The Community

American Health Information Community

July 29, 2008
8:15 a.m. - 1:30 p.m.

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

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July 29, 2008

8:15 a.m. - 1:30 p.m. (EDT)

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

8:15 a.m. **CALL TO ORDER –** *Secretary Leavitt*

8:20 a.m. **Introductory Comments** – *Secretary Leavitt*

8:25 a.m. **Comments –** *Kerry Weems, Vice-Chair, Acting Administrator, Centers for Medicare & Medicaid Services*

Comments – *Robert M. Kolodner, National Coordinator for Health IT*

8:30 a.m. **The Evolving Landscape of Products and Approaches that Consumers May Use to "Mobilize" (Access, Use, and Share) Their Personal Health Information – Consumer Perspective**

- *Nancy Davenport-Ennis, Chair, Consumer Empowerment Workgroup*
- *John Moore, Chilmark Research*
- *Carol Diamond, Markle Foundation*
- *Jeffrey Blair, Lovelace Clinic Foundation*

9:30 a.m. **The Evolving Landscape of Products and Approaches that Consumers May Use to "Mobilize" (Access, Use, and Share) Their Personal Health Information – Industry Perspectives and Approaches**

- *Andrew M. Wiesenthal, MD, SM, The Permanente Federation*
- *Jerry W. Bradshaw, Arkansas Blue Cross Blue Shield*
- *William Crawford, Children's Hospital Boston, representing Dossia*
- *Sean Nolan, Health Solutions Group, Microsoft*

10:30 a.m. **BREAK**

11:00 a.m. **AHIC Standing Committee of the Whole: Successor**

- *John Glaser, Partners HealthCare Systems*
- *Lillee Gelinas, VHA, Inc.*
- *Janet Marchibroda, eHealth Initiative*

12:00 p.m. **Supplemental Priority Development Pathway for Clinical Research Applications of Electronic Health Information**

- *Gregory Downing, Office of the Secretary*
- *Rebecca Kush, Clinical Data Interchange Standards Consortium (CDISC)*
- *Kenneth Buetow, National Cancer Institute, National Institutes of Health*
- *Greg Simon, FasterCures*
- *Amy Miller, Personalized Medicine Coalition*

12:45 p.m. **Health IT Strategic Plan**

- *Robert M. Kolodner, National Coordinator for Health IT*
- *Charles Friedman, Deputy National Coordinator for Health IT*

1:15 p.m. **Public Comment**

1:30 p.m. **ADJOURN**

Meeting Report

American Health Information Community
June 3, 2008

The American Health Information Community (the Community), 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 22nd meeting on June 3, 2008, at the Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW, Washington DC 20201.

The purpose of the meeting was to bring together Community members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to the Department of Health and Human Services (HHS) on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting focused on: (1) an AHIC 2.0 successor update; (2) comments from the Office of the National Coordinator for Health Information Technology (ONC) on accelerating interoperability; (3) an update from the Healthcare Information Technology Standards Panel (HITSP); (4) an update from the Certification Commission for Healthcare Information Technology (CCHIT); (5) a discussion on Community interoperability priorities; (6) recommendations from the Personalized Healthcare Workgroup; (7) an update from the State Alliance for e-Health/National Governors Association; and (8) a presentation on defining key health information technology terms.

HHS 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 two-year terms.

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

Call to Order

Joining Secretary Leavitt around the table were:

S. Ward Casscells, Assistant Secretary for Health Affairs, Department of Defense (Mr. Casscells was also represented by Celia Quivers, Deputy Chief Information Officer for Health Care Strategies, Military Health System, Department of Defense)

Brian DeVore, Industry Affairs Manager for Intel's Digital Health Group (Mr. DeVore represented Craig Barrett, PhD, Chairman of the Board, Intel)

Cita Furlani, Director of the Information Technology Laboratory, National Institute of Standards and Technology's Information Technology Laboratory, Department of Commerce (Ms. Furlani was also represented by Lisa Carnahan, Information Technology Laboratory, National Institute of Standards and Technology)

Lillee Smith Gelinas, RN, MSN, FAAN, Vice President and Chief Nursing Officer of VHA, Inc.

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention (also represented by Dr. Leslie Lenert, Director, National Center for Public Health Informatics, Centers for Disease Control and Prevention)

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

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

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

Kevin Hutchinson, At-Large Community member, President and CEO, Prematics

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

Mike Kaszynski, Policy Analyst, Office of Personnel Management (Mr. Kaszynski represented Linda Springer, Director of the Office of Personnel Management)

Robert Kolodner, MD, National Coordinator for Health Information Technology

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

Kerry Weems, Acting Administrator, Centers for Medicare and Medicaid Services, and Vice-Chair, the Community

Introductory Comments

Secretary Leavitt acknowledged that he is anxious to protect the progress that the Community has made by ensuring that AHIC 2.0—now referred to as A2—is created as a self-sustaining organization that will continue to go forward after his term (with 231 days remaining as of the date of this meeting) expires. It is critical that A2 be held accountable to measurable progress on the interoperability agenda.

Secretary Leavitt then updated the Community on the Electronic Health Record Demonstration, which provides a strong financial incentive for providers to use certified EHRs to improve the quality of care that patients receive. The demonstration focuses on small to medium-sized practices where adoption is typically at its lowest, yet where most Americans receive their care. At the May 17 deadline, 30 applications had been received, which will be whittled down to 12 communities that will be selected for the demonstration (an announcement on the selected communities was expected the week following this meeting). Those 12 practices will ultimately bring 1,200 practices into the demonstration—it is expected that this will amount to 3.6 million Americans who are part of those practices.

Secretary Leavitt also discussed a second effort underway at HHS, a new proactive surveillance capacity being built at the U.S. Food and Drug Administration (FDA). The project, called Sentinel, profoundly increases FDA's capacity to monitor the safety of drugs and other medical products once they are on the market. The Sentinel Project will allow the FDA, for the first time to be able to query electronic data proactively to discover adverse effects as they occur. By linking Medicare's data on hospital-based treatments with prescription drug information, Medicare will be able to see a broad picture of a patient's

health and treatment. Secretary Leavitt summarized that it will be possible to understand what events are leading to the hospitalizations that Medicare beneficiaries are experiencing, and what drugs may be preventing them. Sentinel will be launched in less than one month with Medicare data.

Dr. Kolodner announced that the *ONC Coordinated Federal Health IT Strategic Plan* was released on the same day as this meeting. Community members were given a copy of the Plan, which also is available online. The Plan was developed as a collaborative effort among all the relevant federal agencies that have to do with healthcare and IT. The Plan has two goals. One is healthcare-related, both from the provider and the individual side. The other is population health-related and includes public health, biomedical research, quality improvement and emergency preparedness. Instead of having one plan for health care and one plan for population health, as the Community has done with its standards and the activities, this plan connects the two, so that if data are being generated for health care, the *ONC Coordinated Federal Health IT Strategic Plan* is intended to ensure that such data can be used to meet population health needs while protecting the privacy of individuals and being handled in a secure manner.

Dr. Kolodner suggested a further discussion of the *ONC Coordinated Federal Health IT Strategic Plan* at the next Community meeting.

Approval of April 22, 2008, Meeting Minutes

Minutes from the April 22, 2008, Community meeting were distributed, reviewed by Community members, and approved unanimously with no changes.

AHIC Standing Committee of the Whole: Successor

Dr. Mark McClellan, Director of the Engelberg Center for Health Care Reform at the Brookings Institution, indicated that the initial phase of the A2 convening process is concluding; the findings and recommendations will be announced at a public meeting on the day following this Community meeting. That announcement will bring to the end phase 1 of the convening process, and phase 2 will begin, which will lead to setting up an organization to embody the recommendations that came out of the phase 1 process.

Results from the phase 1 process indicate that the successor organization cannot be sustained by dues alone. Instead, there must be a clear and sustainable business model through which public and private partners can drive practical and relevant standards identification as well as standards harmonization. The design for such an organization, which will be discussed in more detail at the public meeting, includes the work of many experts collaborating to create the model in a short time period. The work was organized into four planning groups that included approximately 80 leaders from throughout the health care community representing a very broad range of stakeholders, including consumer perspectives. All together, the effort included more than 1,600 volunteer hours over the last several months and resulted in an organization intended to build on the strengths of the current Community body, while expanding the forum into one that involves continuing broad private-sector participation and that sustains credibility among public and private-sector stakeholders.

Dr. McClellan indicated that the successor is going to be a public-private "membership organization of organizations." It will be empowered to make decisions through a board and committee structure, and will be partially funded through dues as well as through a funding model that focuses on added value from the activities of the organization. There will be a process through the A2 structure for stakeholders

to engage in priority setting focused around value cases and the mechanism for building out a long-term business plan. The longer term activities of the organization will be determined by what have been called "value cases." This term reflected the input obtained from a number of sources that urged A2 conveners to refer to a combination of a use case and business case, with a focus on measuring value to the broad stakeholder community. This includes the recognition that for sustainability, this organization will have to mobilize sufficient financial resources on its own to support its activities, but at the same time, because it is intended to be a broad-based organization, it must solve problems that are relevant to all of the stakeholders in the health care community. A2 will have a business case that can get the endorsement and support of a broad range of groups, including consumers and other industry organizations.

Dr. McClellan noted that this approach is intended to stimulate collaboration across industry sectors so that stakeholders recognize and take advantage of the kinds of affinities that can exist through health IT—interoperability, harmonization, and effective adoption—to have public benefit for a broad range of stakeholders. The A2 conveners are recommending that the Community successor create a priority-setting process that is based on a health care information roadmap, which will serve as the evolving map of the nationwide activities that the organization is going to undertake. This roadmap will be developed during phase 2 of the convening process.

A key characteristic of this policy-setting process is that priority decisions will be made by broad stakeholder representation, but funding for the priority initiatives comes from the constituents who have the greatest stake and the greatest ability to support the efforts. Dr. McClellan explained that this priority-setting process can be thought of as a cycle, modeled on the current cycle of Community Workgroup recommendations, use case development, and harmonization, but one that is specifically designed to engage the health care community in a unified process is which a structured framework and criteria are used to evaluate and select use cases and turn them into value case applications. The intention of this emphasis on reflecting value priorities is to minimize any possible complications related to sustainability or broad-based support during the transition and during the key formative months by assuring that the activities are going to have broad-based stakeholder support, and that the specific activities can be sustained financially.

Dr. McClellan emphasized that this approach also incorporates the role of the government in recognizing interoperability specifications, such as those products that come out of HITSP harmonization. In particular, is has been recommended that only HITSP products that meet federal guidelines be a part of this effort, and that any efforts that come out of this process must meet federal guidelines and policies for privacy and securities.

In developing the structure of A2, the conveners were trying not only to continue the ongoing support and momentum for the organization, but also to minimize potential risks facing the organization in this succession process. In particular, the group looked at risks that could be related to: (1) funding; (2) the occurrence of similar, but not coordinated efforts that could dilute the focus of the activities of the successor; (3) the potential for membership attrition or loss of interest; (4) the risk presented by priorities not being well aligned among all of the organizations active now; and (5) harmonization and certification activities. Therefore, the group focused on creating a flexible funding structure that includes commitments for government support in the short-term, a limited dues structure, and an emphasis on the development of value cases in the months and years ahead.

Dr. McClellan then presented a slide illustrating the activities of the Community from Round 1 in 2006 to a fully functioning Community successor in 2010. This timeline illustrated the fact that the new Community needs to be positioned quickly to set priorities and act on them. The current priorities are based on the use case cycle, but as soon as January 2009, priorities need to be addressed on the Community successor roadmap, in order to make the transition to the long-term independent

sustainability of the organization. He also noted that the roadmap will be informed by not just the succession process in the months ahead, but increasingly and in the end, completely by the Community and Community successor memberships, themselves. The roadmap will be updated on a regular basis, each time the Community successor goes through its priority-setting cycle.

Discussion Highlights

"I think that the practical reality is in front of us, and that the members of the Transition Planning Group…understands what the task is at hand. We do have the same concerns that have been voiced here many times. Who is the effective leader? Who's got that panache to pull the troops with them? And that is a concern. We don't have that solved yet." – Ms. Gelinas

"When AHIC 1.0 first started, we had our own group bonding…and now we're there. It's a very practical group now, and we hit the ground running and don't let a lot of politics get in the way. We would envision that 2.0 will have some similar need for the group to come together. And momentum is lost in that gap. So how do you bridge that?" – Ms. Gelinas

"There is so much volunteer work that goes on within the government and in the private sector, and we want that volunteer work to continue as we transition to A2. And how much of that can we be assured is going to happen? I know all the commitment is there, absolutely, from private organizations, public organizations, but there is a lot of work to actually transition to A2. And from a funding perspective, the biggest question is…on day one, how much can you move out of the [old] house to the new house in the first 3 to 4 months?" – Mr. Hutchinson

"Are there things that we could be doing right now at HHS that would advantage your transition?"
– Secretary Leavitt

"Mr. Secretary, I'd say there are a couple. The first is helping us get clear articulation on the role and relationship of CCHIT, and HITSP, and NHIN, to A2. There is some confusion around that…Secondly, the relationship of the health care strategic plan and the whole premise of value-based health care…that link with the value-based health care foundation that HHS has set during this administration would be enormously helpful, just making sure it's clear. And third, understanding the priorities that have to remain inherently governmental." – Ms. Gelinas

"There are certainly some big policy issues that are going to remain outside the scope of the Community successor, so privacy and security policy…and there are also other big policy issues like financing, reimbursement reform, benefit designs, things that get right to the core of your leadership on value-driven health care, in terms of having care that's focused on good information and payments and benefits that support better quality care at a lower cost. That's not something that the Community successor is going to be able to make happen by itself." – Dr. McClellan

"We mentioned the importance of searching for the right 'gavel pounder CEO.' But I'm wondering whether there would be any value in having a Board of Directors appointed early, and perhaps even an interim Board of Directors, so that there was an organizational structure there to kind of build itself as it was learning to fly. Because if you try to bring people in new, it would take them a long time to get up to speed." – Dr. Geberding

"We've got some starting points for what could be a board in terms of the leadership of the workgroups…Tomorrow, we'll be announcing a nomination process and a timeline for completing it, to get the full, broad-based board in place, in the coming weeks. So that is a high priority for phase 2."
– Dr. McClellan

"I would like to underscore what has been said about the need for the government agencies to remain engaged here. What gives the Community, A1, or A2, its throw weight, is our willingness to condition things we do on the use of these standards." – Secretary Leavitt

Status Report on Accelerating Interoperability

Dr. John Loonsk, Director of the Office of Interoperability and Standards, ONC, defined interoperability as reduced implementation and integration costs for health IT, so that the systems can be adopted with less cost, and so that they can work with each other. The definition also includes progress in the implementation of security and confidentiality standards. He noted the need to recognize that interoperability is necessary, but not sufficient for information exchange. Having people want or need to exchange information is a critical factor in advancing interoperability, as well as advancing the overall health IT mission.

Dr. Loonsk described the process that has been put in place to carry forward priorities from the Community and from the Community working groups and convert them into use cases. Those use cases are advanced to HITSP, which identifies minimal standards to meet those needs. There is a public notice process when the standards are available, and eventual Secretarial recognition approximately one year later. Then, there are processes for verification of the fact that those standards are, indeed, in systems, all driving to the point of broad use of these standards.

Dr. Loonsk noted that the Community received via e-mail a document called *Information Exchanges Requested by AHIC Use Cases*. This document details the information exchanges that the Community has asked for, through the use cases, relative to what EHRs need to put out and what they need to take in from a data perspective. Overall, there are 169 different information requests that are at various points in the process, which his important to consider as the Community decides whether it should be looking at more gaps and extensions rather than completely new use cases.

Dr. Loonsk pointed out that there are challenges associated with the use of standards, such as: (1) limited incentives for exchanging information (e.g., when the "value" of exchanging is high, it costs to not use standards); (2) many incentives for not exchanging information (e.g., data "ownership," integration services profits, existing non standards-based systems); and (3) historically, there has been a problem with the availability of definitive and detailed standards. Although the national health care agenda and HITSP have made significant progress in making definitive and specific standards available, there also are ongoing challenges associated with standards harmonization. These include the fact that in some areas, identifying a single standard, a help for interoperability, is challenged by the variation in installed systems. Other challenges include the fact that testable standards need to be very specific and "tight," as well as the difficulty in communicating highly technical and complex material.

To help overcome these challenges, several "levers" are being used to increase the value of standards use. These include voluntary certification, use in federal systems and contracts, and legislation for administrative standards. While acknowledging that the CCHIT has made great strides in interoperability, there are challenges associated with using certification as the "driver" of standards use. For example, it is a voluntary process. In addition, the product vendors—the purchasers of certification—are challenged to rapidly implement detailed standards.

Discussion Highlights

"If you could wave your magic wand and one thing happened…what one thing would you have happen that would be the differentiator, be the 'big bang'?" – Ms. Gelinas

"Well, I think if there was truly a magic wand, we would really hope that there would be compelling needs to exchange information securely across organizational boundaries. That will greatly facilitate the entire process. And I guess short of a magic wand, the question for A2 to be thinking about is how to structure themselves in such a way that they can help push on that and move in that direction, and whether there are structural questions that need to be considered in regard to helping make that happen." – Dr Loonsk

"The reality is that consumers have not yet begun to engage in a way that energizes the uptake on this. So it really leaves you with two alternatives. One is that government, in the interest of consumers, begins to put more pressure on the exchange of data for an overriding public purpose, or we just count on the new developments in the market to ultimately begin to cause it to surge." – Secretary Leavitt

"We have to move from the early adopters to the mainstream. And it seems to me that the spark for jumping that gap may well happen in the consumer sector…And when they start to recognize that there are health providers that let you do it and health providers that don't, and they start to switch doctors or switch hospitals, I think that's more powerful…than a regulation. – Mr. Leavitt

"The use cases have to be transformed to value cases. And I think that's been one of the challenges…The use cases, they're excellent and they're thorough, but there is a paragraph in every one that says, 'Please note, there is no business case for this, and these other problems have to be solved before it can happen.' So within the use case, this can't really be real yet, until this business problem is solved. So the value cases aren't allowed to have that paragraph." – Mr. Mark Leavitt

"Between the 52 recognized [standards] and the 60 accepted, there was a year. So what happens to the standards in that year? Are they significantly modified during the course of public input and so forth? Is that really a useful timeframe to pass, and could that be shortened to accelerate movement from acceptance to recognition?" – Dr. Gerberding

"The intent of the year is for the standards not to change significantly, so it's a year of public availability for small refinements of a technical nature to make sure that people know what the standards are and can implement in their systems. Obviously, there is lead time necessary to actually implement standards in systems, and the intent of that year is that vendors and developers know the standards are available, know what they're going to be, and then before there is an expectation, that they actually have them implemented." – Dr. Loonsk

"From my standpoint, I think this year you're crossing the threshold from standards being a limiting factor. I believe after this year, standard availability is no longer the rate limiting factor in adoption of interoperable health IT." – Mr. Mark Leavitt

"There is a lot of money going out of CDC that is relevant to systems design and development. And we want to leverage adaptation. But it seems right now that it's kind of spotty. We don't have the whole package of standards, so we would be willing to put grant language in or incentivize people to do this. But I'm not sure we have a complete package of what's necessary, so it's a moving target. Is there a way we could look at that as an opportunity, when we're making prioritization decisions so that we could use our grants more effectively, if we had more standards to support that lever?" – Dr. Gerberding

"What was the process in planning out the identification and the certification and then the testing? It seems like you missed the testing piece and didn't build that functionality out. Because it sounds like we've got a backlog of stuff coming out through the funnel. And now standards aren't the limiting factor, but we…have just started putting the testing ability into the process. How are you going to speed that up so we can actually get what we've got, all these numbers coming down the pipe faster?" – Mr. DeVore

"What we were talking about here is trying to break that broader cycle, that cycle of actually trying to put interoperability into systems where there has traditionally not been interoperability, and where the alignment of need has not been encouraging enough of that interoperability to make it happen." – Dr. Loonsk

"[With regard to] some products that will be in the marketplace. They've achieved some degree of standards, those necessary to allow those to communicate. Is there a reason that those standards that they've developed couldn't ultimately be part of the CCHIT…or are they incompatible? Are they competing standards? Or how do we harmonize what's going on in the private sector with what we're doing in this process?" – Secretary Leavitt

"Well, certainly we're already in process with that…Continua is well aligned with HITSP, so our 2008 use case for remote monitoring and teleconsultation is actually being done jointly with Continua. And I expect it's actually the work products that come out of Continua that will go to the HITSP technical committees and be harmonized." – Dr. Halamka

"So we're about recognizing standards, however they develop. Harmonizing them and adding to the body of it and coordinating them, and then certifying as they go." – Secretary Leavitt

"HITSP does not create the standards. We look to standards development organizations, implementation guide writers, collaborative organizations like Continua and IHE." – Dr. Halamka

"Ultimately, you'll know things are solved when we work ourselves out of a job. So for example, in the case of Continua, there is no competing standard. The personal telehealth vendor said 'We need a standard, here it is.' So you don't have to harmonize it with a competing standard or referee, some kind of battle. It's going to fit in." – Mr. Mark Leavitt

"There may be others who are using more of the standards. But if we just look at what's included in the certification, we're under-representing products that may already have some of the additional standards in them. Is there some way to recognize those that have exceeded …the 'floor of certification'?" – Dr. Kolodner

"Right now we have something called provisional criteria…We test it, but it doesn't count in the score. We're trying to make sure we get the test right, but that could be repurposed or expanded so that you test it, and you find this vendor is an early adopter of the standards and they get some market advantage. You check the crash rating on your cars, some get five stars, some get four. But they're all federally approved, and you can buy them. Something similar to that. We don't want to make it too complicated. But I think there is some room for help there." – Mr. Mark Leavitt

"As we start looking at the emergence of Greenfield standards, and the sorting out of the legacy standards, then as we look for our agenda, we're looking to fill gaps that might close—if you think of it as a puzzle. I've used that analogy here before. It may be the bridge piece between the corner that we've

organized and someone who has developed a piece on their own, that no one had done before. And it's that gap piece." – Secretary Leavitt

"We need to look at the source data, the health plans, the practice management systems, the lab information systems, where there actually is electronic data stored. And how do we, through patient-matching means, or some way, grab that demographic information for patients and pre-populate the more strategic clinical IT systems that we are trying to deploy. Because what we're running into a barrier on is, even where we are implementing those systems, we don't have the capability to drive the effective utilization. We're focused on higher-level clinical things, and the basic demographics of loading of these systems remains very, very weak without a manual entry." – Mr. Hutchinson

"We actually, as part of this continuity of care document, created all the demographic standards that are necessary. And in successive years we have created the ability to exchange demographics using a variety of secure and private mechanisms, including patient matching. Are those adopted? Well, they are adopted in some demonstration projects. Are they baked into all the products? No." – Dr. Halamka

"Lab results are great. Lab orders are great. Medication orders are great. Medication renewals are great. But when the actual data for the patient is not in those systems, it doesn't do anything." – Mr. Hutchinson

Healthcare Information Technology Standards Panel Update

Dr. John Halamka, HITSP Chair, began his presentation by reviewing the background of interoperability standards work. The round 1 (2006) use cases were:

- IS01 – Electronic Health Record Laboratory Results Reporting
- IS02 - Biosuveillance
- IS03 – Consumer Empowerment

Secretary Leavitt recognized interoperability standards for these use cases in January 2008.

