally occurring or man-made health events is a critical issue for the nation. The ability to detect events rapidly, manage the events, and appropriately mobilize resources in response can save lives. The specific charge for the predecessor Biosurveillance Workgroup focused on transmitting key elements of clinical data to public health to provide a real-time view of the health of our communities. The broader charge of the enhanced PH/CCC Workgroup, building on the foundation established by the specific charge of its predecessor, supports real-time nationwide public health event monitoring and rapid response management across public health and clinical care.

The real-time nationwide public health event monitoring and rapid response management is addressed through four underlying priority areas. These priority areas were defined and ranked by the Workgroup based on an iterative process. The prioritization was followed by a visioning exercise to baseline the current state, and establish mid-state (by 2010) and end-state (2014 and beyond) visions for each priority area. The PH/CCC Workgroup defined and recommended the implementation order for the following priority areas:

1. Case Reporting
2. Bi-directional Communications
3. Response Management
4. Adverse Events Reporting

This letter includes recommendations that are overarching of all four priority areas, as well as more specific recommendations in the areas of Case Reporting and Bi-directional Communications. These recommendations are based on Workgroup input, and informed by a testimony on Case Reporting from the Council of State and Territorial Epidemiologists (CSTE).

In February 2007, the Workgroup began hearing testimony and deliberating on possible recommendations in the two priority areas of Response Management and Adverse Events Reporting.

RECOMMENDATIONS:

1. Overarching

The overarching recommendations are interrelated and targeted at establishing the basis on which specific public health use cases can be defined by HHS, prioritized by AHIC and applicable standards can be harmonized by the Health Information Technology Standards Panel (HITSP). An improved business case would provide the basis for articulating the benefits of automated data/information exchange between public health and clinical care. Public health standards for data exchange and vocabulary exist to varying degrees at the state, local and national levels, as do functional requirements for information systems that support public health activities. However, a next step is to articulate the need for public health standards in terms of use cases to be prioritized by AHIC and promoted for harmonization by HITSP. Harmonized

standards for public health would then inform certification of public health systems used at the local, state and national levels as well as certification of clinical care systems to address public health needs. The reliance on HITSP for standards harmonization necessitates that adequate resources be available; and recommendations are therefore included to identify public health resources to help build HITSP's capacity to harmonize standards for AHIC population health use cases. Finally, harmonized standards and nationally accepted standards in this domain must be made available through a centralized authoritative website. This website needs to be administered by a neutral party, but include processes to accept input and support collaborative discussion by multiple parties with varying interests.

Recommendation 1.0: The State Alliance for eHealth, 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 ASTHO, 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 eHealth, 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 website 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.

2. Case Reporting

Case Reporting is done at all levels of public health (local, state, and national levels). It is predominantly a passive activity that waits on physicians and laboratory staff to recognize a case and then know that it needs to be reported. Except for a limited number of conditions reportable by telephone (such as diseases of international concern, diseases caused by recognized bioterrorism agents, or cases associated with a known or suspected outbreak) reporting is typically manual and done by mail; therefore, it is not very timely. Currently, notifiable disease lists vary in accordance with law, interest, and surveillance capacity in each state, and disease reports are often not standardized across states. Exceptions to this include diseases for which there is federal funding tied to surveillance. Specific reporting is usually mandated in legislation at the state level, and clinicians are occasionally required by law to report to more than one public health agency, at times in different formats and at varying levels of detail.

In the long-term, it is envisioned that initial Case Reporting would integrate case criteria and reporting mechanisms into EHRs. These mechanisms should trigger recognition of a higher percentage of potential cases. For routine notifiable conditions, clinicians would be prompted to approve sending cases automatically to the appropriate local/state health departments, with anonymized case abstracts sent to the Centers for Disease Control and Prevention (CDC). This approach recognizes the traditional investigation roles at local and state public health levels and that local and state jurisdictions have lead roles in public health investigations. In the circumstance that parallel reporting to all levels of public health is necessitated, the methods, and types of data involved in parallel reporting, and policies governing parallel reporting, will be determined jointly by local, state, and federal public health officials.

This automation would result in significant reductions in the time it currently takes to achieve a full reporting cycle, decrease the time it takes to make a report, and increase the number of reports made. As EHRs become more prominent, public health will want to realize the benefits of a reduced reporting cycle and requests to exchange case reports electronically will become prevalent. EHR vendors will be challenged to automate case reporting if required to accommodate variations that currently exist in case reporting requirements from state to state.

The first step to facilitating automated electronic case reporting from EHRs is to standardize a common list of notifiable conditions required to be reported for use by all levels of public health. The next step is to establish case definitions for all reportable conditions that are standardized for use by each jurisdiction reporting that condition, and to determine the data elements to be included on each condition report. Additionally, terminology and defined formats for those data elements must be standardized to support electronic case reporting. Currently, CSTE and CDC have instituted an on-going process for defining the list of conditions reported by states to the CDC and the case definitions for these conditions do exist. This process provides a good candidate foundation on which to build the consistency needed to facilitate automated case reporting to all levels of public health.

