The Community

American Health Information Community

June 12, 2007
8:30 a.m. - 2:30 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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American Health Information Community: Agenda

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June 12, 2007
8:30 a.m. - 2:30 p.m. (EDT)
Hubert H. Humphrey Building, Room 800
200 Independence Avenue, S.W.
Washington, DC 20201

8:30 a.m. **Call to Order** - Secretary Leavitt

8:35 a.m. **Introductory Comments** - Secretary Leavitt

8:45 a.m. **Comments** - Robert M. Kolodner, National Coordinator

9:00 a.m. **AHIC Standing Committee of the Whole** - Secretary Leavitt and Rob Kolodner
Presentations from three Contractors
- Bob Hutchens, Vice President, Booz Allen Hamilton
- Shannah Koss & Sheera Rosenfeld, Avalere Health LLC
- Sharon Benjamin, Alchemy & Lisa Kimball, Group Jazz

11:00 a.m. **Standards Roadmap and Healthcare Information Technology Standards Panel (HITSP) Update**
- John Loonsk, Office of the National Coordinator for Health Information Technology
- John Halamka, Chair, HITSP

11:45 a.m. Break

12:15 p.m. **Workgroup Recommendations:**
Chronic Care Workgroup
- Craig Barrett, Intel Corporation, Co-Chair
- Tony Trenkle, HHS/Centers for Medicare and Medicaid Services, Co-Chair

Electronic Health Records Workgroup
- Lillee Gelinas, VHA, Inc., Co-Chair
- Jonathan Perlin, Hospital Corporation of America, Inc., Co-Chair

Confidentiality, Privacy and Security Workgroup
- Kirk Nahra, Wiley Rein LLP, Chair

1:30 p.m. **Privacy and Security Framework** - Discussion - Rob Kolodner

1:45 p.m. **AHIC Recommendation Implementation Status Report** - Rob Kolodner

2:15 p.m. **Public Input**

2:30 p.m. **Adjourn**

Meeting Report

American Health Information Committee
April 24, 2007

The American Health Information Community (the "Community"or AHIC), a federally chartered committee formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within ten years, held its 13th meeting on April 24, 2007, at the Department of Health and Human Services (HHS), 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 HHS on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting's discussions focused on: (1) a report on the first year of the Nationwide Health Information Network (NHIN), (2) a presentation on the National Governors Association-State Alliance for e-Health, (3) an update from the Personalized Healthcare Workgroup, (4) a discussion of AHIC's successor, and (5) recommendations from the EHR Workgroup. HHS Secretary Michael O. Leavitt chairs the Community. The remaining 17 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 this meeting follow.

Call to Order

Joining Secretary Leavitt around the table were:

David Brailer, MD, PhD, Vice Chairman, AHIC

Robert Kolodner, MD, National Coordinator for Health Information Technology/HHS

Craig Barrett, PhD, Chairman of the Board, Intel (Dr. Barrett was represented by Colin Evans, Director, Policy and Standards, Digital Health Group, Intel for part of the meeting)

S. Ward Casscells, MD, Assistant Secretary for Health Affairs, Department of Defense (Dr. Casscells was represented by Steve Jones, DHA, Principal Deputy Assistant Secretary of Defense for Health Affairs, and by Ron Pace, Director of Enterprise Architecture and Information Management for the Military Health System, for part of the meeting)

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

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

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

Gail Graham, Director of Health Data and Informatics at the Department of Veterans Affairs, Veterans Health Administration (Ms. Graham was represented by Linda Fischetti, Department of Veterans Affairs, for part of the meeting)

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

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

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

Steven Lampkin, Vice President, Benefits, Compliance, and Planning, Wal-Mart (Mr. Lampkin represented John Menzer, Vice Chairman, Wal-Mart)

Adele Morris, Senior Economist, U.S. Treasury (Ms. Morris represented Dr. Phillip Swagel, Assistant Secretary for Economic Policy, U.S. Treasury)

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

Paul Uhrig, General Counsel and Executive Vice President of Corporate Development, SureScripts (Mr. Uhrig represented Kevin Hutchinson, CEO of SureScripts)

Jeff Wells, MD, Director, Office of Medicaid Policy and Planning, Indiana Family and Social Services Administration (Dr. Wells represented E. Mitchell Roob, Secretary of the Indiana Family and Social Services Administration

Introductory Comments

Secretary Leavitt welcomed everyone to the meeting, thanking Community members for their ongoing efforts and underscoring his sense of urgency relative to AHIC's mission. He noted that AHIC has made great strides in enabling the success of health information technology (HIT). The Community is identifying areas that can offer near-term breakthroughs, has begun to process harmonizing standards, and has called for (and seen the reality of) a certification process that is now entering its second phase. AHIC also has called on the Office of National Coordinator (ONC) to contract the development of prototypes of an NHIN—this effort is now in its second phase. In addition, the Community has put in place Workgroups that are necessary to help it advance recommendations. Secretary Leavitt also congratulated Dr. Robert Kolodner, who is now the National Coordinator for Health Information Technology (previously, Dr. Kolodner was the Interim National Coordinator for Health Information Technology). Secretary Leavitt concluded his opening remarks by noting that for AHIC to be successful in the private sector, it has to have a business model; HHS has been establishing contracts to develop business models for AHIC's successor, and Dr. Kolodner has been asked to manage these contracts.

Dr. Kolodner noted that when the President issued the Executive Order in April of 2004, ONC was charged with developing a strategic plan for HIT. The ONC is working on this plan, and hopes to present it at the June AHIC meeting. Following public input, and input from AHIC, the plan will undergo a final review before submission to HHS. This national strategic plan for HIT also will reflect input from multiple federal agencies.

Dr. Kolodner explained that AHIC and its Workgroups made a total of 35 recommendations in 2006 and have made 58 to date in 2007. ONC is in the process of reviewing these recommendations and indicating what actions have been taken in response to them. AHIC Workgroups will be involved in determining when recommendations should end, setting priorities, and evaluating the outcomes of these recommendations. More details will be provided at the June AHIC meeting.

Approval of the March 13, 2007, Meeting Minutes

Minutes from the March 13, 2007, AHIC meeting (which was held via teleconference) were distributed, reviewed by Community members, and approved unanimously with no changes.

Report on the First Year of the NHIN Initiative

Dr. John Loonsk, Director of Interoperability and Standards, ONC, characterized the NHIN as mobilizing data not just between jurisdictions, but between providers and between providers and consumers, as well as trying to ensure that the different components of the health information infrastructure can work together and move information. The NHIN is operating under a number of assumptions, such as the assumption that the Network will be a "network of networks," with no central data store or centralized systems at the national level. It will be constructed out of shared architecture, standard services, and requirements.

Dr. Loonsk described an health information exchange (HIE) as a multi-stakeholder entity that enables the movement of health-related data within state, regional, or non-jurisdictional participant groups. NHIN HIE (NHIE) was defined as an HIE that implements the NHIN architecture (services, standards, and requirements), processes, and procedures, and participates in the NHIN Cooperative (where these HIEs will collaborate and form this network of networks). The NHIN moves data when a patient moves, but more critically, ensures secure data movement whenever appropriate. Eventually, the NHIN Cooperative may include specialty networks as well as NHIEs. In the first year, however, these NHIEs will form the core of connected networks that will make up the NHIN.

A number of products from 2006 are serving as guidance for 2007 trial implementations. These products include seven AHIC use cases, three sets of Healthcare Information Technology Standards Panel (HITSP) standards, NHIN functional requirements developed in conjunction with the National Committee on Vital and Health Statistics (NCVHS), public input, privacy and security work, prototype architectures, core services and capabilities for an NHIE, and a report on service interfaces.

Virginia Riehl, a health care management consultant for the Gartner Group, presented findings from an analysis conducted by her company. She noted that many of the findings confirm or expand on the working framework developed in response to the challenges set by the national HIT agenda and AHIC. The prototypes provided validation and refinement to those working models. For this reason, the prototypes have made an important contribution to advancing the national HIT agenda, and support the

next steps towards implementing the NHIN. Ms. Riehl also noted that there was a significant amount of consistency across the prototypes.

In terms of architecture, the prototypes confirmed that the NHIN can be a network of networks, does not require a central hub, and does not need a central repository. The prototypes concluded that the networks should be fully standardized in their interactions with other NHIEs. There needs to be a very high degree of rigor in those interactions and standards compliance. The NHIEs can help bridge standardized implementations of EHRs and personal health records (PHRs) to full standards compliance.

With regard to providing data for secondary use, the prototypes confirmed this activity's importance to the NHIN. For the purpose of Gartner's analysis, the focus was expanded to include public health quality monitoring organizations and researchers, and at least from an analytic standpoint, testing the findings against them. All of the prototypes agreed that the NHIEs can greatly facilitate appropriate secondary use of data, including forwarding the data to appropriate secondary users and enabling anonymization of data where a source system is not able to do so. Ms. Riehl explained that most of the prototypes demonstrated how secondary use could be supported, and most saw this as an important aspect of sustainability; this is not a secondary service, it is a core service, from their perspective.

The prototypes also identified common services that the NHIEs must provide to participate in the NHIN. These services fall into the following four areas:

- **Key Data Services.** The NHIEs provide the service of moving the data to EHRs and PHRs, doing so in a secure manner. They also provide the service of locating where data is, again doing so in a secure manner, so that they can send data in response to requests or for other needs.

- **Key User and Identity Management Services.** The NHIEs ensure that the individuals who are interacting through them, and through the NHIN, are appropriate; should be there; and are validated by identity proofing, authentication, or attestation to their identities. The NHIEs also arbitrate identities between entities; this is a service that is critical, given that there is no national identifier. Ms. Riehl noted that each of the prototypes demonstrated methods for linking patient records together in the absence of a national patient identifier.

- **Key Management Services.** With respect to management services, another area of security is ensuring that the system partners in the NHIE are trusted partners, and that the communications among them occurs in a secure fashion. There also are needs for emergency access to data; the prototypes discuss the circumstances where this would be needed, at both the individual and community levels.

- **Key Consumer Services.** Both AHIC and the ONC emphasize examining consumer services and what can be done to advance the role of consumers. The prototypes each had ideas about how to do this, and implemented approaches to providing these services. Based on their efforts, they identified consumer services that the NHIEs should be able to support, including:
  - Identifying a PHR home.
  - Searching for other places where data about an individual exists.
  - Controlling who can access an individual's PHR.
  - Viewing who has accessed an individual's PHR or made NHIE look-ups and how their data may have been disclosed.
  - Sending change requests to data providers when they think the data are wrong.
  - Choosing not to use network services.

Dr. Loonsk explained that there are several levels to these services, and that Gartner has produced a report that details, at a very high technical level, the specifics of implementation to support these activities. He added that the consumer services are key in moving forward with some of the areas that AHIC has prioritized. In 2006, ONC had prototype architectures that were led by systems integrators, each of which was expected to have several markets participating in their consortia. In 2007, state, regional, and potentially non-geographic HIEs are anticipated to be the leads of new consortia that will bring to bear technical expertise, business and operational expertise, as well as open governance, trust, and buy-in from that appropriate HIE jurisdictional community, to move forward with those efforts. There will be a focus on the services and interfaces, rather than spending a great deal of time dictating how these HIEs are architected on the inside.

In addition, a cooperative of awardees will be established and charged with moving forward with the next step of developing interoperability. A key deliverable of this next round of trial implementations will be when all of the NHIEs are brought together in one place at the end of the year and demonstrate that they can connect with each other, as well as with the central services necessary to support this exchange. Dr. Loonsk noted that the ONC will be allocating roughly $22 million in 7-10 contracts. Each awardee is expected to carry out the core services described by Ms. Riehl and to conduct two breakthroughs. Coverage of all of the AHIC breakthroughs that have been put forward to this point is expected.

Discussion Highlights

"At the end of that first year, we should have a cadre of health information exchanges that can work together and exchange data. They should be able to reconcile identities across each other so not that we will have a common national identifier, but when data does need to flow, it can be accurately associated with the appropriate patient. And we should have initial implementations of all of the breakthrough areas that the AHIC has advanced. That will include connecting up with other networks and services, as well as the HIEs." – Dr. Loonsk

"Each of the prototype architectures looked at the issues associated with matching patients to their data, and have come up with approaches for doing that within a jurisdictional area, in a regional health exchange, for example. So a regional health exchange may use an identifier for the purposes of indexing patients in that exchange. What we're advancing is a network of those different health exchanges, without a common identifier across them, but where those different health exchanges can do the appropriate adjudication of identities, so that when necessary, and [as] data move from one HIE to another, they can do the match up." – Dr. Loonsk

"Each of the prototype architectures was conservative in their approach as well, so what they opted for were few false positives, and the issue is, to some extent, is that the right balance…if we fail to get data associated with a patient, how does that manifest itself, and what are the outcomes? I think that's part of what the trial implementations will hopefully help us work through." – Dr. Loonsk

"Just from a consumer perspective, it's daunting to feel like you might have different numbers in different exchanges or different systems, if you move from place to place." – Dr. Gerberding

"It is an issue. I think that the idea of having a personal health record home where you could say, 'this is my network address,' or 'this is where my data are,' and expecting that to be managed by the HIEs, which is what we're talking about here, so that you would say, 'this is my personal health record home, I am saying this is where my data are, this is my identity,' and having that appropriately identity proofed and authenticated, et cetera, can help. Whether it solves all the issues is another question." – Dr. Loonsk

"Do you foresee the day where, if I'm a doc in practice using an EHR, and I want to transmit data from my office to somewhere else in the health care system, that I will not have to use an NHIE, or will I always have to go through an NHIE, kind of like an Internet service provider?" – Dr. Henley

"I think the networked activity is going to continue…We probably will need to have the role of an NHIE to advance this, although it could be applied to a number of different organizations…As we've structured this now, we do anticipate that there will be some requirements, some standards, some processes and procedures to bring these networks together to make this coherent and workable." – Dr. Loonsk

"There has been a great deal of interest in the so-called 'broker-free' NHIN, where there is a peer-to-peer [interaction], not unlike Napster would have been in days gone by…Based on the work of the NHIN contractors, is that a feasible solution? Is that in the realm of sets that are still being examined?" – Dr. Brailer

"It's not technically inconceivable, but one of the key things that's lacking is what we would call a 'trust model,' wherein if it's totally peer-to-peer, how do you know that that's an EHR and not a dog that's on the other end of that, so how do you know who you're sharing data with? And one of the key services here that is suggested for NHIE, is that they would attest for or play a role in attestation for the identity and the capabilities of that other group." – Dr. Loonsk

"Over time, what's the business model for these different entities that is going to keep them going, once you sort of know what kind of linkage we want to have?" – Mr. Kahn

"It is something that we're working on, struggling with in a number of different settings, because sustainability of these HIEs is critical to this activity, as well as many of the other parts of the national agenda. Each of the prototype architectures and prototype consortia were asked to look at sustainability, and each of them thought that they could project out, having a sustainable system approach in a roughly 5-7 year timeframe. Many of them were heavily dependent on secondary use data as a potential source for how that would be sustainable." – Dr. Loonsk

"A number of states have gotten involved in health information exchange, have made it known that they do view the business model not being a value-realized model, in terms of secondary use of data, or, hopefully, primary use of data, which is that the actual sharing of data that has value to providers and plans and others, such that the model can support itself on its merits. But that they do view this as a public utility that shouldn't be subjected to a business case." – Dr. Brailer

"My sense is this is going to be very heterogeneous for a while. I think the question before us, not today, but at some point will be, what boundaries do we want to put on that? What kinds of principles or operating rules about how it could happen? And I could easily see health information exchange paying part of their bills through the public health support, paying part of their bills through perhaps some general non-value added public support, through secondary uses of data, and hopefully, through end-stage user subscriptions, doctors, hospitals, plans, because they see that this is cheaper than sharing data another way, which is through paper." – Dr. Brailer

"It seems to me that one thing that's lacking in the discussion is figuring out how to make the person, who actually is going to ultimately benefit the most from having the record, be involved in making sure this runs. I mean all of us have water. All of us buy power. And it seems to me that this is something on that level, that we ought to think about." – Mr. Kahn
"I think it's clear that the consumer ultimately pays for it, regardless. I think it's a question of whose hands it goes through to get to the consumer." – Dr. Brailer

"The question of hands, though, affects the incentives of those who are operating the system. And so I think in terms of records, and ownership of the records and paying for the records, if we're too convoluted in the type of system we have…we may end up setting up a system that is either perverse, or has incentives that the consumer, at some stage, may question." – Mr. Kahn

"If you took the public utility model, and suggested that folks who buy a phone, or buy a Treo, or some device like that, that they're going to carry with them to get information, that perhaps that be built into that model, if you will. I don't know what all we pay for when we buy a cell phone, and we use it for personal reasons or business. But I know that it's all calculated in, and I wonder if we could take that approach and say that as part of the information exchange for all Americans, that ought to be part of it." – Mr. Lampkin

"To me the question starts ultimately from where does value get realized in these exchanges, which I think tells us what tools we have economically to work with for sustaining their finance. But I was surprised, and actually pleased along the way, again, that several governors and others have seen this as a public model. And so this is going to feed directly into that." – Dr. Brailer

"One of the things that we've learned in our company at Wal-Mart is to not let perfect get between doing good. And so to the question about can we access everything, maybe not initially, but I'll bet we'll have access to a whole lot more than we do today. So if we could move in that direction, perfection can come later, if at all. But I think we shouldn't let that get in the way of us doing some really good things to advance the cause, so to speak." – Mr. Lampkin

"One of the things we didn't touch upon is the importance of a summary record in moving some of this forward, because it is not necessarily a question of getting all the data all the time. And a summary record, and now that there is a harmonized standard for that, I think that can play a critical role in getting some of the good." – Dr. Loonsk

Before moving on to the next agenda item, Dr. Brailer recognized and welcomed new AHIC member Dr. Ward Casscells, Assistant Secretary for Health Affairs at the Department of Defense, who was attending his first AHIC meeting as a member of the Community.

National Governors Association – State Alliance for e-Health

Jodi Daniel, Director, Office of Policy and Research, ONC, explained that the State Alliance for e-Health was created with the vision of having an advisory body by and for states, about state governor- and government-level issues regarding HIT. With the recognition for the need for partnership between the federal government, state governments, and the private sector regarding HIT issues, the National Governors Association Center for Best Practices was engaged and contracted to form the State Alliance for e-Health. The Alliance, which held its first meeting in January 2007, is comprised of governors and high-level executives of U.S. states and territories. The Alliance has the following two charges:

- Identify, assess, and through consensus solutions, map ways to resolve state HIT issues that affect multiple states and pose challenges to interoperable electronic health information exchange (HIE).

- Provide a forum in which states may collaborate to increase the efficiency and effectiveness of the HIT initiatives that they develop.

Ms. Daniel discussed the role of the State Alliance for e-Health and how it links with other ongoing activities in the area of HIT. At its core, the Alliance is about state government consensus across jurisdictions, with a focus on examining state government policies and roles that state governments may have, or state programs may have, in HIE and HIT. One goal is to take ideas and issues raised through state and federal initiatives and bring them to the State Alliance for discussion and consensus. An example is the Health Information Security and Privacy Collaboration (HISPC), which presented at the last AHIC meeting on work being done at the state level on privacy and security issues.