The round 2, 2007 use cases were :

- IS04 – Emergency Responder Electronic Health Record
- IS05 – Consumer Access to Clinical Information
- IS06 – Quality
- IS07 – Medication Management
- Security and Privacy Constructs (deferred from Round 1)

Secretary Leavitt accepted interoperability standards for the Security and Privacy and 2007 use cases, with the exceptions of the Medication Management Use Case and Reliable Document Interchange.

The round 3 (2008) use cases include:

- Consultations and Transfer of Care
- Personalized Healthcare
- Immunizations and Response Management
- Public Health Case Reporting

- Remote Monitoring
- Patient Provider Secure Messaging

HITSP is currently harmonizing interoperability standards for these six use cases, with acceptance scheduled for January 2009.

Following this overview, Dr. Halamka described the interoperability standards that are currently being advanced for acceptance (to be recognized in June 2009)—IS07 Medication Management and T31 Document Reliable Interchange. He also noted that round 1 interoperability specifications have been updated with minor revisions of a technical nature to reference the security and privacy standards.

IS07 – Medication Management Interoperability Specification (v1.0)—This interoperability specification defines specific standards to facilitate access to necessary medication and allergy information for consumers, clinicians, pharmacists, health insurance agencies, inpatient and ambulatory care, etc. It includes four new HITSP constructs: (1) T40 Patient Generic Health Plan Eligibility Verification, (2) T42 Medication Dispensing Status, (3) TP43 Medication Orders, and (5) TP46 Medication Formulary and Benefits Information. HITSP worked with CMS to ensure IS07 was consistent with the ePrescribing federal initiative led by CMS including, when applicable, adherence to standards required for ePrescribing under Part D of the Medicare Modernization Act (MMA). IS07 uses the version of the NCPDP SCRIPT Standard Implementation Guide cited in MMA (currently Version 8.1) in most circumstances and Version 10.1 to include specialized data elements not included in Version 8.1. To obtain and exchange local patient identifiers for communication between prescriber, dispenser, and payer organizations, IS07 defined a bridge between standards typically used in prescriber settings (HL7) with those typically used in payer and dispenser settings (NCPDP and X12N). For exchange of a patient's medication history, IS07 uses standards consistent with MMA to exchange medication history detail (NCPDP SCRIPT) and standards to include medication history in a clinical summary that also includes allergies, problem lists, etc.

T31 Document Reliable Interchange (v1.0)—T31 Document Reliable Interchange provides a standards-based mechanism for conveying a set of medical documents in a point-to-point network-based communication. This may involve direct interchange between EHRs, PHRs, quality measurement organizations, public health authorities, and other health care IT systems in the absence of a document-sharing infrastructure such as that enabled by the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework. The content of the communication might include clinical documents, quality documents, or public health documents. This mechanism uses the IHE Cross-Enterprise Document Reliable Interchange (XDR) Integration Profile, a companion to the IHE Cross-Enterprise Document Sharing (XDS) Integration Profile.

Dr. Halamka acknowledged that Secretary Leavitt asked that three "turns of the crank" be completed before January 19, 2009, and indicated that this would be accomplished. By that date, HITSP will have presented those last six use cases from 2008 for acceptance by the Community.

Dr. Halamka used CDC's BioSense as one of two examples of public health information network reporting. BioSense's standards were developed five years ago, and today 500 health care organizations are connected to BioSense. He then compared this to Google Health and other organizations exchanging data using current and next-generation Web technologies. This is an example of a situation in which two standards were in use and so two needed to be chosen when identifying acceptable mechanisms. Dr. Halamka also acknowledged that eventually, the two technologies will probably converge, and then the two standards will evolve into one. He presented this concept to illustrate how multiple standards sometimes are being accepted.

Discussion Highlights

"What is the universe of patients or consumers able to utilize that today?" – Secretary Leavitt

"Currently, at least speaking of the Google project, Google has linked together, Longs, Walgreens, CVS, Quest as a laboratory provider, the Cleveland Clinic, and Beth Israel Deaconess." – Dr. Halamka

"So if I'm a customer or a patient of any of those institutions, then I would be eligible in the first phase of that project, to sign up for an account and have my medication history, so far as it's contained in those organizations' files, assembled for me on my GHealth account?" – Secretary Leavitt

"Correct. So Quest, for example, on the laboratory side does about half the labs…in this country, so you would assume between CVS and Longs and Walgreens and Quest, you would probably know better on the pharmacy side. We are getting a very substantial amount of the population." – Dr. Halamka

"I have a scenario for you. So at Beth Israel Deaconess today, an unconscious patient comes in and the spouse or caregiver says, 'Oh, we did do Google Health; I'll get you in, and you can see the prescription history.' How many of your colleagues would accept that and treat on that basis?" – Mr. Isenstein

"This is an interesting question. How do you deal with the fact that a personal health record may not be completely accurate? Well, the way Google has particularly addressed this, is that as they connect to a third-party provider of information, Long, CVS, Quest, et cetera, the patient cannot change that data. They could mask it from a privacy standpoint. They could annotate it, but they cannot change it. So what it shows on the screen is this patient is on Lipitor, and it shows the dose and the route and all the rest. It shows source of data. And there is no capacity to change the 5-milligrams to 25-milligrams. As an emergency physician, I often fly blind. If I was given a screen that said non-repudiation from Walgreens, I'd trust it." – Dr. Halamka

"One of the challenges of standard harmonization is constraints. You want to be really, really specific. But the problem is that you have to start somewhere. So if we started with 700 possible candidate standards, and we got down to 52, that was a lot of constraints. Can we go from 52 down to 40? Maybe, and eventually we'll probably see some convergence and some constraints. So what we've tried to do is get to the fewest number of standards we can, and if we can't get to just one, then we have mappings between the two. So you could say 'These are the two choices, but here are the mappings between the two that will allow translation between these two,' with the eventual notion that you won't have mapping any longer, and you'll get down to one." – Dr. Halamka

Certification Commission for Healthcare Information Technology Update

Mr. Mark Leavitt, CCHIT Chair, presented a status report on the CCHIT as it is finishing up its certification work for 2007. The Commission is about to launch certification activities for 2008 against the 2008 criteria, and are starting to develop the criteria for 2009. Mr. Leavitt presented a slide showing three gears—representing: (1) providers, doctors, and hospitals that have been slow to buy EHR systems; (2) vendors that make the systems but cannot seem to sell them at a low enough price or include the interoperability needed; and (3) purchasers who have been reluctant to offer incentives for the purchase of health IT when they are not confident in the benefits of that health IT. The goal, Mr. Leavitt said, is to "unstick" these gears.

Starting with the providers, Mr. Leavitt noted that the question is, are they paying attention? Do they know about certification, and are they relying on it, when they think about buying an EHR? He indicated that there is broad endorsement at the upper level, with all the primary care professional associations of physicians having not only endorsing the work, but embracing it. Surveys indicate that 72 percent of physicians believe published certification standards have an impact on EHR adoption. About 66% of CIOs are aware of certification; 55 percent of them plan to require it in their purchase decisions.

In terms of vendor acceptance, Mr. Leavitt reminded Community members that more than 150 EHR products have been certified in the last two years, and that certified vendors represent more than 75 percent of the EHR marketplace. He added that when it comes to acceptance, vendors must be measured by their actions, not necessarily by what they say they do. Certification is enabling EHR adoption incentives. Mr. Leavitt provided examples in the public sector (the CMS EHR demonstration project, Stark/AKA safe harbor for donation of certified EHRs, state eHealth initiatives) and in the private sector (EHR adoption incentives announced by several health plans).

Mr. Leavitt then discussed the status of 2008 criteria development. Updated domains include the Ambulatory EHR and Inpatient EHR. Proposed final criteria for the Ambulatory EHR were published on April 17, with the final criteria published on May 20. Certification applications open July 1, with optional additional certifications available in the areas of child health and cardiovascular medicine. Proposed final criteria for the Inpatient EHR were published on May 20, with final criteria expected to be published on June 20. Certification applications will open on August 1. In addition, Mr. Leavitt described two new domains: (1) Emergency Department EHR (proposed final criteria published May 20, final criteria to be published June 20, certification applications open August 1); and(2) Health Information Exchange (alpha testing complete, pilot testing underway, final criteria published in August, certification applications open October 1).

Mr. Leavitt then summarized progress in interoperability as follows:

- 2006 – Receiving lab results in Ambulatory EHRs (basic).

- 2007 – Stronger compliance testing of lab results in Ambulatory EHRs, ePrescribing in Ambulatory EHRs

- 2008 – Stronger compliance testing of lab results in Ambulatory EHRs, additional ePrescribing functions in Ambulatory EHRs, sending and receiving clinical summaries (CCD) in Ambulatory and Inpatient EHRs, and transmitting lab results and clinical summaries via networks/health information exchanges.

Looking ahead, Mr. Leavitt identified four strategic directions for future work: (1) expand certification to new health care domains; (2) guided by Community priorities and HITSP standards readiness, drive standards-based interoperability into all certified health IT systems; (3) enhance technical robustness and automation of certification inspection and testing; and (4) enhance outreach and communications. He announced that in the next 2 weeks, development will be launched in two new areas: behavioral healthcare (which is an add-on to ambulatory certification) and personal health records. Two other areas will take a little longer to pursue: long-term care—an area with an even lower penetration of clinical IT than solo doctor's offices—and other specialties beyond cardiology.

Mr. Leavitt presented figures showing that a transition from contract funding to financial self-sustainability is progressing according to plan. There are other elements of sustainability that are equally important, such as credibility, engagement, and vitality. Mr. Leavitt noted that strong volunteer interest is the best indicator of the continuing vitality of CCHIT's efforts—recently, there was a call for volunteers

for which about 136 slots needed to be filled. More than 500 applications were received from 280 individuals. CCHIT volunteers come from all over the country, and from practices ranging from prominent academic medical centers to small family practitioner groups. Large and small vendors participate, as well. Volunteers have initial face-to-face meetings, but the work is essentially carried out in a 90-minute to 120-minute telephone conference call every week or every 2 weeks, along with periods of intense "homework" lead up to each publication. Secretary Leavitt indicated that he would be interested to watch one of the vendor certification tests in progress. Mr. Leavitt noted that he would look into arranging for an audit of a test.

Discussion Highlights

"It seems to me that there is a rather remarkable difference, looking at your slide called 'Progress' in interoperability between 2007 and 2008. Is that a fair characterization?" – Mr. Weems

"It's a big step forward in '08, that continuity of care record, yes." – Mr. Leavitt

"So should we have a preference for that?" – Mr. Weems

"I think that would reduce the number of systems available…We'll start testing in July and August. The announcement will be three months later, so September. So if you got ahead of it, that would be a problem. The good thing is, even if they buy a system certified in '07, [there are] vendors that are there are wanting to keep up." – Mr. Leavitt

"But for example, how would something for public health get in there? Is there a gap there that we need to look at and address in some fashion?" – Dr. Kolodner

"Yes, there is. So if you looked at the three 2006 use cases, one was lab results, one was consumer empowerment and one was the biosurveillance. And both lab results went in right away. Consumer empowerment is in now with the CCD. We needed to wait for the standard. And the biosurveillance isn't. And the reason is none of the vendors said they could do it, and what's more, there was no place, no socket on the other end of the plug to send it…So, too many other missing pieces, too big a gap between the value of the buyer of the system and reality. So that's why that hasn't made it in yet." – Mr. Leavitt

"I'm most excited about the fact that you're next going to tackle the issue of behavioral health, and how that information can become embedded in electronic health records and PHRs. Talk about the ability to improve quality and to some extent, control costs, particularly with patients with multiple chronic diseases. This is going to be a huge step in that direction to integrate that data, behavioral health, mental health data, and clinical data or other clinical data. Given that there are some significant privacy and confidentiality concerns about that, how quickly do you see that playing out?" – Dr. Loonsk

"We believe that group can complete its work in time to launch a behavioral health additional certification in basically July of '09 when all the update to ambulatory and the update to everything is done." – Mr. Leavitt

"We have roughly 13,000 disabled adults and children on Medicare waivers, who we provide custodial care to, who are on a completely electronic environment. And about 25,000 primarily senior citizens living in nursing homes, who are in a similar environment. Eighty percent or 70 percent of all long-term care beds in America are funded by Medicaid. And if they're not funded by Medicaid, they're funded by…the Medicare budget. So it is an area ripe for opportunity, but one which, to really get at, you've got

to get at the funding mechanisms of it up front. Otherwise, providers will simply say, 'I don't have the budget to do it.'" – Mr. Roob

"The CDC is not ready to receive the data for public health data. If [we are] using the same standards that the Beth Israel is using to transmit data to us, we could be taking it right now. We're ready for hospital systems to be certified for transmitting the bioterrorism use case in the same way that Beth Israel is. And of course, there isn't a market for this…Does this require a different type of support, since it's not something your vendors will necessarily be excited about paying for, do you need extra additional help in this area, or is this something that you will eventually get around to as part of your processes, and then when will you get around to it, and is that dependent on the funding?" – Dr. Lenert

"In the ambulatory space, I know on the road map for next year, is immunization registry exchange. So definitely there are public health elements that the Workgroups felt they can get to, soon. I haven't seen the biosurveillance reporting on the inpatient and emergency department group, probably because those are newer groups. I think probably the reason is that certification is not as mature. We started those a year later for inpatient, two years later for emergency department. Ambulatory is ready. Their feet are on the ground. They're ready to add public health elements, like the immunization registry." – Mr. Leavitt

"We know that electronic laboratory reporting for infectious diseases is much more effective than relying on manual methods, and that maybe 80 percent of potentially notifiable conditions are missed by waiting for doctors or nurses to send a card to their local public health department. And that the timeliness of such reporting is much improved by electronic reporting. Similarly, if we are to have a real-time surveillance system for the nation for acute healthcare threats, that has to be built into hospital information systems. And it needs to be certified for it, so that while there isn't a market for these activities, it clearly needs to be a national priority." – Dr. Lenert

"Are we, in effect, raising the CCHIT bar and then raising the pricing bar, which is just creating kind of a conundrum for the providers, since price is one of the factors in purchasing?" – Mr. DeVore

"The question of pricing, I'm sure the vendors will want to answer for themselves, but several people have commented it probably will lower prices because with software, it costs you nothing to print the extra CD. It costs you to sell it…So when we decrease the hesitancy of people to buy it, the potential is there to have much lower costs. Software price…even more than hardware, the price can go down with volume. You're amortizing your development costs much more broadly. So I don't think there is anything inherent that should drive prices up. [It] should drive them down." – Mr. Leavitt

"To what extent is HITSP driving consolidation of the marketplace? There have been some big mergers, and that was occurring already with 200 vendors. But isn't that a good thing, that it's reducing, and therefore, lowering the cost? Basically what you're saying on slide four, you cannot lower prices until provider adoption accelerates. You could lower the costs the other way by having greater market share, right?" – Mr. Isenstein

"But then you could also drive out innovation, so we're seeing both. There has been healthy merger and acquisition activity, and there have also been 25 new vendors coming in this year to be certified. So actually, you want both. You want both flow of new innovation and you want, where appropriate, some consolidation. So I think that the EHR marketplace is healthier than it's ever been." – Mr. Leavitt

Community Interoperability Priorities Discussion (Continued from April Community Meeting)

Dr. Loonsk reminded the Community that at the last meeting, there was a question about whether HITSP should focus its efforts on new use cases or concentrate on extensions and gaps. The general consensus among the Community was that it is an appropriate time to "think more horizontally" and take on those gaps and extensions. Since the last Community meeting, Secretary Leavitt has indicated that a full newborn screening use case is an important priority for HHS and needs to be moved ahead in this part of this process. Therefore, a new list of extensions and gaps was distributed to all the Community members. This list included extensions and gaps that had not been accepted or approved, as well as some possible extensions and gaps that related to the use cases previously described. Dr. Loonsk presented an updated Community priorities and use case road map that included information on 2006, 2007, 2008, and candidate 2009 use cases as well as approved and other potential extensions/gaps. He noted that at the last Community meeting, Community members identified a series of eight extensions and gaps that meet criteria for moving forward.

Discussion Highlights

"CMS will have a rather significant demonstration project on medical home going on, so this is obviously a place where we can learn from one another on that, and I want to make sure that we don't come up with conflicting standards or conflicting views of the world, especially as we're learning things from the medical home demonstration." – Mr. Weems

"The lack of electronic sophistication of the provider base [in long-term care], and whether or not you choose to include the developmentally disabled in that group makes an enormous difference. And I'm fearful that when we go down that path, we need to guard against automating a system that is already too nursing home-dependent, because it now becomes easier to check somebody out of a hospital into a nursing home environment. Because a nursing home environment is where they have an ability to deal with the hospital, as opposed to a home health provider or somebody else who doesn't. We need to be cognizant of what policy outcome we're creating, and not paving well-warn paths electronically." – Mr. Roob

"This year the intent is to do roughly the equivalent of six use cases, even if that's extensions and gaps. I think there has been a discussion that we've had in an ongoing way, that there may be an opportunity to do more if resources can be brought to bear to HITSP, and if a community has sufficient volunteerism, because of the interest of the stakeholders in working on harmonizing those standards." – Dr. Loonsk

"That path may not start by going straight to certification or inclusion in certification, but would be of use to those communities so they would have the standards to build around, and then as knowledge proceeds, the standards would be there that could be built in. And that may not necessarily even be government money. It may come from the research community in general, and there are a number of entities that are there. If that's something that the Committee thinks would be appropriate, at least having the sense of the Community, one way or another, would be useful, as those are being explored." – Dr. Kolodner

"I think the missing piece for us would be the pharmaceutical clinical trials, although we participate in some of those. But I think it's a community that would like to be engaged, and would. We're looking at more and more warehousing of the data and making it available in central locations…which would only be benefited. And I think some of the things that NIH is doing, as well, would certainly feed into this." – Ms. Graham

"If clinical trial eligibility criteria could be wrapped with, let's say case recognition for public health reporting which bears many technical similarities, we may be able to get over the energy barrier for inclusion of public health in hospital systems for certification and other things there. So I think that there is a package here, it's not one functionality, it's not one capability. It's thinking about similar functionalities and pulling a package together that would be compelling to make the public health and other public uses combined with clinical trials. Because it's a big carrot, as far as potential funding." – Dr. Lenert

"Remember your funding. The use case is developed this year. That means that the standards are identified next year, and this would be recommended forward, and this would be due at the end of 2009/early 2010 for recognition, assuming that process continues even with A2, which is certainly the intent. And certification really is more like 2011, 2012. So the question is, will long-term care still be without any place to plug it in?" – Dr. Kolodner

"I just would challenge us, as an entity and as a process, that as we pass these other information exchange needs, that we look at standards that we have already vetted through other processes, and make sure that those get a higher priority to see if we can't use those in these other settings and allow the systems to filter through what's needed and what's not needed in that environment." – Mr. Hutchinson

"[In terms of] the maternal and child health pediatric- and adult-focused [potential gaps/extensions], that part of the delivery system is prepared and ready for an electronic environment. It's a vastly more sophisticated…much of that care is…very routinized, and I think will pay enormous dividends. To me, on that list, it's the low hanging fruit. It's the stuff that will get done fastest, that will have the highest, quickest payback." – Mr. Roob

Following these comments, the group approved by consensus the plan to move forward with the top eight items on their list of the candidate "other" potential extensions/gaps. These include:

- ***Medical Home: Co-Morbidity***
- ***Medical Home: Registries***
- ***Maternal and Child Health: Pediatric-Focused***
- ***Prior-Authorization and Scheduling in Support of Treatment, Payment, and Healthcare Operations: Scheduling***
- ***Maternal and Child Health: Adult Focused***
- ***Patient/Consumer Adverse Event Reporting***
- ***Prior-Authorization and Scheduling in Support of Treatment, Payment, and Healthcare Operations: Authorization Information***

Personalized Healthcare Work Group Recommendations

Community member Dr. Henley, Co-Chair of the Personalized Health Care Workgroup, defined pharmacogenomics (PGx) as the study of variations of DNA and RNA (genes and gene products) characteristics as related to drug response. PGx has the potential to inform therapeutic choices, clarify dosing decisions, reduce adverse drug reactions, and optimize prescribing patterns of providers. This field of study is novel to health care providers; the information generated from the laboratory is very complex. Dr. Henley noted that examples of clinical scenarios where PGx testing may apply include anticoagulation therapy (warfarin) and carbamazepine-containing drugs.

Despite its promise, the integration of PGx into routine clinical practice has been slow. Factors contributing to this slow integration include: (1) lack of an evidence-base and information on clinical utility, (2) lack of clinical guidelines for the use and interpretation of PGx tests in pharmaceutical selection and treatment decisions, (3) impediments to reimbursement for the performance of laboratory tests, and (4) a paucity of clinical practice experience with PGx. Dr. Henley commented that improved EHR functionality may help motivate clinician adoption of electronic tools and pharmacogenomics.

Janet Warrington, a consultant and member of the Personalized Health Care Workgroup, presented the group's recommendations, which fell in the following three areas: (1) fostering EHR data standards to enable clinical research and development activities, (2) clinical decision support in health care delivery, and (3) integrating PGx into medication prescribing practices.

Fostering EHR Data Standards To Enable Clinical Research and Development Activities

- **Recommendation 1.0:** HHS agencies should maintain existing relationships with appropriate standards development organizations (SDOs) and industry stakeholders to expand the standards development process for documenting pharmacogenomic data and for submitting to other databases.

- **Recommendation 1.0.1:** HHS agencies and the National Institute of Standards and Technology (NIST) should work together to clarify and determine the role that each will play in developing standards for pharmacogenomic data.

- **Recommendation 1.1:** FDA, National Institutes of Health (NIH), and other federal agencies involved in clinical research should convene a workgroup and develop a document or checklist that clarifies best practices for use of informed consent between patients and caregivers and for data use by physicians, pharmacists, regulators, researchers, and other relevant stakeholders when pharmacogenomics data is submitted to research databases. Issues to consider include: national privacy standards; de-identification of data; appropriate use of data; and educational information to provide to research participants.

- **Recommendation 1.2:** Coordinated by the Agency for Healthcare Research and Quality (AHRQ), HHS agencies, including FDA and NIH, should identify a core set of data elements relevant to the outcomes of clinical interventions driven by pharmacogenomic tests that need to be captured in EHRs. HHS should facilitate development of standards for coding these outcomes data and standards that enable exchange of pharmacogenomic test results and/or interpretations from different EHR platforms and other databases that collect relevant outcomes data, while ensuring the confidentiality and privacy of a patient's information. HHS should facilitate standardization of methodologies to analyze and report outcomes of pharmacogenomic tests.

- **Recommendation 1.3:** AHRQ, NIH, and federal health care providers should identify opportunities for and encourage pilot projects to demonstrate the use of EHRs for supporting clinical research and integrating pharmacogenomic data into clinical research databases utilizing existing standards and terminology.

- **Recommendation 1.4:** A multi-stakeholder workgroup, including clinicians, health IT specialists, industry, laboratories developing or performing pharmacogenomic tests, medical device/product reviewers, pharmacists, and researchers, should be formed to develop a core minimum data set (potentially including gene names, gene mutations, coded interpretations, and associated medications) and common data definitions available for inclusion of pharmacogenomics data with demonstrated clinical validity and utility in an EHR.