The streamlining of case reporting requirements, to the extent possible, will enable EHR vendors to implement solutions that will work across jurisdictions rather than requiring customizations, or translation tools, to handle the variances that currently exist. Not only should this reduce complexity, but it should also result in cost savings for EHR vendors, to be carried over to those who are implementing EHR solutions.

The initial recommendations in this priority area are aimed at enabling automated, standardized case reporting and creating incentives for the adoption of standardized case reporting. A recommendation for harmonizing the standards to support notifiable disease reporting is included in recommendation 2.2, and includes defining the terminologies for standardized national case definitions. This recommendation complements recommendation 2.1, which is focused on defining the basic list of nationally notifiable conditions, their associated case definitions, and the data elements to be reported to public health. While the focus of recommendations in this section falls under automated case reporting, the Workgroup recognizes that the priority area of Case Reporting includes additional components that will become the focus of future efforts.

Biosurveillance would benefit from receiving data via Electronic Laboratory Reporting (ELR) to use as surrogates for initial disease information. Authorized public health investigations would be better enabled through electronic queries to clinical care, requesting details to determine risk factors, enable contact tracing, investigate exposure sources, and identify patients for treatment or prophylaxis. To summarize, the case reporting priority area includes:

- Automated case reporting from clinical care to public health.
- Providing information to clinicians for making diagnoses.
- Automated Electronic Laboratory Reporting that is integrated into case reporting and response.
- Reporting appropriate information to local, state and national levels of public health.
- Integrating with disease registries.

Future recommendations will consider those areas of the Case Reporting priority area not included in the recommendations below.

Recommendation 2.0: By April 30, 2007, CSTE, in collaboration with CDC, should define an on-going 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 Certification Commission for Health Information Technology (CCHIT) should include 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.

3. Bi-directional Communications

Bi-directional communication refers to the dissemination and interactive exchange of information, both horizontally and vertically, between the general public, clinical care entities, public health entities, and incident command entities. Communication modes include:

- e-mailing alerts
- collaborative technologies which are used for more discussion-like exchange
- web pages
- electronic exchange based on messaging standards (e.g., HL7 messaging)

Communications may vary from secure exchanges for a limited audience to more publicly available information. Both data and information are disseminated using the modes of communication listed above. In biosurveillance, for example, clinical care would provide case reports and clinical data to appropriate public health entities. Public health would derive information from multiple sources of data (e.g., clinical care, veterinary, FDA, environmental sources) and send this information to clinicians to assist them in decision-making. Public health

may provide a variety of communications such as health alerts, investigation findings, updates to case criteria, and guidelines for the general public. When appropriate, public health information would be shared with incident command entities that would then provide direction to all appropriate parties.

It is recognized that achievement of the future-state as described will require an iterative process beginning with clinically relevant first steps. The most likely candidate for those first efforts are case reporting by clinical care providers to public health followed by appropriate feedback from public health to clinical care providers. Even with a stepwise approach, it is anticipated that all levels of bi-directional communication will benefit from development using a common set of communication standards.

The recommendations for Bi-directional Communications are initial steps toward standardizing alerting, and the exchange of contact information among public health and clinical care. Alerts, in these recommendations, refer to a communication sent to appropriate, targeted audiences based on the nature of the event, the delivery time, the type of response required, the jurisdictions affected, the severity of the event, and the sensitivity of the information. Directories are needed to track contact information about people and organizations who receive communications. Contact information is regularly updated and therefore directories holding that information need to be exchanged among communications partners on a regular basis, in a standardized manner.

> **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.**

These recommendations are supported by information obtained through research and testimony to the Population Health and Clinical Care Connections Workgroup which is contained in the supporting documents available at http://www.hhs.gov/healthit/.

Thank you for giving us the opportunity to submit these recommendations. We look forward to discussing these recommendations with you and the members of the American Health Information Community.