To put the State Alliance for e-Health in context with other state-level activities, Ms. Daniel explained that the Alliance focuses on state government roles; includes governors, legislators, and high-level state officials and technical experts; and generates action-oriented recommendations to state governments to spur HIE adoption within and across states. By way of comparison, state-level HIE initiatives focus on state-level HIE practices; are comprised of state-level HIE leaders; and generate best practices for HIE in terms of governance, funding, and data exchange practices. Another state-level activity is HISPC, which focuses on state, territory, and organizational privacy and security practices and laws. HISPC is composed of state/territory HIE stakeholders and will produce an assessment of organizational practices and state laws, solutions, and specific implementation plans to enable HIE while preserving privacy and security of the health information.

John Thomasian, Director of the National Governors Association Center for Best Practices, explained that HIE has to make sense to providers and patients, as well as those individuals in charge of the regulation oversight of health care in the states and those in charge of enforcing patient protections. He explained that the Alliance is an effort to bring those individuals together to begin to develop the capacity and to focus on some of the issues arising from the large amount of ongoing activities. States play a key role in the regulation oversight and shaping of health care, and they do protect patient privacies. States also are major market participants through the public programs in Medicaid and through their own employee benefit plans. Mr. Thomasian explained that states have a major stake in ensuring that HIE works and is portable.

Currently, there are major state activities ongoing in the area of HIE. Twenty Executive Orders have been issued by governors calling for HIT and HIE, seven in 2007 alone. Legislatively in 2005 and 2006, 121 bills were introduced in 38 state legislatures that specifically focus on HIT; 37 bills were passed in 24 state legislatures. In 2007 so far, 68 bills have been introduced in 30 states that specifically focus on HIT. Quality, patient safety, and rising costs are the primary drivers for state interest in HIT and HIE.

Mr. Thomasian described three goals of the Alliance, to: (1) build consensus among states, and among the different players within states for HIT solutions; (2) provide states with realistic, timely, and well-researched options; and (3) allow for input of experts and practitioners working on HIT endeavors to inform state policymaking. The Alliance includes 12 voting members (two Governors, two Attorneys General, two State Insurance Commissioners, four state legislators, and two former Governors) as well as an eight-member non-voting advisory group (comprised of state health government representatives, relevant private-sector members, and technical experts). The Alliance has a short, three-year timeline, and is being conducted in a transparent fashion with input from the states. All Alliance meetings are open; the group currently meets on a quarterly basis.

Kathleen Nolan, Director of the Health Division at the National Governors Association Center for Best Practices explained that the Alliance has three Taskforces composed of public and private-sector representatives. The three Taskforces are:

- **Health Information Protection Taskforce.** The charge of the Health Information Protection Taskforce is to support the State Alliance for e-Health on policy options around protection of consumer health information. Focus topics include privacy and security, as well as further

development of solutions identified in HISPC. The initial Taskforce work product is an analysis that: (1) examines the rationale behind the major state health privacy protection laws that affect the sharing of health information across entities; (2) discusses the applicability of each kind of protection, with an emphasis on an individual's health in an electronic HIE environment; and (3) provides recommendations for addressing issues arising from such protections.

- **Health Care Practice Taskforce.** The charge of the Health Care Practice Taskforce is to support the State Alliance on policy options regarding the regulatory, legal, and professional standards that impact the practice of medicine and interoperable, electronic HIE. Focus topics include licensure issues, state laboratory laws and regulation, and liability concerns. The following three work products have been identified:
  - Examine state licensure laws and describe how such laws, rules, and procedures permit or hinder the exchange of electronic health information (including telehealth). Suggest solutions to permit the interstate transaction of health information and services.
  - Conduct a study of case law and opinion concerning liability issues arising from the exchange of electronic health information and produce as assessment that identifies current practices that may result in malpractice challenges.
  - Conduct an analysis of malpractice insurance coverage for e-health across states that identifies the availability of and options for coverage. As part of the analysis, identify coverage issues that impair the electronic exchange of health information across state lines. Suggest solutions to expand the availability of coverage.

- **Health Information Communication and Data Exchange Taskforce.** The charge of this Taskforce is to support the Alliance on the appropriate roles for publicly funded health programs in HIE, including ways states can enhance Medicaid, SCHIP, employee health benefits, and public health through HIE activities. The Taskforce focuses on opportunities for publicly funded programs to participate and contribute to HIEs in relation to data sharing and protection requirements, core mission support, governance, and funding. The following two work products have been identified: (1) conduct an analysis of state coverage programs and identify opportunities within these programs to further electronic HIE, and (2) provide an overview of the landscape of current state action to support the creation and operation of electronic HIE networks.

Ms. Nolan concluded her remarks by describing some near-term issues for the State Alliance on e-Health, such as increasing knowledge of business models and sustainability issues (e.g., in the context of public health, public utility options, and potential government oversight needs). Recommendations for action from the Taskforces' work products are expected by August 2007. These recommendations will focus on licensure, privacy recommendations for special information classes, and priority opportunities for publicly funded programs.

Ms. Daniel noted that some of the issues being addressed by the State Alliance for e-Health came directly from AHIC recommendations. For example, four of the AHIC Workgroups proposed recommendations related to state-level activities over the course of the last year; all four of those are being considered and incorporated into the work of the State Alliance.

Discussion Highlights

"This is really drilling down on the importance of the recommendations that are coming out of the HISPC about privacy, and information portability, and the significant amount of work that would flow from that in terms of changing state or potentially federal laws, to bring them into this digital era. How would you envision that body of material, those findings, moving forward? Do they go over to the State e-Health

Alliance? And then does it become more of an action discussion? And then does it go out to the states from there?" – Dr. Brailer

"The states have identified both implementation plans and solutions within their state, where they've identified there is some law in their state, for instance, that may be a barrier to health IT, and those are incorporated in there. Those are really intrastate issues." – Ms. Daniel

"They've also identified some interstate issues, and needs for regional coordination or national coordination. And so where there are those types of solutions that are being recommended, they would have an opportunity to communicate directly with the Health Information Protection Taskforce that's looking at some of these issues, helping them identify where there is a need for cross state discussion and solutions on some of these policies; and for the Health Information Protection Task Force to recommend solutions up to the State Alliance." – Ms. Daniel

"We also hope, in the future, that the HISPC project, as it goes into next iterations, will not only focus on the state-by-state issues, which was really the focus of the first year, but start looking at some more collaborative issues as well. And we'll have to figure out the best way to coordinate that, but it may be that they take on some of the recommendations that are coming out of the State Alliance. So I see this as a sort of an iterative process." – Ms. Daniel

"I think the Alliance would like to take the privacy and security issues on and try to make it actionable. Some of the information that's bubbling up, for example, is making it clear that there are differences among states, and states want to preserve those differences in terms of privacy protections. Among the differences, there may be iconic approaches that are out there...So I think the Alliance sees a value in them sorting this out, and then offering up some consensus solutions." – Mr. Thomasian

"In a practical sense, is there something we at AHIC can do, that would address some of the issues that you're trying to address and bring a greater sense of urgency, because I'm very respectful of your timeline and timeframe here, but again, on a very practical sense, we really need the e-health initiative across the states to get on steroids." – Ms. Gelinas

"We have been talking quite a bit about the dissemination approach to this. First of all, between the task forces and the State Alliance, itself, there are public-sector folks on the Taskforces…We have attempted to be very broad in our approach, so that we can get as many states involved. And then with turnover, we think even within the next year we'll be pretty close to all of them playing at least some role.. So I agree that it's not everybody at the table all the time, however, we are looking very seriously at how we engage, not just disseminate, engage all the other states." – Ms. Nolan

"The urgency is out there. I don't think any of us can deny that. I would suggest to you that there is no Governor out there that is satisfied with the current health care system…We're building capacity in the Alliance to be able to understand that decisions have to be made. I think we will be soon offering up potential solutions. But again, this is a big jigsaw puzzle. They've just started playing with it. I think we'll get to some conclusions fairly shortly, though." – Mr. Thomasian

"Is there any one thing that AHIC can do to speed your work?" – Ms. Gelinas

"I think they're very appreciative of the standardization efforts. They don't want to play in that realm. They want that adopted. I think all the work that you're doing and feeding into this is important, because that's one less thing that they need to work on." – Mr. Thomasian

"We've had ONC come to each meeting so far…to really try to represent and to get the best sense we can of what is going on out there, what is being taken care of, and that's been one of their first questions. So I think that as much as possible, the AHIC and others can represent what's being done, so that we can move from there, rather than try to sort that out." – Ms. Nolan

"We have also been looking [at] the process by which people obtain licensure, and could we, at the very least, streamline that. If we weren't able to get to the issues around what is required to be a licensed physician or nurse in different states, could we at least look at how you go about getting licensed, and making sure that that process is as simplified as it can be while still protecting the public's health. And so that's another set of issues beyond just the requirements for licensure that we want to get to." – Ms. Nolan

"Is there a way that the state medical boards engage in this process? I mean they're not on the list, so is there a dialogue, is it informal, is it formal?" – Dr. Brailer

"It's very formal, and we have been working with them. It's mostly been from the testimony perspective, but we're also working with them on the work product itself, to ensure that we've got a viable approach." – Ms. Nolan

"Just as an example, if there are some states that may want to move forward and begin piloting or collaborating with other states, in a more porous licensing process for health IT collaboration, or telemedicine, it's in the realm of possibility that they could orchestrate that together without having everyone else necessarily come along. It's not an all or nothing phenomenon." – Dr. Brailer

"Absolutely. And that's true, pretty much, of all of this, is that we don't expect an all or nothing approach in many of these areas. We expect a wave of states to take on these issues and see how they work." – Ms. Nolan

Personalized Healthcare Workgroup Update: Vision and Priorities

Personalized Healthcare Workgroup Co-Chair and Community member Dr. Douglas Henley described the relevance of personalized health care to the AHIC, commenting that the evolving science of genetic and genomic tests clearly demand attention to the necessary common data standards to embed that information in EHRs and PHRs, and to assure the interoperability of that data. This important connection clearly relates to the work of the Community. In addition, one of the primary tools in personalized health care is the family medical history—a more structured approach to family medical history and standardization of that nomenclature, including that information in EHRs and PHRs, is another important connection to the Community. Furthermore, the need for clinical decision support tools, delivered at the point of care, via the use of HIT, is another connection directly to the work of the Community. Finally, as this evolving science moves forward, the concerns of both consumers and clinicians in terms of the confidential nature of this information and its use in that regard, and how it is kept private and secure, also makes an important connection back to AHIC.

Dr. Henley then described the Personalized Healthcare Workgroup's broad and specific charges, which are as follows:

- **Broad Charge:** Make recommendations to the Community for a process to foster a broad, community-based approach to establish a common pathway based on common data standards to facilitate the incorporation of interoperable, clinically useful genetic/genomic information and

analytical tools into electronic health records to support clinical decisionmaking for the clinician and consumer.

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

The Personalized Healthcare Workgroup has met on several occasions via conference call, and has had one in-person meeting, held on March 12, 2007, which constituted the group's visioning exercise through assessment of the current status of personalized health care and consideration of an envisioned future. This work was approached from the perspectives of four constituencies: (1) consumer, (2) clinician, (3) researcher, and (4) health plan/payer. Dr. Henley explained that the Workgroup views personalized health care as a consumer-centric system in which clinicians customize diagnostic, treatment, and management plans. Personalized health care takes into account a variety of factors, including culture, personal behavior, preferences, family medical history, and the individual's unique genetic/genomic makeup. Personalized health care also is based in the confluence of advances in HIT and improved understanding of the relationships between health, disease, genetics/genomics, and treatment options. Dr. Henley provided the Community with the Workgroup's vision from the perspective of the consumer, clinician, researcher, and health plan/payer, with consideration given both to the current status and the desired future:

Consumer Perspective

- Current Status:
  - Health care practices are rarely based on family history or a person's genetic makeup.
  - Fragmented health care sector.
  - An emphasis on treatment and acute care rather than on prevention.
  - Lack of easy access to information about genetic/genomic tests.

- Desired Future:
  - Complete, organized, and quality consumer information, including family medical history, captured in a PHR.
  - Easy access to information about genetic/genomic-based risks and treatment options.
  - Personalization of diagnosis and treatment using genetic/genomic information leads to higher quality care with greater value.

Clinician Perspective

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

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

Researcher Perspective

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

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

Health Plan/Payer Perspective

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

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

Near-term priorities related to genetic/genomic tests include: (1) inclusion of relevant genetic/genomic test results in the EHR; (2) information to describe analytical validity, clinical validity, and clinical utility of genetic/genomic tests; (3) incentives for development and evaluation of new genetic/genomic tests; (4) consumer education about the potential benefits and risks associated with genetic/genomic tests; and (5) harmonization of standards for submission of clinical pharmacogenomics data and state-mandated newborn screens. Dr. Henley also discussed near-term priorities related to family medical history, such as consumer and clinician entry of family medical history information in the interoperable PHR and EHR. Supporting clinician use of consumer-entered family medical history information, standardization of nomenclature for family relationship and other data, and characterization of the validity and utility of use of family medical history in making clinical decisions are additional near-term priorities tied to family medical history.

Longer-term priorities for the Personalized Healthcare Workgroup fall into the areas of clinical decision support and confidentiality, privacy, and security. Longer-term priorities for the Workgroup as they relate to clinical decision support include: (1) development of approaches to informing the clinician of the clinical utility of test results, (2) development and assessment of genetics/genomics predictive algorithms, (3) development and assessment of genetics/genomics-based clinical decision support to guide treatment and medication dosing decisions, and (4) incentives for development and incorporation of clinical decision support tools in EHRs.

In terms of longer-term priorities related to confidentiality, privacy, and security, Dr. Henley discussed the following:

- Technical solutions and policy considerations to ensure that genetic/genomic information will be used appropriately.

- Capabilities to link large data sets to generate large-scale, individual-level genetic/genomic data with sufficient protections and limits of use.

- Balancing the desires of the research community to have secure and consented access to clinical databases with the privacy and confidentiality rights of the consumer and clinician.

- Understanding the risks associated with certain types of genetic/genomic information, such as: (1) contextual access criteria limits to necessary information; (2) ensuring privacy and confidentiality rules apply to all collection/exchange of health information; and (3) research to assess confidentiality, security, and privacy of the NHIN and consumer confidence.

More immediate, next steps for the Personalized Healthcare Workgroup include formation of two subgroups, one focusing on genetic/genomic tests, and one focusing on family medical history. Recommendations from these subgroups are planned for presentation to the Community at its July 31, 2007, meeting. In the longer term, the Workgroup plans to form a subgroup to coordinate activities with AHIC's Confidentiality, Privacy, and Security Workgroup. There also are plans to form a subgroup focusing on coordination of activities across AHIC's EHR, Personalized Healthcare, Population Health and Clinical Care Connections, and Quality Workgroups. In addition, some members of the Personalized Healthcare Workgroup are involved in the evolving AHIC *ad hoc* Workgroup addressing the need for clinical decision support tools that become part of EHRs in the future.

Discussion Highlights

"This is an area that is quite important for us, because unlike many of the things that we deal with today, where we're trying to get the horse back in the barn, this is a chance to get it right from the beginning. And we're certainly taking advantage of that." – Dr. Brailer

"It might be helpful, in the future, if you could give us a report on how personalized health care is viewed by the Department of Defense and the Veterans Administration…When some of us saw the MyHealth*e*Vet on how the veterans have their own Web site to view their own personal health information, I remember being highly impressed by that…I know I would like to know a whole lot more about how personalized health care is viewed in the VA and DoD. And that could inform our thoughts as well." – Ms. Gelinas

"After a series of our Workgroup meetings on the phone, we've had presentations, meetings with the VA and also recently with DoD, and will be continuing to support the Workgroup's activities with additional supplemental information about the readiness for these." – Dr. Downing

"From a definition standpoint, what types of tests fall under genetic or genomic tests? Does that include things such as proteins and biomarkers, or is this strictly limited to specific gene tests?" – Mr. Wells

"The definition of genomics and genetics is a fairly broad one, and it's a definition that we've adopted for this Working Group activity from the National Human Genome Research Institute…it does adopt those components that are sort of downstream components of genetics, meaning proteins, metabolites epi-genomics. As we see those parts of the research frontier start to open up in clinical practice, those may follow in the same pathway that's established for more common genetic tests that are currently used today." – Dr. Downing

"Consummate with the discussions that occurred this morning about the information exchange aspects, that the ability to gather the right kinds of information, understand where these tests play a role in health

care decision-making, is really a frontier that's supported by the kinds of efforts that AHIC is working here." – Dr. Downing

"I noticed that in the membership of the Workgroup, FDA is represented, but I didn't see a CMS representative. And I know that there is some discussion about where the locus of regulation of genomics exists, if it's an FDA or if it's in CMS. I wonder if this is across the Workgroup, and if it would be valuable to have a CMS participant on that Workgroup." – Dr. Brailer

"We have adopted a nomenclature of senior advisors, and we do have a member from CMS now [who have] been participating in the last two Workgroup meetings." – Dr. Downing

"Because some of these tests and data items are so new, is it possible in this field to avoid some of the legacy vocabulary problems we had for some of the other standardizing clinical issues in the past, since we kind of know we're going towards standardization already, to, from the get go, kind of develop systematic nomenclatures and data approaches?" – Ms. Morris

"There is the potential for that. Certainly the people who have volunteered on the two subgroups that I mentioned, one about genetic and genomic tests, and one about family medical history, they see a desperate need to standardize not only the architecture and structure of how who you enter the data, but the nomenclature as well. We have every intent of trying to address that, as we also address the issue of common data standards that would then feed into the CCHIT process. We're going to take a stab at it." – Dr. Henley

Planning for AHIC's Long-Term Succession and Sustainability

Secretary Leavitt noted that the purpose of this discussion was to advance the process of creating a sustainable process widely understood to be the means by which standards are established in HIT. The goal has been to create this process, give it substance, describe how it operates, connect it with appropriate entities, fund it, and give it a sense of momentum. This portion of the agenda was dedicated to examining the business models that can be used to perpetuate this process.

Dr. Brailer reminded Community members that the AHIC Charter was established under the Federal Advisory Committee Act authorities for creating a public/private collaborative. AHIC's two primary functions are to: (1) advise the Secretary and recommend specific actions to achieve a common interoperability framework for HIT, and (2) serve as a forum for participation from a broad range of stakeholders to provide input on achieving widespread adoption of interoperable HIT. Dr. Brailer briefly discussed some potential roles for an AHIC successor, including:

- Operating as a public-private entity in the private sector with voluntary membership representing all stakeholders in health care.
- Setting priorities for national standards harmonization and adoption.
- Maintaining a trustworthy and effective governance model on a national level.
- Establishing guidelines for data stewardship based on consensus.
- Developing and maintaining principles for data-sharing policies.

- Advising ONC on the roadmap for NIHN implementation.

- Evaluating market trends and economic models to support interoperability, HIE, and EHR adoption.

- Coordinating federal and state relationships and governance activities.

In discussing the timetable for developing AHIC's successor, Dr. Brailer emphasized that Secretary Leavitt wants to have the process complete so that there is one year of effort under his leadership to ensure that there is an established, firmly rooted, sustainable, financed successor in place. With a transition expected to begin in January 2008, there is urgent work to be done in the next seven months. The key step in the short term is determining the business model. Three contractors, working independently, will describe potential business models based on a delineation of responsibilities between the successor and existing federal entities, including: (1) the appropriate role of government; (2) short-, mid-, and long-term goals of the entity; (3) mechanisms to ensure diverse and voluntary membership representing all stakeholders in health care; (4) a transition plan; and (5) a path to sustainability. These efforts will be informed by case studies of other governance entities and guiding principles.