- **Recommendation 1.5:** The unidirectional information-flow from EHRs to clinical research applications (such as case report forms) should be prioritized for Use Case Development.

Clinical Decision Support in Health Care Delivery

- **Recommendation 2.0:** When the public-private CDS entity is developing strategies to incorporate accepted CDS technologies into health care information technology and clinical processes, and describing high level, standard workflows and types of CDS interventions that are applicable to health professionals' workflows, the electronic exchange of clinically useful pharmacogenomic and other relevant health information among the patient, pharmacist, and prescribing clinician should be considered.

- **Recommendation 2.1:** When developing a minimum data set of personal attributes that contribute to individualized care, the public-private CDS entity should include pharmacogenomic test information and/or interpretations as part of that minimum data set.

- **Recommendation 2.2:** AHRQ and NIH should continue to work with appropriate agencies and organizations, including clinical laboratories, to evaluate how pharmacogenomics-related CDS tools affect clinicians' and patients' decision-making, and to ensure that developed tools will be utilized by end-users. Clinician expertise and complicating factors such as comorbidities and polypharmacy need to be examined in combination with the CDS tools.

- **Recommendation 2.3:** The public-private CDS entity and CDS Collaboratory should include standards for reporting, annotating, tracking, and updating versions of pharmacogenomic and related algorithms. Algorithms should be stored in a CDS repository and should be continually updated as new variants and/or pharmacogenomic data are developed.

Integrating Pharmacogenomics Into Medication Prescribing Practices

- **Recommendation 3.0:** HHS should work with stakeholders, including professional associations representing clinicians, clinical laboratories, pharmacists, and others, to develop a white paper on the opportunities and challenges associated with dispensing pharmaceutical drugs based on pharmacogenomic test-derived interpretations in inpatient, ambulatory, and mail-order services. Issues to consider may include: incorporation into workflow, identification of the party responsible for utilizing the dosing algorithm (which incorporates pharmacogenomic data with other clinical data), identification of contraindications, and ensuring that testing precedes dispensing, where appropriate.

- **Recommendation 3.1:** The information-flows between the clinical laboratory, patient, pharmacist, and prescribing clinician, including pharmacogenomic-based dosing interpretation of clinically validated test/drug combinations, within e-prescribing technology should be prioritized for use case development.

- **Recommendation 3.2:** AHRQ, CDS Collaboratory, and FDA should convene a meeting with various stakeholders, including associations representing clinicians, patients, and pharmacists; clinical laboratories that develop and perform pharmacogenomic tests; commercial drug database industry; EHR vendors; e-prescribing vendors; and other organizations to determine how information from FDA label changes may be integrated into electronic prescribing or CDS tools for point-of-care decision-making.

- **Recommendation 3.3:** National Library of Medicine (NLM) should lead an effort to complete and vet an ongoing activity to integrate structured genetic information, including pharmacogenomic test results and interpretations, into an EHR/PHR. This effort should include necessary normalization and translation of clinical standards into those compatible with the research setting.

Discussion Highlights

"The Library of Medicine certainly has been working in this area [Recommendation 3.3], and it seems to me that they would be a natural owner for this, and that they would convene stakeholders as they have been to continue to drive the work that's already underway." – Ms. Warrington

"This is an area [Recommendation 3.3] that they've led the way in terms of developing structured genomic databases and have been very interested in moving more of this into clinically adaptable formats, and have really sought us out from the Workgroup in terms of the endorsement from this Community as being an important driving factor towards the endpoints of application of a lot of their structured databases. It's really the capstone on the clinical relevance aspects of much of their development work thus far, and have been engaging many community efforts around this effort already. So this is solidifying that effort and could be completed in a relatively short period of time, 3 to 6 months." – Dr. Downing

This is a very fascinating area…I always come back to tying it to reimbursement. You may look at tying it to Part D, as the largest purchaser of those services. Mark McClellan did an interesting paper about a year ago in the *New England Journal of Medicine* that may tie to this in terms of a funding mechanism. So you might consider engagement and funding at some point in time in understanding how you're going to drive that change." – Mr. Roob

"There has recently been a study…and they found that the number one driver for uptake was peer-to-peer discussions among health care professionals, the folks who are using it and finding it useful, talking with other people in their own community with respect to their own experiences with it…We think that really it's going to be this peer-to-peer interaction and people actually realizing the value of this that will help sway it. Reimbursement is certainly high on the list, but I think that on the other side of it, too, we really need data. We need data to get out there and get into the hands of the people who are actually practicing medicine." – Ms. Warrington

"I'd just like to add, Mr. Secretary, that although not captured in these recommendations, it wasn't quite time yet, we have been working with [Mr. Weems] and members from CMS and ASPE at developing some forums around trying to advance the clinical utility aspects of this and looking at reimbursement structures that values the combination of the test with the decision making processes and therapeutic areas. So as these standards areas begin to unfold, I think some of the reimbursement policies and considerations for quality improvement aspects will be following in their footsteps. And so we're very excited about those opportunities that will be building on this foundation." – Dr. Downing

Following these comments, the group approved by consensus all of the Personalized Healthcare Workgroup's recommendations.

Update From State Alliance for e-Health/National Governors Association

Jodi Daniel, Director of the Office of Policy and Research, ONC, explained that the State Alliance for e-Health has been up and running for about 1.5 years. The Alliance was developed to engage state leaders, governors, legislators, attorneys general and the like to come together to discuss common issues related to health IT, discuss the states' roles with respect to health information technology adoption, and build consensus on approaches for states to act in the area of policy, as well as in their own programs. Ms. Daniel reported that the Alliance now has accepted more than 30 recommendations from the original three task forces in the area of health care practice, privacy and security, as well as publicly funded programs.

Kathleen Nolan, Director of the Health Division at the National Governors Association (NGA), explained that the first two sets of recommendations are critical with respect to obtaining political and financial support from states. States have been called on to examine how they could carry out road mapping, how they could develop executive orders and legislation, and other activities to put leadership on these issues at the state level. Ms. Nolan noted that the Alliance also has examined the investment in health IT and health information exchange development by states, working within the context of the federal landscape, how states can bridge among their programs, and how to drive this agenda forward with state funding.

Like the Community, the Alliance has discussed standards as well as the use and the implementation of standards, at length. The Alliance has called on states, as they write their contracts and put together their programs and initiatives, to use the available standards. The Alliance also is making efforts to get states involved in the standards development process.

With regard to privacy and security, the recommendations received to date focus on bringing all of the privacy requirements at the state level into a single chapter of state law. This may seem relatively simplistic, but one of the things heard frequently from the Health Information Security and Privacy Collaboration is that there is a great deal of confusion about how to implement these requirements at the state level. The Alliance is trying to highlight where there are interactions and contradictions in state law, and is trying to make these activities as transparent as possible.

In terms of the public programs themselves, Ms. Nolan explained that to a large extent, there is not a great deal of understanding, engagement, and interaction at the level of public agencies, public health, and Medicaid/state personnel regarding state activities in these areas. The State Alliance has discussed the fact that states need to support leadership training, skill building, and then contracting—where necessary—with outside expertise.

The Alliance's Health Care Practice Task Force examined licensure, given that e-health, tele-health, and other new programs are not geographically based. Much of the discussion centered around how to make it more practical for providers to be licensed in more than one state. The Task Force also considered approaches to obtaining seamless multi-state licensure.

With regard to recommendations related to consumers, Ms. Nolan explained that more tools must be developed for engaging consumers, while acknowledging that there is a substantial history involving public health agencies and Medicaid agencies working with consumer groups. She pointed out the need to move the health IT and health information exchange dialogue into those groups where they exist. The Alliance believes that there is a need to learn from natural experiments, for example, state personnel. This is a place where benefits are provided for a large number of state residents and their families. So how can they get better in contracting in that arena, how can they improve as purchasers?

Going forward, the State Alliance will be looking at financing and oversight for health information exchanges, in collaboration with the University of Massachusetts Center for Health Policy and Research. This is not an examination of how health information exchanges are put together, how they function, how they sustain themselves, but rather how state governments interact with these entities. Ms. Nolan indicated that a number of models will likely be developed that states could consider as ways that they could interact. Once a framing model document is completed, it is hoped to identify natural experiments to engage the states.

Other priorities the Alliance taken up in moving forward are children's health records and e-prescribing. The group has considered how to get some movement in states, and how they can act in partnership with federal agencies in the private sector. At their most recent meeting, the State Alliance adopted a statement calling for the NGA to take on leadership in this role, and to help work with states individually and as a collective to try to promote e-prescribing activities.

Discussion Highlights

"Do you know of any state that's begun to look at recodifying their privacy into one chapter?" – Secretary Leavitt

"I don't know of any state that has taken that up specifically." – Ms. Nolan

"Once you make that recommendation…what happens to it?" – Secretary Leavitt

"One of the things that we would really like to do is engage in ONC on how we go about tracking the uptake of these recommendations, because we do have ways we can do that already in place, but we think that that's one of the things that needs to happen as we put it out there. In terms of what we're hoping to provide from the NGA Center for Best Practices is places where we can get some learning and some networking going among the states." – Ms. Nolan

"NGA also has a relationship with the National Council of State Legislators, so on issues where there are recommendations regarding legislation, putting the privacy provisions into one code and that sort of thing, they have that organization on board as well to work with them and try to work through the legislative process. So that is part of the strategy in trying to get the different branches of government involved." – Ms. Daniel

"There is a commission on uniform state laws…Have they begun to look at any of the licensure issues at all?" – Secretary Leavitt

"We had a conversation with them early on in that licensure dialogue, and they have a longer-term process that takes quite some time, but they are interested in this, and so we are keeping engaged with them. We've also started a dialogue with the Federation of State Medical Boards in order for us to test the waters, see where this is, what they have been able to do. They've already been working at the Federation in licensure form. That would be uniform across all states. So now we're hoping that they can begin to really drive implementation of that, but then also moving forward, [on] the opportunities for doing any modeling, state law models, uniform state laws." – Ms. Nolan

"Is there any organization you know of that consists of the various pivotal or key people in states on this subject, where there could be some focused work in being able to implement as opposed to just having a report?" – Secretary Leavitt

"I don't know that there is a group, but I think one of the things that we have been talking about is this sustainability discussion, is the piece of where does this go from our perspective. And I think what we'd like to do is work with ONC and other lead Governors to try to figure out what does happen to it, how can we get some level of accountability. We'll have that in states as Governors and as legislators move to make this a priority in their states. We can do that, but in terms of making it a coherent national strategy, there is no one home for this at this time. There are so many parties involved in it. But I think we need to take that into consideration and sit down and figure out what we can offer as a strategy for implementation in the way that you're specifying." – Ms. Nolan

"I think that's the next logical step in your work." – Secretary Leavitt

"From an IT perspective, the market is ready to answer a lot of the questions of delivering care in different settings, but these barriers are holding us back…It's really a very cumbersome process to get licensed. If you're trying to figure out what the floor of privacy is in those things, it really is holding back the market. I've always believed that states are the ones that feel the pain, first, because of the Medicaid spend and they have the balanced budgeted amendments. Those are the ones that will cry 'uncle', I think. A letter from you in your current role, signed by the current Governors that are chairing the E-Health Alliance, to fellow Governors saying this is a wave coming [might help]." – Mr. DeVore

"That's a pretty good idea…I'm most willing to do that. It is now May. Governors will begin their legislative agenda preparation very soon. And I have been involved in a number of these things, and they're hard, particularly in difficult subjects like this. But it does require someone to begin to catalyze the discussion. It's a fascinating part of the future of states. States have got to figure this out if we're going to keep the federalist form of government we have, which is, in my judgment, the perfect form of government for a networked world, but you've got to have a way of being able to unify around standards." – Secretary Leavitt

"Within the nursing community, what's really interesting is that in times of disaster, Governors sign our licenses, and we're good no matter where we go. And I think it's sometimes that disaster issue where we said well, 'Why does this work during disaster and it doesn't work day by day?'" – Ms. Gelinas

"The Minnesota governor has now signed into law that all prescriptions must be written electronically by 2011. Do you see that as a trend at the state level beginning to happen where legislation is going to be passed at the state level, and if so, are they also defining in that same legislation standards that would be used?" – Mr. Roob

"I'm not sure about the standards piece, but…yes, we do expect this to be something where states are moving down the road towards requiring. We do see other states that have taken on incentive types of programs, either through other state personnel, which is, in fact, where Minnesota started, was in their contracting vehicle for their state personnel benefits, requiring that of their providers." – Ms. Nolan

Defining Key Health Information Technology Terms

Dr. Karen Bell, Director of ONC's Office of Health IT Adoption, commented that clear communication with consistent language is necessary to enable health policies that are well informed and products that can be marketed with transparency so that protections can be applied to well-defined solutions. She explained that this panel would be presenting clear, concise, and unambiguous consensus definitions for some basic health IT terms.

Jane Horowitz, Vice President and Chief Marketing Officer for the National Alliance for Health Information Technology, described their consensus process. The National Alliance, in collaboration with others, is defining the building blocks for infrastructure as it relates to EMRs and EHRs for health care professionals, PHRs for individuals, health information exchanges to tie the infrastructure together, and then regional health information organizations (RHIOs) as the local organization to put that infrastructure together. Ms. Horowitz and colleagues carried out a comprehensive literature review of all the terms, and used these results to frame the issues. Workgroups tasked with this project were multi-stakeholder groups representing physicians, nurses, CEOs, and CIOs from across the spectrum of health care. These volunteer workgroups met twice a month over a 6-7 month period. They also held two public forums and two public comment periods to vet concepts, validate the definitions, and understand where gaps exist. To ensure that good definitional practices were followed, a lexicographer provided assistance in these efforts.

Don Mon, Director of Practice Leadership at the American Health Information Management Association, presented the following definitions relating to health records:

- **Electronic Medical Record:** An electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one health care organization.

- **Electronic Health Record:** An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization.

- **Personal Health Record:** An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared, and controlled by the individual.

Mr. Mon discussed some key concepts related to health records terms. He explained that EMRs prevail today, focused on care and information within a single organization. Interoperability standards incorporated in EHRs in 2008 start the migration to information shared among organizations. PHRs under the control of the individual, not the provider, are interoperable with provider records, and other health related sources. In addition, PHRs are the source for diverse and varied applications to meet customer needs.

Bill Bernstein, a Partner at Manatt, Phelps, and Phillips, LLP, presented definitions relating to networks:

- **Health Information Exchange:** The electronic movement of health-related information among organizations according to nationally recognized standards.

- **Health Information Organization:** An organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.

- **Regional Health Information Organization:** A health information organization that brings together health care stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community.

Mr. Bernstein then described key concepts related to network terms, noting that they allow for efficient exchange of reliable and secure health-related information, and that they can connect an EHR to an EHR, an EHR to a PHR, and support population-based approaches to improving health and care. They use

nationally recognized standards for interoperability, incorporate privacy and security policies and procedures, and are governed by oversight structures that also ensure accountability. Mr. Bernstein reminded the Community that health information exchange is a process, not a structure, and that the health information exchange process incorporates nationally recognized standards and is not limited by geography. A health information organization provides oversight for various types of health information exchange processes (e.g., among specialty care entities, within a geographical area, health data banks, etc.). Health information organization functions may include: (1) maintenance of agreements, (2) support for architecture, (3) fiduciary responsibilities, and (4) conformance to nationally recognized standards.

Mr. Bernstein also explained that RHIOs are a type of health information organization. RHIOs are geographically bound; represents contiguous geographic areas; and have scopes that can be local, statewide, or span state boundaries. RHIOs also have distinct purposes and features. For example, they are organized for the purpose of improving health care in their communities and facilitate collaboration in a transparent manner.

In closing, Ms. Horowitz presented a slide with a diagram of how these defined terms relate to each other, highlighting the interoperability of the information that comes from electronic health records and personal health records to feed health information exchange and RHIO activity.

Discussion Highlights

"Somebody brought this up at one of the previous Community [meetings], about including the definition for what is health privacy, what [is meant] by health security. It seems to be one of the things I keep bumping into if you tell a state government you've got to work on health privacy, health security, and their answer is, 'If I ask 50 attorneys, I get 50 different answers.'" – Mr. DeVore

"If you're a clinical researcher, electronic medical records, or health information technology means an entirely different thing than if you are a clinician, or a consumer, or an insurance company or a pharmaceutical company. It's still health information technology, but it all takes on a different form. And beginning to define these terms in a way that will accommodate the mobilization of this data, I think, is very important. And we may have other terms we'd like to now pitch to you for you to begin to work." – Secretary Leavitt

"It's so important to communication…You can actually really understand the language that's used and what people are talking about. And I think we just need to make sure we do more of it." – Dr. Gerberding

"This is very helpful, and I'm going to begin to organize my speeches in a way that I'm disciplined to those definitions. I would invite the rest of you to do it, and I think we'll want to think through the impact it will have on HHS, but I think you can count on the fact that your work will be used, and we will have more for you." – Secretary Leavitt

"Why [wasn't] portability included in the definition of a personal health record?...I know you referenced it, but there has been much work done at least among the insurers, and the standards are out there in the public domain for a PHR to be portable, so that that consumer can take it wherever they go. And that's different than 'interoperable,' so I just wanted to know, was that a conscious decision to leave that out?" – Ms. Handelman

"The word 'portable' is not in the actual sentence, but it is in the surrounding text. And my apologies for not making that very clear. The point that I was saying about how if…your record was housed by or sponsored by an insurance agency, and you went from one insurer to the other, and then you were able to

take that health information to the next insurance, that was that portability concept. That was just one aspect of it. Portability also applies to the other example that we gave as well, where if your health information is in the underlying record of the provider institution, then your ability to take that information from hospital one to hospital two and so on would be an example of portability." – Mr. Mon

Public Comment

Speaker Number 1—Dr. Sarah Corley, an internist, Chief Medical Officer for a health information technology vendor, and a CCHIT volunteer, made comments to discourage the Secretary and Community from promulgating the definitions that were presented. She indicated that although using these definitions may sound like a good idea, it may have unintended consequences. She noted that there were no electronic medical or health vendors participating in the definition generating process, and the cost of changing all of the marketing materials and trademarks will be tremendous. Dr. Corley explained that certifying through the CCHIT defines a product as being interoperable. She added that the definition can be used by any organization to label a product, and could mean that someone could purchase a product that is thought to be interoperable, but the definition carries no requirement for certification. She asked why the definition is needed when certification tests for issues covered in the definition.

Speaker Number 2—Ms. Katherine Serkes of the Association of American Physicians and Surgeons discussed survey results related to barriers to physician adoption as a follow up to a discussion from January's Community meeting. Ms. Serkes repeated this survey with some slightly modified language and additional questions to try to further define issues related to physician resistance. Ms. Serkes presented some preliminary findings and offered to present the full and complete results to the Community at a future date. The mailed survey was sent to approximately 1,800 physicians in full-time practice. There was a 25 percent response rate, with more than 400 responses. The average respondent age was 56, with an average of 25 years in practice; and the average practice size was six physicians.

The number one reason or barrier for adoption, she found, was concern about government mandates for implementation. The number two barrier was concern about links to centralized government medical records. Number three was the lack of initial capital for software and training. There was a tie for number four between concern about patient privacy protection and the potential for linkage between EHRs and pay-for-performance. Number five was that the practitioner preferred personal clinical notes, and number six was concern about disruption to practice.

Ms. Serkes noted that one respondent reported having a $60,000 grant for the initial startup, and that this did indeed cover his initial startup in the purchase of his software. However, this physician ended up with what his practice accounted for as a half-million dollars in loss of revenues, because of they had to downgrade their number of patients per hour—their patient load was still is not back to normal at the time of the survey. Plus, this physician reported, it has cost about $10,000 in annual maintenance. The practice has hired one person who does nothing but scan patient records for their electronic records, so they have actually added personnel, and their productivity is down 15 to 25 percent. Ms. Serkes added that she has pages and pages of additional comments, including the following: "I'll retire before investing in a system that causes more problems than it solves." "The quality of our admissions in DC summaries has plummeted." "I wouldn't do it because privacy cannot be protected." "I'm actually playing with an EHR system." "I discovered that it slows me down." "Has been very expensive, about $300,000." "Will still require paper records." "I tried EHR system five years ago and it greatly increased my charting time."

Secretary Leavitt asked if 55 or 56 years old was the median age range of the Association's members. Ms. Serkes replied that her best guess is that the median membership age is slightly higher, because of retired physicians who are still members—this survey was from those in active practice only. Secretary Leavitt asked about the median age of physicians in the country overall. Dr. Corley commented that the average age differs by specialty. Mr. Weems wondered what the age distribution would have been if the survey had been sent via e-mail. Ms. Serkes explained that they chose to mail the survey because they wanted to replicate as closely as possible the methodology used by the University of Massachusetts survey that was reported on at January's Community meeting.

Speaker Number 3—Mr. Gary Dickinson, a consultant representing CentrifyHealth, an emerging PHR vendor, noted that there was a *Guardian* survey last year in the United Kingdom indicating that fully 60 percent of the general practitioners in the United Kingdom will not submit their patient records because of concerns for protection of privacy. Approximately 15 percent indicated that they weren't sure if they would submit their patient records. Mr. Dickinson also said that, for a relatively small vendor, the HITSP specifications are very daunting, with hundreds of pages of interoperability specifications that point to thousands of pages of standards that have to ultimately be implemented from this process. He commented that the discussion this morning indicates that this trend is going to continue fairly dramatically, and will have significant consequences for small vendors that have to somehow consume this and implement it. He emphasized the importance of considering the fact that simplification drives adoption by reducing costs to develop and implement, and reducing costs to market.

Closing Remarks

Before adjourning the 22nd meeting of the Community, Dr. Kolodner thanked the Community members, speakers, and participants for their attendance and participation.

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

American Health Information Community

Personal Health Records

Nancy Davenport-Ennis
National Patient Advocate Foundation
Chair, Consumer Empowerment Workgroup

July 29, 2008

Personal Health Records – Definition*

- An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared, and controlled by the individual.