Sincerely yours,

Charles N. Kahn III
Co-Chair, AHIC Population Health and Clinical Care Connections Workgroup

Sincerely yours,

John R. Lumpkin, MD, MPH
Co-Chair, AHIC Population Health and Clinical Care Connections Workgroup

Sincerely yours,

Julie L. Gerberding, MD, MPH
Co-Chair, AHIC Population Health and Clinical Care Connections Workgroup

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Population Health and Clinical Care Connections Workgroup

Recommendations

Charles Kahn, Federation of American Hospitals
John Lumpkin, Robert Wood Johnson Foundation
Julie Gerberding, Centers for Disease Control and Prevention

March 13, 2007

Workgroup Member List

- **Co-Chairs:**
  - Charles Kahn — Fed. of American Hospitals
  - John Lumpkin — The Robert Wood Johnson Foundation
  - Julie Gerberding — CDC
- **Members:**
  - Michael Barr — American College of Physicians
  - Scott Becker — Association of Public Health Laboratories
  - Larry Biggio — State of Wyoming
  - Art Davidson — Denver Public Health Department
  - Leah Devlin — NC Department of HHS
  - Thomas Frieden — NYC Dept. of Health and Mental Hygiene
  - Shawn Fultz — Department of Veterans Affairs
  - Shaun Grannis — Regenstrief
  - James Hadler — Connecticut Department of Health (CSTE)
  - Amy Helwig — Agency for Healthcare Research and Quality
  - Brian Keaton — American College of Emergency Physicians
  - Martin LaVenture — Minnesota DoH
  - John Loonsk — ONC/DHHS
  - Bob Martin — CDC/NCPHI
  - David Parramore — Department of Defense
  - Dave Ross — Public Health Informatics Instit
  - Lisa Rovin — FDA
  - Edward Sondik — CDC/NCHS
- **Office of the National Coordinator:**
  - Kelly Cronin
  - Laura Conn
  - Shu McGarvey

Broad Charge: What are we trying to accomplish?

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.

Recommendations - Overarching

- **Recommendation 1.0:** The State Alliance for eHealth, 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.

Recommendations – Overarching, cont.

- **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 ASTHO, 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.

Recommendations – Overarching, cont.

- **Recommendation 1.4:** By June 30, 2008, HHS, in collaboration with ASTHO, NACCHO, the State Alliance for eHealth, 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.

Recommendations – Overarching, cont.

- **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 website 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.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendations - *Case* Reporting

- **Recommendation 2.0**: By April 30, 2007, the Council of State and Territorial Epidemiologists (CSTE), in collaboration with CDC, should define an on-going 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.

Recommendations - Case Reporting

- **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 Certification Commission for Health Information Technology (CCHIT) should include requirements for flexibility in and certification criteria for automated case reporting of Nationally Notifiable conditions in electronic health records by 2009.

Recommendations - Case Reporting

- **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.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendations – 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.

Recommendations – Bi-Directional Reporting

- **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.

☐ **Accept** ☐ **Table** ☐ **Reject**

March 13, 2007

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

Dear Mr. Chairman:

The Confidentiality, Privacy, and Security (CPS) Workgroup is submitting this letter to the American Health Information Community (AHIC) as a follow-up to the patient identity proofing recommendations presented at the January 23, 2007 AHIC Meeting.

During this meeting, the CPS Workgroup presented five recommendations pertaining to patient identity proofing. The AHIC approved the first four recommendations and tabled the fifth recommendation. The original and revised recommendations are listed below.

Version Presented on January 23, 2007:

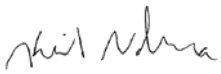
Recommendation 5: Where applicable, the Certification Commission for Healthcare Information Technology (CCHIT) should develop certification criteria for the systems and networks they certify to support the identity proofing practices in these recommendations.

Revised Version:

Recommendation 5: 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.

Thank you for giving us the opportunity to submit this revised recommendation. We look forward to discussing it with you and the AHIC Members.

Sincerely yours,



Kirk J. Nahra
Chair
Confidentiality, Privacy, and Security Workgroup

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Confidentiality, Privacy, and Security Workgroup Recommendations

Kirk Nahra, Wiley Rein LLP
Jodi Daniel, HHS/Office of the National Coordinator

March 13, 2007

Confidentiality, Privacy, and Security (CPS) Workgroup Member List

- **Chair:**
  - Kirk Nahra — Wiley Rein LLP
- **Members:**
  - Peter Basch — MedStar e-Health
  - Jill Callahan Dennis — Health Risk Advantage
  - Steven Davis — Oklahoma Department of Mental Health and Substance Abuse Services
  - Don Detmer — American Medical Informatics Association
  - Flora Terrell Hamilton — Family and Medical Counseling Service, Inc.
  - John Houston — University of Pittsburgh Medical Center, and National Committee on Vital and Health Statistics
  - Sam Jenkins — TRICARE Management Activity, Department of Defense
  - Susan McAndrew — DHHS/Office of Civil Rights
  - David McDaniel — Veterans Health Administration
  - Deven McGraw — National Partnership for Women and Families
  - Alison Rein — National Consumer League
  - Tony Trenkle — DHHS/Centers for Medicare and Medicaid Services
  - Paul Uhrig — SureScripts LLC
  - Thomas Wilder — America's Health Insurance Plans
  - Jodi Daniel — Office of the National Coordinator

CPS Workgroup Overview

Broad Charge:

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.

Specific Charge:

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.