Dr. Kolodner explained that contracts have been issued to three different firms (Booz Allen Hamilton, Avalere, and Alchemy) to carry out this work. Representatives from each of these companies were in attendance at this AHIC meeting so that they could be informed by Community members' discussions. At the June AHIC meeting, these firms will present their progress and findings to the Community for consideration. Dr. Brailer added that AHIC will develop and gain consensus on evaluation criteria for the proposed business models. The Community will evaluate the proposed business models. Recommendations will be proposed to the Secretary on July 31, 2007. These recommendations will address a governance structure and business model, the role of government, a transition plan, and a path to sustainability. Dr. Brailer explained that it is hoped that these efforts will set a trajectory for at least the next five years of progress.

Discussion Highlights

"I think this is a great idea, and I'm very supportive of it. Let me say that the model that we have out there for it, which I've been involved with some, is a frustrating one, and that's the National Quality Forum. [It is] frustrating because it doesn't have sufficient funding to be doing the kind of priority setting it needs to do, and frustrating because even though it has a dues base, it receives most of its funding to consider endorsements of measures from those who want to get their measures endorsed." – Mr. Kahn

"We need to be careful that we don't have a business model that has an agenda driven by its business model. And that's why I think broad-based financing of some type, and whatever it is, is really fundamental here to make this work. If the head of the new [entity] has to worry about where the money is coming from every day, it's not going to work. And then issues over time of conflict of interest and other concerns will arise, I can assure you." – Mr. Kahn

"The business model question is clearly linked to the scope of the AHIC, and how broad it goes beyond this core charge that we've had here, and that's one of the issues that's going to be discussed, to get a decentralized business model that has to have a decentralized scope of work." – Dr. Brailer

"Are there one or two examples that you could give of this sort of successful implementation? [I'm] not trying to presuppose the output of the three groups, but just in the existing private/public partnership type of activity. Are there one or two examples you could reference where the movement has moved out of the public sector into more of a private [one]?" – Dr. Barrett

"One from a retail standpoint that we have found very helpful, is GS1, Global Standards One. And the elements that…we found to be successful in that space, is one, it needs to be user driven. It needs to be absolutely driven by those end users, not by technology companies or others who have a proprietary interest. It needs to be, if at all possible, a public/private initiative that is nonprofit and independent…so it's really something that stands alone, and that a variety of players can engage in without feeling like their personal interests or their companies are at risk." – Mr. Lampkin

"There are lots of standards-setting bodies around, obviously, and they come in different flavors and different formats, and when you say it's user driven, then you get to the definition, well, who is the user, and who is the consumer, and who are you benefiting, et cetera, et cetera. I was just trying to get a feel, if you've given this thought, what direction you might want to model this after, because of the wide variety of options that you have." – Dr. Barrett

"There is no question that there is a wide variety. I also think that there's little question that it's somewhat unusual for a government to undertake the proposition of 'let's create something and spend it out of government.' Government isn't accustomed to doing that." – Secretary Leavitt

"One of the jobs of the contractors will be to go out and analyze every possible model and say, 'where are the applicable experiences that we can learn from?' We likely have to invent some things along the way. If this was easy, it would have happened a long time ago. Heaven knows the need is there. But I suspect that will come out of the various proposals." – Secretary Leavitt

"One of the most important aspects will be assuring that government purchasing power is committed to the outcome of AHIC. We have an Executive Order right now. Part of the Executive Order that both creates AHIC and also that requires government departments and agencies to adhere to it is what drives a lot of the change…One of the most significant changes we've already seen as a result of this is the commitment on the part of the VA and the DoD to begin to upgrade their systems together. I think there is no question that would not have occurred, absent this convening." – Secretary Leavitt

"[The contractors are] not being told to do things differently, but they are being asked to work independently, and they come from very different vantage points in terms of the industry. And I think part of the challenge of the AHIC will be to take the best of each, and figure out how they fit together in something that we want it to be, as opposed to just endorsing one of the three solutions. It's possible one would be superior, but I think it's unlikely." – Dr. Brailer

"Let's put a lot of smart people thinking about this, use their best ideas, and come up with a new model that will allow us to perpetuate the best of private-sector thinking connected to government purchasing power. And I believe this is the way to go about it. We're pioneering here in many respects. But it's a good process, in my judgment." – Secretary Leavitt

"This is a formalized collaboration that has to be hooked to a whole series of other functions, such as certification, standards harmonization, et cetera. And it also needs to be integrated, I might add, with the whole process of quality. There are a number of pieces we're inventing at the same time here, and all of these have to be integrated, and for that to occur, this has got to be part of larger vision than simply health IT standards." – Secretary Leavitt

"The relationship of this entity and its governance to the standards process, to the HITSP, to the certification process, and even to the governance of the NHIN is still something that is up in the air, and I think those are things for us to consider, to see what's the best way, how might those fit together; and to consider not necessarily ruling those pieces out, but also not assuming that those are part of the organization or the governance." – Dr. Kolodner

"We need to call out why AHIC has been successful, Mr. Secretary, and that's been your leadership. And the leadership of this new entity needs to be very strongly considered by the contractors, and what that will mean, because through leadership, much gets done. Lack of leadership, nothing gets done. And I would say that you have allowed the Workgroups to face really tough questions, and you've also stepped up to the plate when you've had to step up to the plate." – Ms. Gelinas

"I would not, in the process, want to lose the fact that health IT, and the charge that we have, is for the public good. And the public good cannot be underestimated, and at the end of the day, what we're doing is in the pursuit of quality and reduction of cost, this is not health IT for health IT. It's for the greater good of increasing quality in the United States and lowering the cost burden at the same time. So I just want to make sure the contractors hear that and it doesn't get lost." – Ms. Gelinas

Electronic Health Records Workgroup Recommendations

Lillee Gelinas, Community member and Electronic Health Records (EHR) Workgroup Co-Chair, emphasized that the leadership of the EHR Workgroup did not want initiative overload to get in the way of focus. She acknowledged the tremendous efforts of the Workgroup in developing a short list of recommendations for presentation to the Community. She reminded AHIC that the Workgroup's broad and specific charges are as follows:

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

- **Specific Charge:** Make recommendations to the Community so that within one year, standardized, widely available and secure solutions for accessing current and historical laboratory results and interpretations is deployed for clinical care by authorized parties.

Ms. Gelinas explained that the EHR Workgroup has been focusing on issues related to EHR adoption and physician practices. The Workgroup will be moving on to tackle EHR adoption in the hospital setting, starting with its next meeting. She reminded Community members that at the May 2006 AHIC meeting, the Workgroup submitted seven recommendations that are in place and have been acted upon.

In generating the current set of recommendations, the EHR Workgroup considered the following five key areas of focus: (1) business case alignment, (2) workflow and cultural concerns, (3) medical-legal issues, (4) privacy and security, and (5) state of the technology. Each of the recommendations presented by Ms. Gelinas falls under one of the first three key areas of focus that are believed to be critical to advancing the adoption of EHRs. The other two key areas will continue to be considered, but generally fall under the purview of AHIC's Confidentiality, Privacy, and Security Workgroup.

Before presenting the recommendations, Ms. Gelinas noted that in terms of business case alignment, recent studies suggest that the EHR adoption rate is still very low, at about 10 percent, due in part to the misaligned business case for physician adoption. EHR systems are costly, but the return on investment is primarily to the entity that holds financial risk for the cost of care. There is, Ms. Gelinas commented, a misalignment of incentives. The Executive Order promoting quality and efficient health care and federal government-administered or sponsored health care programs, which was released in August of 2006, directed the federal government, in its contracts with commercial health plans and insurers, to include language that promoted the adoption of HITSP interoperability specifications. This provides an opportunity for the federal government to guide commercial health plans towards programs that are likely

to accomplish this goal. In the ambulatory care sector, adoption of HITSP standards is most effectively accomplished by the adoption of certified EHRs.
Pay-for-performance plans can be strong motivators for physician behavior; this has been a key topic of EHR Workgroup testimony. Most pay-for-performance programs are based on process and outcomes measures, which favor those who already have adopted EHRs. Ms. Gelinas noted that it takes roughly three years to demonstrate improvements in clinical outcomes after EHR implementation. Structural measures have been defined by the Medicare Payment Advisory Commission and include, for example, patient registry systems to monitor and track patients, evidence-based clinical decision support at the point of care, and medication safety checks.

The EHR Workgroup heard testimony from both Bridges to Excellence and the Pacific Business Group on Health in conjunction with the Integrated Healthcare Association, which have offered programs that pay for structure, as well as process and outcomes, in a way that is weighted towards moving practices along the path of adoption, and the path of better outcomes. The Workgroup learned that physicians who implement certified EHRs, and those whose care is supported by these types of structures, can be rewarded, at least in part, on these measures, until their systems have matured to the point of improved outcomes.

Following these comments, Ms. Gelinas presented the following recommendations from the EHR Workgroup:

Business Case Alignment

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

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

Recommendations 1.0 and 1.1 Discussion Highlights

"We have the National Quality Forum, which is the entity that endorses measures, endorses safety practices, and ought to be endorsing here, and it plays that role in government policy, and it really should be here rather than MedPAC. MedPAC is not the right entity here. It doesn't play this kind of role. It does make policy recommendations. It does advise Congress on an ongoing basis regarding payment policy for Medicare, but this is the wrong track. And what we are all seeking, I think all the stakeholders, generally, is to try to have NQF play this role as the ultimate filter." – Mr. Kahn

"When we…make recommendations about pay for performance, we need to be awfully careful about what the 'it' is and what we're talking about. One person's pay for performance is not another person's pay for performance…I can't be against pay for performance…but I think we have to be very careful to say that we want to provide some incentive. But I would almost step back and say, 'why do we even need

to get into the current term of art, and just simply say, financial incentives of some type ought to be included?'" – Mr. Kahn

"This is finally putting, in general, a financial incentive on the table to move the adoption of electronic health record technology in a meaningful way, a positive financial incentive, and so I applaud the Workgroup in moving this direction. I share some of Chip's concerns about semantics, and the groups that we referred to such as MedPAC. MedPAC is not the right entity as compared to NCQA, and some of the others that Chip referred to." – Dr. Henley

"So with those qualifications, I think both of these recommendations are on target, but let's modify them so that we get it right in terms of the entities involved. I view this as pay for use rather than pay for performance. I mean that's another term that one might use, or just simply 'let's build in positive incentives for the adoption of certified EHRs,' and leave it at that. But the goal is the same." – Dr. Henley

"We think this is a great starting point…There are things that we're doing, and we don't want to shut down where there may be some real innovative ideas. And for example, one thing I know Doug is involved that we're doing is the advanced medical home. And how can we do things in that area and continue to incent? So we just want to make sure that we don't limit it, that we allow incentives that are appropriate." – Ms. Handelman

"I'm not hearing opposition to incorporation of EHR in a pay for performance. It is that it should be written more broadly." – Dr. Brailer

"The one thing that we think is important in the short term, certainly we agree [on] pay per use, and it's something our plans are doing; but it needs to be tied to…paying for outcomes. That's very important." – Ms. Handelman

"[Recommendation 1.0] is aimed at the federal government that contracts with health plans and carriers to promote this, and being a representative of one of those government entities, I have a practical concern about how to implement...Currently, we're operating under an Executive Order that has us implementing HIT standards through, among other things, the contract mechanism. And there is a section in that contract, in that Executive Order that says that 'your efforts shall not increase costs.' Well, just on the face of it, pay for performance is a method of transferring cost from the contract payer to the provider." – Mr. Green

"There are many plans already doing pay for performance. Not that many are using structural measures. So if monies are already going into pay for performance programs, our hope is that there would be an opportunity, for at least a limited period of time, to use structural measures. And the reason that we outlined MedPAC's structural measures is because they are based, essentially, on the ones that were developed by NCQA." – Dr. Bell

"Just to be clear here, you're not calling for the adoption of pay-for-performance measures, per se. You're calling for if they're going to be used, that they include some kind of an incentive or a bonus within that, for the use of an EHR to improve quality." – Dr. Brailer

"The [term] 'budget neutrality' is not here. When Lillee described it, she said it takes three years. We know that the capital investment, the workflow issues, the development, and the effect on care of records is not an immediate thing. So for us to say we're going to budget neutrally, take from some people and give to other physicians, is, I think, problematic. And part of the semantics of talking about financial

incentives, in my mind, is not necessarily saying that this body is qualified to say it ought to be done in a budget neutral fashion." – Mr. Kahn

"Here we know it will have a positive effect, we're confident of that, but it's not a standard of care, at this point. It may become one eventually. And I think to imply that somebody should be penalized, and somebody else rewarded, I think is a problem. As soon as you say 'budget neutrality,' you're dealing with penalties. And I think this body is not the right one to adjudicate that, for one. And two, I just find it troublesome." – Mr. Kahn

"It all boiled down to the testimony that we heard from those payers that had remarkable, higher, better clinical quality and lower cost, and the use of health IT was the railroad track that got them there. It was very powerful. And it was very compelling. And really was part of what informed the recommendation as it is." – Ms. Gelinas

"I'm all for even the requirement over time. But at least in the short run, to talk about budget neutrality implies that you're going to penalize someone. It's great to say 'we're going to have an incentive program,' but when you say 'budget neutrality,' you immediately say 'we're going to penalize some and reward others.'" – Mr. Kahn

"We're not discussing whether or not money gets put out of some form of reimbursement, whether it's bonus dollars or some other dollars into pay for performance. We're assuming that there is money in a pay-for-performance pool…And the question is, is that money allocated purely on the basis of their outcome measures, or in many programs, simply the reporting of outcome data; or is some of that earmarked such that the money that is either allocated to outcomes or to data, reporting is given preferentially to people who do it with electronic health records. So we're not talking about a penalty, we might be talking about a smaller incentive, if you do it manually." – Dr. Brailer

"What we're trying to achieve here is that structural measures should become part of those programs so that physicians and other providers, to the extent they implement certified EHRs, can have access to that pool of money. Not the basic fee schedule pool, that stays the way it's always been. But the incentive, the positive incentive for pay for performance becomes pay for use, in addition to pay for performance. And you can still stay in the paper world, if you want to, and report process or outcomes measures, and you might get some financial incentive for that as well. Or you can do an EHR, plus the other, with your EHR, and get more access to that money." – Dr. Henley

"If you look at this on a purely economic basis, it recognizes that, in fact, as ironic as this sounds, it's actually more expensive to do these things in the short term, with electronic health records, because the systems aren't set up…So this is, in a sense, trying to keep a level incentive for those who are using the tools, so that there is not a disincentive for the electronic health record to be put in place…Budget neutrality can be defined not necessarily in the same budget year. It could be a 5-year budget neutrality." – Dr. Brailer

"Experience with the government is that budget neutrality means that generally there is less spent, overall" – Mr. Kahn

"I really do like the idea of pay for adoption or pay for use, because I think it's broader, and I think the broader we can be to envelop or at least to enable us to look at a broader array of possibilities would be good; because the common ground here is that I think we all have agreed, and many, many others outside this room have agreed, that the technology is not the end game, it's the enabler. It's what's going to help us to improve quality, safety, effectiveness, efficiency, all of those things in the health care field." – Mr. Lampkin

"We're going to have to look for new, very innovative ways to think about paying for adoption, and so I think as large employers, as the government, we should be looking at everything—not just electronic health records, but electronic consultations, electronic messaging, phone calls to the office that perhaps will save the patient and the system a whole lot of money over time. Electronic clinical decision support. All those things that work together to drive quality, and safety, and effectiveness, and efficiency." – Mr. Lampkin

"I would like to see the language broadened to get away from contracts…For what we're talking about now, at least in my program, the contract is not necessarily the correct vehicle to accomplish this. And so I would recommend additional language that gets at promoting adoption, and incentives and such things, but not necessarily restricted to a contracting vehicle." – Mr. Green

"Based on our discussion, I think I hear three things. First, there is significant enough concerns with the scope and wording of this that it requires some more work. Secondly, there is a general thrust of support for what this is intended to be; and therefore, the Workgroup should recognize that we are going to send this back to them for that kind of a tune-up and expansion. And thirdly, that the AHIC stands ready to approve this when it comes back, if it's in that form." – Dr. Brailer

Following these discussions, Community members agreed that Recommendations 1.0 and 1.1 will be brought back at a future Community meeting after being revised. [Tabled]

Workflow and Cultural Concerns

- ***Recommendation 2.0:*** HHS should provide continued support to DOQ-IT U for new module development, upgrades, maintenance, and CME credit management beyond the 8th SOW funded by CMS. The program should be supported by a learning management system that is user friendly, has search functionality, and provides links to other key sites.

Recommendation 2.0 Discussion Highlights

"Do we have data from the user community, those 5,000 practices or whatever, that, in fact, this tool has been useful? I know at some point in time, there was supposed to be an evaluation of the program. I'm not aware that the evaluation, from the user perspective, has occurred. And so if that evaluation from the user perspective was glowing about this program, and the need for constant upgrades, wonderful. Let's make that happen. But if the user community said this wasn't worth [it], then why are we continuing to put money into it?" – Dr. Henley

"We needed to give especially small physician practices tools that were free, and that worked. And certainly the testimony we heard was that they worked. Our concern with just bringing this to you and saying, 'we need to continue with DOQ-IT,' is that its funding ends with the eighth scope of work. And therefore, if we're going to move with a tool that will enable physician practice adoption, there are two things that have to happen: the funding, and then the upgrading in order to meet current needs." – Ms. Gelinas

"I want to make sure that we're separating the DOQ-IT U, which is the educational module, from DOQ-IT as the program. I think this specifically is talking about this educational tool for helping doctors to understand how to choose electronic health records, not the entire DOQ-IT program." – Dr. Kolodner

"This particular tool has been used by folks outside of the DOQ-IT program itself. So they've not actually worked within DOQ-IT, but they've used the tool and have found it very, very helpful. In fact,

there is even a university that has used it as a teaching module in its programs, and has been very successful in that arena as well. It certainly is just fairly new. It's just taking off now. But those who have used it have given very, very positive feedback." – Dr. Bell
"The original funding for the development of the DOQ-IT University was about $3 million. Ongoing funding would be certainly much, much less than that." – Dr. Bell

"I would just suggest…[having an] ongoing evaluation of the program. I think it's clear, whether it's been evaluated or not, people need to know the successes and the failures, and so let's just make sure that we note that. I hear no objection to this, so I would say by acclamation, let's accept this." – Dr. Brailer

Following these discussions, Community members agreed to accept Recommendation 2.0.

Medical-Legal Issues

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

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

Recommendations 3.0 and 3.1 Discussion Highlights

"I know that one of the key issues with defensibility in these cases is about attribution, which is the ability to have a positive identification of who did what at what time, which is potentially quite disruptive to physician workload, to have to potentially sign on every time a certain prescription is given or add a new password. You're calling for the CCHIT to make those kinds of tradeoffs about its workflow requirements for doctors versus these kind of protections. Is that fair?" – Dr. Brailer

"That was my understanding, but we really didn't go into this particular aspect about attribution, single sign on, that kind of thing in depth." – Ms. Gelinas

"I would just add that that is one of the reasons that we would like to encourage the Certification Commission, itself, to work with the medical-legal lawyers to determine what's the best way to move that forward." – Dr. Bell

Following these discussions, Community members agreed to accept Recommendations 3.0 and 3.1.