**Source: The National Alliance for Health Information Technology (NaHIT)*

Personal Health Records – Significant Issues

- Dynamic Market
- Privacy Policies
- Authentication and other Security and Technology Standards

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

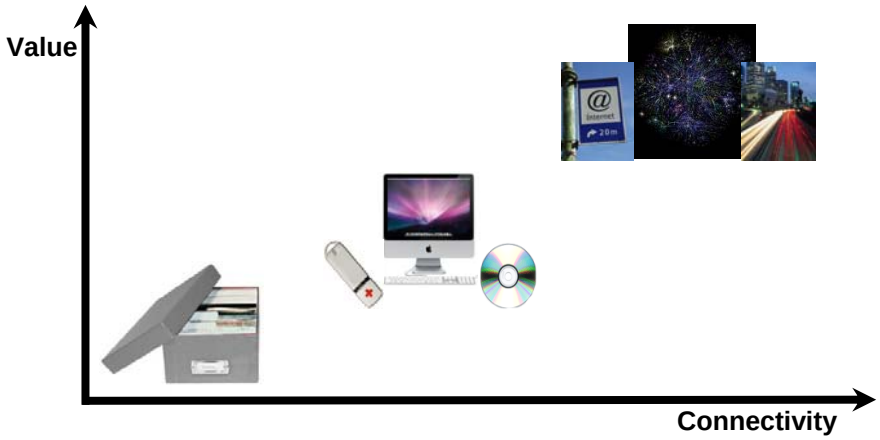
American Health Information Community

Managing Personal Health Information
Current Tools & Products

John Moore
Chilmark Research

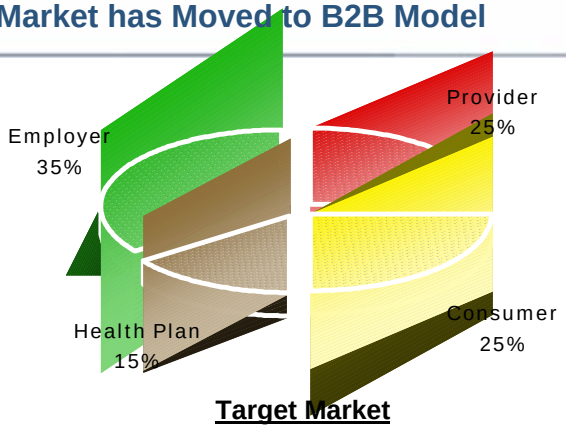
July 29, 2008

Today, Three Dominant PHI Modalities



Web-Based PHI Solutions Will Dominate

PHR Market has Moved to B2B Model



Target Market

- High Barriers to Entry in Provider Market
- Employer & Health Plan Markets Similar
- Consumer Plays are Often Legacy

Stand-Alone, Consumer PHI Apps: *Manage Health*

Attributes	Rating	Notes
Data Source	NA	Self-entry, Cumbersome, Current/Trusted?
Control	High	Owned & managed by consumer
Interoperability	Medium	Standards adoption increasing (CCR dominant)
Portability	Medium	Highly variable across vendors
Tools	Modest	Highly variable across vendors
Personalization	Low	Generic, simplistic solutions dominate
Adoption	Low	Self-entry key detriment, Highly motivated only

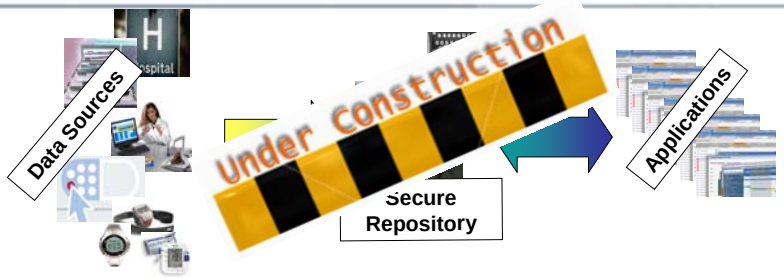
Employer & Health Plan Sponsored Platforms: *Manage Risks, Lower Costs*

Attributes	Rating	Notes
Data Source(s)	NA	Claims, PBM & HRA, Partial View
Control	Low	Sponsor controlled
Interoperability	Medium	Potential there, more talk than action
Portability	Low	Tethered to employer or insurer
Tools	Good	Significant activity, behavioral change
Personalization	High	Leverage HRA & claims data
Adoption	Medium	Trust, Incentives often required

Provider Sponsored Platforms: *Consumer Retention*

Attributes	Rating	Notes
Data Source(s)	NA	EMR, Gold Standard, Myopic
Control	Low	Portal to host EMR
Interoperability	Low	Disparate systems, competitive pressures
Portability	Low	Tethered to EMR
Tools	Medium	Communication for engagement/retention
Personalization	Low-Med.	Most do poor job, some exceptions
Adoption	Variable	Perceived value?

Utility Service Model for PHI: *Create an Ecosystem*



Attributes	*Potential*	Notes
Data Source(s)	NA	Virtually any pertinent data source
Control	High	Strong consumer control of data
Interoperability	High	Adoption of Open Systems and standards
Portability	Medium	Still under development
Tools	Very Good	Multiple tools/widgets, communications???
Personalization	High	Farther down the road
Adoption	High	Perceived value?

Conclusion

- Visibility & Interest in PHI Platforms is Accelerating
  - Significant increase in press mentions/articles
  - Vendors reporting strong double digit growth
- Consumer Expectations May be Higher than Reality
  - Solution capabilities vary greatly
  - Most solutions still require too much consumer input
- Data Liquidity is Paramount
  - Incentives to create, compile, access and share data
- Internet-based PHI Platforms Evolving Rapidly
  - Too early for prescriptive definitions and requirements
  - Defer to frameworks and guiding policies

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

American Health Information Community

Connecting for Health

Common Framework for Networked Personal Health Information

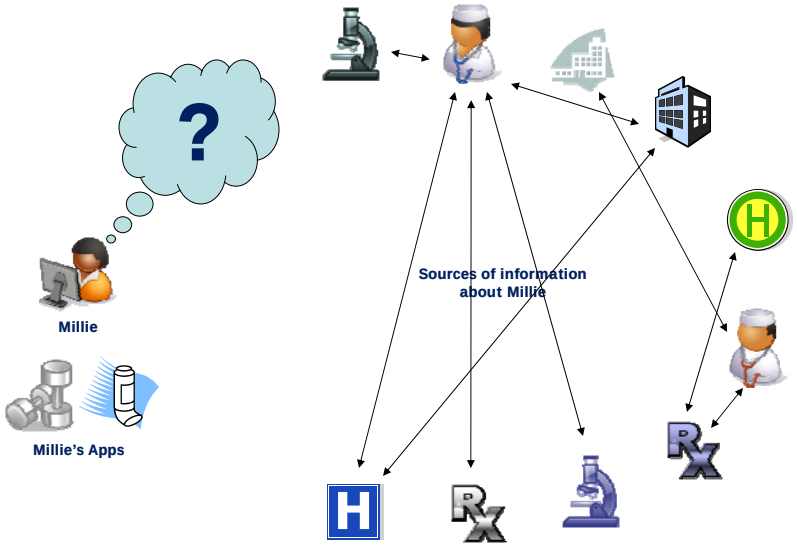
Carol C. Diamond
Markle Foundation

July 29, 2008

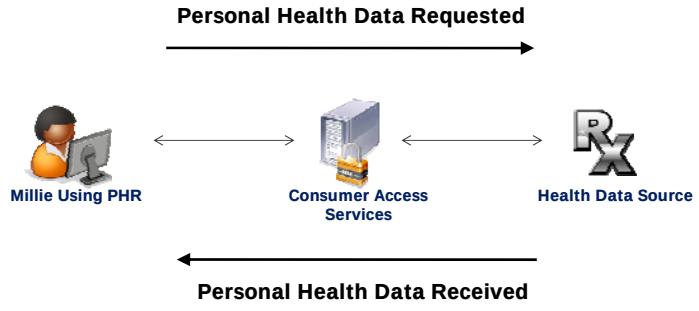
Connecting for Health Common Framework

- The landscape for new internet services that help consumers track and improve their health has shifted dramatically the past several years.
- The public appreciates the potential value of these services but at the same time expresses significant concern about the privacy of personal health information.

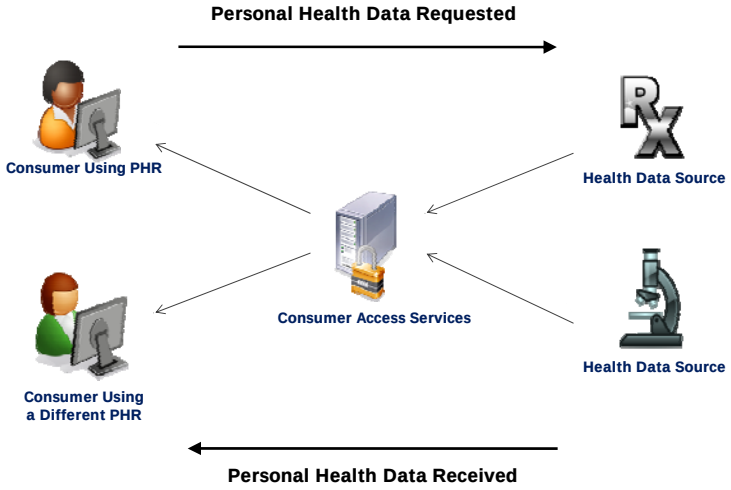
Business data streams of Millie's information

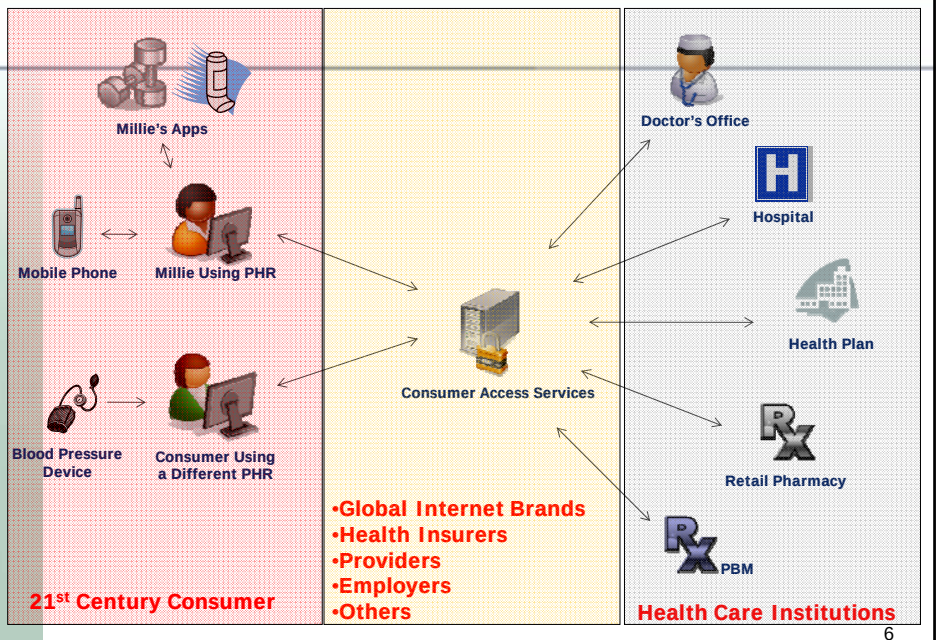


Consumer data streams of Millie's information



Consumer data streams of different consumers' information





The Internet enables these connections ...

... but what will be the rules to facilitate trust on the network?

See: http://www.connectingforhealth.org/flash/ccframework/

Americans Overwhelmingly Believe Electronic Personal Health Records Could Improve Their Health

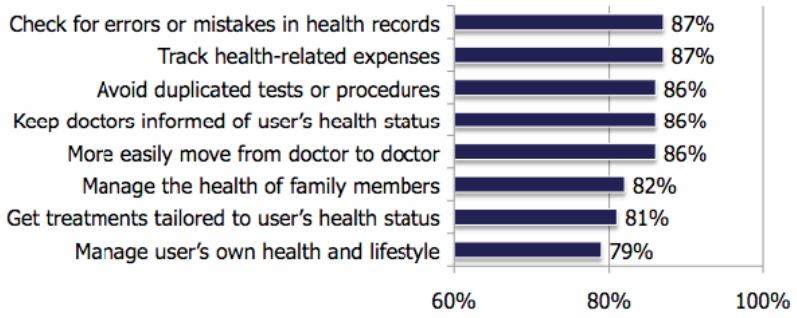
Nearly 9 in 10 Say Privacy Practices Are a Factor In Their Decision to Sign Up for One

- Markle commissioned Professor Alan F. Westin to develop a public opinion survey on the potential and privacy considerations of individually controlled electronic personal health records (PHRs).
- Conducted by Knowledge Networks among 1,580 Americans representative of total adult (18+) population, both on and not on the Net.
- Knowledge Networks places error rate at +/- 2.5%.

High Perception of Value

When the general public was asked how use of an online PHR service would affect individual handling of health and health care, large majorities said such services could improve several activities "a great deal" or "somewhat."

How many believe PHRs would improve their abilities to:



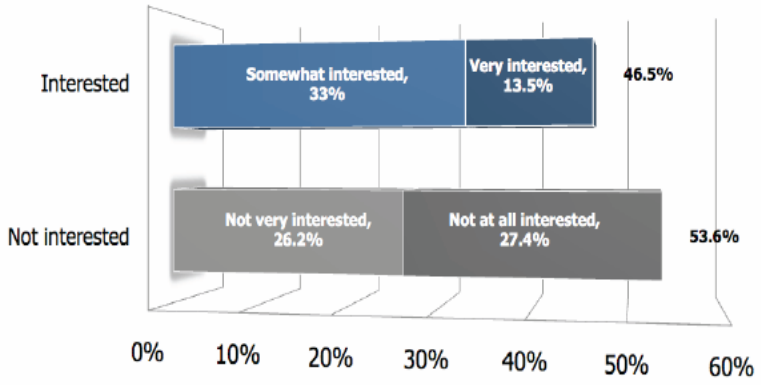
Interest in Joining Online PHR Service

"Some Internet technology companies and health care organizations are inviting individuals to join free online electronic personal health record services. You could obtain, store, and update your health information on a secure web site. You could control which health care providers can see or update your PHR, and you could automatically receive valuable information from the Internet related to the medical and health conditions and interests you indicated in your PHR."

How interested would you be in joining such a service?

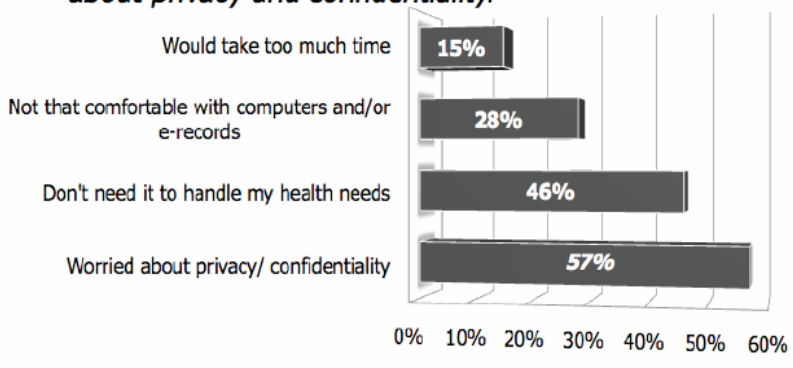
High Interest

Almost half the public say they are interested in joining a free online PHR system, with 13.5% saying they are "very interested."



Privacy Concerns

'Not interested' – Why not? *More than half of these respondents not interested in PHRs cited "worries about privacy and confidentiality."*



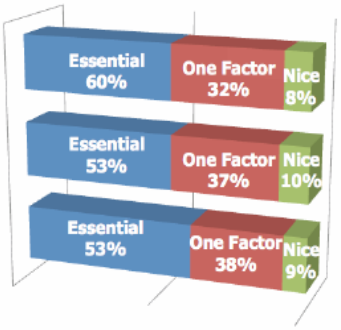
Practices Matter

When asked how important a set of privacy and information practices would be in their decision whether to sign up for an online PHR service, large majorities said each of these would either be "essential" or "a factor in making their decision."

Affected people would be notified if their information falls into unauthorized hands in a way that could compromise their identity or expose their health information.....

An individual would be able to review who has had access to their personal health information.....

Individuals would have a clear process to request corrections or dispute the way their information is handled.....



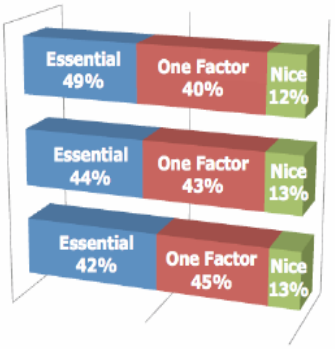
Practices Matter (continued)

When asked how important a set of privacy and information practices would be in their decision whether to sign up for an online PHR service, large majorities said each of these would either be "essential" or "a factor in making their decision."

Individuals would NOT be denied care or penalized financially based on whether they decided to provide certain medical information to an Internet-based service...

Having individuals control what information from their medical records is made available to others. For example, an individual with a sensitive medical condition could decide NOT to include information about treatment for that condition.....

Individuals could make informed choices about how their information is collected and used.....



Variety of Enforcement Tools

"How effective do you believe each of the following would be to ensure that PHR suppliers abide by privacy protections regarding personal health information?"

- Having an independent organization audit the PHR organization and provide a seal of approval to certify it is following good practices ..... **80% believed it would be effective**
- The Federal Trade Commission or state attorneys general enforcing existing consumer protection laws, by finding any PHR that does not follow its own policies is engaging in false and misleading practices... **80% believed it would be effective**
- Market forces – consumers choosing the products and brands they trust and not using others that do not follow good privacy practice ..... **76% believed it would be effective**
- Congress passing a new health privacy law to cover the special features of online PHR services..... **76% believed it would be effective**

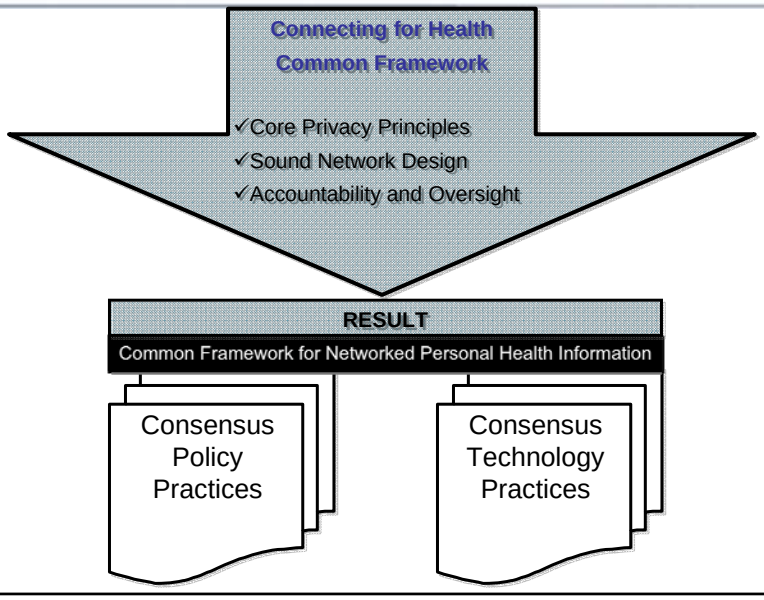
Markle Survey: Key Findings

- Four in five believe that online PHRs would be beneficial in managing their health and health care.
- Nearly half the public expresses some interest in using one.
- Among those not interested, concern for privacy is the most frequently cited reason why.
- Majorities of 87 percent to 92 percent say six key privacy practices are factors in their decision to use an online PHR.
- More than 90 percent said their express agreement should be required for each use of their online health information.
- More than 75 percent said each of four possible policy enforcement mechanisms would be effective.

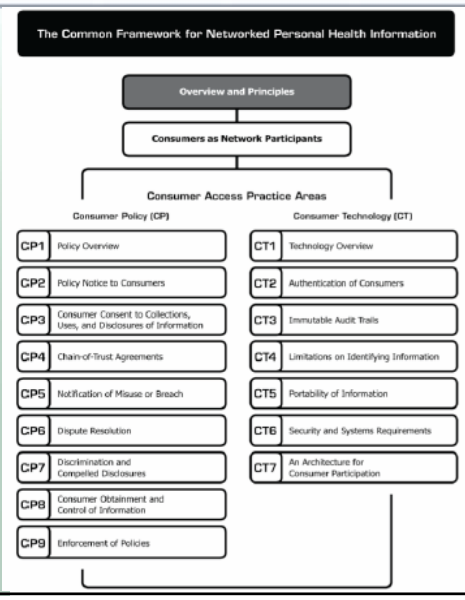
Key Implications

- Among many possible keys to stimulate broader public adoption of online PHRs and related services, a majority of the public sees a comprehensive set of privacy practices to be essential.
- And, they support the effectiveness of a variety of possible mechanisms to enforce these practices.

Our Approach



The purpose of the Connecting for Health Common Framework is embodied in "Millie"

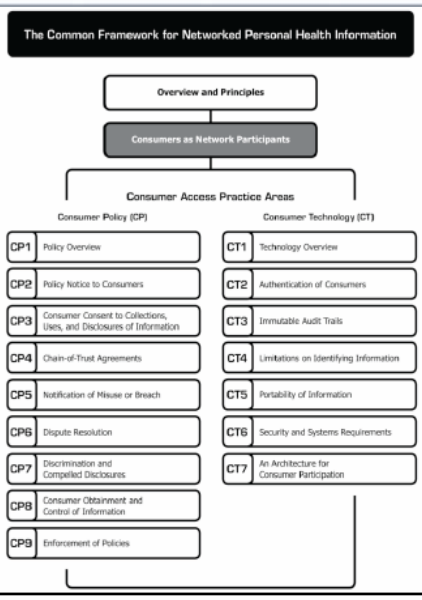


Millie illustrates the needs of millions of U.S. adults who could benefit from greater connectivity in health and health care.

Consumers should be able to collect, store, manage, and share copies of health information.

The Common Framework is based on fair information practices and focuses on network rules, not application standards.

Consumers as Networked Participants



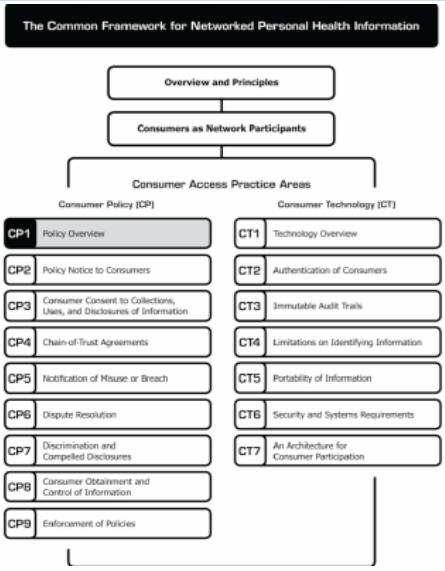
Millie could manage her health using a wide variety of networked tools and services

Consumers can help transform the health sector, as they have in other areas.

"Networked PHRs" are an important tool for consumer empowerment.

But to have an environment of trust, some basic rules should guide the emerging industry.

CP1: Policy Overview



Millie would know that there are rules for how her information will be collected, used, and shared.

New services present potential benefits and risks for consumers. Many are not covered by HIPAA.

This emerging, innovative new space is evolving without a common set of information practices and expectations.

CP1: Policy Overview

- This Connecting for Health Common Framework for Networked Personal Health Information is a positive step that industry can take now toward increasing trust.
- All PHRs and supporting services, whether they are covered by HIPAA or not, should address each element of the Common Framework.