Patient Identity Proofing Recommendation #5

***Version Presented on January 23, 2007*:**

Recommendation 5: Where applicable, the Certification Commission for Healthcare Information Technology (CCHIT) should develop certification criteria for the systems and networks they certify to support the identity proofing practices in these recommendations.

***Revised Version*:**

Recommendation 5: 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.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation Implementation Suggestions

We suggest that these recommendations, if accepted by the AHIC, be considered by the Department of Health and Human Services (HHS) for adoption as HHS policy regarding current and future activities, including appropriate federal contracts, and pilot and demonstration projects as they relate to the specific Workgroup charges listed above and their broad charges where appropriate. Furthermore, it is the Workgroup's intention that these recommendations apply more broadly to the health care system, and that public and private sector organizations would parallel HHS in their implementations.

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Privacy and Security Panel
Privacy and Security Framework

Jodi Daniel, HHS/Office of the National Coordinator
Susan McAndrew, Office of Civil Rights

March 13, 2007

The Intersection of Health IT and HIPAA

- HIPAA as a baseline and a foundation for protection
- Privacy and security risks may change as opportunities for data sharing increases
- Health IT presents new challenges and opportunities
  - Non-covered entities (e.g., some PHRs, health information exchanges)
  - New roles and capabilities for consumers
  - Opportunities for additional clarity and/or guidance
- HIPAA issues being raised by Privacy & Security Solutions Contract

Technology and Policy

- Need to be developed in concert
- Flexible technology for future policy options
  - NHIN trial implementations
- Incremental strategy that will develop over time
  - Health information protection is at the core
- Health IT will enable consumers with new ways to manage their health data
  - May include new capabilities to control the flow of their health information

Collaborative Activities to Advance Privacy & Security

Current Activities

✓ Privacy and Security Solutions for Interoperable Health Information Exchange
- 34 states & territories identified variations in privacy and security policies and practices
- Solutions & implementation plans being developed to address the variations identified

✓ NCVHS privacy and security recommendations for the NHIN

✓ Identity proofing recommendations by AHIC advanced to HHS

✓ NHIN Prototype Security Architectures

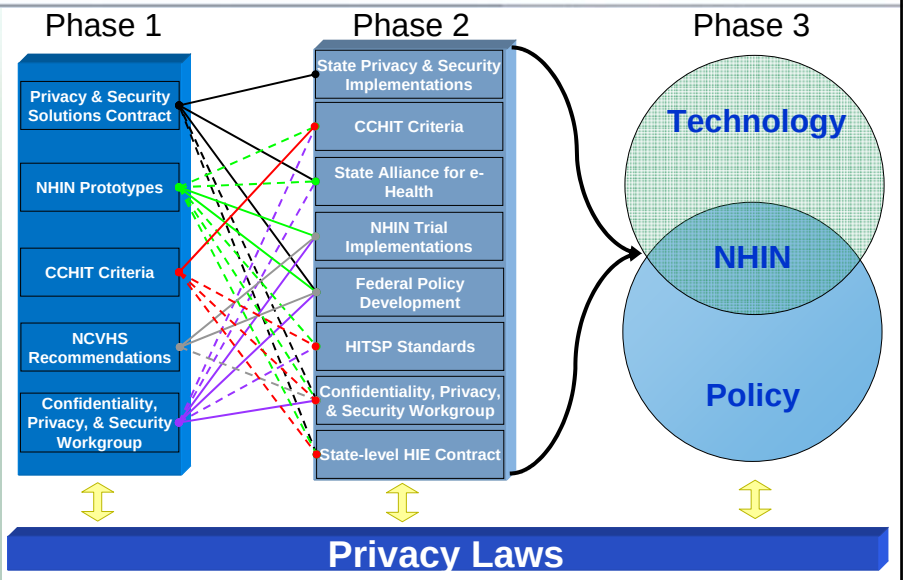
✓ CCHIT Security Criteria

Collaborative Activities to Advance Privacy & Security, cont.

Planned Activities

- ❑ Final deliverables from Privacy and Security Solutions contract
- ❑ State Alliance – Health Information Protection Taskforce
- ❑ State Privacy and Security Implementations
- ❑ HIPAA Guidance on exchanging data with PHRs
- ❑ HITSP to advance security standards
- ❑ NHIN – consumer capabilities
- ❑ State-level health information exchange best practices/guidelines

Privacy and Security Activities



Department of Health & Human Services
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Privacy and Security Panel

Privacy & Security Solutions for Interoperable Health Information Exchange

Linda Dimitropoulos
RTI International

March 13, 2007

Progress Since June 2006 Briefing

- State Project Teams completed training in the conduct of the assessment of variation and the use of the National Resource Center portal (June-July)
- OMB Clearance to Conduct the Assessments (August)
- 10 Regional Meetings (43 states participated)
- Interim Reports
  - Assessment of Variation (November 2006)
  - Analysis of Solutions (January 2007)
  - Implementation Plans (February 2007)
- National Meeting (March 2007)