Overarching Recommendation

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

Recommendation 4.0 Discussion Highlights

"This needs to been rewritten even in its current form, because the 'market basket' is a hospital-side term, and all this is done under the sustainable growth rate…regardless of other providers that Medicare may pay, this is a very dangerous area to tread on, because we have an SGR that is broken, and we have a

physician payment system that's broken; and even though Congress did…pass some differential update in the middle of the year, based on reporting, which is problematic on its face; I think it's very difficult to get into this area of Medicare on physician payment." – Mr. Kahn
"As a theme, one of the things that this group needs to recognize is that the big loser in better care, more efficiently provided, with better outcomes, is the revenue of doctors, hospitals, and other health care providers. Now, they ought to make less revenue, if we can get better care. But the point is that all these things that make things more efficient, one, frequently cost capital, capitalization and ongoing operating expense; and two, you're taking money out of the people who are ultimately going to lose because of what you're doing." – Mr. Kahn

"I think this group ought to recognize that the return on investment on IT for providers isn't there. And if it's a good thing, if it's for the public good, we ought to be providing an incentive for it, but in terms of return on investment, it's not there." – Mr. Kahn

"I, too, believe that Recommendation 4 is not ready for prime time and goes too far. [Recommendations] 1.0 and 1.1 is where we should have started and stopped in terms of, again, providing a positive financial incentive for the adoption of electronic health records, whatever the final semantics are that we reach at our next meeting." – Dr. Henley

"Adopting [Recommendation 4.0] enters into the Medicare fee schedule and creating a negative disincentive, if you don't adopt an EHR. And I just think that sends entirely the wrong message in terms of trying to raise all boats. And that's what quality improvement should be about. And this would create a negative incentive for that." – Dr. Henley

"This is as important a technology to improve medical care as a CT scan is, as an MRI scan is, as the next ultrasound scan is. And when we create CPT codes for those, we include what the cost of that business is…The current resource-based relative value system does not include the cost of this medical technology, called an EHR, in the practice expense equation…We would have to go back and totally reevaluate all those codes, as this being a new technology. I don't think CMS or anybody else wants to do that. So I think we should stick with [Recommendations] 1.0 and 1.1 as a positive incentive, as part of structural measures for pay per view, et cetera, and not adopt this recommendation." – Dr. Henley

"You guys are talking about the system. You're not talking about the consumer. You're not talking about benefit to the end user of the system. You're talking about benefit to the system. I don't think we're about benefit to the system. We make investments, because we have to make investments to satisfy our consumers, our customers. And I'd really like to have the conversation always about return on investment for the consumer, return on investment for the customer." – Dr. Barrett

"We sit here and debate, and debate, and debate about EHRs, and how do we get these put in place. And every time we come up with a motivation to do that, we come back to 'the system doesn't like it.' I just find objection to that. The customer likes it…There is a fundamental difference of opinion, I think, on what we're trying to accomplish." – Dr. Barrett

"I think in reality, tons of providers are going to adopt EHRs, some of which will implement them, and change their business practice in a way that will improve outcomes; and some, unfortunately won't at the outset, and maybe ever, be able to implement them in a way that improves outcomes. The question is are we going to be subsidizing the adoption of these, knowing that many of those may not go well? So you may want to add on to it one demonstration of an implementation that resulted in a positive outcome." – Mr. Wells

"Did the Workgroup have that same diversity of views, and what was the nature of the dialogue that brought to this reconciliation, and what you put before us?" – Dr. Brailer

"We never would have brought this to you if there wasn't Workgroup consensus. Was there dissent? You bet. Was there concern? Absolutely. Did the conversation need to be held? Yes. And I want to emphasize…that the conversation was around, at the end of the day, quality and cost. Not about the health IT system, as it was. And I just want to make sure we represent that." – Ms. Gelinas

"We recognized this would be controversial. And one of the reasons it is listed as an overarching recommendation is that we really did believe the conversation here was critical, and that's why the Workgroup chose to bring it here." – Dr. Bell

"Was there [Workgroup] discussion on how you would define the term of 'use' or 'nonuse' of an EHR? Because I know that there was a report brought to the AHIC that HHS had done, sometime last year, on adoption rates on EHR…while the adoption rate might have been around 20 or 25 percent, when you actually looked at those that were using the full capability, and not turning off clinical decision support in some of those important features, e-prescribing, that we see real benefit, we were probably down to about 9 percent. So they were really only putting their records in an electronic form, not using the features." – Ms. Handelman

"The conversations around the adoption was only 10 percent. At the end of the day, you couldn't use all of the adoption data. We're talking fully implemented and used is only 10 percent…So I think that's good counsel, and we should go back and define 'use' and 'nonuse,' especially as we get into hospital EHRs, because that aspect can be all over the board." – Ms. Gelinas

"I would suggest that the Workgroup take this back, after hearing this discussion, and focus on three efforts. First, to clarify some of the nonsemantic issues within this…we're really mixing metaphors between end patient and ambulatory care….Secondly, I think we do seek input on what minds can tell us we have authority to do within the department, and what boundaries that would be put on this, and the degree of feasibility that comes from that. And thirdly, I would suggest…that the Workgroup have some form of substantial public input through a town hall or through an open hearing…to make sure that when you come back to us again, not only do we have a more precisely written recommendation, but you can represent, I think, the broader debate and be able to tell us either that you could reconcile it or you couldn't." – Dr. Brailer

"This may be a wonderful type of test case to put before those possible structures [related to AHIC's successor], because I think these are the sort of issues that you're going to come up with, and these are the issues of what are you trying to accomplish? Are you trying to promote higher quality, lower cost health care to the end user, or are you trying to protect the system? Because the extreme arguments are kind of useful sometimes to couch the discussion, and so the three contractors that you have may want to look at this type of a situation to see exactly how you could structure something which would give you the full bodied and healthy debate that we're having on this topic." – Dr. Barrett

"I think another angle that we probably ought to have the Workgroup think through, in the spirit of Consumer Empowerment, how do we not only incent appropriately providers for adoption, but how do we incent the consumer? How do we incent the patient?" – Mr. Lampkin

Following these discussions, Community members agreed that Recommendation 4.0 would be brought back at a future Community meeting after being revised. [Tabled]

Public Input Session

Speaker Number 1 – Mr. Stephen Keeler of CapMED PHR thanked the Community for its efforts, noting that the impetus that the Community has provided, in terms of raising awareness of how technology can save companies money and improve individuals' lives is of tremendous value. He noted that one company that has 80 percent of its assets involved in truck drivers delivering propane gas is adopting methodologies to determine how many drivers are diabetics, capture their blood glucose levels remotely, and send them alerts. Mr. Keeler noted that the issue of sustainability reaches across several fronts, from what to do about the AHIC successor to EHRs and physician adoption. He noted that there is another model for sustainability that has not yet been discussed by the Community—the subscription model. Developing residual streams of revenue could be used to pay for physician adoption.

Speaker Number 2 – Dr. Ross Martin, Director of Health Care Information Convergence at Bearing Point, noted that with regard to the conversation focused on the National Governors Association and the state initiatives, there is an ANSI-accredited standards organization known as MedBiquitous. MedBiquitous deals with medical education standards, as well as physician credentials, demonstrations of competence, and the exchange of state license information. Its members include entities such as the Federation for State Medical Boards, and the National Board of Medical Examiners; and it has been working on pilots for exchanging that type of information already. He encouraged AHIC to include these efforts in their consideration. Dr. Martin also asked about the AHIC successor in terms of the global conversation about standards development. He commented that the future role of AHIC, and its successor, should include stronger global representation and/or feedback, so that these efforts can be coordinated on a global scale.

Speaker Number 3 – Kathryn Serkes, representing the American Association of Physicians and Surgeons (AAPS), expressed support for more public input, noting that she has found attending AHIC Workgroup sessions to be extremely valuable. Ms. Serkes also commented that instead of viewing consent and privacy laws as barriers to the NHIN, the NHIN could be considered a barrier to privacy and consent. Ms. Serkes added that the issue of embedding clinical decision support tools into HIT, which was discussed during the presentation by the Personalized Healthcare Workgroup, always raises red flags and causes concern for physicians. She asked that AHIC keep this in mind when discussing the issue further.

Ms. Serkes also spoke on behalf of the Patient Privacy Coalition, a nonpartisan coalition of more than 40 organizations that has issued its patient privacy rights/principles for 2007. Highlights include points such as: patients have the right to opt in and opt out of electronic services, health information disclosed for one purpose may not be used for another purpose without informed consent, and audit trails should be included in the design of any system so that any information could be tracked. Patients should be notified of any breaches, and strong measures for meaningful enforcement mechanisms for violations are needed. In addition, Ms. Serkes explained, full disclosure should be given by any states developing patient identifiers

Closing Remarks

Dr. Brailer thanked Community members and speakers for their efforts and adjourned the 13th AHIC meeting.

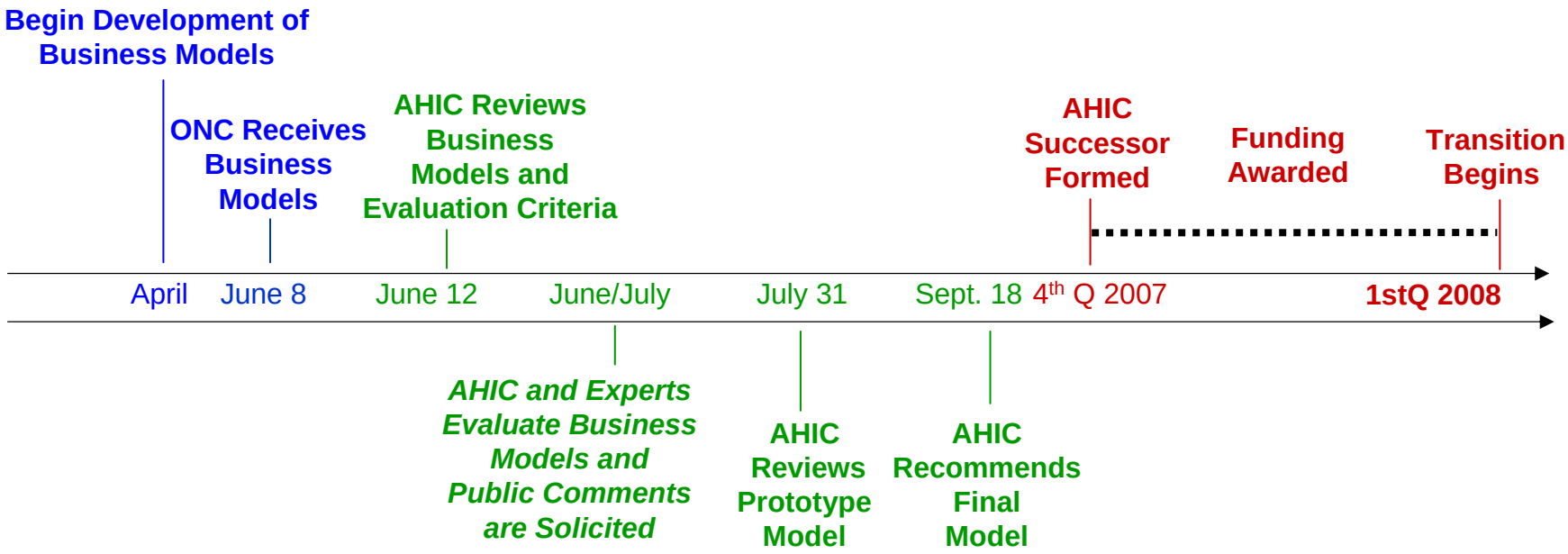
American Health Information Community

Planning for Long Term Succession and Sustainability

Robert M. Kolodner, MD

June 12, 2007

Work Process for Developing the AHIC Successor



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

Draft Principles for Successful Governance

- The entity should exist for the purpose of individual/consumer benefit.
- The entity should establish and enhance trust among stakeholders.
- The entity should have broad participation across the health care industry stakeholders.
- The governing bodies of the entity should have necessary authority to make decisions, but only the authority that is necessary to do this.
- The entity should be feasible to establish and operate, and sustainable into the future.
- The entity should be adaptable over time and across future circumstances.

Draft Evaluation Criteria for Proposed Approaches

- Individual/Consumer Benefit:
  - Is the purpose of the proposed entity to advance the health and well-being of all residents of the United States?
  - Are there provisions in the governing documents, structure and operations of the proposed entity that ensure the privacy of consumer and provider data?
- Trust:
  - Will the proposed entity be operated to ensure that decisions can be made in an informed, fair and equitable manner?
  - Are the rights and obligations of members common across industry sectors and equitable between industry sectors?
  - Do decisions made by the proposed entity have mechanisms to ensure that they incorporate the views of all sectors of the health industry, and cannot be dominated or controlled by any?

Draft Evaluation Criteria for Proposed Approaches

- Broad Participation:
  - Does the proposed entity allow membership by individuals and organizations from all sectors of the health community?
  - Is participation voluntary, with simplicity of entry and ease of exit that result in minimal impact on the ongoing activities of members?
  - Can existing federal, state and private sector health information technology initiatives participate as a smoothly functioning whole in the proposed entity with minimal disruption and in a way that enhances their capacity and progress?
  - Does the proposed entity have a clearly delineated power to set fees, if any, with sufficient restrictions on that power to prevent inequity or abuse?

Draft Evaluation Criteria for Proposed Approaches

- Necessary Authority:
  - Does the proposed entity have a clear delineation between rights and responsibilities of members and those of any of its governing bodies, and whether governing bodies are elected by, and fairly represent, members of the entity?
  - Do governing bodies of the proposed entity have sufficient authority to create necessary rules and procedures to guide their own operations and functions, determine conformity with them and enforce compliance when necessary, with sufficient restraints on that authority to prevent abuse?
  - Are the decisions, actions and regulations of the proposed entity limited to that which is essential for the successful collaborative development and operation of the entity, and are all other decisions, actions and regulations reserved to the independent action of its members?

Draft Evaluation Criteria for Proposed Approaches

- Feasibility:
  - Is the proposed entity consistent with applicable laws and regulations, and is it governed in a manner which ensures that its decisions and actions will not place members in violation of laws and regulations to which they are subject?
  - Is there is a clear, practical plan to bring the proposed entity into being and commence initial operations by December 2007?
  - Is there a clear, practical plan of action for the first three years of operation ending December 2010, and for financial sustainability after that?
  - Does the proposed entity have a practical plan for attracting a sufficient mass of members at inception from key industry sectors?
  - Can the proposed entity attract and adequately reward outstanding leadership and staff?

Draft Evaluation Criteria for Proposed Approaches

- Adaptability:
  - Is the proposed entity durable with respect to purpose and principles over time, yet malleable in form and function, allowing it to evolve in response to changes in technology, communications and the environment in which it must operate without harming its objectives?
  - Can the proposed entity ensure that all members can self-organize at any time, at any scale, for any reason consistent with its charter, purpose and principles, and that the resulting organization can have a right of membership without depriving its constituency of theirs?
  - Can the proposed entity ensure continual delineation between decisions, actions and rules necessary for the degree of collaboration and cooperation required to function effectively, and those necessary to preserve freedom of action and competition between members? Are the powers necessary for the effective functioning of the entity vested in the successor organization and all others vested in the members?

Determining the Business Model

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

AHIC's Role in Planning the Successor

- Initial discussion of three approaches on June 12
- Staff and expert review of approaches and development of draft prototype by June 29
- Public comment on working draft prototype July 2-20
- Prototype presentation to AHIC on July 31:
  - A governance structure and business model
  - The role of government
  - A transition plan
  - A path to sustainability
- Refinement of prototype in August - September
- Final recommendations from AHIC to the Secretary on September 18

Business Model for a Successor to the American Health Information Community

Report to the AHIC

June 12, 2007
Washington, DC

Booz | Allen | Hamilton

Agenda

- Mission and Goals
- Governance Structure
- Business Model
- Transition Plan

Mission and goals

- Achieve widespread adoption of interoperable health information technology by providing a forum where member organizations, a full-time staff, and the public sector work collaboratively, effectively, and efficiently
  - Govern a nationwide strategy and roadmap that establishes the specific priorities for the short, mid, and long term
  - Provide a clearinghouse for product certifications, interoperability specifications, and best practices
  - Coordinate among dispersed health information initiatives to maximize reuse of successful approaches

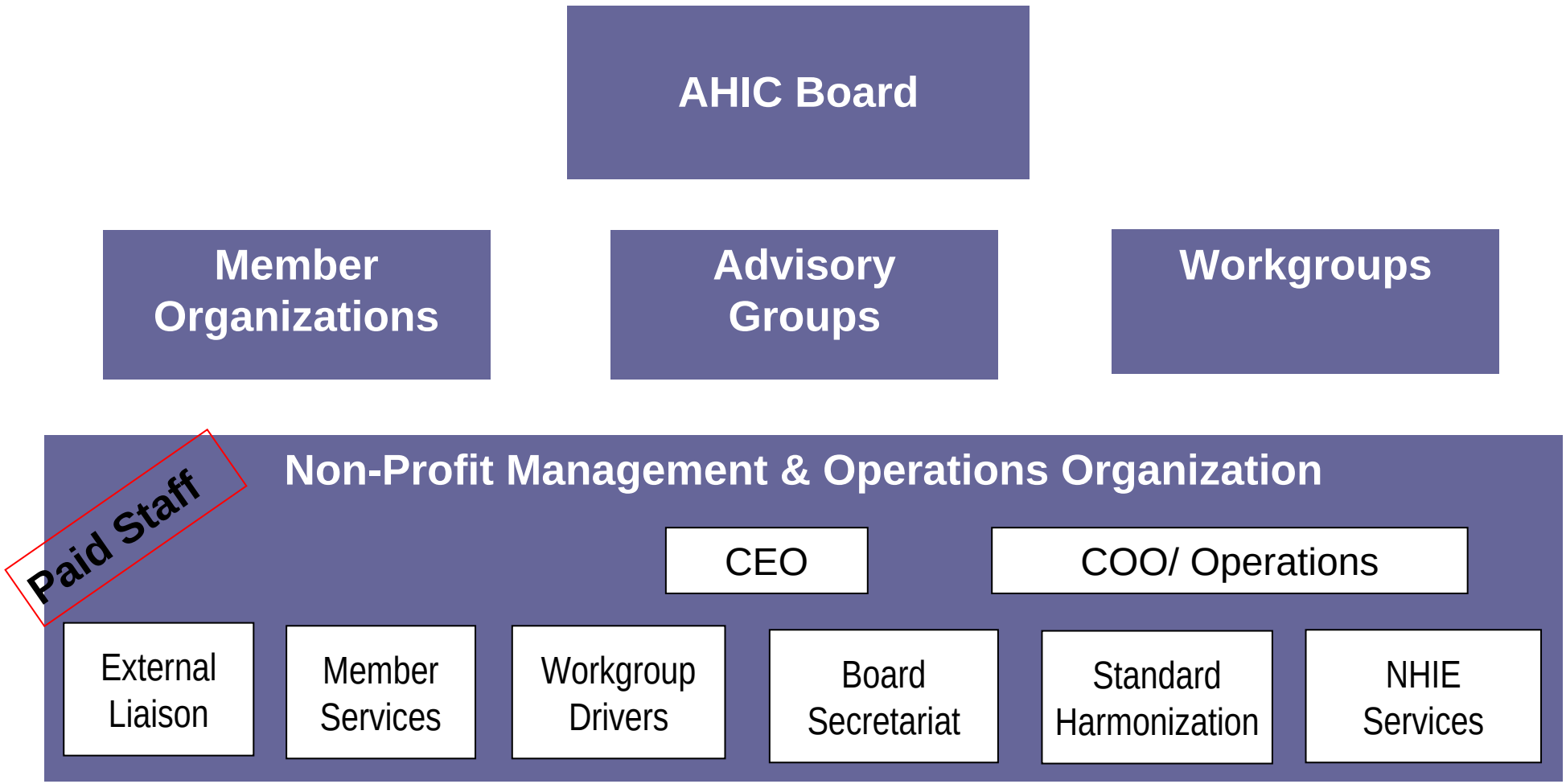
AHIC Governance Principles

- Provide strong, committed, and stable nationwide leadership that is responsive to unbiased input from all sectors and types of stakeholders
- Remain open to all relevant and affected parties
- Make balanced, equitable decisions now and in the future on unlimited but often unknown issues
- Ensure an equitable balance among all sectors so that no one sector, participant or combination of interests can dominate or control discussions, deliberations or decisions
- Maintain clarity of scope, clear processes for actions and decisions, and clear metrics and performance measures to assess progress and success