The Common Framework for Networked Personal Health Information

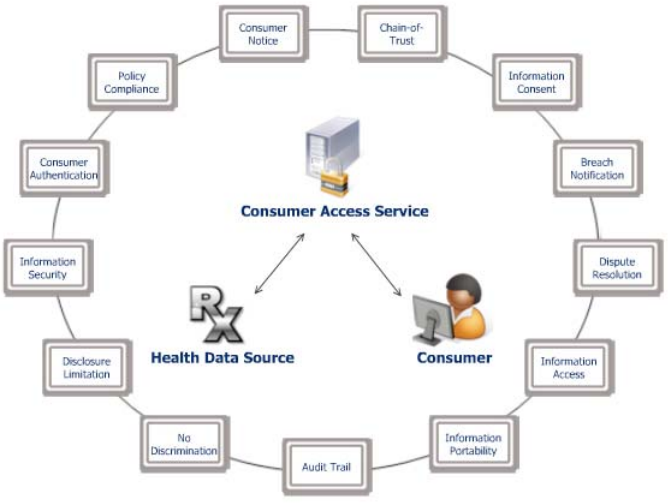
Overview and Principles

Consumers as Network Participants

Consumer Access Practice Areas

Consumer Policy (CP)		Consumer Technology (CT)	
CP1	Policy Overview	CT1	Technology Overview
CP2	Policy Notice to Consumers	CT2	Authentication of Consumers
CP3	Consumer Consent to Collections, Uses, and Disclosures of Information	CT3	Immutable Audit Trails
CP4	Chain-of-Trust Agreements	CT4	Limitations on Identifying Information
CP5	Notification of Misuse or Breach	CT5	Portability of Information
CP6	Dispute Resolution	CT6	Security and Systems Requirements
CP7	Discrimination and Compelled Disclosures	CT7	An Architecture for Consumer Participation
CP8	Consumer Obtainment and Control of Information		
CP9	Enforcement of Policies		

When taken together, the practices enhance participation and protect personal health information

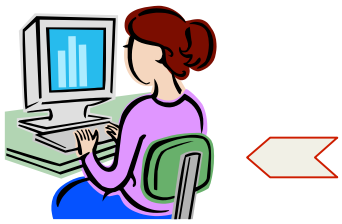


Endorsers of the First Detailed, Consensus-Based Framework for Networking Personal Health Records

AARP
Aetna
American Academy of Family Physicians
Association of Online Cancer Resources (ACOR.org)
America's Health Insurance Plans
BlueCross BlueShield Association
CapMed
Center for Democracy and Technology
Center on Medical Record Rights and Privacy
Cisco Systems Inc.
Consumers Union
Dossia
FollowMe
Google
Geisinger Health System
Health Care For All
InterComponentWare Inc.
Intuit Inc.
MedicAlert
Microsoft Corp.
National Breast Cancer Coalition
National Partnership for Women and Families
NewYork-Presbyterian Hospital
Pacific Business Group on Health
Palo Alto Medical Foundation
Partners Healthcare System
RxHub
SureScripts
U.S. Department of Veterans Affairs
Vanderbilt Center for Better Health
WebMD

Key Points

- Consensus practices among health sectors and technology innovators can help internet health information products flourish.
- A stable set of principles and practices will foster innovation and improve consumer choice for these emerging services.
- This collaboration lays out specific practices that all PHRs and related services can use, whether they are covered by federal privacy rules or not, so they can enhance public trust.
- See http://www.connectingforhealth.org/phti/



Common Framework for Networked Personal Health Information: Consumer Policy (CP) Briefs, June 2008

How "Millie" — a 21st Century consumer — would benefit under a Common Framework to help her obtain and control electronic copies of her personal health information and connect to health information services.

Overview and Principles

*The purpose of the **Connecting for Health** Common Framework is embodied in "Millie." Her character illustrates the needs of millions of U.S. adults who could benefit from greater connectivity in health and health care.*

CP1 Policy Overview

Millie would know that there are rules for how her information will be collected, used, and shared.

CP2 Policy Notice to Consumers

Millie would have easy access to clearly stated rules for how her information will be handled. The roles of all actors handling her information — including her own roles — would be spelled out clearly.

CP3 Consumer Consent

Millie would understand and exercise meaningful choices about her information. She would be asked specifically about uses and disclosures of her personal health information.

CP4 Chain-of-Trust Agreements

The organizations that touch Millie's health information would be contractually bound to handle the information according to specified policies. For example, the policies would disallow business partners from assembling unauthorized profiles about Millie.

CP5 Notification of Misuse or Breach

If Millie's information or identity becomes compromised because of a mistake, data leak, or fraud, Millie would be notified about it in a timely way. She would be told what she can do, and what others will do, to limit any harm.

Consumers as Network Participants

Millie could manage her health the way she can manage her finances or travel. For example, she could choose applications to download and upload critical health information, track her vital numbers, order prescription refills, get lab results, and connect to professionals and communities of patients — all in an electronically interconnected environment that she trusts.

CP6 Dispute Resolution

If Millie has a problem with a service, or finds an error about her information, she would be able to easily figure out the process for resolving it.

CP7 Discrimination and Compelled Disclosures

Millie wouldn't lose her job, insurance, or other benefits because of information about her on the network. She also wouldn't be forced to allow insurers or employers to see her information in order to get a job or benefits.

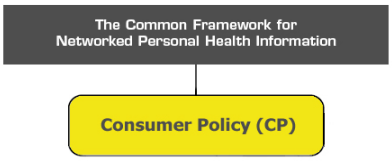
CP8 Consumer Obtainment and Control of Info

Millie would be able to get copies of her records electronically, instead of on paper. She would be able to manage personal health record accounts for her children, and for her ailing mom. She would also be able to terminate those accounts and keep the information out of anyone's hands, if she wants to.

CP9 Enforcement of Policies

Millie would know that there are mechanisms to make sure that the organizations touching her information play by the rules.

See Consumer Technical (CT) Briefs



Common Framework for Networked Personal Health Information: Consumer Policy (CP) Briefs, June 2008

Key messages of the policy resources in the Common Framework:

Overview and Principles

- Consumers should be able to collect, store, manage, and share copies of personal health information.
- The Common Framework is based on fair information practices and focuses on network rules, not application standards.

CP1 Policy Overview

- New services present potential benefits and risks for consumers.
- Many new information services are not covered by HIPAA.
- This emerging, innovative new space is evolving without a common set of information practices and expectations.
- This Common Framework of sound practices is a positive step that industry can take now toward increasing trust.
- All PHRs and supporting services should address each element of the Common Framework, whether they are covered by HIPAA or not.

CP2 Policy Notice to Consumers

- Notices should be easily accessible, clear, comprehensive, summarized, updated.
- Policy notice is necessary, but not sufficient protection.
- Many consumers don't read notices, so the full Framework is necessary.

CP3 Consumer Consent

- Obtaining the consumer's consent is a critical fair information practice.
- However, consent by itself does not adequately protect people.
- A complete framework of protections is necessary, no matter the 'I agree' statement.
- Specific, "independent consent" is advisable for practices that would be unexpected by a reasonable consumer.

CP4 Chain-of-Trust Agreements

- Contracts are one mechanism to bind parties to policies.
- Chain-of-trust agreements should disallow unauthorized uses of information.
- There are limitations to chain-of-trust agreements, including inconsistent enforcement and scaling difficulties.

Consumers as Network Participants

- Consumers can help transform the health sector, as they have in other sectors. "Networked PHRs" are a vital tool for consumer empowerment.
- Some basic rules should guide the emerging industry.

CP5 Notification of Misuse or Breach

- There should be policies to notify affected consumers in the event of a potentially harmful breach of information.

CP6 Dispute Resolution

- There should be mechanisms to resolve disputes such as breach or misuse, data quality or matching errors, allegations of unfair or deceptive trade practices, etc.

CP7 Discrimination and Compelled Disclosures

- Some new services will co-mingle information from professionals and consumers.
- It is important to disallow discrimination based on information in PHRs or similar consumer tools.
- Participating organizations should take a strong stand against "compelled disclosures" (i.e., when consumers must allow organizations access to personal information in their PHR as a condition of employment, benefits, or other critical services.)

CP8 Consumer Obtainment and Control of Info

- Consumers should be able to: request their personal information in electronic format; electronically collect, store, and control copies of their personal health information; request corrections; delete data; designate proxy access; terminate their account, and limit retention of data in inactive accounts.

CP9 Enforcement of Policies

- Many possible enforcement mechanisms should be considered, each with pros and cons.
- There should not be attempts to create a one-size-fits-all enforcement mechanism.
- Different practices will need different combinations of enforcement mechanisms.
- More thought and experimentation are needed to create optimal frameworks for enforcement.

See Consumer Technical (CT) Briefs

Common Framework for Networked Personal Health Information: Consumer Technical (CT) Briefs, June 2008

How "Millie" — a 21st Century consumer — would benefit under a Common Framework to help her obtain and control electronic copies of her personal health information and connect to health information services.

Overview and Principles

*The purpose of the **Connecting for Health** Common Framework is embodied in "Millie." Her character illustrates the needs of millions of U.S. adults who could benefit from greater connectivity in health and health care.*

CT1 Technology Overview

Millie's health information moves many places, in lots of different bits and bytes. Each organization touching information about her has different roles and plays by somewhat different rules.

CT2 Authentication of Consumers

Millie would be able to prove she is who she says she is, and link to her information in various systems, without an enormous burden to herself. However, the methods would make it extremely hard for someone to pose as her.

CT3 Immutable Audit Trails

Millie would be able to see who has accessed her accounts and the information in them. It would all be tracked, and accessible to her anytime.

CT4 Limitations on Identifying Information

Unauthorized organizations would not be allowed to build profiles about Millie by combining her information with other databases. The organizations that touch her data would take care not to disclose identifying information about her, unless there's a clear need for it agreed to by Millie.

Consumers as Network Participants

Millie could manage her health the way she can manage her finances or travel. For example, she could choose applications to download and upload critical health information, track her vital numbers, order prescription refills, get lab results, and connect to professionals and communities of patients — all in an electronically interconnected environment that she trusts.

CT5 Portability of Information

Millie would be able to download copies of information about her for personal use. In the future, she would be able to push a few buttons to move her health information electronically from one service or application to another, if she wants to.

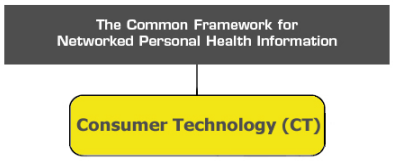
CT6 Security and Systems Requirements

Millie would know that the best practices for securing her information are in place, and they will continue to be updated as appropriate.

CT7 An Architecture for Consumer Participation

The way the network is set up, Millie's information wouldn't need to be in big repositories just so it could be shared. If she wanted to put it in a repository, she would be able to, but there would be an easy way to find her information when she asks for it, without relying on one big database.

See Consumer Policy (CP) Briefs



Common Framework for Networked Personal Health Information: Consumer Technology (CT) Briefs, June 2008

Key messages of the technology resources in the Common Framework:

Overview and Principles

- Consumers should be able to collect, store, manage, and share copies of personal health information.
- The Common Framework is based on fair information practices and focuses on network rules, not application standards.

CT1 Technology Overview

- Health data streams are enormously complex, resulting in copies of information being held at many different points.
- Information can be combined to build revealing profiles of individuals.
- As consumers become network participants, new "consumer data streams" are being created.
- Consumers need better tools and assurances that their information will be handled according to fair information practices.

CT2 Authentication of Consumers

- Sound authentication practices are a cornerstone of information security.
- There is no magic bullet, or one-size-fits-all approach, to authentication.
- Depending on their capabilities and relationship with consumers, PHRs and supporting services should consider using in-person proofing, 'bootstrapping' of in-person proofing by other organizations, and remote proofing as alternatives to in-person proofing.

CT3 Immutable Audit Trails

- PHRs and supporting services should maintain an easy-to-comprehend, user-accessible, and clearly labeled electronic audit trail containing immutable entries that pertain to the consumer's account, data, and policy consent.

Consumers as Network Participants

- With new Internet-based tools, consumers can help transform the health sector, as they have in other sectors.
- "Networked personal health records" (PHRs) are a vital tool for consumer empowerment.
- Some basic rules should guide the emerging industry.

CT4 Limitations on Identifying Information

- PHRs and supporting services should limit the scope of the identifying data disclosed to third parties to only those that are reasonably necessary to perform the specified and consumer-authorized function(s).
- Care should be taken to limit the release or exposure of electronic identifiers that can be directly or indirectly tied to an individual, including IP address, cookies, and web beacons.

CT5 Portability of Information

- Consumers should be given the ability to compile their health data electronically from multiple sources for personal use.
- Consumers should be able to download their data into applications they control.
- The ideal future state is one in which the consumer can transfer personal data electronically between PHRs and supporting services.

CT6 Security and Systems Requirements

- PHRs and supporting services should adopt best industry practices for data transaction and storage security to enforce privacy policies and practices and, in doing so, build network and consumer trust.

CT7 An Architecture for Consumer Participation

- **Connecting for Health** technical principles should shape how PHRs and supporting services fit within a sound and flexible architectural approach to a Nationwide Health Information Network (NHIN).

— *See Consumer Policy (CP) Briefs*

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

American Health Information Community

Why Personal Health Record (PHR) Systems and Networks Must be Standards-Based and Interoperable

Jeff Blair
Lovelace Clinic Foundation

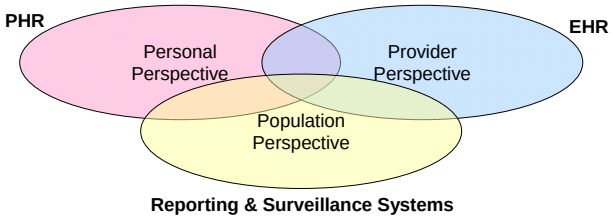
July 29, 2008

Patient-Centered PHRs and Data Sharing

- Many PHR systems/networks will import patient information from health care providers and health plans, and:
  - Organize this information into a virtual health record for a specific patient/consumer
  - Over time, become a lifetime health record for the patient
- Eventually, PHR systems/networks could export information to:
  - Health care providers (EHR systems, etc.)
  - Clinical research organizations
  - Public health agencies (community health registries, emergency response, bioterrorism, etc.)

Same Data, Multiple Perspectives

- This concept is represented by the following diagram:



- The overlapping perspectives in this diagram helped to identify the need for a national health information infrastructure (including interoperable EHR systems, PHR systems, HIE networks, e-Rx networks, etc.)
- The Nationwide Health Information Network (NHIN) has been developed to provide interoperability within and among these perspectives

Levels of Interoperability

- A high level of interoperability uses HIT standards to enable:
  - Basic interoperability (electronic communications)
  - Semantic interoperability (ability of receiving computer to accurately interpret clinical data)
- It is very important that PHR systems/networks support a high level of interoperability so that we don't preclude very substantial benefits to PHR users and the rest of the health care delivery system

Benefits of High Level Interoperability

- Many of the benefits of high level interoperability result from more accurate interpretation of clinical data
  - More accurate diagnoses
  - Enables clinical decision support (i.e., clinically specific data can trigger alerts, clinical guidelines, etc.)
  - More consistent and comprehensive measurement of patient outcomes enables:
    - improved clinical processes
    - improved administrative workflows
    - evolution to a reimbursement system that rewards better outcomes
  - Significant improvement in quality and cost of clinical research

HIT Standards Remove Barriers

- PHR systems/networks need to employ HIT standards to remove barriers to:
  - Ability to import/export health care data with many different health care providers
  - Portability of PHR information between PHR vendors
  - Communication of consumer preferences to limit access to their data
- PHR systems/networks also need to connect to the NHIN in order to:
  - Enable both patients and providers to locate patient records that may be scattered across multiple health care facilities
  - Support electronic updates to PHRs from existing and new providers

The Need for Consistent Policies and Services

- All systems within the health care delivery system should work together to agree upon consistent policies and services for privacy and security to enable a trust infrastructure
  - User authorization
  - User authentication
  - Audit logs

Conclusion

- Personal health records systems/networks are an important and growing aspect of the healthcare delivery system and the national infrastructure for health information technology
- The full benefits that flow from an interoperable national infrastructure for health information technology can only be realized if all of the systems and networks comply with common national standards for health information exchange

Appendix

Levels of Interoperability

Level	Description	Examples	Characteristics
1. Non-electronic data	No use of IT to share data	Mail and telephone	Communication from one human being to another human being
2. Connectivity (Machine Transportable Data)	Transmission of non standard information by basic IT	Fax and scanned images	The receiving computer can print or display the information, but only a human can interpret it
3. Basic Interoperability (Machine Organizable Data)	Transmission of structured messages containing non-standardized data	Email of free text or HL7 V2.x messages	The receiving computer can accept data but it may not be able to interpret all of the data, and some of the interpretations may not be clinically accurate
4. Semantic Interoperability (Machine Interpretable Data)	**Transmission of structured messages containing standardized terminologies and code sets**	**Electronic processing of health claims, summary patient records, lab orders, prescriptions, decision support, etc.**	**The receiving computer can interpret the healthcare data in the message with precisely the same meaning as the sending computer**

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

American Health Information Community

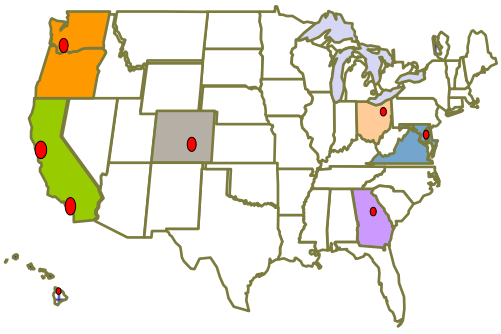
My Health Manager:
A personal health record that works

Andrew M. Wiesenthal, MD, SM
Associate Executive Director
The Permanente Federation

July 29, 2008

KAISER PERMANENTE

Kaiser Permanente at a glance



- Integrated health care delivery system
- 8.7 million members
- 14,000 physicians
- 156,000 employees
- Serving 9 states and D.C.
- 36 hospitals and medical centers
- Approx. 430 medical offices
- $31.1 billion operating revenues

KAISER PERMANENTE

My Health Manager—our numbers tell the story

Active users:

- More than 2.2 million members are registered and activated
- 60% of users logged in 5 times or more in 2007

Email your doctor:

- 12,000+ Permanente physicians use e-mail with patients
- Averaging nearly 500,000 messages to providers a month in 2008

View lab results:

- Most popular feature on the site
- Averaging 1.3 million tests viewed a month in 2008

KAISER PERMANENTE®

What Kaiser Permanente's My Health Manager offers:

A secure view of the shared record:

View lab test results, immunizations and allergies
View past office visits
View problem list and healthcare reminders

Interaction with doctors:

E-mail your doctor (part of record)
Complete a Health Risk Assessment (part of record)

Convenient transactions:

Refill prescriptions
Make, view and cancel appointments
Act for a family member

Educate:

Embedded links to our health and drug encyclopedias
Online behavior change programs

KAISER PERMANENTE®

What members are saying

"Yesterday morning I went in for a routine lab work-up to monitor my cholesterol. By lunchtime that same day your system forwarded the lab results to me. WOW! This is well done! I am impressed. Your system is so much better than the piecemeal, inefficient methods being used by other health care providers. My wife and I thank you for helping to serve me!" ***Richard Starck, Kaiser Permanente Member, Mid-Atlantic Region***

"Recently, I thought I had a bladder infection. I emailed my Dr. through kp.org. Dr. ordered a lab test, I went in and got my results on-line later that day and my Dr. called to explain the results. No registration fee. No waiting. Love the service." ***Hawaii member, Fall 2005***

KAISER PERMANENTE®

What Does the Future Hold?

- KP members will have reasons to bring data in to our system and to take it out to other systems
- We must provide for that bidirectional movement of data, under member control
- We cannot afford, nor will we tolerate, a multitude of technical approaches to solving this problem
- We will promote a single, standardized (CDA/CCD-based) solution because it makes the most sense for us and for the country
- With that as a condition, we envision a utility-based solution that does not limit consumer choice as to setting or vendor, so long as privacy concerns are met

KAISER PERMANENTE®

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

American Health Information Community

Qchart Payer Based Personal Health Record

Jerry W. Bradshaw
Arkansas Blue Cross and Blue Shield

July 29, 2008

Arkansas Blue Cross Health IT Timeline

1996 – Partnership with Leading AR Health Systems
- Seed EMR Systems in Physician's Offices
- Interface Hospital, Physician, and Payer Systems
- Tie it All Together with One of the Nation's First HIEs

1998 – Advanced Health Information Network (AHIN) Beta
- Two Large Integrated Delivery Systems (Lab, Rad, Reports)
- Multiple Physician's Offices
- Multiple Payers
- Identified Major Omissions in Patient Records
- Began to Investigate Using Claim Coding to Augment Record

Arkansas Blue Cross Health IT Timeline

2000 – Health Systems Discontinued Project Funding
- Clinical Portion of the System Mothballed
- Continued to Maintain/Enhance Financial/Admin. System
- Today System Serves 95+% of Arkansas Providers

2006 – Renewed Interest in Clinical Information System
- Revisited Research on Use of Claim Coding to Build Record
- Completed Design with Claim Coding as Primary Data Source
- Design Anticipates Importing Discrete Clinical Beginning 2009

2007 – PHR Beta Release July 2007 to 2,000 Employees
- General Release to 850,000 ABCBS Members October 2007
- Released to Authorized Arkansas Physicians December 2007

System Features and Functions

Health Summary Page
- Demographics
- Emergency Contact
- Chronic Conditions/Risk Factors (Rules Engine)
- Treatment Opportunities (Rules Engine)
- Recent Medications
- Recent Outpatient Visits
- Recent Inpatient Visits
- Access to Greater Detail for any Information Category

System Features and Functions

- Personal Profile
  - Basic Demographics and Primary Insurance (S)
  - Extended Demographics (M)
  - Secondary Insurance (M)
  - Emergency Contact (M)
  - Employer Information (M)
  - Preferred Language (M)
  - Organ Donor Status (M)
  - Living Will Status (M)
  - Durable Power of Attorney Status (M)
  - Advance Directive Document Holder Contact Information (M)

M = Member Entered S = System Entered

System Features and Functions

- Inpatient Visits
  - Listing of Known Inpatient Encounters
  - Data Source = Medical Claim Transactions
  - Configurable to Show Last 3, 6, 12 Months or All
  - Can be Sorted by Admission Date, Diagnosis, Provider or Facility
  - Each Visit Expandable to Show Procedures Performed, Facility Address, etc.
  - Member Can Unhide System Hidden Visits and/or Procedures
  - Member Can Hide Additional Visits and/or Procedures
  - Member Can Hide/Unhide Single Visit/Diagnosis/Procedure or all Occurrences of Diagnosis/Procedure Within the Record
  - Member and/or Physician Can Annotate Record

System Features and Functions

- Outpatient Visits
  - Listing of Known Outpatient Encounters
  - Data Source = Medical Claim Transactions
  - Configurable to Show Last 3, 6, 12 Months or All
  - Can be Sorted by Service Date, Diagnosis, Provider or Facility
  - Each Visit Expandable to Show Procedures Performed, Facility Address, etc.
  - Member Can Unhide System Hidden Visits and/or Procedures
  - Member Can Hide Additional Visits and/or Procedures
  - Member Can Hide/Unhide Single Visit/Diagnosis/Procedure or all Occurrences of Diagnosis/Procedure Within the Record
  - Member and/or Physician Can Annotate Record

System Features and Functions

- Diagnoses
  - Listing of Known Diagnoses for the Member
  - Data Source = Medical Claim Transactions
  - Only the Last Occurrence of Each Diagnosis is Presented
  - Can be Used as a Problem List by Treating Physician
  - Configurable to Show Last 3, 6, 12 Months or All
  - Member Can Unhide System Hidden Diagnoses
  - Member Can Hide Additional Diagnoses
  - Member Can Hide/Unhide Single Diagnosis or all Occurrences of the Diagnosis Within the Record

System Features and Functions

- Procedures
  - Listing of Known Procedures Performed for the Member
  - Data Source = Medical Claim Transactions
  - Procedures Performed Multiple Times are Shown
  - Configurable to Show Last 3, 6, 12 Months or All
  - Each Procedure Expandable to Show Entire Visit
  - Member Can Unhide System Hidden Procedures
  - Member Can Hide Additional Procedures
  - Member Can Hide/Unhide Single Procedure or all Occurrences of the Procedure Within the Record
  - Member and/or Physician Can Annotate the Record
  - Importation of Discrete Clinical Results Anticipated 2009