Progress Since June 2006 Briefing (continued)

- National Meeting (March 2007)
  - Day 1: 4 Tracks
    - Consent
    - Data Security and Quality
    - Legal and Regulatory Issues
    - Interpreting and Applying HIPAA
  - Day 2: 4 Tracks
    - Reducing Mistrust through Education and Outreach
    - Moving Forward in States at Different Points in the Process
    - Governance and Implementation
    - State Legislation and Business Policies

Sources of Variation

- Variation Related to Misunderstandings and Differing Applications of Federal Laws and Regulations
  - HIPAA Privacy Rule
    - Patient Authorization/Consent
    - Variation in Determining "Minimum Necessary"
  - HIPAA Security Rule
    - Confusion regarding the different types of security required
    - Misunderstandings regarding what was currently technically available and scalable
  - CFR 42 part 2
    - Variation in the treatment facilities', physicians', and integrated delivery systems' understanding of 42 C.F.R. pt. 2, its relation to HIPAA, and the application of each regulation

Sources of Variation (continued)

- Variation Related to State Privacy Laws
  - Scattered throughout many chapters of law
  - When found, it is often conflicting
  - Antiquated--written for a paper-based system
- Trust in Security
  - Organizations
  - Consumers/Patients
- Cultural and Business Issues
  - Concern about liability for incidental or inappropriate disclosures
  - General resistance to change

Interim Solutions

- Four major categories:
  - Practice and Policy Solutions
    - Adopt a Uniform Consent Policy
  - Legal and Regulatory Solutions
    - Modify state statutes to resolve differences regarding *when* and *how* patient consent is obtained and documented
  - Technology and Data Standards
    - Standard data format to document consent that recognizes the differing state-based consent policies, laws and regulations yet promotes normalization and interpretation
  - Education and Outreach (organizations and consumers)
- Multi-state and National Level Recommendations

Implementation Plans

- Document practical approaches and actionable steps for implementing solutions
  - Actions
  - Governance and Leadership
    - Realignment of teams
  - Resources required
    - Funding
    - Staffing
  - Timelines

Next Steps

- Final Assessment of Variation and Analysis of Solutions Reports (March 30, 2007)
- Final Implementation Plans (April 16)
- Nationwide Summary (June 30, 2007)

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Privacy and Security Panel
Health Information Security and Privacy Collaboration (HISPC)

Rex E. Gantenbein
State of Wyoming

March 13, 2007

Planning process in Wyoming

- Variations were identified through small workgroups and individual conversations with a variety of stakeholders
- Solutions were proposed by stakeholders after reviewing Variations Report
  - Focus was on incremental steps that would reform business practices at the state level
  - Stakeholders were adamant that the project should lead to action and not “another report on the shelf”
- Implementation plans were developed at a core stakeholders meeting
  - Will be vetted at a statewide security and privacy symposium in late March

Variations identified in Wyoming

- Inconsistent and incorrect interpretation of HIPAA
  - No authoritative interpreting body exists
  - Smaller facilities lack resources to interpret law
  - Fear of legal reprisal for wrongful disclosure engenders conservative practices
- 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
  - Most providers resist centralized or mandated systems
- Outdated state statutes inhibit exchange of health information
  - Recently passed “credit freeze” laws protect financial information, but do not specifically address health information
  - Existing health privacy laws only apply to in-patient facilities

Proposed solutions

- HIPAA interpretation => establish an HIE research and policy coordinating center for Wyoming
  - Analyze, clarify, and communicate legal and technical issues
  - Provide education and training
- Lack of infrastructure => create an HIE pilot project
  - Develop an interface mechanism for information exchange among disparate systems
  - Demonstrate benefits and trustworthiness of HIE to providers and consumers
- State statutes => generate changes in state law
  - Extend protection and notification laws to health records
  - Review and update several statutes to assure consistency
  - Address other specific needs such as high-risk juveniles

Implementation plans

- HIE research and policy coordinating center
  - Wyoming Health Information Organization (WyHIO) will house and facilitate establishment of the center
  - Initial tasks
    - Appoint an advisory board to determine mission
    - Develop a business plan and seek funding
      - State support
      - Membership model (Utah Health Information Network)
  - Goals
    - Provide consistent and clear interpretations of HIPAA, particularly for small rural facilities without legal advisors
    - Act as a non-vendor advocate for HIT
    - Support multidisciplinary research and education

Implementation plans

- HIE pilot project
  - WyHIO will also be responsible for this project
  - Initial tasks
    - Complete a preliminary network design and a basic application area (medications, trauma or secondary/specialty care)
    - Identify funding sources (a bill in 2007 Wyoming Legislature that proposed $4,000,000 for a project died in committee)
    - Contract with a developer to create a prototype
      - Work with existing or developing EHR systems
  - Goal: demonstrate feasibility of non-centralized HIE and build trust among providers and consumers