Governance Requirements

Success Factors	Governance Design Requirements
Trust	1. Engage larger and diverse stakeholder population
Shared Vision	2. Balance decision making based on overlapping vital interests 3. Coordinate among related initiatives in industry 4. Coordinate among related initiatives in government
Flexibility & Adaptability	5. Adapt to market needs over time
Results	6. Drive tangible recommendations and results
Independent	7. Be financially self-sustaining
Leadership & Commitment	8. Have an element of permanence and stability in leadership

Governance Structure – *volunteer-based entity with a non-profit management organization*



Member Organizations

Key Features	• Description
Membership Model	▸ Dues based, open membership; a community of organizations, not individuals, with unique and independent interests and an overlapping interest in health information exchange ▸ Government membership subject to the same bylaws as private industry membership
Member Categories	▸ Members self-select a stakeholder identity used in determining balance of representation when selecting AHIC Board membership

AHIC Board

Key Features

• Description

Membership & Election Processes

- Balances the need to follow best practices (< 20 members) with the need for wide representation
- Members elected via formal and transparent process that ensures a balanced set of voting members
- Chair and Vice-Chair roles are filled by private sector representatives and are selected by Board Membership from among Board Members

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Decision-Making Model

- Board will strive for consensus in decision-making. When consensus cannot be reached, root causes of disagreements further analyzed by a subgroup
- If consensus still cannot be reached, decision will be based on a majority vote with dissenting views noted

Advisory Groups

Key Features

• Description

Creation & Membership

- Requested by the Board and formed by the Management Organization to further support board decision-making
- Primarily “audience based” groups that advise board members from a particular stakeholder perspective (e.g., Nursing Industry Advisory Group, Consumers)

Decision-Making Model

- Advisory groups provide counsel, but do not directly make decisions
- Groups will strive for consensus in input in order to encourage buy-in from all stakeholders
- Root causes of disagreements will be noted for Board consideration

Workgroups

Key Features	• Description
Creation Process	▸ Dynamic and serve as a key mechanism to adapt to market needs ▸ Launched at the request of the Board to conduct research and analysis on specific issues, and recommend a set course of action to the Board ▸ Co-led by public and private sector leaders
Operating Model	▸ Focus on “specific charges” for a pre-determined period of time, disbanding at the end ▸ Scope of work changed only with Board approval ▸ See recommendations through to implementation to the extent practical ▸ Mix of volunteer and paid staffing depending on topic and duration of effort

Management Organization

Key Features

• Description

- **External Liaison:** Coordinate with full range of related efforts in the federal, state and private sectors
- **Member Services:** Proactively elicit new members through targeted outreach and communication and administers current membership relationships
- **Workgroup Drivers:** Provide full-time leadership, project management, and facilitation capabilities to workgroups; provides subject matter expertise and other staff as appropriate
- **Board Secretariat:** Support AHIC Board activity
- **Standards Harmonization:** Drive harmonization of standards aligned with the AHIC road map for interoperability

Management Organization (continued)

Key Features	• Description
Service Units	▸ **NHIE Products and Services:** Revenue earning products and services that support implementation of nationwide health information exchange
Manage-ment	▸ Led by an AHIC CEO that also sits on the AHIC Board ▸ AHIC COO oversees majority of day-to-day activities ▸ A senior-level management staff will lead all revenue and funding generating activities ▸ A senior-level management staff will lead the workgroup process

Business Model – *Revenue can ultimately cover costs*

Cost Elements	Annual Cost
CEO, COO	$600,000
Secretariat	$400,000
Workgroup Support	$1,200,000
Liaison	$200,000
Member Services	$200,000
Standard Harmonization	$4,000,000
Operations	$1,000,000
Non-head count costs	$1,000,000
NHIE Services	TBD
Board Members	$80,000
Advisory Committee	$80,000
Workgroup Paid Members	$1,200,000

Total Estimated Cost : $10 mm

Revenue Sources	Revenue
Memberships	$4,000,000 - $6,000,000
Conferences	$1,000,000 - $4,000,000
Training	$90,000 - $300,000
Publications	$30,000 - $100,000
NHIE Services/ Product Certification	TBD

Total Estimated Revenue: $5 - $10 mm

AHIC Short-term Potential Revenue – *focus is member organizations*

Revenue Source	Potential Revenue	• Assumptions
Membership	$4,000,000 - $6,000,000	• 300-500 members • $1,000 to $25,000 each
Conferences	$1,000,000 - $4,000,000	• Partnering, holding a smaller summit, or a new conference
Training	$90,000 - $300,000	• 300 to 500 members • 1 to 2 per year at $300 each
Publications	$30,000 - $100,000	• 300-500 members • 1 to 2 per year at $100

AHIC Longer-term Revenue Sources - *focus is NHIN participants*

Definition of the NHIN

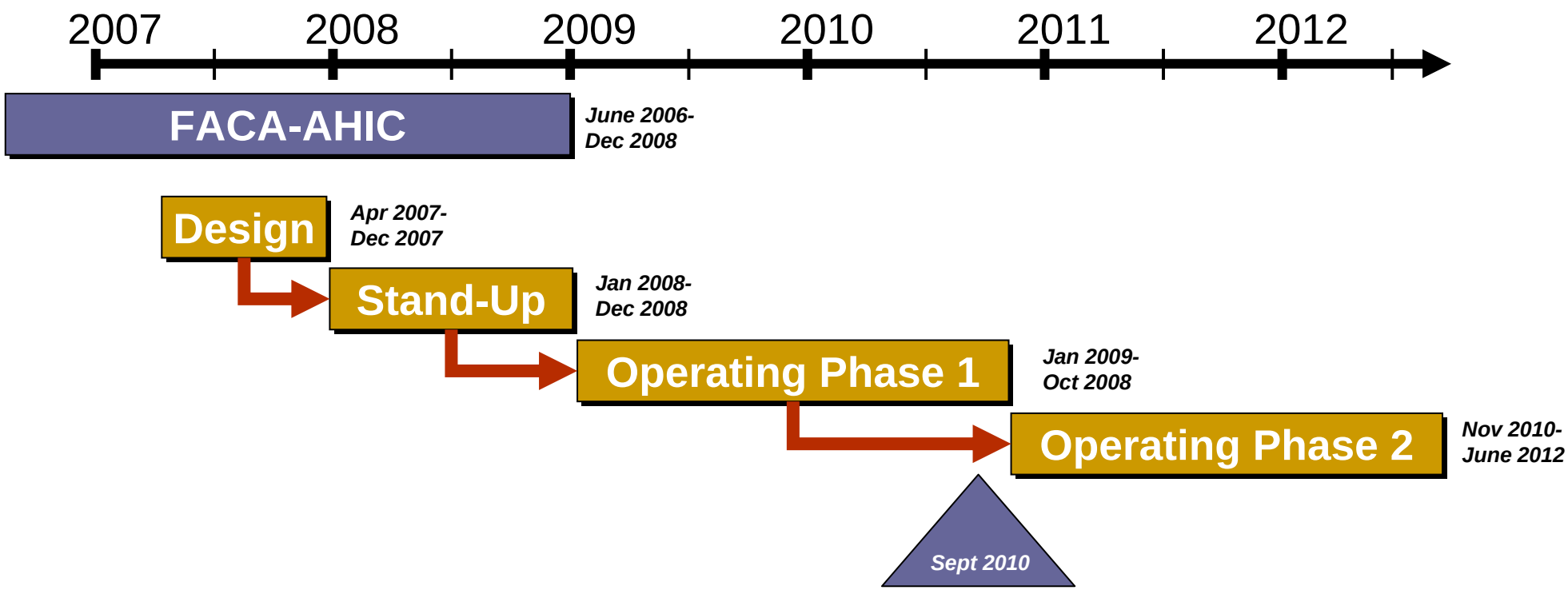
- The National Health Information Network (NHIN) is a network-of-networks that is powered by the Internet
  - Locality-based health information exchanges (HIE) (e.g., Regions, States, Territories)
  - Domain- based HIE (e.g., Cancer Research Exchange)
- Based on shared community-defined norms and rules that prescribe what behavior may, must, or may not be performed by members

Nationwide HIE Services

- Practice Consultations
- NHIN HIE Community Certification
- Utility Computing
- De-identified Health Information
- Health Information Translation
- Health Information Indexing
- Registries
- Product Certification

Transition Plan - *Staged to mitigate risk to current momentum*

Proposed Transition Approach



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Transition Activities
Design

Timing	April-Dec ‘07
Governance Model	▸ Current AHIC
Transition Activities	▸ Prototype ▸ Develop detailed designs based on prototype ▸ Develop detailed transition plans ▸ Establish performance measures

Transition Activities
Standup

Timing

Jan-Dec ‘08

Governance Model

- Current AHIC with transition to interim Board

Transition Activities

- Staff key leadership positions
- Build out infrastructure & processes
- Assemble & transition to interim board
- Begin building membership

Transition Activities
Operate-Assess-Operate

Timing

Jan ’09 – Dec ‘10

Governance Model

- Primarily government funded, but private sector led AHIC

Transition Activities

- Hold board elections
- Assemble advisory groups
- Transition workgroup oversight
- Expand membership
- Develop suite of member services
- Develop initial NHIE products & services
- Measure performance

Transition Activities
Operate-Assess-Operate

Timing	Jan ’11-Dec ’12
Governance Model	▸ Self-funding, private sector led AHIC
Transition Activities	▸ Expand portfolio of NHIE products & services

Clarifying Questions?

American Health Information Community Successor – Partnership for Health and Care Improvement

AHIC Meeting Prepared for the Office of the National Coordinator

June 12, 2007

Shannah Koss, Sheera Rosenfeld, Greg Fuller, Madeleine Konig, and Sharon Siler

Vision for the Partnership for Health and Care Improvement (PHCI): The AHIC Successor

An interconnected United States health system that enables real-time, secure, authorized access to health information by each relevant stakeholder, when and where it is needed.

PHCI's Core Mission Is to Prioritize, Enable, and Synchronize HIT Needs and Activities in the US

Consistent with the combined needs of health industry stakeholders, PHCI will:

Prioritize

- Prioritize the expanded information needs of the health system
  - » Determine health system goals to improve information capabilities that require industry-wide collaboration
    - – *Quality*
    - – *Consumer empowerment*
    - – *Population health*

Enable

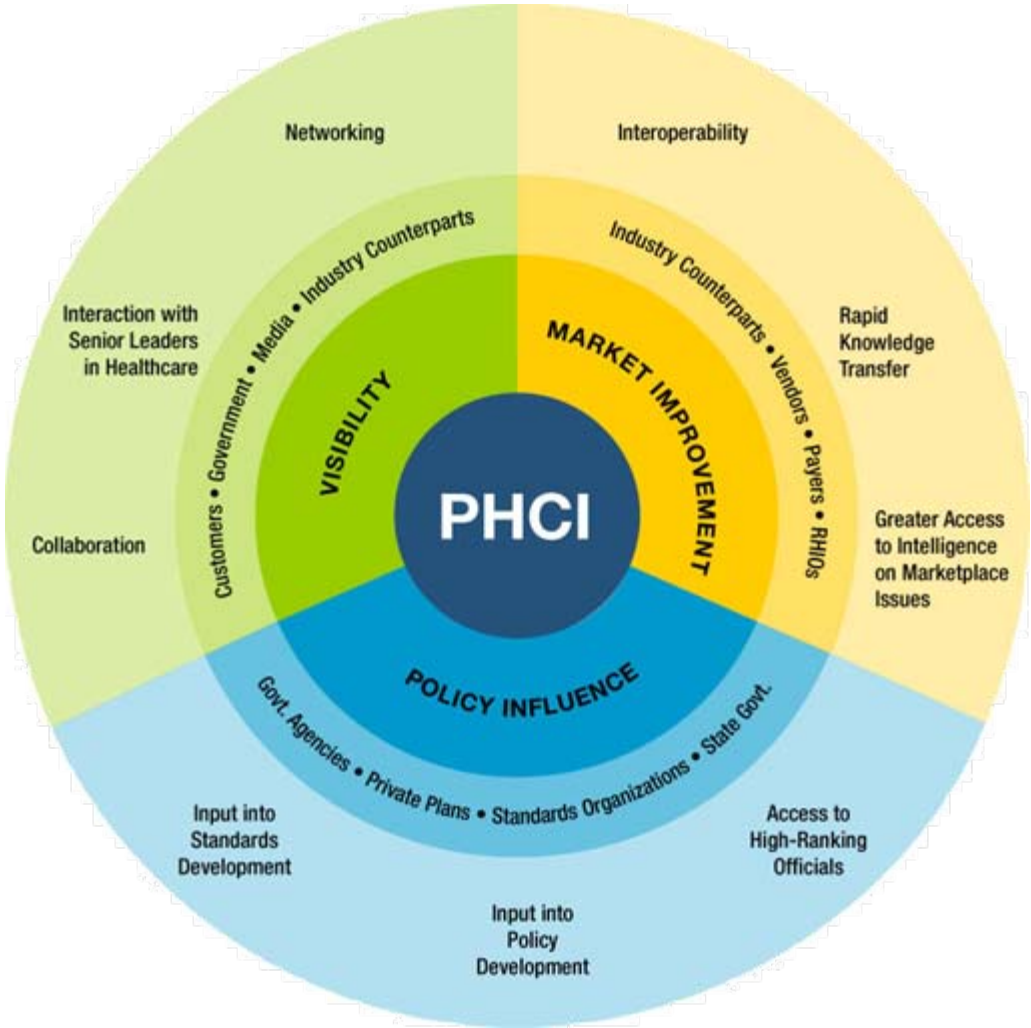
- Enable the generation, transmission, and use of information at the individual and population level
  - » Through delegation, collaboration, and development as needed, identify barriers and solutions to enable needed capability

Synchronize

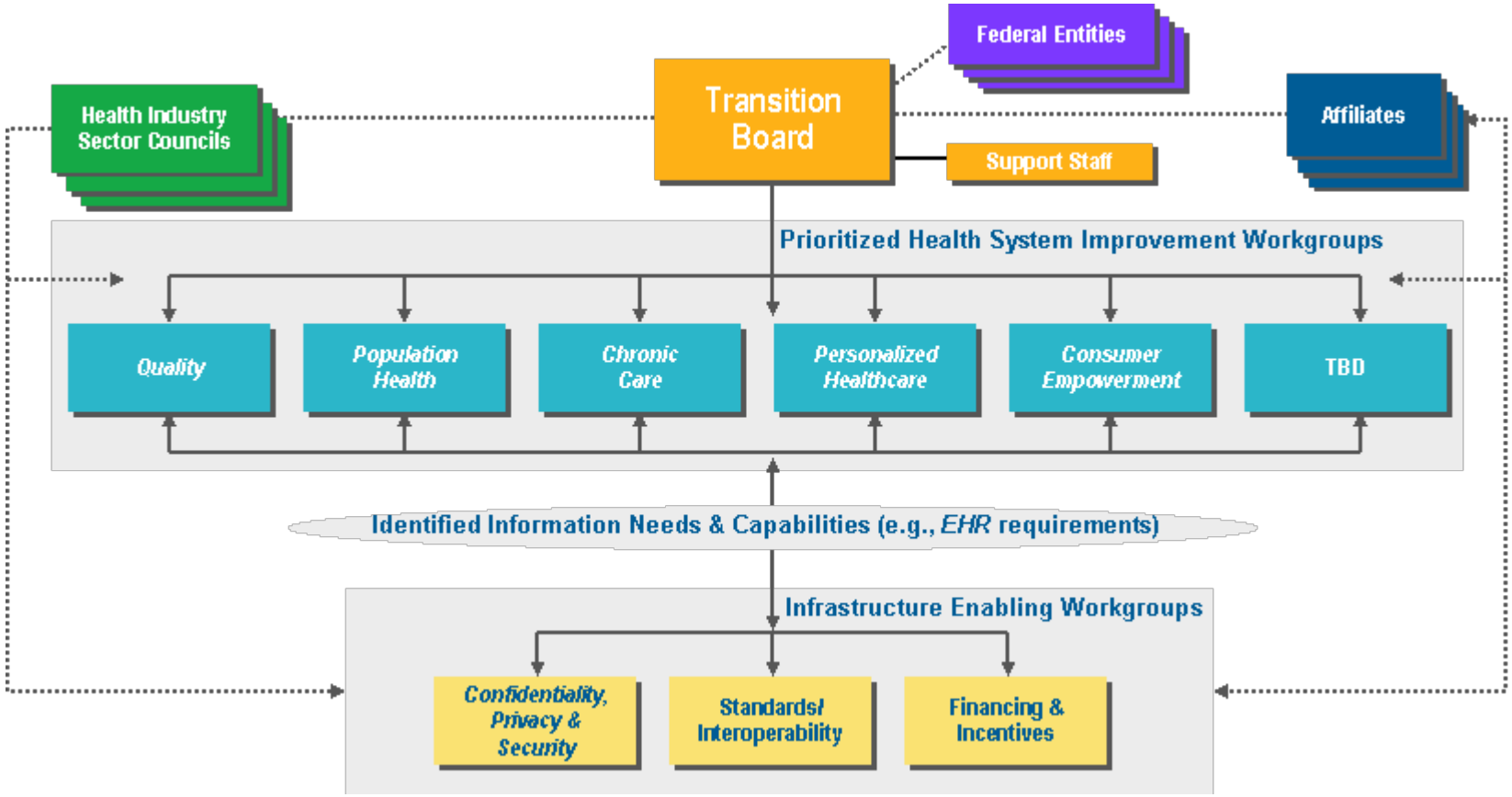
- Synchronize the array of related activities across the public and private sectors
  - » Identify how activities and initiatives are interrelated or interdependent and how to coordinate

Quality, Consumer empowerment, and Population Health are current AHIC priorities, but Transition Board may designate different priorities.

Multidimensional Value Proposition will Drive Sustained Participation



Initial Transition Board Structure and Proposed Model Framework Will Mature into the PHCI



Quality, Population Health, Chronic Care, Personalized Healthcare, and Consumer Empowerment Workgroups represent current AHIC priorities, but Transition Board may designate different priorities.