System Features and Functions

- Lab/Radiology
  - Listing of Known Lab/Radiology Procedures for the Member
  - Data Source = Medical Claim Transactions
  - Configurable to Show Lab Only, Radiology Only or All
  - Configurable to Show Last 3, 6, 12 Months or All
  - Each Procedure Expandable to Show Entire Visit
  - Member Can Unhide System Hidden Procedures
  - Member Can Hide Additional Procedures
  - Member Can Hide/Unhide Single Procedure or all Occurrences of the Procedure Within the Record
  - Member and/or Physician Can Annotate the Record
  - Importation of Discrete Clinical Results Anticipated 2009

System Features and Functions

- Medications
  - Listing of Known Medications Filled by the Member
  - Data Source = Pharmacy Claim Transactions and Member
  - Configurable to Show OTC Only, Prescription Only or All
  - Configurable to Show Last 3, 6, 12 Months or All
  - May be Sorted by Date, Medication, Pharmacy or Prescriber
  - Each Prescription Expandable to Show Details
  - Member Can Unhide System Hidden Prescriptions
  - Member Can Hide Additional Prescriptions
  - Member Can Hide/Unhide Single Prescription or all Occurrences of the Prescription Within the Record
  - Member and/or Physician Can Annotate the Record

System Features and Functions

- Immunizations
  - Listing of all Known Immunizations for the Member
  - Immunizations System Entered If a Claim is Filed
  - Member May Enter Additional Immunizations
  - Importation of Immunizations from Health Dept. Late 2008
- Allergies
  - Listing of all Known Allergies for the Member
  - Data Source = Member

System Features and Functions

- Medical History
  - Data Source = Member
  - Personal History Includes Height/ Weight and Calculated BMI, Health Rating, Dietary Questions, Recent Medical Tests and Documentation of Chronic Conditions/Illnesses
  - Family History Includes Documentation of Health Status for up to 19 Family Members
  - Social History Includes Documentation Related to Work, Education, Religious Preference, Alcohol/Drug Use, Pets, Stress, Recent Travel and Sleep

System Features and Functions

- Clipboard
  - Summary of the Information Contained Within the PHR
  - May be Printed or Saved to External Media, e.g., Thumb Drive
  - Accepted by Many Providers in Lieu of Completing a Patient Information Form
- Activity Log
  - Documentation of Activity Within the Member's PHR
  - Record of Physicians Who Have Accessed the PHR
  - Record of Who/What/When Changes Were Made to the PHR
- Tutorial, FAQ and Data Entry Wizards

Privacy and Security

- Data Access and Control
  - Member May Opt Out of Participation Entirely
  - Sensitive Data is Automatically Hidden by the System
  - Member May Hide Additional Data at Their Discretion
  - Member May Unhide Any Hidden Data at Their Discretion
  - Next Release Limits Access to Specific Individuals at the Member's Discretion
- Tiered Architecture for Added Security
  - All Member Data Protected by Firewalls Between Tiers
- Anti-Phishing Process to Guard Against Identity Theft

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

American Health Information Community

Dossia: The Employer-Driven Personally Controlled Health Record Platform

William Crawford
Children's Hospital Boston / Dossia

July 29, 2008

Dossia is an employer-led non-profit organization dedicated to **improving healthcare** in the USA

We're paying the bill so we're getting involved

What Dossia Does

- Funds development of a web-based framework through which US employees, dependents, and retirees (and later public-at-large) can maintain private, personal, and portable **Personally Controlled Health Records ("PCHRs")** – personally controlled collected copies of health data

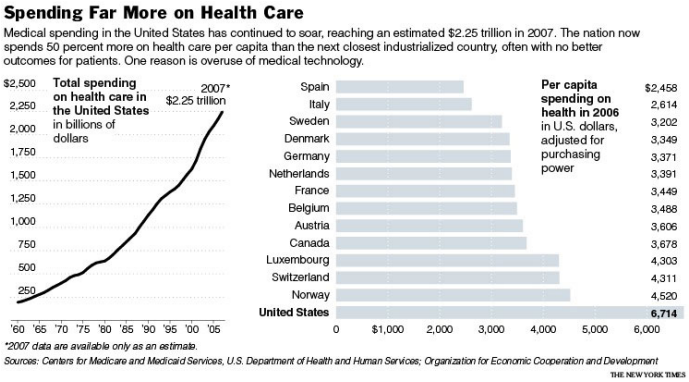
- **PCHRs** will empower individuals to take control of their health and costs by:
  - Providing meaningful, user-centric, electronic access to vital data
  - Improving healthcare literacy for Americans
  - Reducing medical errors and waste from paper-based healthcare
  - Helping healthcare consumers be true partners in managing their health
  - Lowering costs for healthcare (e.g. avoidance of duplicative procedures/tests, generic medications, treatment adherence)
  - Improving access to healthcare – more affordable for more people

What Makes Dossia Distinctive

- Independent ***employer-driven non-profit*** organization
- ***Collaboration*** between academic research at Children's Hospital Boston and Harvard Medical School and private industry
- Commitment to ***open source*** – software will be made available for other public health and research efforts
- Deployed as part of ***comprehensive healthcare outreach*** to employees via wellness programs and closely aligned with public health goals and programs
- ***Non-tethered solution*** – employees are free to take their data when they change plan, doctor, employer

Why Employers as the Catalyst for Change?

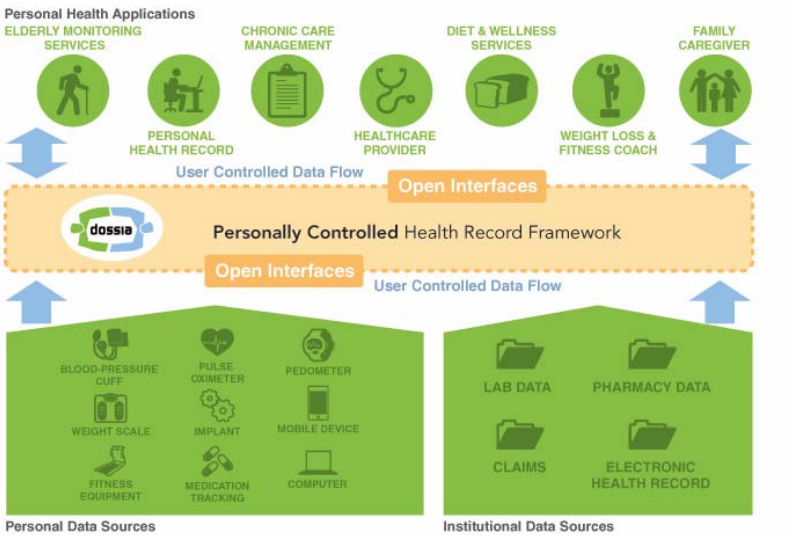
- Current US healthcare system is not economically sustainable
- Dossia can play a role in addressing the issues with cooperative efforts
- Critical component of any new system is informed consumers



Empowered patients make smarter decisions and ask smarter questions about health and healthcare

Enabling patients to become consumers

- I need access to my health information
- I want to understand my health information.
- I need to personally control my health information – privacy is critical to me
- I do not want to be tied or tethered to one application or service
- I do not want to be tied to one health plan, or provider, or doctor, or employer



Summary

- The US healthcare system is breaking – employer provided healthcare is shrinking and previous healthcare market efforts, governmental efforts, and private efforts have not resulted in necessary disruption, empowerment, or systemic change.
- Healthcare literacy is key to driving healthcare costs down and improving the quality of care for all healthcare consumers
- People can only act on what they know – Giving them access to their own personal and private health data will help them be better healthcare consumers.

We can change US healthcare by helping people help themselves

Empowering healthcare consumers

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

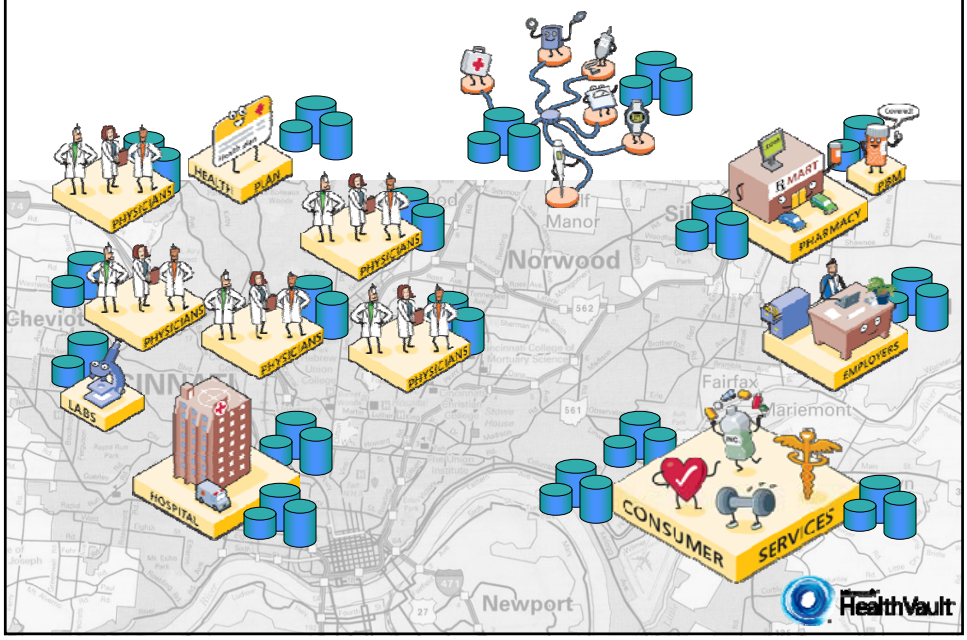
American Health Information Community

Bringing Healthcare into the Internet Age

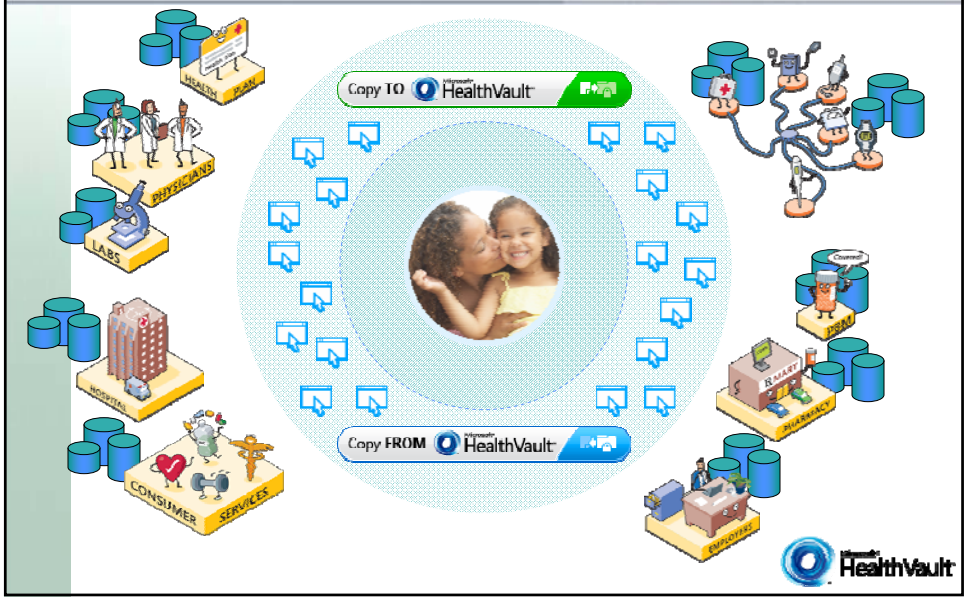
Sean Nolan
Health Solutions Group, Microsoft

July 29, 2008

The Problem: fragmented silos of health information



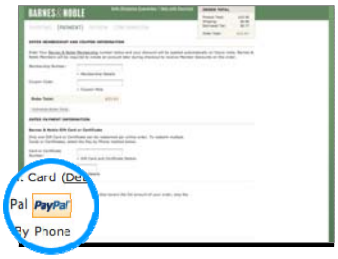
Our Bet: patients as the hub of communication



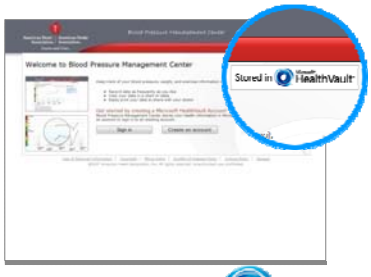
What is HealthVault?

HealthVault is “PayPal for health information”

PayPal is a platform that allows you to store and share your **banking information** with thousands of online retail applications.



HealthVault is a platform that allows you to store and share your **health information** with thousands of online health applications.



HealthVault Design Principles

Privacy and Security Focused

HealthVault is unique because it **puts the consumer in control** of their health information

- In control of their **privacy**
- In control of how they **share** information
- In control of which **applications** they use

Inclusive of Industry Standards

HealthVault is an **open platform,** it is easy to participate

- Free Published SDK and APIs, Community Promise
- Easily Extensible Data Model
- Strong Developer Community:
  - MSDN Documentation, Developer Forum and Blogs
  - Codeplex Community (API Wrappers, connectors and bridges to existing standards)

Free for Users and Developers

There are **no fees or charges** to use the platform

- Developers host their own application, create their own business model

A tipping point for patient-centric care?

- 40 applications and 50 devices live today
- 300 companies at June 2008 partner conference
- 10,000+ SDK downloads
- 15 Be Well Fund grants totaling $4.5 million

Most importantly, questions are increasingly about "how" and "when" – not "if" or "why"

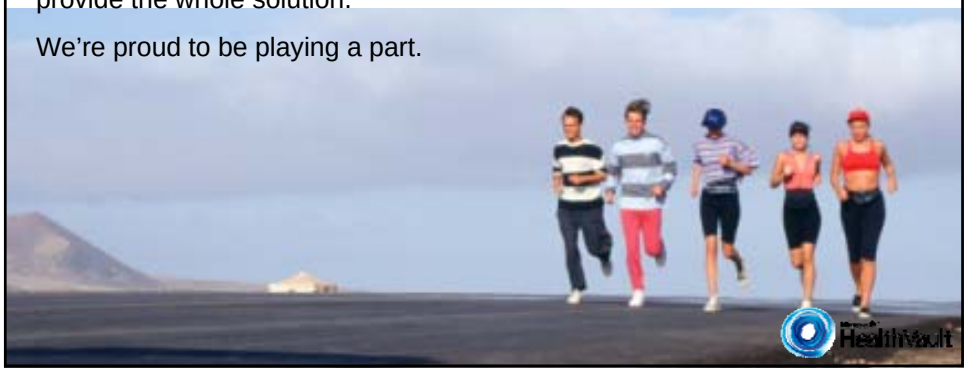
The Beginning of a Long Journey…

Now ▶

This is a long journey

Healthcare is a big and complex issue -- no single company is going to provide the whole solution.

We're proud to be playing a part.



Microsoft HealthVault

Be well. Protected.

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

American Health Information Community

AHIC Standing Committee of the Whole: Successor

John Glaser
Partners HealthCare Systems

Lillee Gelinas
VHA, Inc.

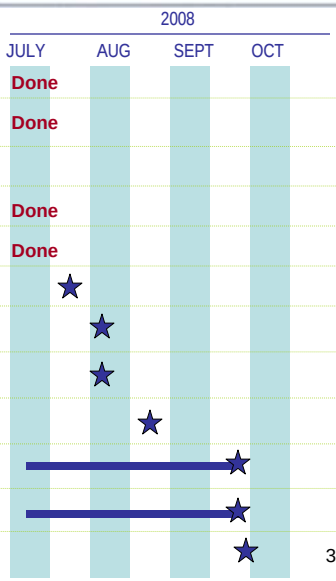
Janet Marchibroda
eHealth Initiative

July 29, 2008

Agenda

- Timeline Overview
- Planning Group Recommendations Presented on June 4th
- Board Nominations Process
- Next Steps

Timeline Overview



- Share Planning Group recommendations
- Incorporate
- Convene Incorporators
  - Hire accounting firm
  - Select interim Executive Director
  - Hire management consulting firm
  - Retain law firm
  - Hire executive search firm
  - Select other contracted support
  - Work with law firm to craft bylaws
  - Facilitate creation of Board of Directors
- Seat Board members/adopt bylaws

Agenda

- Timeline Overview
- Planning Group Recommendations Presented on June 4th
- Board nominations process
- Next steps

Governance Planning Group: Members

- **John Tooker,*** American College of Physicians
- **Lori Evans,*** Office of Health Information Technology Transformation, New York State Department of Health
- **Dennis Barry**, Moses Cone Health System
- **Helen Darling**, National Business Group on Health
- **Jean-Paul Gagnon**, Sanofi-Aventis Pharmaceuticals
- **Martin Hickey**, Excellus Blue Cross Blue Shield
- **Robert Juhasz**, American Osteopathic Association
- **Charles Kahn**, Federation of American Hospitals
- **Linda Kloss**, American Health Information Management Association
- **Michael Lardiere**, National Association of Community Health Centers
- **Les Lenert**, Centers for Disease Control
- **Robert Levine**, Juvenile Diabetes Research Foundation
- **Deven McGraw**, Center for Democracy and Technology
- **Sherry Reynolds**, Alliance4Health
- **James Schuping**, Workgroup for Electronic Data Interchange
- **Jane Thorpe**, Centers for Medicare and Medicaid Services
- **Paul Uhrig**, Surescripts

* Co-chairs

Membership Planning Group: Members

- **Jon Perlin,*** Hospital Corporation of America
- **Janet Marchibroda,*** eHealth Initiative
- **Janet Corrigan**, National Quality Forum
- **Angela Fix**, Association of State and Territorial Health Officials
- **Paul Cotton,** AARP
- **Mark Frisse**, Vanderbilt University
- **Gail Graham**, Veterans Health Administration
- **Garth Graham**, HHS Office of Minority Health
- **Walt Hauck**, Pfizer
- **Brent James,** Intermountain Health
- **Steve Lieber**, Health Information and Management Systems Society
- **Blackford Middleton**, Partners Healthcare System
- **Arnie Milstein**, Pacific Business Group on Health
- **Ruth Perot**, Summit Health Institute for Research and Education
- **Tony Rodgers**, State of Arizona
- **Steve Schoenbaum**, The Commonwealth Fund
- **Zachary Sikes**, American Association of Homes and Services for the Aging
- **Jeanette Thornton**, America's Health Insurance Plans
- **Reed Tuckson**, United Healthcare
- **Margaret Van Amringe**, The Joint Commission
- **Michelle Vilaret**, National Association of Chain Drug Stores
- **Dave Wanser**, National Data Infrastructure Improvement Consortium

* Co-chairs

Sustainability Planning Group: Members

- **John Glaser,*** Partners Healthcare System
- **Rachel Block,*** NY eHealth Collaborative
- **David Bates**, Partners Health System / Brigham and Women's Hospital
- **Christine Bechtel**, eHealth Initiative
- **Michael Berkery**, American Medical Association
- **Troy Brennan**, Aetna
- **Wendy Everett**, New England Healthcare Institute
- **Tom Fritz**, Inland Northwest Health Services
- **Dan Garrett**, Pricewaterhouse Coopers
- **Thomas Garthwaite**, Catholic Health East
- **Gregory Gleason**, NueVista Strategy LLC
- **Alan Harvey**, Massachusetts eHealth Collaborative
- **Mark Halloran**, Medco Health
- **Roberta Herman**, Harvard Pilgrim Health Care
- **Kraig Kinchen**, Eli Lilly
- **Ken Majkowski**, RxHub
- **Robert Marotta**, HLTH Corporation
- **Donald Mon**, American Health Information Management Association
- **Orlando Portale**, Palomar Pomerado Health District
- **Eva Powell**, National Partnership for Women & Families
- **Rick Ratliff**, Surescripts
- **Jim Scanlon**, HHS, Office of the Assistant Secretary for Planning and Evaluation
- **Carla Smith**, Healthcare Information Management Systems Society (HIMSS)
- **Robert Tennant**, Medical Group Management Association
- **Charlene Underwood**, HIMSS Electronic Health Record Vendors Association
- **Andy Wiesenthal**, Kaiser Permanente

* Co-chairs

Transition Planning Group: Members

- **Lillee Smith Gelinas,*** VHA
- **Peter Elkin,*** Mayo Clinic
- **Laura Adams**, Rhode Island Quality Institute
- **Linda Fischetti**, Veterans Health Administration
- **Carol Gassert**, University of Utah, College of Nursing
- **Justine Handelman**, Blue Cross Blue Shield Association
- **Bart Harmon**, Harris Corporation
- **Kevin Hutchinson**, Prematics
- **Brian Kelly**, Accenture
- **Gwen Lohse,** Council for Affordable Quality Health Care
- **Ross Martin**, Bearing Point
- **Stephen Phillips**, J&J
- **Rose-Marie Robertson**, American Heart Association
- **James Turner**, Verizon
- **Robert Wah**, Computer Science Corporation
- **Jon White**, Agency for Healthcare Research and Quality

* Co-chair

Volunteer Staff

- Tom Leary, HIMSS – Governance Planning Group
- Allison Viola, AHIMA – Membership Planning Group
- Jennifer Covich, eHealth Initiative – Sustainability Planning Group
- Steve Zlotkus, CAQH – Transition Planning Group

The AHIC Successor Purpose and Scope set the context for the Planning Group discussions

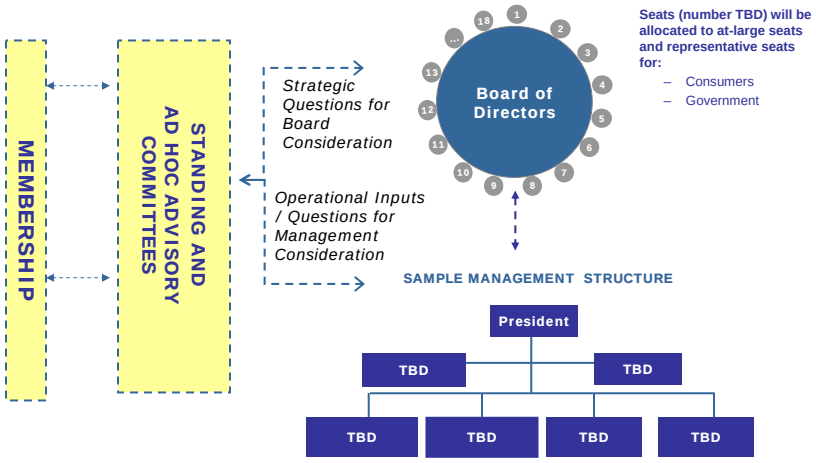
The AHIC Successor will be an independent, sustainable public-private enterprise that brings together the best of the public, non-profit and private sectors into a trusted, purpose-driven organization for the creation and use of a secure interoperable nationwide health information system. Its vision is to realize interoperability that engages individuals, providers, institutions and other stakeholders in a patient-centered learning health care system that supports continuously improving health care quality, safety, efficiency and accessibility. The AHIC Successor's primary purpose is, through achievement of its vision, to improve and maintain the health and well-being of all individuals and communities in the United States.