Implementation plans

- State statutes
  - Work with legislator and attorney stakeholders to draft changes and/or enact new bills for 2008 Wyoming Legislature
    - Create a health information privacy law requiring notification of all consumers affected by a compromise of health records
    - Update Wyoming Hospital Records and Information Act and Wyoming Public Records Act to address inconsistencies with HIPAA and each other
      - Will require a study to evaluate laws and effects of change
    - Create a health information exchange act to define who is allowed to share information about juveniles, particularly in high-risk situations or matters of public health/safety

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Privacy and Security Panel
Health Information Security and Privacy Collaboration (HISPC)

William J. O'Byrne
State of New Jersey

March 13, 2007

INTRODUCTION

- HINT = NJ Health Information Electronic Data Interchange Technology Act
- HISPC and NPI Groups--Same committed individuals and business entities, including:
  - Governor Thomas Corzines' office
  - Thomas Edison State College
  - NJ DOHS & NJ DOHSS
  - Horizon BCBS
  - NJ Hospital Association and all major trade groups
  - NJ University of Medicine and Dentistry
  - NJ Business and Industry Association
  - New Jersey Manufactures Insurance Companies

IDENTIFICATION of the PATIENT

- NJ State and Regional Master Patient Index [MPI]
  - Unique ID
    - Cross walked to legacy numbers
  - Assigned:
    - At birth
    - At hospital / ED admission
    - Upon patient request
  - Goal: reliably link each NJ patient with their health care record
  - Opt-out permitted
    - No longer part of EHR /RHIO
    - Payment may be delayed

IDENTIFICATION of the PATIENT

- NJ Legislature Hearings on MPI, EHRs, RHIOs
  - HIMSS Article, *Business Process Optimization for RHIOs* states a Master-Patient Index is one of 14 necessary foundation blocks for a RHIO to interoperate, Volume 21, Number 1, Winter 2007
- Health ID Cards with Bar Coding or Electronic Strip
  - Similar to driver's licenses and credit cards
  - Patient name and MPI number
    - Include charity and Medicaid patients
  - Solve data problems, including
    - Incomplete data
    - Misdirected data
    - Incorrect data

LEGAL AND POLICY ISSUES

- Understanding and Resolving Legal and Policy Issues, *especially consent management and sensitive data controls*
- One of the major barriers found in the NJ-HISPC project, and know that this is also a major barrier for other HISPC projects and other state work:
  - NY-HISPC asked NJ-HISPC to work together at the RTI National meeting
  - NJ DOBI work with MD Healthcare Commission
  - NJ-HISPC and MA-HISPC sharing information, ideas, and conclusions
  - NJ-HISPC phone conversations with WA, FL, NC, PR
  - NJ-HISPC phone conversations with RTI HISPC Advisory Committee
  - RTI webex meetings
  - NJ Projects
    - South Jersey – EMR Exchange
    - NJ PreHIO

CONSENT MANAGEMENT & SENSITIVE DATA CONTROLS

- Federated Design Model
  - The Plan = public service type entity
  - Custodian and gateway
  - Web Portal
  - Akin to a credit reporting agency
  - Part of NJ-HISPC Interim Implementation Planning Report
  - Being discussed with major NJ-HISPC stakeholders
  - NJ's AHRQ ambulatory grant proposal

CONSENT MANAGEMENT & SENSITIVE DATA CONTROLS

- Planned Functionality
  - Back state law and regulations for patient consent and sensitive data into the technology solution
  - Core EHR content developed
  - Ordering medical tests
  - Opt out capability
  - Standard HIPAA Business Associate Agreement document
  - Authorization, Access, Audit and Disclosure standards
  - RHIOs will need to be accredited under NJ DOBI administrative rules

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Privacy and Security Panel
Health Information Security and Privacy Collaboration (HISPC)

James I. Golden
State of Minnesota

March 13, 2007

Privacy Barriers to HIEs

- Implementation of Minnesota's Patient Consent Requirements
  - Patient consent required for nearly all disclosures of health records – **including treatment**
    - Patients need to give written consent
    - Consent generally expires within one year
    - Limited exceptions to consent
      - Medical emergency
      - Within "related" health care entities
    - Consents that do not expire
      - Disclosures to providers being consulted
      - Disclosures to payers for payment

Liability for Inappropriate Disclosures

- 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
- Providers are very cautious in disclosing data and respond to privacy/security concerns by not disclosing patient data

Patient Consent - Variations and Barriers

- Minnesota's patient consent requirements cause a barrier to the electronic exchange of health information because:
  - Health care providers cannot agree on **"when"** and **"how"** patients are required to exchange their health information
  - Minnesota's requirements were designed for paper-based exchanges and are not conducive to a real-time, automated electronic exchange