HISCs Provide a Structure that Promotes Broad Stakeholder Representation and Direct Input to the PHCI

Health Industry Sector Councils*

Long Term Care	Providers	HIT and HIE	Labs and Radiology	Employers
Alliance AHCA AAHSA NAHC	AAFP ACP AMA AMGA ANA MGMA NACDS AphA NCPA	eHI HiMSS NaHIT AHIMA Markle AMIA NAHDO	ACLA ASTRO ACR	NBCH NBGH HLC Business Roundtable WBGH Leapfrog
Consumer Groups and Consumer Advocates	**Payers**	**Drugs and Devices**	**Institutional Providers**	**State and Local Government**
AARP NCL Consumers Union Consumer Coalition for Quality Health Care CAPS	AHIP BCBSA Small Business Health Plans NCQA	PhRMA BIO AdvaMed MDMA AAMI	AHA FAH NACHRI NACHC AAMC Joint Commission	NGA NCSL APHA NACCHO NASMD

* Modeled after Industry Sector Councils in the Critical Infrastructure Partnership Advisory Council.
The complete listing of names/acronyms is available in the full slide presentation.

Affiliate Organizations with Related Objectives Will Play an Essential Role in Supporting the PHCI

Affiliates

Structure

- These organizations are capable of supporting other needed development components (e.g., research, standards development, certification, quality metric specifications)
  - » Likely affiliates could include CCHIT, HITSP, NQF, AQA, HQA, NGA, IOM, NCQA
  - » Affiliates could be asked to form ad hoc workgroups or technical advisory panels to focus on key areas (e.g., Quality)

Roles and Responsibilities

- As Transition Board determines priorities and gaps in current information capabilities, it should also consider what these affiliate organizations could accomplish
  - » Offers alternative to creating a new workgroup or duplicating efforts already underway
- Transition Board should develop memoranda of understanding with affiliate organizations that establish the relationship and expedites consideration of PHCI recommendations
- Affiliates should be recognized as expert resources—input should be regularly sought

MOU: memoranda of understanding

Each Federal Entity Will Play a Different Role and Offers Differing Value

Government Entity	Role and Value
2007 AHIC Government Involvement	▪ Provide a near-term mechanism by which Transition Board recommendations are accepted and shepherded throughout the federal health system ▪ Support establishment of sector councils
Interagency Council for Health Care Improvement (CHCI)	▪ Through a new Executive Order, create the Interagency CHCI that would maintain the federal components of the AHIC to advance similar goals on behalf of the Federal government and explicitly work as a counterpart to the PHCI
Federal Agencies Subject to Executive Order (EO)	▪ All agencies subject to the transparency EO shall incorporate recommendations from Transition Board and PHCI consistent with the EO and CHCI guidance
ONC	▪ Work with agencies to facilitate government-wide adoption ▪ Work with contractors to implement and advance agreed upon standards, supporting pilots, and recommended policy ▪ Channel funding, existing contracts, and staffing as needed and appropriate
National Center for Vital and Health Statistics (NCVHS)	▪ Upon AHIC's transition, provide a mechanism to direct recommendations to Secretary* ▪ Provide ongoing support for public hearings and other FACA processes, offering technical expertise as needed

*This role may require a change in the NCVHS charter

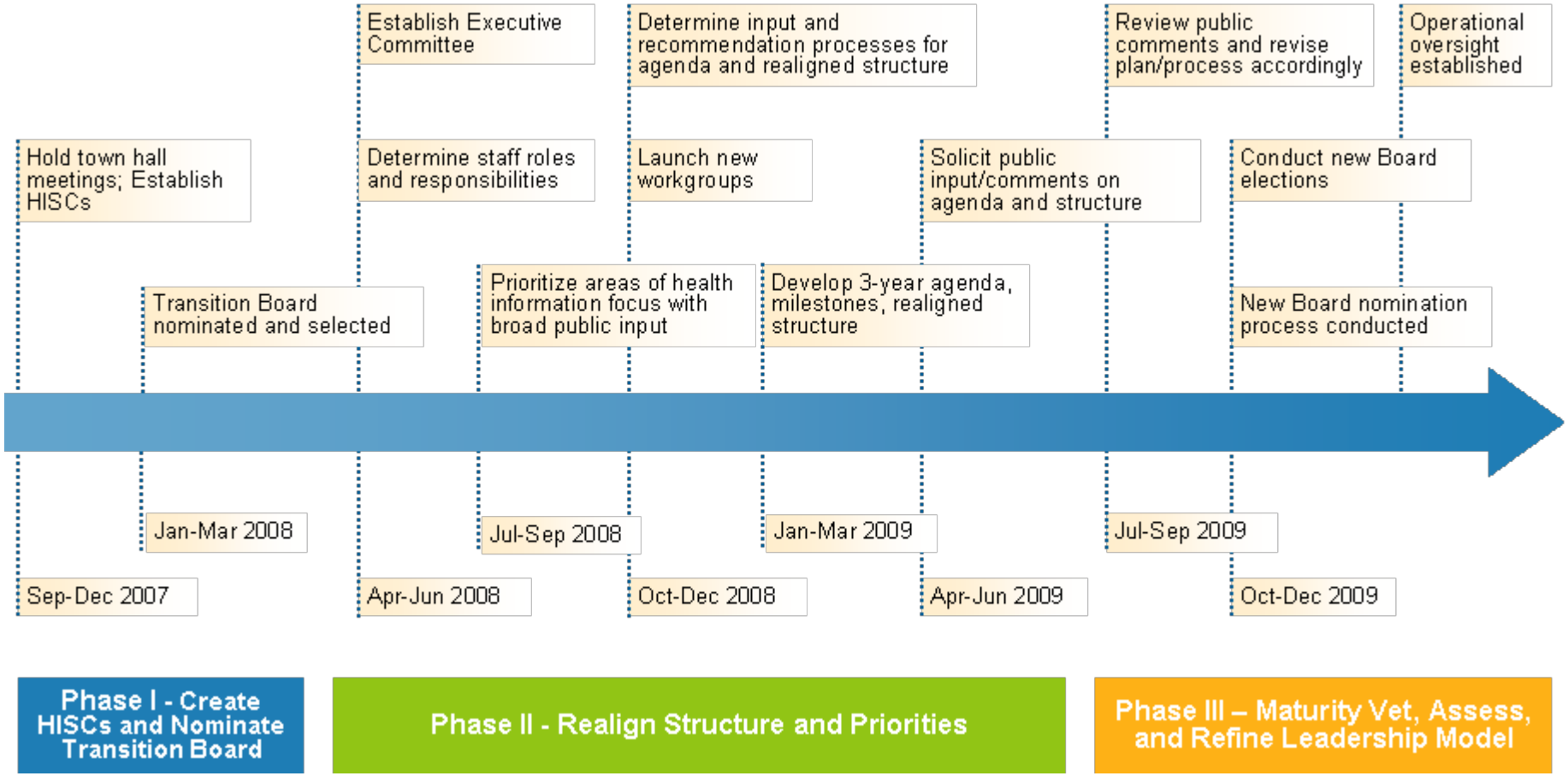
FACA: Federal Advisory Committee Act

Key Relationships and Processes Will Ensure the PHCI is Coordinated with States

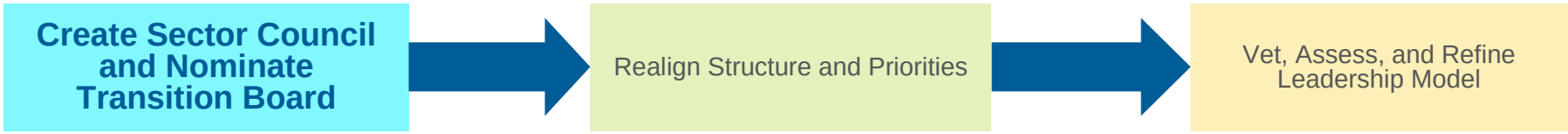
State and Local Government HISC	State Affiliate	State and Community Public Forum
Purpose: ▪ Provide board/workgroup nominations, input, ongoing feedback on recommendations **Structure**: ▪ Association oriented » Representative of governors, state legislators, Medicaid, public health, and local health officials	**Purpose**: ▪ Channel to help PHCI address state-level HIT issues including barriers to interoperability, privacy and security issues, and state law and regulatory barriers **Structure**: ▪ Standing Affiliate devoted to state policy and legislative issues » Recommended entity is NGA (State Alliance for e-Health)	**Purpose**: ▪ Achieve regular input from array of state and local representatives **Structure**: ▪ Semi-annual, national conference ▪ Issue- or stakeholder-oriented breakout groups
Standing Group	**Standing Group**	**Meets Twice a Year; Attendees Vary**

PHCI will coordinate and direct workgroups to state-based input mechanisms.

PHCI Timeline – Key Tasks and Phased Transition



Fostering HISC Creation Is a Critical First Step



Structure and Purpose

- HISCs are comprised of all interested associations related to the industry sector
- HISCs provide broad representative stakeholder input starting with the nominations for Transition Board membership

Processes

- AHIC members work with sector associations to hold town hall meetings and foster HISC formation
- Interim principles established for HISC operations based on open and inclusive processes
- Town hall meetings conducted for individuals, companies, organizations, and associations that represent the designated sectors
  - » Five meetings held across the country, with virtual component, to reach potential HISC membership; break out sessions held for individual sectors
- Once HISCs formed, each develops a list of two to three Transition Board nominees, ensuring equitable balance in industry representation and transparent selection

Funding

- Leverage current AHIC and ONC funding (2008 AHIC funding)
- Government grants and contract/support for transition support and town hall meetings

Key Role of Transition Board Is to Realign Structure and Priorities for Successor Body

Structure and Purpose

- 18 Member commission - 10 HISC representatives, 4 Congressional appointees, 4 Federal representatives from current AHIC commissioners; five initial staff – executive and deputy director, general counsel, two support staff
- Transition Board will re-evaluate the structure and priorities of current AHIC to determine what, if any, realignment is necessary to promote and maintain industry support/buy-in
- Board will prioritize future PHCI activities using an open and transparent process

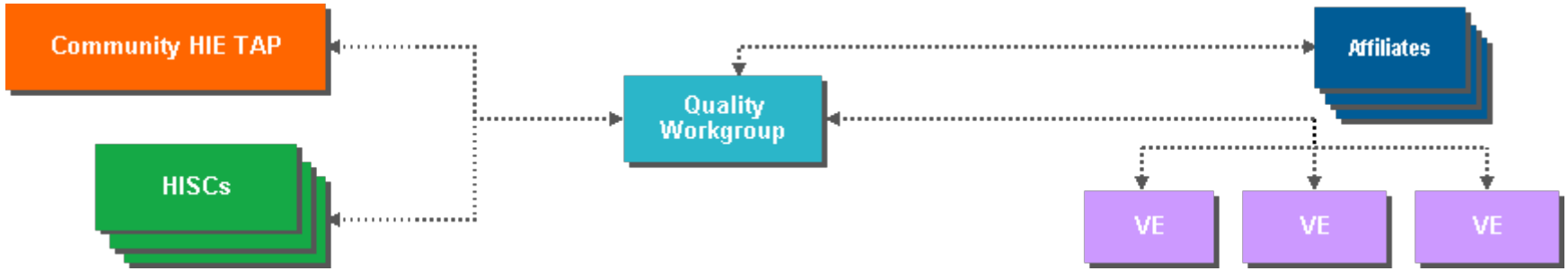
Processes

- Board and HISCs will identify affiliate organizations that should play ongoing substantive role in advancing an interconnected health system (e.g., CCHIT, HITSP, NQF, IOM, NGA)
- HISCs and Affiliates will be engaged in prioritizing health system goals and related information capabilities
- Board, HISCs and Affiliates will determine the future PHCI workgroup structure and processes
- PHCI will develop additional workgroups based on needed information and prioritized goals
- Input, discussion, decision, and recommendation processes use FACA as a model for openness

Funding

- Government grants and existing
- Federal and private sector in kind support
- Small percentage contribution from HISC association dues

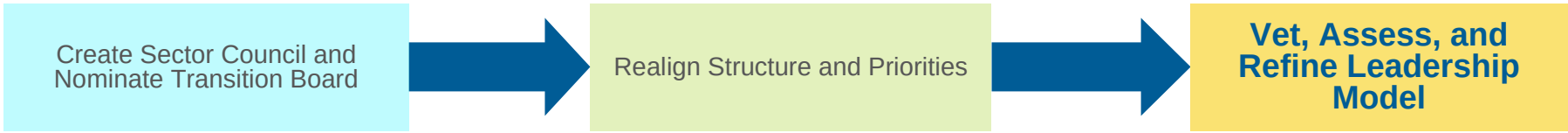
Quality Workgroup: An Example of Oversight, Collaboration, and Coordination



- Quality workgroup will foster relationships with similarly missioned organizations, creating a formal and informal network:
  - » National organizations, such as NQF, NCQA, Leapfrog, and the Quality Alliance Steering Committee would serve as affiliates to the PHCI
  - » Technical Advisory Panels (TAPs) will be sought and established[1] to gain needed technical expertise regarding quality improvement, performance metrics, and state and local HIE initiatives
  - » HISCs and quality related pilots (e.g., Value Exchanges (VEs)) will provide real-world experience to inform the process
  - » AHRQ chartering terms likely to require VEs to share lessons learned and experiences
- Grouping of organizations will afford information to the workgroup as it devises its agenda to address gaps in data collection, aggregation, performance measurement, quality reporting, and translation
- Once the agenda is created and tasks delegated to Affiliates, these organizations will also provide feedback to the workgroup to help it to assess the relative success of its efforts
- The iterative and consistent exchange of information across activities will facilitate a coordinated framework overseen by the PHCI and Quality workgroup and will ensure open collaboration and coordination

[1]Modeled on the Remediation Technologies Development Forum (RTDF)

Final Phase of Model Reconfirms Direction for PHCI and Establishes Leadership for the Future



Structure and Purpose

- New structure will be determined through public vetting processes
- Work with HISCs, Affiliates and Federal entities as part of the vetting process to validate the realigned PHCI structure and priorities
- Formalize public vetting process for agenda, milestones, and realigned structure

Processes

- Solicit input on whether and how Board composition should change to ensure balance
- Solicit comments on the revised design and determine need for further revision
- Seek nominations for Board changes and implement new Board elections consistent with new structure recommendations, balanced similarly to the Transition Board membership: 10 broad industry stakeholder representatives, 4 Administration representatives and 4 Congressional designees

Funding

- Percentage contribution from HISC associations
- Federal grants
- Sponsorship opportunities
- NHIN Operational fees

Mature PHCI Will Also Offer Various Operational Services that Support the NHIN

Operational Functions

Structure and Purpose

- Newly staffed subcomponent of PHCI would provide operational review services for the mature organization
- The operational function would have separate and additional staff with legal, policy, and data analysis expertise
- Oversight and certification of NHIN activities including
  - Policy and legal underpinnings of community based HIE as opposed to technical infrastructure
  - Standards and processes regarding access to national level secondary data through the NHIN

Processes

- Establish policy for evolving integration and interoperability of local and regional health information networks and national data access
- Conduct reviews, evaluations, and certification of participating entities to ensure that the necessary agreements/contracts are in place and the applicant is a “trusted” NHIN participant
- Provide certification of secure interoperable services that meet national exchange standards
- Review request for access to national level data through the NHIN, rather than from individual data sites or certify designees authorized to review requests for National level data access and utilization

Funding

» NHIN fees charged to registered HIEs that meet standards for nationwide interoperability*

» Fees charge for review and approval of data access requests and for certification of NHIN data access review organizations

*Registration would occur in the future.

Various Entities Play Key and Distinct Roles in Transition Plan

Phases	Activities	Responsible Entities
Phase I	Establishing Health Industry Sector Councils	Current AHIC, ONC, Association leadership
	Selecting the Transition Board membership	HHS Secretary, Congress, Non-Federal AHIC members
Phase II	Recasting the current AHIC	U.S. President, with input from current AHIC
	Prioritizing health information focus areas	Transition Board, HISCs, Affiliates, Federal entities and current AHIC
	Launching new work groups and transitioning from existing AHIC workgroups	Transition Board, Existing workgroups, New workgroups, HISCs, Affiliates
	Developing and vetting the draft agenda, milestones, and realigned structure	Transition Board with input from interested organizations and individuals (public comment)
Phase III	Finalize the revised agenda, milestones, and structure	Transition Board and PHCI staff
	Elect new board	HISCs, Transition Board , Congress, Executive branch (CHCI, ONC)

Summary of the Funding Mechanisms Across PHCI Phases

	Existing Government Contracts	Grants	Federal In-kind Support	Private In-kind Support	HISC Association Dues	Operational Fees	Sponsorship	Other Federal Funding
Phase I	X	X	X	X				
Phase II		X	X	X	X			
Phase III		X		X	X	X	X	X

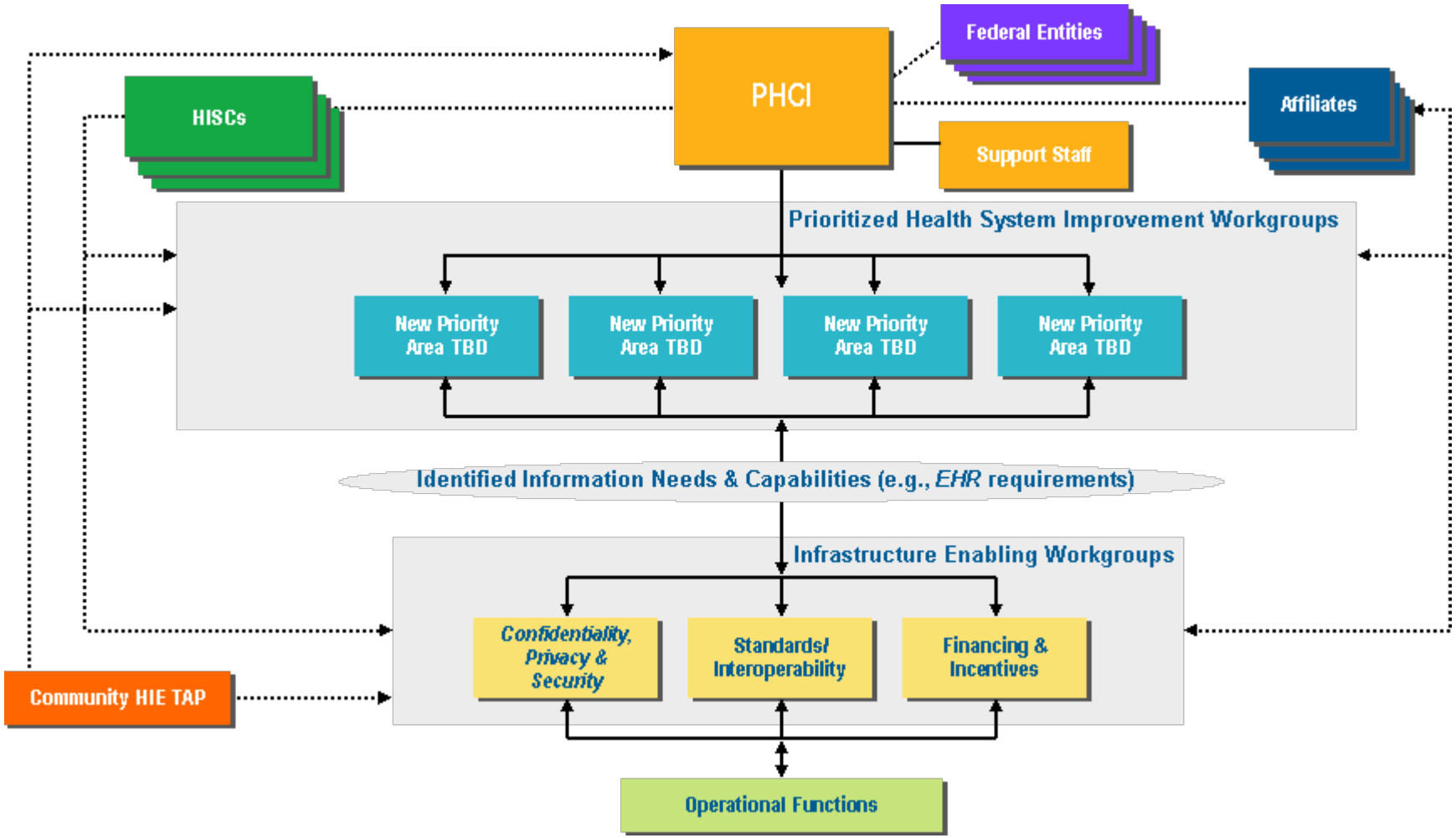
Draft Charter and Bylaws for Transition Board and PHCI

The Charter and Bylaws* Outline the Following Functions and Processes:

- **Purpose, Vision, and Objectives**
- **Selection and Appointment of Transition Board**
- **Description of Health Industry Sector Councils**
- **Duties of Transition Board**
- **Roles of Transition Board Officers**
- **Formation and Operation of Workgroups**
- **PHCI Staff**
- **Meeting Procedures**
- **Voting**
- **Duration and Termination**
- **Selection and Appointment of Permanent Board**

*The draft Charter and Bylaws are included as a separate document.