1. Accelerate the adoption of interoperable health IT by ensuring the availability of harmonized, coordinated, up-to-date standards and rigorous conformance testing through certification.
2. Prioritize stakeholder requirements for health IT interoperability.
3. Advance health information policies and technical approaches that promote AHIC Successor's vision and purpose and protect confidentiality, privacy, and security, consistent with the policies established by HHS and applicable federal and state laws.
4. Oversee and facilitate the Nationwide Health Information Network (NHIN – a network-of-networks).

The recommendations of the Planning Groups are presented on the following slides

We recommend a public-private membership organization of organizations

Proposed Organization Structure



The Board of Directors will have a fiduciary duty to the AHIC Successor and will set its strategic direction

- Composed of 18 Directors that are a blend of at-large members and specific seats (two each) that represent government and consumers (including vulnerable populations)
- Board tenure is term-limited with staggered elections
  - Of the initial Board 1/3 will have a one-year term, 1/3 will have a two-year term, and 1/3 will have a three-year term; subsequent terms are for three years
  - All Board members will be able to serve up to two consecutive terms
- Powers of the Board include the following:
  - Defining and re-evaluating the strategies by which the organization fulfills its mission and monitoring the implementation of those strategies;
  - Selecting, monitoring, evaluating, compensating and replacing the President, including contingency and succession planning;
  - Reviewing and approving operational matters (e.g., financial plans; internal control systems and audit); and
  - Overseeing the execution of the organization's strategic plan

The AHIC Successor establishes health IT priorities.

Committees are recommended as a means of ensuring input from specific stakeholder perspectives

- Standing Committees
  - Chaired by a Board member and including both at-large and representative members from relevant member segments
  - Structured to require diverse member representation
  - Nominating, Finance and Audit, and Membership standing committees are anticipated
- Issues-Related and Ad Hoc Committees
  - Chaired by best-qualified member regardless of Board status and including both standing and representative members from relevant member segments
  - Structured to require diverse member representation
  - Issues-Related Committees will be focused on topics and issues raised by the Board and requiring significant analysis and research
  - Ad Hoc Committees will be focused on short-term initiatives that require governance participation

Membership segmentation ensures appropriate outreach and representation of all stakeholders

- Consumers
- Employers
- Government and Public Health
- Health Care Providers
- Health Informatics, Research, Academia
- Health Information Exchanges and Regional/State-Level Public-Private Partnerships
- Health Plans and Other Players
- Infrastructure and Standards (Technical)
- Other Health Entities (Pharma, Labs, Device Manufacturers…)
- Quality
- Vendors, Consultants (Supply Chain)

Recommended membership segments (1 of 2)

Stakeholder Segment	Member Outreach Sub-Segment
Consumers	Consumer organizations, organizations representing vulnerable populations, patient advocacy organizations, organizational representatives of racial/ethnic communities (as defined by OMB), organizations serving rural populations, organizations serving low-income and elderly populations, unions, consumer advocacy organizations, provider organizations providing care to the underserved
Employers	Large, small, coalitions, self-insured
Government and Public Health	Federal programs, county health programs, state Medicaid programs, state health departments
Health Care Providers	Hospitals, physicians, nurses, home health / community health care, skilled nursing facilities, assisted living facilities, organizations with multiple levels of care, community health centers, hospice, retail clinics, provider/specialty associations, EMS, ambulatory surgical centers, specialty care centers, public health departments, medication management
Health Informatics, Research, Academia	Should include specialty organizations like HIMSS, segments of health care cutting across other categories, academic medical centers, foundations, publishers
Health Information Exchanges and Regional/State-Level Public-Private Partnerships	Community, local, regional, state, state/regional-level collaboratives

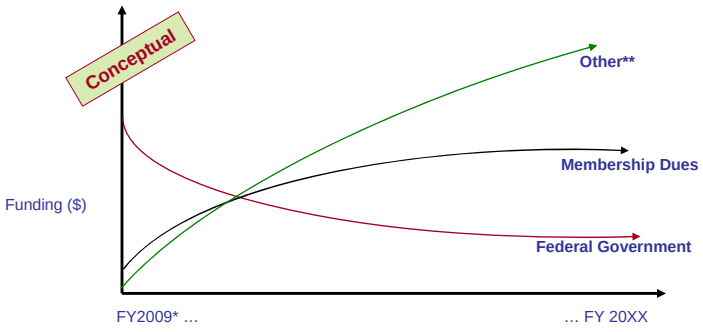
Recommended membership segments (2 of 2)

Stakeholder Segment	Member Outreach Sub-Segment
Health Plans and other Payers	Large national (Medicare, Medicaid, other), regional and local plans, integrated delivery systems, federal delivery systems, general health plans, employer-based health plans, long-term care insurance providers
Infrastructure and Standards (Technical)	Standards development organizations, e-prescribing infrastructure companies
Other Health Entities	Pharma, contract research organizations, device manufacturers, trade associations not previously listed, labs, pharmacies
Quality	Patient safety organizations, chartered value exchanges, risk management / compliance organizations, accrediting organizations, quality alliances
Vendors, Consultants (Supply Chain)	Consulting, software (EHR/PHR vendors), and e-prescribing companies

Membership interest is anticipated and is based on both short- and longer-term value propositions

- Membership in the AHIC Successor means having a seat at the table to:
  - Set priorities and identify and quantify opportunities for standards identification and harmonization;
  - Provide expertise on policies related to an interoperable, standards-based electronic health care system;
  - Support the implementation of standards through market-driven approaches; and
  - Provide technical resources.
- The willingness of the market to embrace the work of the AHIC Successor will be significantly enhanced if both federal and state governments actively support the work (requiring standards/certification for their procurement activities, Medicare reimbursement, etc.).
- Longer-term value propositions for each unique stakeholder segment were examined and will be published on www.AHICSuccessor.org.

There are numerous funding sources for the AHIC Successor



Notes:
*For fiscal year (FY) 2009, starting in October 2008, the Federal government plans to provide $5-8M. During this period, the AHIC Successor will be in its initial stage of operation and will receive minimal membership dues.

**Other is defined as additional potential sources of revenue to include Value Cases, accreditation of RHIOs, governance of the NHIN, conferences, training, publications, service or transaction-based fees, and/or in-kind and philanthropic contributions.

We recommend focusing on the cost of a core set of activities to inform early budget planning

Budget Formation Strategy

- Develop a budget to sustain the core activities for the 2-3 years following the expiration of current grant funding
- Obtain "fair share" of Federal funding defined by Federal government's role as a provider, payer, and employer
- Obtain the remaining core funding through member dues
  - Leverage a conventional funding model
  - Adopt conservative estimates of dues revenue
  - Minimize the number of revenue streams that must be developed in the first year of operation
- Utilize FY09 HHS funding to explore additional revenue sources

Core Activities

- Setting priorities for standards harmonization and certification criteria development
- Ensuring that momentum is maintained with harmonization and certification activities
- Providing thought leadership in the creation and use of a secure interoperable nationwide health information system to support improvements in the quality, safety, and value of accessible health care

Based on these core activities, we estimate an annual operating budget of approximately $3.2M

- Revenue assumed from a tiered membership dues structure and based on an estimated 120-160 members
  - Dues structure differentiates between non-profit and for-profit organizations.
  - A range of membership dues between $1,000 and $50,000 is recommended
  - Includes a class for members that may not be able to pay dues or pay only a minimal amount (e.g., $100)
- Expenses assume 7 FTEs including the President, contracted resources, and physical plant
  - Expenses assume three (3) working groups, membership drive, and 2 existing and 4 new use cases

Estimated Operating Budget (FY 2010)

REVENUE	
Membership	$1,200,000
Government Contributions	$2,000,000
Total Revenue	$3,200,000
EXPENSES	
Salaries, Wages, Fees	$1,302,750
Functional Expenses	$1,054,333
Other Expenses	$840,600
Total Expenses	$3,197,683
NET SURPLUS	$2,317

What are Value Cases[1]?

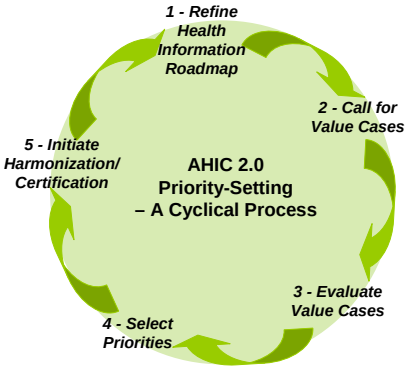
- **A Value Case:**
  - Describes an opportunity for information exchange;
  - Illustrates specific scenarios for interoperability (similar to a use case); and
  - Demonstrates a case for action based on value.

- **Specifically, a Value Case:**
  - Presents the costs and benefits of implementing the specific scenario; and
  - Describes potential measures of actual impact on improving care.

Note: [1]Concept developed outside of the Sustainability Planning Group by the leadership of the AHIC Successor.

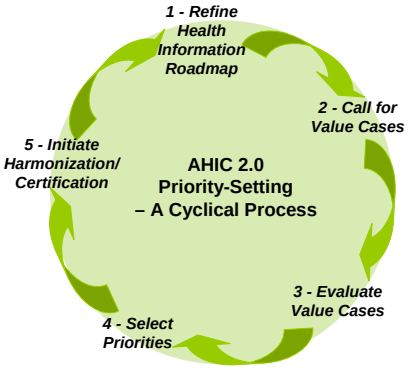
How will Value Cases be developed?

1. The roadmap, which will be developed by Fall 2008, will serve as the national guide to interoperable health information exchanges
2. Following the roadmap, the AHIC Successor will determine the priorities for harmonization and call for "value cases," which bring the best aspects of a use case and a business case. The process will allow for broad stakeholder engagement in priority-setting. Value Cases will be submitted to the AHIC Successor for consideration and prioritization on a regular and published cycle.

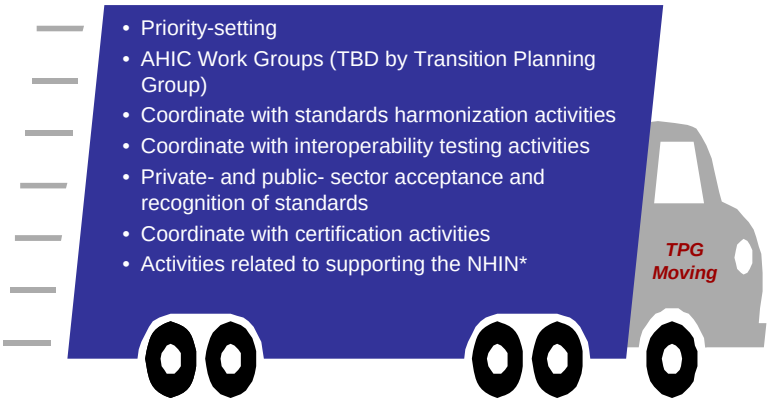


How will Value Cases be developed? (Continued)

3. A framework will be used to evaluate and select Value Cases. The framework will align funding to value creation and standards with federal privacy and security policy.
4. The AHIC Successor will select Value Cases that will make the greatest impact on interoperable health information exchanges.
5. The AHIC Successor will coordinate the priority-setting, harmonization, and certification.



The Transition Planning Group is identifying the current AHIC Work Group activities that will transition to the Successor



*Refers to a national-level function to support dispute resolution and other dynamic needs for ensuring a secure and reliable "network of networks."

Agenda

- Timeline Overview
- Planning Group Recommendations Presented on June 4th
- Board nominations process
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High-Level Timeline of Process as of July 29*

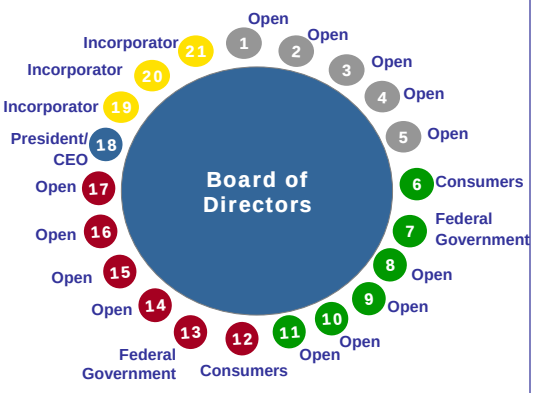
- Finalize nomination process and selection criteria (June 23-July 14)
- Request nominations (July 14-August 4)
- **Close nomination process August 4 (Extended)**
- Evaluate nominations (August 4-August 22)
- Develop draft initial slate of 30 candidates (August 22)
- Review draft slate of 30 candidates for conformity to agree-upon process (August 25-September 5)
- Select BOD (September 5-September 12)
- Review BOD for conformity to agreed-upon process (September 12 – September 15)
- Finalize BOD, obtain organizational approvals (September 15-September 29)
- **Announce BOD (late September)**

Note: *Timeline may change based on feedback from Planning Group members and public comments.

Sources of information to create process and criteria for the AHIC Successor BOD

- Governance Planning Group recommendations
- June 4th public meeting presentation
- Two conference calls with Planning Group members
  - Over 50 Planning Group members participated
  - Over 40 people from the public listened
- Numerous comments submitted via website

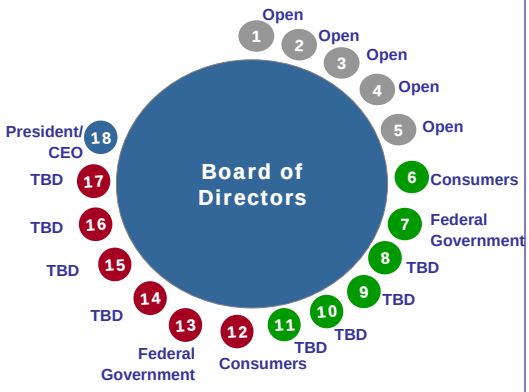
AHIC Successor Board of Directors for 1st Year



Board Composition
15 -Open seats for nominations
13-At-large seats
2-Consumers
2- Federal government
1 - President / CEO
3 – Incorporators (First year only)
TOTAL: 21 Seats

Initial Board Tenure
- One-Year (permanent) – exp 9/09
- Two-Years (permanent) – exp 9/10
- Three-Years (permanent) – exp 9/11
- Ex-officio (President/CEO)
- One-Year (First year only)

AHIC Successor Board of Directors for 2nd Year



Board Composition

5 -Open seats for nominations
5- Open at-large seats
8-TBD from Year 1
2- Consumers
2- Federal government
1 - President / CEO
TOTAL: 18 Seats

Initial Board Tenure

- 3 years left (permanent) – exp 9/12
- 1 year left (permanent) – exp 9/10
- 2 years left (permanent) – exp 9/11
- Ex-officio (President/CEO)

Seats for Incorporators

19 20 21

After the first year, the seats for the Incorporators will be eliminated. Incorporators will be placed in the regular nomination and appointment process to be the on Board.

Agenda

- Timeline Overview
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Next steps

- Get the word out on the Board nomination process. More information can be found on the AHIC Successor website:
  - www.ahicsuccessor.org
- Keep informed by
  - Visiting our website
    - Consolidated June 4th recommendation
    - June 4th public meeting presentation
    - The AHIC Successor Board process
  - Signing-up to receive e-mail updates
  - Reading "*The Better Health Connector*" newsletter

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

American Health Information Community

Supplemental Priority Development Pathway for Clinical Research Applications of Electronic Health Information

Greg Downing
Immediate Office of the Secretary
Program Director, AHIC Personalized Healthcare Workgroup

July 29, 2008

Clinical Research Panel

- Rebecca Kush – Clinical Data Interchange Standards Consortia (CDISC)
- Kenneth Buetow – National Cancer Institute
- Greg Simon – *FasterCures*
- Amy Miller – Personalized Medicine Coalition

Background

- Clinical research was originally identified as a priority by AHIC but was not selected for use case development.
- June 3rd meeting: AHIC recommended that ONC explore options for a 'supplemental' process to support use case development, standards harmonization and consideration in the rest of the national HIT agenda activities.
- The needs for EHRs to support clinical research have been increasingly recognized and the clinical research community has the capacity, infrastructure, and interest to join the national HIT agenda activities.
- The supplemental (supported by external resources) pathway broadens bandwidth of standards harmonization without compromising existing processes, and could help establish a partial support model for advancement of standards harmonization when it moves to the private sector.

Why is clinical research relevant to health information standards and interoperability?

- As EHR adoption increases, there will be new opportunities for health information exchange to support clinical research activities.
- The clinical research community is developing standards to improve reliability and reproducibility of research data, regulatory reporting, data analysis, and accountability.
- This activity will:
  - Avoid the emergence of separate standards in health care and clinical research environments thereby creating impediments to the utility of patient data.
  - Provide the opportunity for considering policy applications for informed consent, disclosures and authorizations, privacy and security, auditing, etc.
  - Improve patient/human research subject safety.

Supplemental pathway may present challenges

- Establishes an additional pathway for standards harmonization during the AHIC transition
- Raises the possibility of another specialization category for certification as it is unlikely all EHR systems will need to support clinical research
- Requires a prioritization process for the scope of use case development given that clinical research is a broad area
- Creates a need for additional expertise to support HITSP processes

Exploratory work completed so far

- Identified early stakeholder community to ensure support and agreement on concept
- Discussed possible pathways with HITSP
- Conducted preliminary environmental scan of existing standards and potential priority areas for use case development
- Presented concept to AHIC and AHIC Successor transition team/incorporators

Proposal

- AHIC to authorize exploration of a “supplemental” pathway to use case development, standards harmonization, and support interoperability of electronic health information to support clinical research information needs
- Continue development of this pathway in connection with AHIC transition to the new AHIC Successor
- Report progress through AHIC via existing work group until the AHIC Successor work formats are established

How will this work?

- Multi-stakeholder working group sets priorities inside of research domain
- Stakeholders provide support for HITSP process
- Stakeholders ensure that volunteers staff HITSP working groups
- Standards will be advanced through national HIT agenda as with primary pathway
- Recommendations are provided to HHS for recognition of standards

Next Steps

- Establish a work group and formalize arrangements with HITSP
- Identify stakeholder support
  - Research priorities
  - Volunteer expertise
  - Financial support
- Prioritize areas of work
- Make recommendations for use case development to HITSP
- Identify issues and potential solutions to facilitate EHR interoperability with research data systems
- Report to AHIC or AHIC Successor

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

American Health Information Community

Supplemental Priority Development Pathway for Clinical Research Applications of Electronic Health Information

Rebecca D. Kush
Clinical Data Interchange Standards Consortium (CDISC)

July 29, 2008

CDISC

- Clinical Data Interchange Standards Consortium – a global, open, non-profit standards development organization (SDO)
- Standards openly available (www.cdisc.org)
- Initiated as volunteer group 1997; incorporated 2000
  - Now > 230 organizational members
  - Biopharmaceutical companies, technology providers, contract research organizations and academic research centers
  - Active committees in U.S., Europe, Japan, China
- CDISC has established global standards for collection, exchange, regulatory submission, and archive of electronic medical research data
- Charter Agreement with HL7 since 2002; commitment to harmonize standards
- Liaison A status to ISO TC 215 (Healthcare)

The CDISC Mission

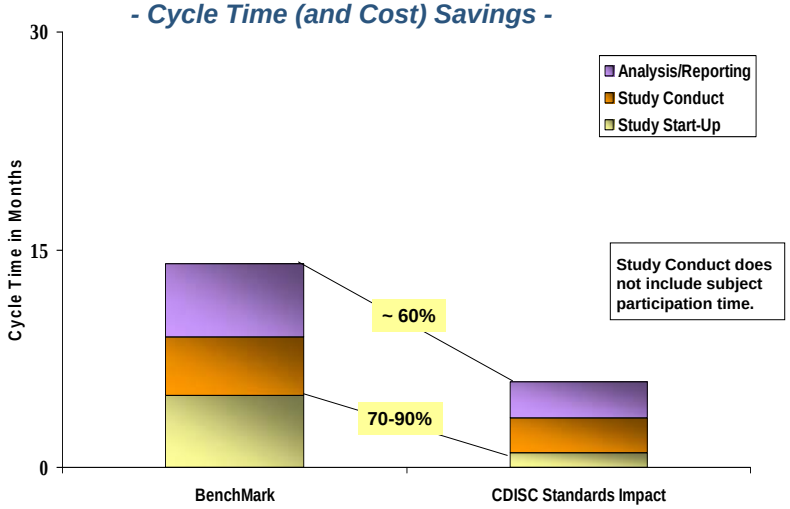
To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

Strength *through collaboration.*

CDISC

Quantifying the Value of CDISC Standards

- Cycle Time (and Cost) Savings -



Note: Figures are benchmarks based on aggregate data; study-specific cycle times and cost metrics will vary.

Gartner

The Value of Data Interchange Standards

- Increase data quality
- Enable data integration into “knowledge warehouses” to improve science, marketing and safety surveillance
- Facilitate review of regulatory submissions
- Facilitate data interchange among partners
- Improve communication among project teams
- Enable efficient exchange of information among a variety of tools and technologies

PRESIDENT’S INFORMATION TECHNOLOGY ADVISORY COMMITTEE

“The same EHR systems critical for improving patient care can also help accelerate clinical research and its impact on practice and improve pharmaceutical safety (pharmacovigilance) and biosurveillance for public health...dual use of EHR systems that could reduce total system costs.”

PITAC ~2005

Research Informs Healthcare Decisions

- Medical Research is too significant to allow it to remain disconnected from healthcare when research informs healthcare decisions and clinical care informs research.
- Approximately $100B spent annually on U.S. Medical Research.
- Data requirements for clinical research overlap substantially with clinical quality, safety and efficacy use cases.
- We must ensure that Healthcare and Clinical Research are on convergent paths – now is the time.

Harmonized Information Exchange Standards for Clinical Research and Healthcare

Harmonization essential:

- To aggregate sufficient information across partners such that research findings lead to informed healthcare decisions
- For timely safety surveillance on a global scale
- To link biomarkers (including an individual's genetic markers) to population characteristics and outcomes
- To facilitate research for clinicians concurrent with clinical care

Net Impact: Reduce time and costs of research and improve quality and effectiveness of healthcare

Progress on Medical Research Standards

- CDISC established global medical research standards to support clinical studies
  - Standards support study registration, conduct, and reporting
  - Referenced in FDA Final Guidance, encouraging use of CDISC standards for eSubmissions (proposed rule/regulation)
  - Pharmacogenomics data standards developed through HL7-CDISC Clinical Genomics work group
- FDA, HL7, NCI and CDISC collaboratively developing terminology/vocabulary (value sets)
  - For core 16 domains (e.g., demographics, medical history, medications, vital signs, physical exam, etc.)
  - Maintained via NCI Enterprise Vocabulary Services

Progress on Medical Research Standards (cont'd)

- CDISC ensuring that research standards harmonized with each other and with HL7 standards for healthcare via BRIDG Model
  - BRIDG Model developed and governed by four key stakeholders: CDISC, HL7, FDA, NCI
  - Process initiated towards ISO standard
- New CDISC data collection standard - CDASH V 1.0 to be released Q3 2008
  - Collaboration with FDA (Critical Path Initiative), biopharmaceutical companies, NCI, NIH, Academic Centers (Duke, Baylor), others
  - Based upon CDISC eSubmission standard for FDA
  - Provides EHR companies a core standard dataset for research
  - Being mapped to HITSP Continuity of Care Document (CCD)

EHRs and Clinical Research: Progress through Standards

- CDISC/IHE Integration Profile: Retrieve Form for Data Capture (RFD)
  - A technology solution to capture research data in a form within the EHR environment; supports data entered once for research and care, regulations, and subject de-identification
  - EHR vendors can use the IHE RFD profile with minimal system modification
  - Profile successfully demonstrated for multiple applications by ~ 25 companies at HIMSS 2007 and HIMSS 2008 (using CDISC CDASH for actual clinical study)
- EHR/Clinical Research Functional Profile Initiative
  - HL7 EHR Functional Profile standard modified to meet core requirements for regulated clinical research – HL7 May 2008 ballot (initiative led by PhRMA and eClinical Forum with HL7 and CDISC)
  - Cross-industry committee pursuing 2010 CCHIT certification as "Expansion" of EHR certification for the research population

Ensuring Convergence

- Harmonization needed NOW --- to avoid divergent and disparate standards that will severely inhibit the use of EHRs for research and clinical decision support
- Leverage what has already been done for clinical/medical research standards
- Without diverting attention from existing HITSP priority use cases, welcome additional resources from the research arena: CDISC, HL7, PhRMA, BIO, HIMSS, eClinical Forum, Critical Path Institute, Academic Research Centers, NCI, other NIH Centers.