Causes of Patient Consent Barriers

- **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

Generating Solutions

- A workgroup of industry representatives and privacy advocates did not reach consensus on a set of best solutions
  - Identified options
  - Documented advantages and disadvantages for each option
  - Connected related options
- MDH developed criteria for evaluating options:
  - maintain or strengthen patients' privacy or control over their health records
  - improve patient care
  - facilitate electronic, real time, automated exchange
  - not place an undue administrative burden on the health care industry
  - increase the clarity and uniform understanding of the statutory language and consent requirements

Legislative Solutions

- **10 Statutory Modifications for Legislative Consideration**
  - Clarify undefined terms and ambiguous concepts:
    - Define “Health Record”
    - Define “Medical Emergency”
    - Define “Related Health Care Entity”
    - Clarify “Current Treatment”
  - Apply consent requirements to new concepts:
    - Introduce and define “Record Locator Service”
    - Introduce and define “Identifying Information”
    - Apply consent requirements to a Record Locator Service

Legislative Solutions (cont)

- **10 Statutory Modifications for Legislative Consideration**
  - Update mechanisms that facilitate the electronic exchange:
    - Create ability of a provider to rely on another provider’s representation of having obtained consent
    - Develop a legal framework for allocating liability between disclosing and requesting providers
    - Permit representation of consent to be transmitted electronically when requesting patient information
  - Recodify Minnesota’s patient consent statutes to make the requirements easier to understand for patients and health care providers

Thank you - Questions

Key Contacts for More Information:

www.health.state.mn.us/e-health/mpsp

Minnesota Department of Health

Jim Golden, PhD

Director, Division of Health Policy

651.201.4819

james.golden@health.state.mn.us

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Employer Panel

Andrew Croshaw, Moderator, HHS/Planning & Evaluation
Peter V. Lee, Pacific Business Group on Health
Jeffrey Rideout, Cisco Systems, Inc.
Chris Nohrden, IBM

March 13, 2007

CISCO

Employers Driving Healthcare: Does It Help Activate Consumers?

Jeff Rideout, MD, MA, FACP
Chief Medical Officer, Cisco Systems
(acknowledgement to P. Hymel, MD, Cisco Health and Wellness Medical Director)

March 13, 2007

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Healthy (vs. sick) employees are:

- **22 percent** less likely to get injured on the job
- **38 percent** less likely to miss work
- **74 percent** more engaged when they are at work

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CISCO

FORTUNE 100 BEST COMPANIES TO WORK FOR 2006 Hall of Fame

- 45K+ employees in 80 countries; 20K at corporate headquarters in San Jose, CA
- Average 5 years length of service; 93% retention rate
- 33% engineering/IT, 33% sales, 33% all others
- All connected to common internet tools
- Nearly all are Cisco shareholders
- Average age of Cisco employee is 38
- 18% of employees drive 81% of cost
- Generous benefits, modest cost sharing

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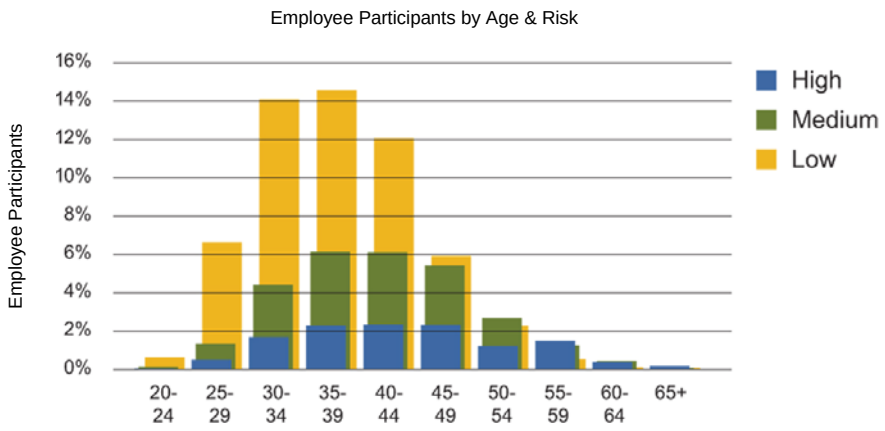
Most Cisco employees have low health risks…