In Maturity, the PHCI Has Used a Broad and Inclusive Approach To Redefine Priorities, Target Areas, and Supporting Infrastructure



Confidentiality, Privacy & Security Workgroup represents current AHIC priorities, but Transition Board may designate different priorities.

AHIC

Business Model for the Successor Organization to AHIC

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- Lisa Kimball
- Curt Lindberg

ALCHEMY

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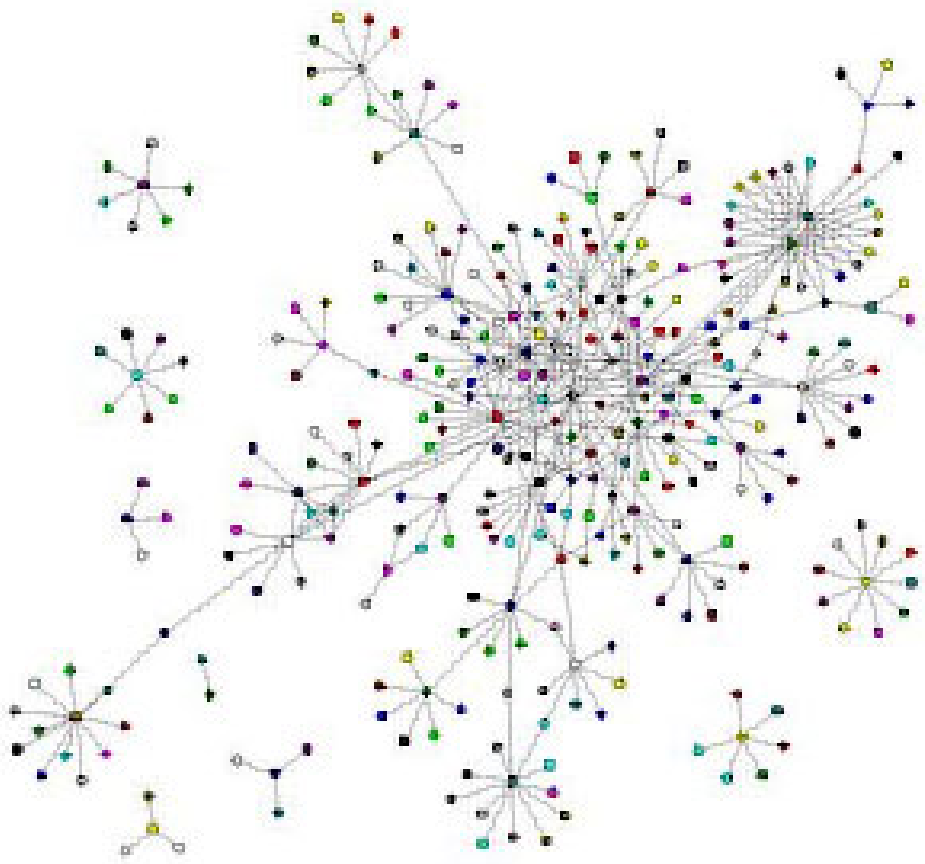
June 2007

It's About the *Network*



Managing the Unknowable: Accepting An Unforeseeable Future

Form follows Function

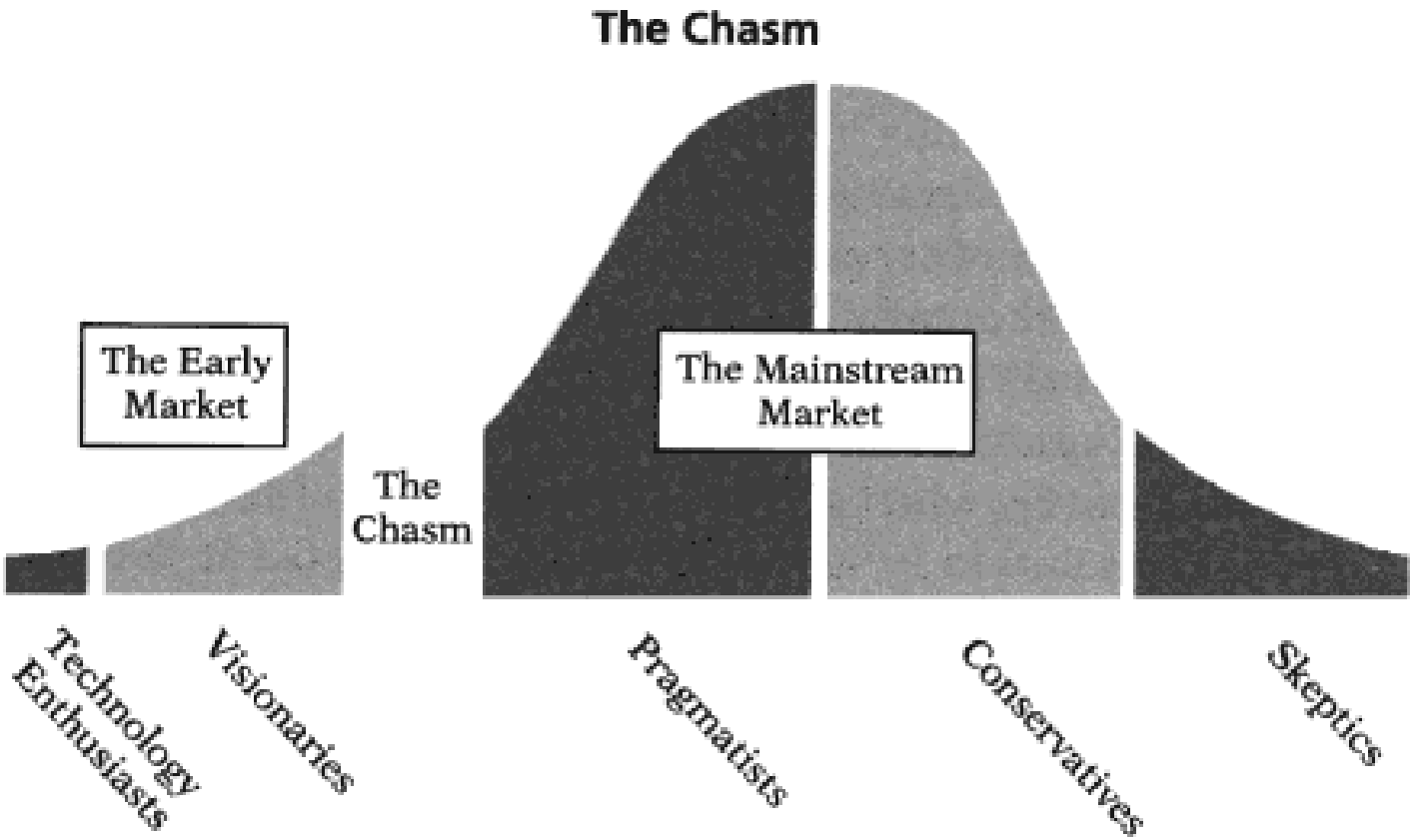
- What business model will enable the new organization to facilitate the key processes needed to steer the community toward the mission?
- What mechanisms will enable it to effectively…
  - ***Convene*** the diverse community around conversations and decisions that matter
  - ***Catalyze*** innovations
  - ***Engage*** peer-to-peer learning

Different Models for Different Tasks

- We recommend three distinct models:
  - The Health Information Roundtable
  - Innovation Fund
  - Diffusion Network

- Additionally, we recommend that HHS' ONC and other HHS functions should continue their important roles as representatives of the public at large.

The HIT Adoption Challenge: Crossing the Chasm



In the Short Term

- Create roadmaps owned by the communities involved that identify and define shared objectives
- Kick start technical development to open standards by a target date
- Take advantage of on-going pilots and launch multiple new experiments and pilots
- Nurture the key relationships among stakeholders
- Establish a vigorous, aggressive and responsive technical assistance network

Health Information Roundtable*

- Set bold direction and catalyze the conversation about the role and power of Health IT in the community of stakeholders
- Create and manage “roadmaps”
- Establish “min specs” for technology development and certification
- Identify and use leverage points: government policy, industry incentives, sector engagement
- Delegate key authorities (for example to CCHIT for certification)
- Coordinate with local, regional, and federal government bodies with related oversight responsibilities for privacy and security issues.

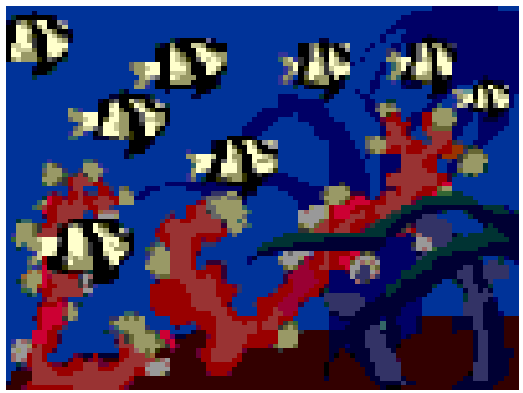
HIR: Distributed Control

Distributed Control:

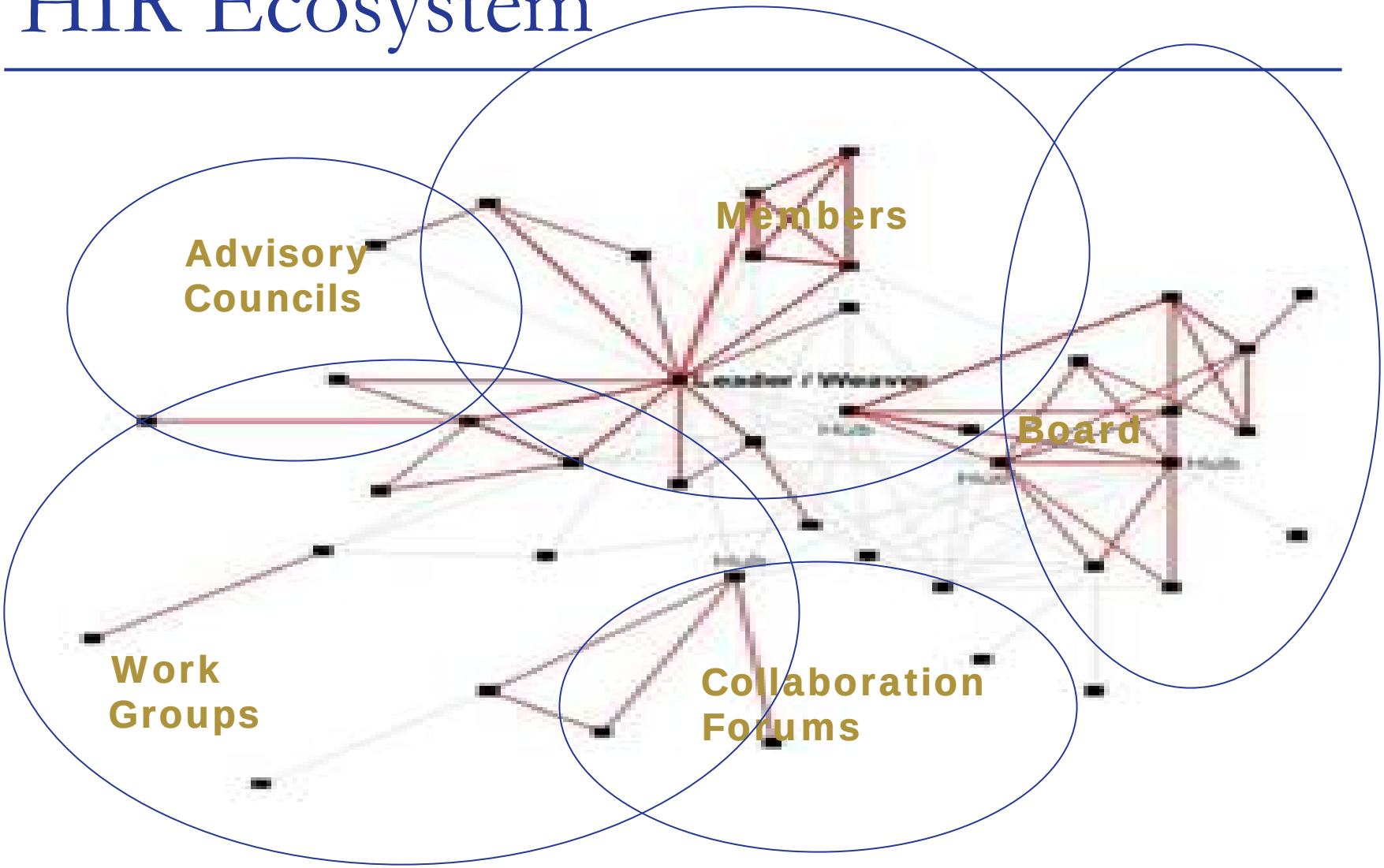
In a Complex Adaptive System control is shared by many elements, rather than centralized in a single command center

Coexistence of Order and Disorder:

In a healthy adaptive system, order and disorder coexist

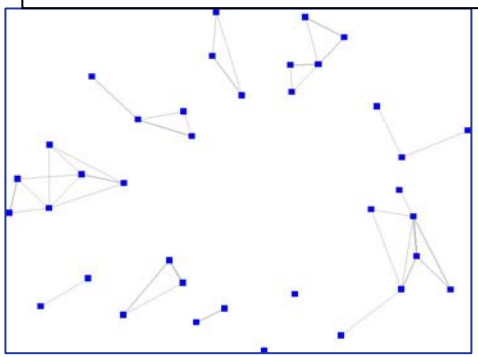


HIR Ecosystem

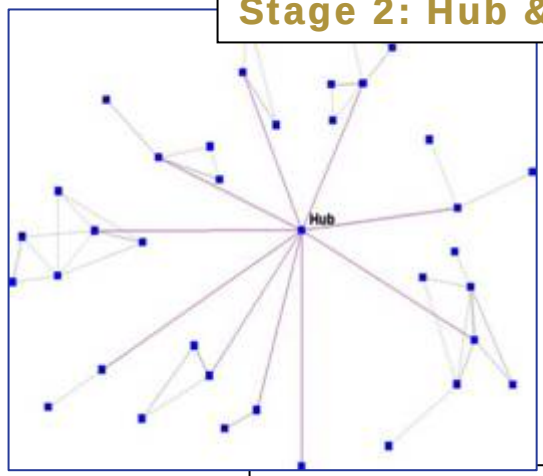


Stages of Network Development

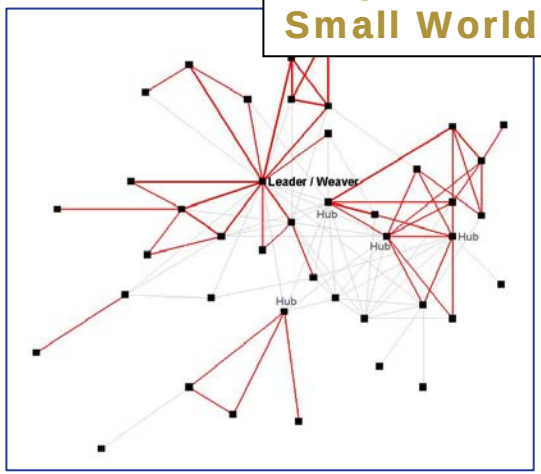
Stage 1: Scatted Clusters & Unconnected Individuals



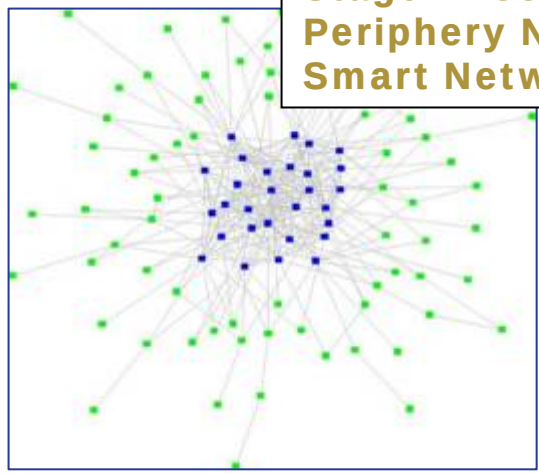
Stage 2: Hub & Spoke



Stage 3: Multi-hub Small World



Stage 4: Core - Periphery Network or Smart Network



Innovation Fund

- In addition to creating a Health Information Roundtable, we recommend establishing an **Innovation Fund** as a strategic investment mechanism to support collaborative research, development and innovation projects that are of importance to the mission of ONC, the new Health Information Roundtable and to meet anticipated unexpected needs.

Diffusion Network

- Biggest problem is USE v. development
- Need for regional outreach mechanism “technical assistance” meaning assistance with application (not just technology)
- Competitive markets take care of technical development, but aren’t good at social development
- We recommend creating a network of regional and local entities that can support adoption and adaptation

Diffusion Network: Theory of Action

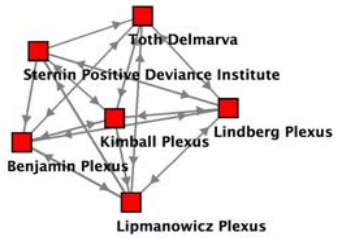
Knowledge does not change behavior

It is easier to act your way into a new way of thinking than it is to think your way into a new way of acting.