Commitment requested from AHIC for a pathway that will ensure convergence of clinical research and healthcare standards

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

American Health Information Community

Supplemental Priority Development Pathway for Clinical Research Applications of Electronic Health Information

Ken Buetow
National Cancer Institute/National Institutes of Health

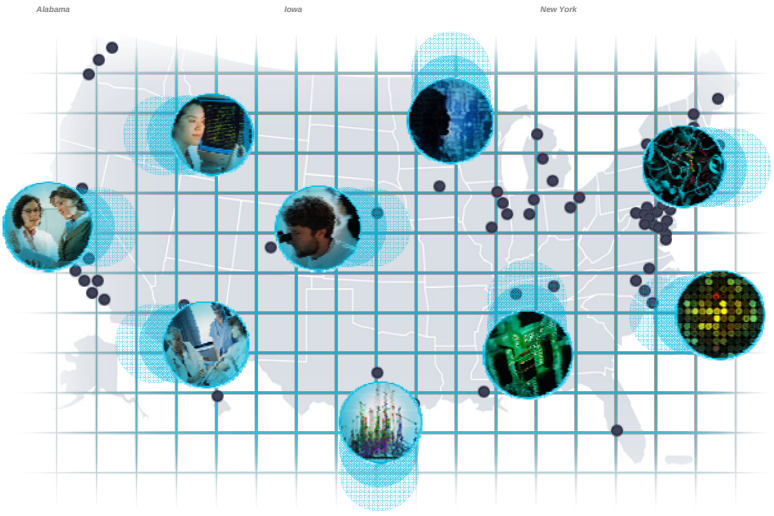
July 29, 2008

The Current World of Biomedicine

- Isolated information "islands"
- Information dissemination uses models recognizable to Gutenberg

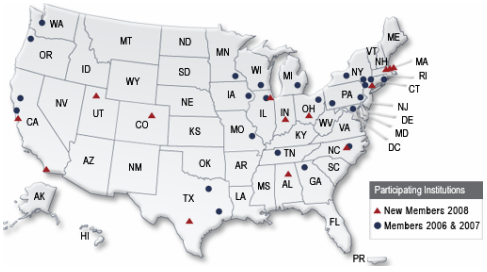
Need to convert islands into an integrated system

NCI is Utilizing Information Technology to Join Islands into a Community



National Center for Research Resources (NCRR) Clinical and Translational Science Awards

- Encourage the development of new methods and approaches to clinical and translational research
- Improve training and mentoring to ensure that new investigators can navigate the increasingly complex research system
- **Design new and improved clinical research informatics tools**
- Assemble interdisciplinary teams that cover the complete spectrum of medical research
- Forge new partnerships with private and public health care organization
- **38 Centers in 23 states**

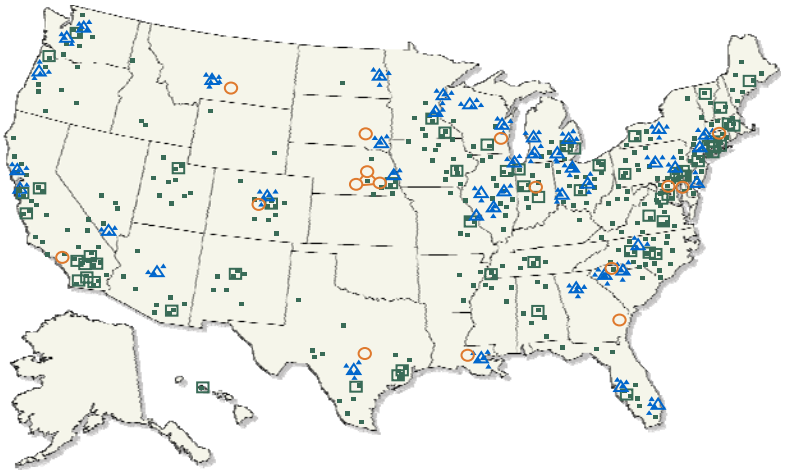


Linking Discovery > Clinical Research > Clinical Care

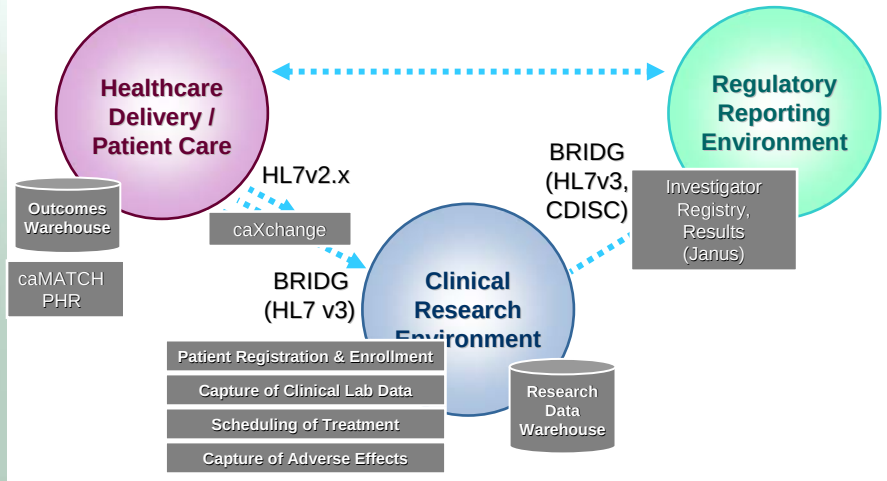
- Tremendous improvement in childhood cancer survival since 1975
  - Overall reduction of cancer mortality by 50%
  - Acute lymphoblastic leukemia survival rate has improved from 5% in the 1960's to more than 85%
  - Molecular characterization used to determine treatment
- Childhood cancer is treated in a context that blends care delivery and clinical research
  - Researchers and practitioners are able to correlate experimental laboratory data with clinical data (treatment, history, pathology, outcome, etc.)
  - Clinical data are utilized to continuously evaluate outcomes
  - Researchers develop and refine evidence-based strategies at an individualized level
  - Care providers improve quality by adherence to care standards

Information flow is critical…
this model cannot be achieved without IT connectivity

NCI-Designated Cancer Centers, Community Cancer Centers, and Community Oncology Programs



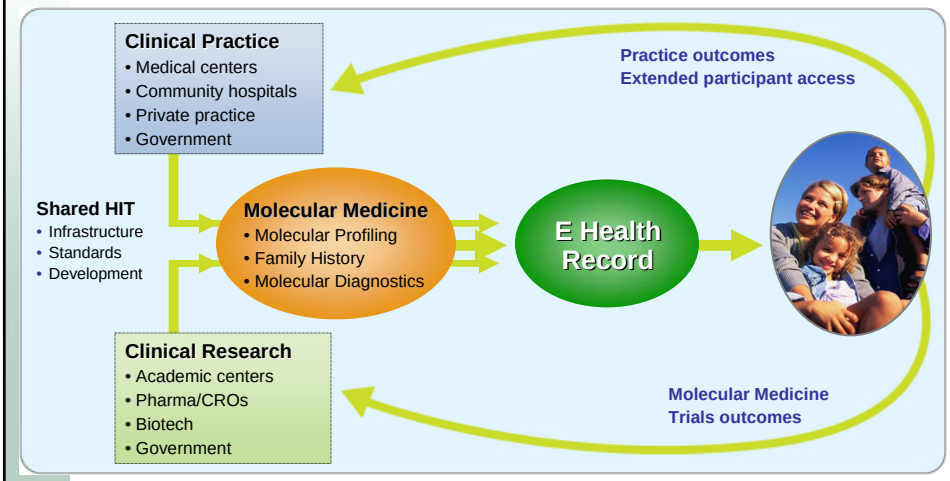
NCI's Proof of Concept Infrastructure Linking Health Care Delivery, Research, and Regulatory Reporting



NCI's cancer Biomedical Informatics Grid (caBIG)

caBIG

A Necessary Bridge Between Research and Care Delivery



Common standards enable integration of molecular data into EHRs… enabling all facets of personalized medicine and continuous learning

Value Proposition for New Pathway

- Research community already addressing standards
  - Family history
  - Molecular diagnostics
  - Pharmacogenomics
  - Clinical outcomes
  - Treatment histories
- Contribution of additional biomedical community insights and resources
  - Identify valuable use cases that compliment/extend existing use cases
  - Community integration
  - Additional insights
  - Work load sharing

FasterCures
The Center for Accelerating Medical Solutions

American Health Information Community:

Supplemental Priority Development Pathway for
Clinical Research Applications of
Electronic Health Information

Gregory C. Simon
President
FasterCures

July 29, 2008

Accelerating Research Through the NHIN: Guiding Principles

- **Bi-Directional Data Exchange**
- **Optimum Use of Patient Data**
- **Collaborative Research**
- **Common Data Standards**
- **Federated Networks**
- **Technology and Content Flexibility**
- **Privacy Protections**

- "Accelerating Research Through the National Health Information Network," Meeting Report, *FasterCures/The Center for Accelerating Medical Solutions*, January 7, 2005.

Include Clinical Research in the NHIN

- ***Pursue a "Connecting for Clinical Research" program.***
- ***Develop a post-marketing surveillance capability.***
- ***Develop strategies for conducting broad-based population health surveillance using EHR data.***
- ***Create an effort that uses EHRs to improve subject recruitment and enrollment into clinical studies.***

- "Ensuring Inclusion of Clinical Research in the Nationwide Heath Information Network," Meeting Report May 2006, *FasterCures/The Center for Accelerating Medical Solutions*

FasterCures

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

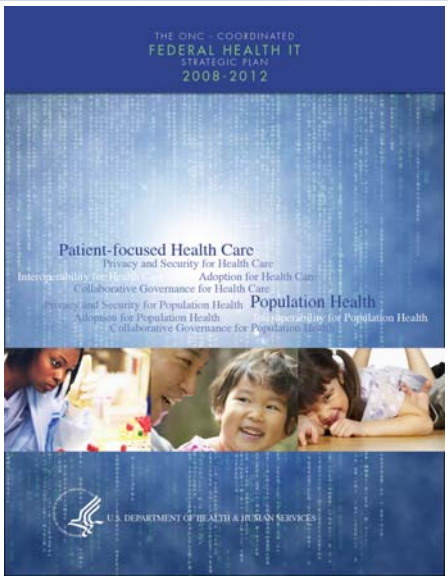
American Health Information Community

The ONC-Coordinated Federal Health IT Strategic Plan 2008 - 2012

Dr. Robert Kolodner
and Dr. Charles Friedman
Office of the National Coordinator for
Health Information Technology

July 29, 2008

ONC-Coordinated Federal Health IT Strategic Plan 2008 - 2012



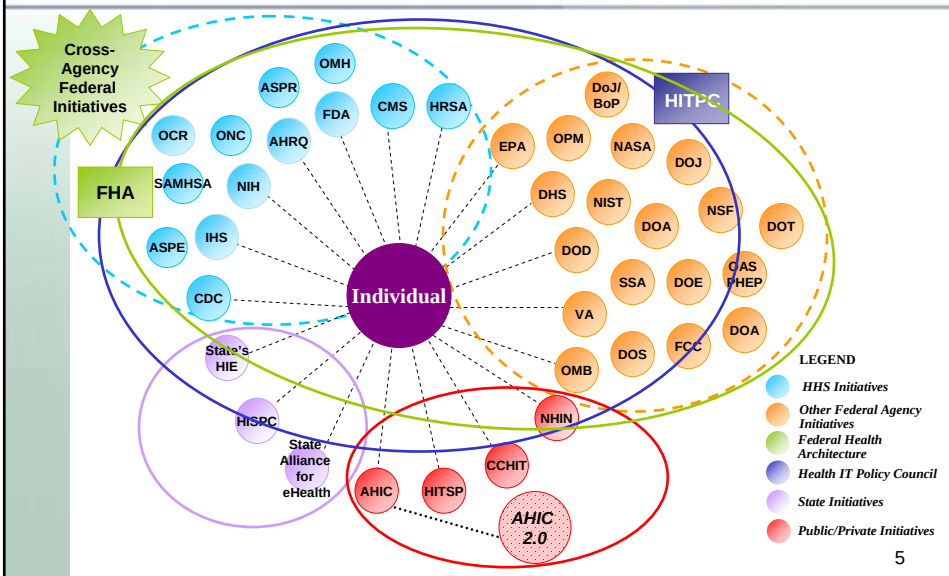
Motivators of the Strategic Plan

- Provides clarity, guidance, and a way to measure progress
- Many have asked for the Plan
  - Presidential Executive Order 13330
  - United States Congress
  - Observations from the Institute of Medicine
  - Natural obsolescence of the Strategic Framework
  - Need for collaboration across the Federal Government
  - Need for clarity and guidance

Characteristics of the Plan

- **Collaborative**
  - Across the government: Seven Departments/Agencies outside HHS
  - Department of Health and Human Services' OpDivs and StaffDivs
- **Integrative**
  - One infrastructure serves the needs of two goals
- **Complete**
  - Eight objectives that improve quality and efficiency of health care and population health
- **Disciplined**
  - Communicate and coordinate
  - How projects of multiple agencies work in pursuit of shared goals

ONC-sponsored Federal Collaborations and National Health IT Initiatives



"The Plan" – Goal One

Enable PATIENT-FOCUSED Health Care

Enable the transformation to higher-quality, more cost-efficient, patient-focused health care through electronic health information access and use by care providers, and by patients and their designees.

"The Plan" – Goal Two

Improve Population Health

Enable the appropriate, authorized, and timely access and use of electronic health information to benefit public health, biomedical research, quality improvement, and emergency preparedness.

Summary of Health IT Strategic Goals and Objectives: 2008-2012

	Privacy and Security	Interoperability	Adoption	Collaborative Governance
Goal 1. Patient-focused Health Care	**Objective 1.1:** Facilitate electronic exchange, access, and use of electronic health information, while protecting the privacy and security of patients' health information.	**Objective 1.2:** Enable the movement of electronic health information to support patients' health and care needs.	**Objective 1.3:** Promote nationwide deployment of electronic health records (EHRs) and personal health records (PHRs) and other consumer health IT tools.	**Objective 1.4:** Establish mechanisms for multi-stakeholder priority-setting and decision-making.
Goal 2. Population Health	**Objective 2.1:** Advance privacy and security policies, principles, procedures, and protections for information access in population health.	**Objective 2.2:** Enable exchange of health information to support population-oriented uses.	**Objective 2.3:** Promote nationwide adoption of technologies to improve population and individual health.	**Objective 2.4:** Establish coordinated organizational processes supporting information use for population health.

Strategies Are Listed For Each Objective

- **Objective 1.3 – *Adoption:* Promote the nationwide adoption of interoperable electronic health records (EHRs) by providers, and the adoption of personal health records (PHRs) and other consumer health IT tools by consumers and their designees.**
  - **Strategy 1.3.1:** Remove business barriers and disincentives for provider and delivery system adoption of EHRs.
  - **Strategy 1.3.2:** Increase the likelihood of efficient and effective EHR purchase and implementation.
  - **Strategy 1.3.3:** Increase the value of EHRs through interoperability, clinical decision support, and other technical advances.
  - **Strategy 1.3.4:** Promote certified health IT products as critical components and standards of clinical care.
  - **Strategy 1.3.5:** Develop the workforce for health IT product development and use.
  - **Strategy 1.3.6:** Identify key PHR functions and features that will allow individuals to link their health information to a wide variety of market-driven personal health tools that they and their designees find valuable in managing their heath and care.
  - **Strategy 1.3.7:** Design methods to promote the use of PHRs and other consumer health IT tools by consumers and their designees.
  - **Strategy 1.3.8:** Minimize liability risks and clarify misperceptions of liability risks for providers using health IT, while preserving or enhancing patient protections.
  - **Strategy 1.3.9:** Remove technical, financial, workflow, and other barriers to diagnosing, treating, and communicating with patients outside the boundaries of traditional health care settings.

Strategies Are Listed For Each Objective

- **Objective 2.3 – *Adoption:* Promote the nationwide adoption of information technologies that enable the reliable and efficient exchange of electronic health information to continuously improve population health activities and individual health care services.**
  - **Strategy 2.3.1**: Establish mechanisms to optimize the exchange of information between care providers using EHRs and authorized users of population health data, as well as among authorized users and recipients of population health data.
  - **Strategy 2.3.2**: Minimize burden on health care providers when reporting clinical data for population health purposes using EHRs and other health IT, while ensuring consistent health information protections.
  - **Strategy 2.3.3**: Establish mechanisms for the electronic exchange of health information among authorized users of population health data, communities, and individual consumers.

Each Strategy Has a Milestone Listed in Appendix A *[first sample below]*

- **Strategies for Objective 1.3 - *Adoption:* Promote the nationwide adoption of interoperable electronic health records (EHRs) by providers, and the adoption of personal health records (PHRs) and other consumer health IT tools by consumers and their designees.**
  - **Strategy 1.3.7:** Design methods to promote the use of PHRs and other consumer health IT tools by consumers and their designees.
    - *Milestone 1.3.7: By 2010, creation of a plan that can guide efforts directed at developing and marketing personal health information tools.*

Each Strategy Has a Milestone Listed in Appendix A *[second sample below]*

- **Strategies for Objective 2.3 - *Adoption:* Promote the nationwide adoption of information technologies that enable the reliable and efficient exchange of electronic health information to continuously improve population health activities and individual health care services..**
  - **Strategy 2.3.2:** Minimize burden on health care providers when reporting clinical data for population health purposes using EHRs and other health IT, while ensuring consistent health information protections.
    - *Milestone 2.3.2: By 2012, certified EHRs will have features that enable them to transmit automated data to population health agencies.*

Index to Current Federal Activities is Provided for Each Objective *[partial table shown below]*

Table 1.2 – Current Health IT Initiatives and Federal Advisory Committees Addressing Objective 1.2
Federal Agency and Department Initiatives
AHRQ: Health IT Portfolio (Page A30), United States Health Information Knowledgebase (USHIK: Page A31)
CMS: ICD-10 (Page A36), Medicaid Information Technology Architecture (MITA: Page A36), Medicaid Transformation Grants (Page A36), Beneficiary Information Services (Page A35)
FDA: Structured Product Labeling for Products (Page A38)
HRSA: Health IT Electronic Health Record and Innovations Grants (Page A39), Telehealth Grants (Page A39), Regional Genetic and Newborn Screening Service Collaboratives (Page A39)
IHS: Resource and Patient Management System (Page A41)
NIH: Cancer Biomedical Informatics Grid (Page A42), Support, Maintenance, & Dissemination of Standard Clinical Vocabularies (Page A43)
ONC: Planning for AHIC 2.0 (Page A48), Certification Commission for Healthcare Information Technology (CCHIT: Page A46), Federal Interdepartmental Health IT Collaborative [Multi-agency] (Page A46), Federal Health Architecture (FHA) [Multi-agency] (Page A47), Healthcare Information Technology Standards Panel (HITSP: Page A47), Nationwide Health Information Network (NHIN: Page A47), Use Case Development (Page A49)
HHS/OS: Personalized Healthcare (Page A52), Value-driven Health Care (Page A53)

Descriptions of Initiatives, Programs, and Projects Are Provided in Appendix C *[sample shown below]*

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

CMS: Beneficiary Information Services
One of CMS' priorities, as indicated in its most recent Strategic Plan, is to empower beneficiaries to make more informed decisions about their health and health care. To support this priority, CMS has implemented an online Medicare account management tool for beneficiaries, the Medicare Beneficiary Portal, and has begun to explore the use of personal health records for beneficiaries.

CMS: EHR Adoption Demonstration
CMS is implementing a new demonstration project in which up to 1,200 small to medium sized primary care practices in up to 12 different locations will be eligible to receive additional Medicare payments for using EHRs to improve care. Under the demonstration, primary care doctors who use certified EHRs to coordinate and provide care to Medicare beneficiaries and achieve certain clinical quality measures will be eligible to earn up to several thousand dollars per year in incentive payments. By design, the demonstration will be budget neutral by requiring that the associated costs be offset by savings resulting from more efficient health care delivery.

CMS: E-Prescribing Efforts
The Medicare Prescriptions Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub.L. No. 108-173) directed the Secretary to promulgate uniform standards for the electronic transmission of prescription and certain other information for covered Part D drugs prescribed for Medicare Part D eligible individuals. CMS adopted a set of foundation standards for e-prescribing under Medicare Part D, worked in collaboration with AHRQ to pilot test additional e-prescribing standards, published a required report to Congress on the results of that pilot, and issued a final rule that will require the use of the successfully tested standards and the National Provider Identifier in e-prescribing Part D covered drugs for Part D eligible individuals under specified circumstances.

Relationship of Goals and Objectives to the Federal Activities is Summarized in a Table in Appendix B *[partial table shown below]*

	Goal 1				Goal 2			
	Obj 1.1	Obj 1.2	Obj 1.3	Obj 1.4	Obj 2.1	Obj 2.2	Obj 2.3	Obj 2.4
ONC-Coordinated Federal Health IT Strategic Plan	Privacy and Security	Interoperability	Adoption	Collaborative Governance	Privacy and Security	Interoperability	Adoption	Collaborative Governance
Department of Health and Human Services								
Agency for Healthcare Research & Quality (AHRQ)								
AHRQ: Health IT Portfolio	☑	☑	☑	☑				
AHRQ: United States Health Information Knowledgebase (USHIK)		☑				☑		
Assistant Secretary for Planning and Evaluation (ASPE)								
ASPE: Health Information Activities		☑	☑			☑	☑	
Assistant Secretary for Preparedness and Response (ASPR)								
ASPR: Homeland Security Presidential Directive 21						☑	☑	☑
ASPR: Pandemic All-Hazards Preparedness Act (PAHPA)						☑	☑	☑
Centers for Disease Control and Prevention (CDC)								
CDC: BioSense						☑	☑	
CDC: EPI-X						☑		
CDC: National Healthcare Safety Network						☑		
CDC: Public Health Information Network						☑	☑	
CDC: Public Health Preparedness Systems						☑		
Centers for Medicare & Medicaid Services (CMS)								
CMS: Beneficiary Information Services		☑	☑					
CMS: EHR Adoption Demonstration			☑					
CMS: E- Prescribing Efforts			☑					

For More Information or a Copy of the Strategic Plan

http://www.hhs.gov/healthit/resources/reports.html