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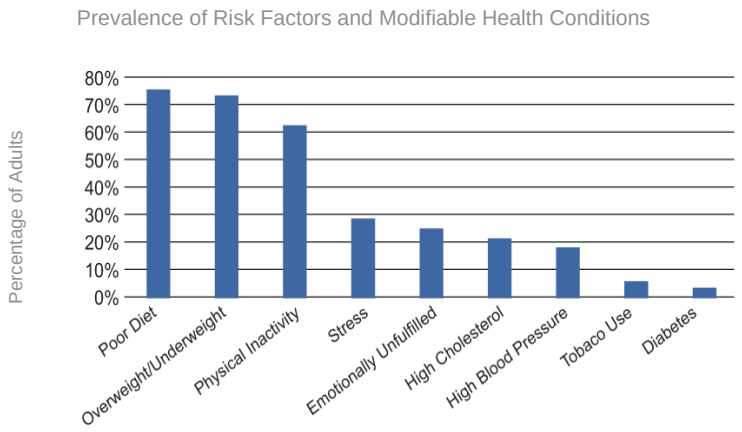
.. but have real health issues



Source: Cisco results obtained from WebMD based on HRA participants

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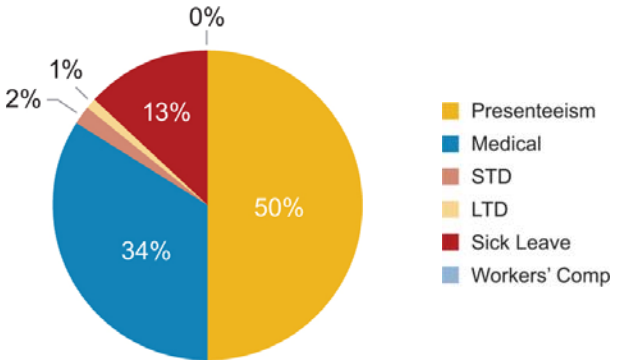
Lost productivity costs much more than direct medical costs

2005 health and productivity program costs



2005 gross health & productivity cost totaled $619.2 million

[1]Source: 2005 Cisco paid and incurred reports; LTD and WC results include reserves for claims incurred in year

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Gibson:IBSG,7

Strategic Initiatives for 2007

- Medical plan RFP- consumer focused options
- Integrated Health Management program-Wellness Advocacy
- Health Incentive Accounts
- Promotion of healthcare information technology for clinicians caring for Cisco employees
  - secure messaging
  - Health IT Pay for Performance
- Integrated Disability Management program
- Increase health assessment incentive
- Onsite clinic and fitness center

health connections
Take Charge. Be Well.

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Gibson:IBSG,8

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Cisco-PAMF pilot proves the value of secure messaging

- 87% reported spending less time away from work; strong preference for communicating in this way
- Speedy direct access to physician perceived as major benefit
- Employees avoided office visits, reducing company's benefit costs by $14,536 in first year
- Secure messaging had positive impact on employee productivity, saving company $126,704
- ROI estimated to be greater than 4:1
- Pilot extended for another year; opened enrollment to all employees and dependents

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SVHIT - Pay for Performance Links Employers and Providers

- Collaborative effort started by employers in 2005
- Selection based on highest volume practice sites for Cisco, Intel, and Oracle employees in Silicon Valley
- 10 IPAs and multi-site medical groups invited--7 participating first
- Incentives based on the NCQA Physician Practice Connections (PPC) 2006 standards
- Each employer paying maximum of $50K to each qualifying group
- Cigna also adding to rewards

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Impact-Preliminary Results

- 23 of 25 practices in the 7 groups have passed PPC; 2 currently under evaluation; more than 1,700 individual physicians recognized by NCQA
- PPC recognition also counts toward California IHA P4P IT measures
- SVHIT became Bridges to Excellence site; Cisco executive now on BTE board
- Employer and medical group coalition focuses on improving care; next step is possible sharing of Rx data
- Coalition may add employers and/or medical groups

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Employers as Health and Wellness Providers

The New York Times

NEW YORK, JANUARY 24, 2005

Company Clinics Cut Health Costs

By MILT FREUDENHEIM

"Frustrated by runaway health costs, the nation's largest employers are moving rapidly to open more primary care medical centers..."

"...they are looking for any solution, " said D.W. Edington, director of the Health Management Research Center at the University of Michigan. "One option is to find ways to take care of people before they get sick."

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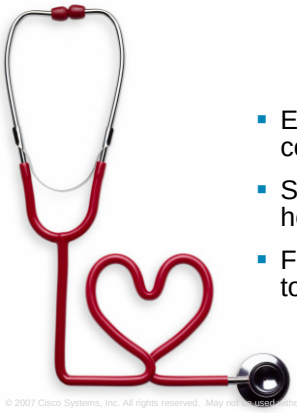
LifeConnections: Creating a New Model



- Change the health management experience for employees
  - Customized services and location
  - Online processes and transactions
  - Electronic health management tools
  - Health coaching
  - Wellness programs tied to fitness center
- Enable cost-efficient, convenient care; reduce benefit costs and increase productivity
- Showcase Cisco technology and interoperability in a healthcare environment
- Further distinguish Cisco in attracting and retaining top hi-tech talent

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