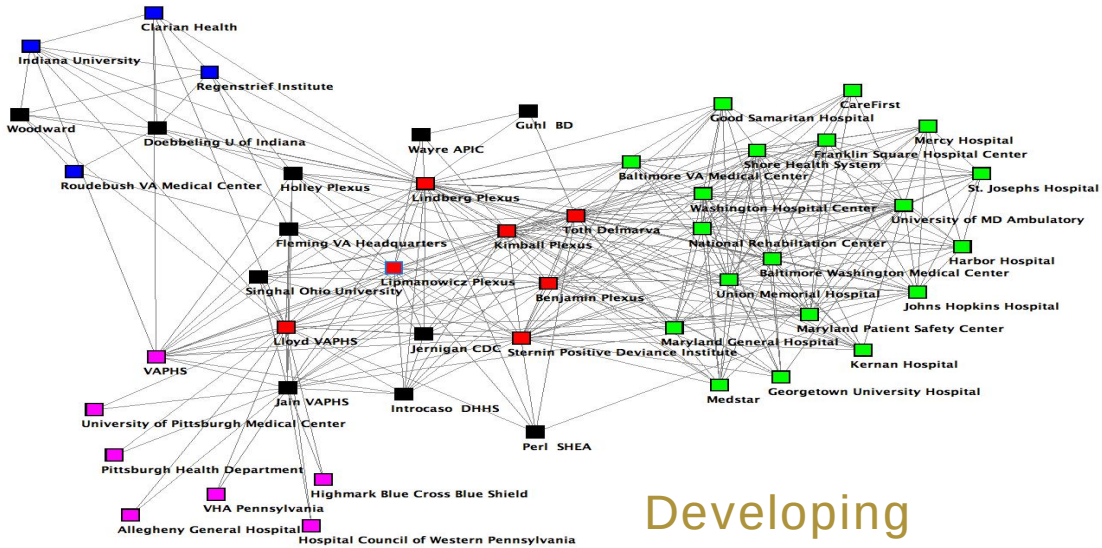
~ Jerry Sternin

Diffusion Network: Outcomes

- Innovation Learning Network example
- MD MRSA network example



Early Stage Network



Developing Network

Power the transition with ***multiple, simultaneous*** actions

Nature is not economical of structures—only of principles.

~ Abdus Salam
Winner Nobel Prize
for Physics, 1979

Principals

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Standards Timeline and HITSP Interoperability Specifications v2.0

John W. Loonsk
Office of the National Coordinator

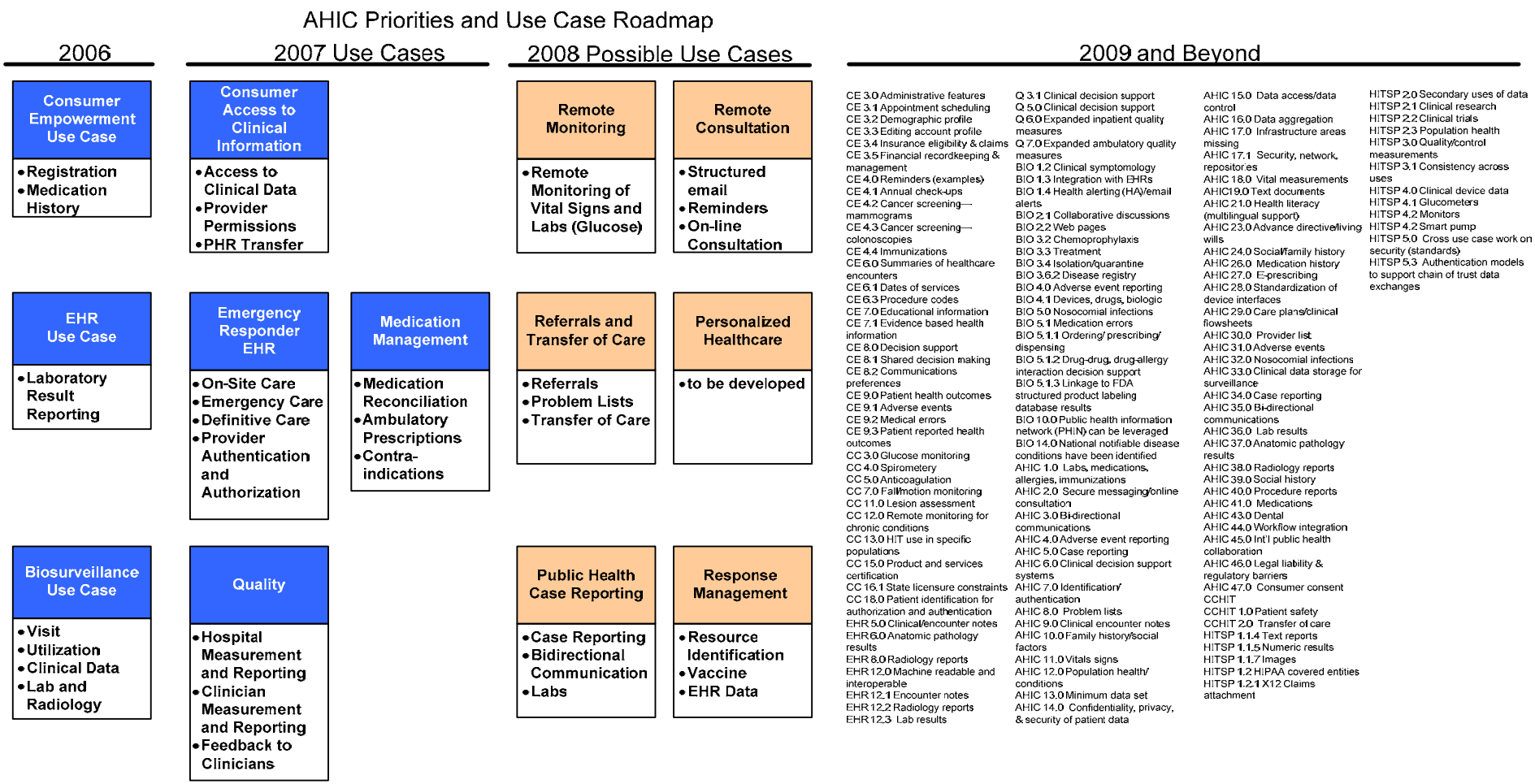
John D. Halamka
Chair, HITSP

June 12, 2007

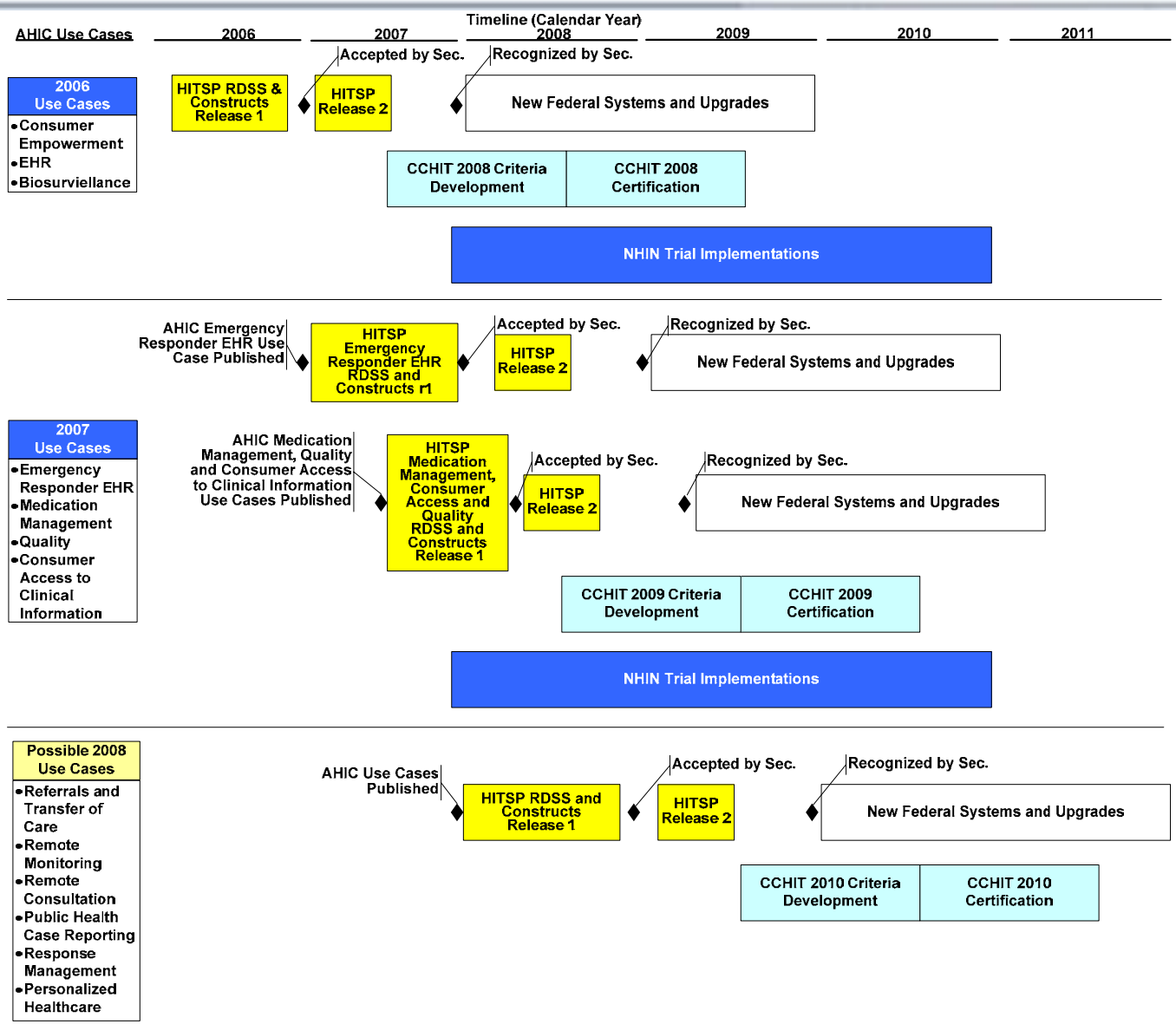
Agenda

- AHIC Priorities and the Standards Timeline
- Interoperability Specifications Version 2.0
  - Consumer Empowerment
  - Biosurveillance
  - Electronic Health Records Laboratory Results Reporting
- Important harmonization accomplishments
- Next Steps

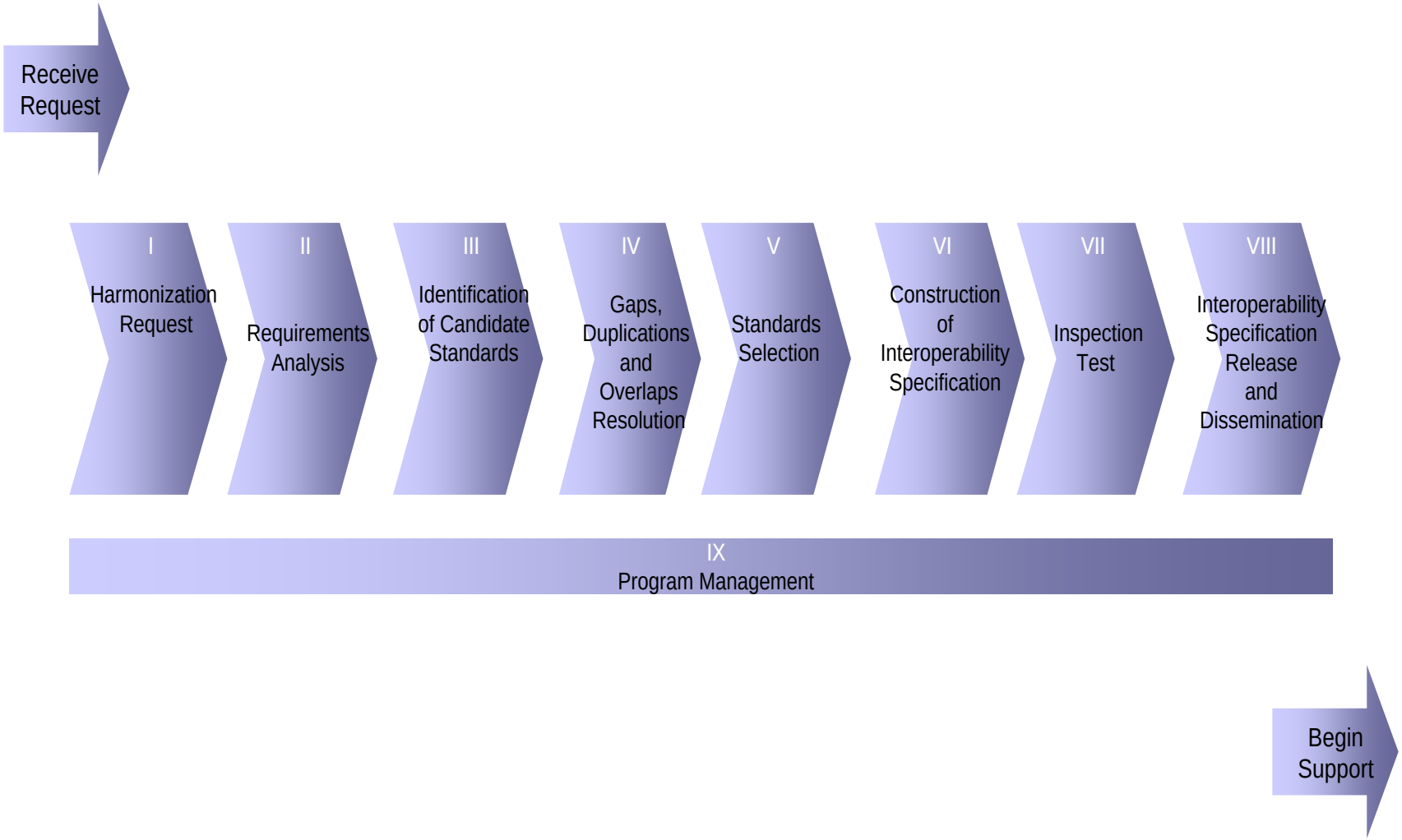
AHIC Priorities and Use Case Roadmap



AHIC Standards Timeline



Standards Harmonization Process



Interoperability Specifications – First Set

- In October 2006, HITSP advanced v1.2 of the Interoperability Specifications to AHIC
  - Consumer Empowerment Registration and Medication History, Biosurveillance, Electronic Health Record (EHR) Laboratory Results Reporting
  - Secretary Leavitt “accepted” the Interoperability Specifications in December 2006 with the intent to “recognize” v2.0, presuming that changes are minimal or of a technical nature
- The HITSP Panel approved the v2.0 Interoperability Specifications on May 11
  - No additional constructs or standards were added to v1.2 as result of the implementation testing feedback
  - All changes between v1.2 and v2.0 were minor or of a technical nature to the implementation guidance

Consumer Empowerment – Registration and Medication History v2.0

- **Scope**
  - Deploy to targeted populations a pre-populated, consumer-directed and secure electronic registration summary. Deploy a widely available pre-populated medication history linked to the registration summary

- **Accomplishments**
  - Addresses core consumer empowerment enabling "connected PHRs"
  - Successful collaborative between HITSP and member organizations including: ASTM, CAQH, CDC, FMT, HL7, IHE, NCPDP, X12, SNOMED
  - Harmonization to the CCD medical summary record

Harmonization of the Summary Record

ASTM working on the Continuity of Care Record (CCR)

- Driven by clear business need
- Direct input from clinical care users
- Specifies the “buckets” for data, but not the specifics of the content

HL7 working on the Clinical Document Architecture (CDA)

- Has overarching considerations for many kinds of clinical documents
- Leverages standards to fill data in critical “buckets” to ensure they can be processed and used
- Needs to be scoped down to a practically implemental summary

HITSP membership, without objection, agreed to support the best of both worlds – the Continuity of Care Document (CCD)

- Developed by ASTM, HL7 and other participating organizations
- Scoped by the CCR data needs
- Benefiting from the coordination of HL7 terminologies

Biosurveillance v2.0

- **Scope**
  - Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in a standardized and anonymized format to authorized public health agencies with less than one day lag time
- **Accomplishments**
  - Maximizes data sources and provides stringent data management to ensure proper routing, security, privacy, and timely reporting
  - Provides support for different architectural environments
  - Addressing gaps with referrals to SDOs through the Foundations Committee
  - Aligning with other public health initiatives
  - Using the same result message as is used for clinical reporting should improve number of public health cases reported

Electronic Health Record (EHR) - Laboratory Results Reporting

- **Scope**
  - Deploy standardized, widely available, secure solutions for accessing laboratory results and interpretations in a patient-centric manner for clinical care by authorized parties
- **Accomplishments**
  - Addresses lack of harmonization among data interoperability standards including vocabulary and laboratory and other messaging standards
  - Accommodates both laboratory message transaction and document sharing paradigms
  - HL7 and HITSP Lab WG are coordinating activities to complete a lab message implementation guide to meet the AHIC use case requirements

Next Steps

- AHIC to review and consider HITSP Work
- Finalized HL7 Implementation Guide and HAVE standards to be incorporated into HITSP Interoperability Specifications
- CCHIT continues to incorporate HITSP work into its functional criteria via the joint CCHIT/HITSP JWG
- HITSP moves to next priorities:
  - Security and Privacy for existing v2.0 ISs
  - Emergency Responder Electronic Health Record
  - 3 new Use Cases -- Consumer Access to Clinical Information, Quality, and Medication Management

Appendix

HITSP Organization

- Partnership of public and private stakeholders operating through a neutral and inclusive governance model
  - Board of Directors
  - Panel
  - Technical Committees
  - Coordination Committees
  - Project Staff
- Majority of the HITSP work is done by representatives of Panel member organizations that serve as volunteers in the Committees
- Currently there are over 300 registered HITSP Organizations
- Currently there are 302 Technical Committee members

Implementation Testing

- The v1.2 Interoperability Specifications were first evaluated by inspection testers (desktop review) and HITSP member reviews (public comment)
- HITSP also enlisted partners to develop test plans, data, and suites to test the implementation and to support a program of progressive testing, feedback and deployment of implementation
- Participation in the IHE Connectathon and HIMSS Interoperability Showcase also provided an opportunity to evaluate test implementations
  - Over 300 comments provided by 14 test implementers

Implementation Testing

- Feedback from test implementations has been used to revise v2.0 Interoperability Specification implementation guidance
- Moving forward HITSP continues to enlist partners to perform additional implementation testing
- HITSP is also working with CCHIT, NIST and ONC to establish a holistic interoperability testing strategy
  - Phase I of an “HIT Implementation Testing and Support” web site is expected to be released in the coming month
  - Long term target definition and short term strategy are being defined

American Health Information Community

Chronic Care Workgroup

Recommendations

Craig Barrett
Intel, Co-Chair

June 12, 2007

Workgroup Member List

Co-Chairs:

- Craig Barrett - Intel
- Tony Trenkle - HHS/Centers for Medicare and Medicaid Services

Members:

- Madhulika Agarwal - Veterans Health Administration/Office of Patient Care Services
- Cheryl Austein-Casnoff - HHS/Health Resources & Services Administration, HRSA/HHS
- Justine Handleman - Blue Cross/Blue Shield
- Shaygan Kheradpir - Verizon Communications
- Herb Kuhn - HHS/Centers for Medicare & Medicaid Services
- Eric Larson - Group Health Cooperative
- Jonathan Linkous - American Telehealth Association
- Stephen McConnell - Alzheimer's Association
- Mohan Nair - The Regence Group
- Anand Parekh - HHS/Office of Public Health and Science
- Jeff Rideout - Cisco
- John Rother - American Association of Retired Persons (AARP)
- Jay Sanders - The Global Telemedicine Group

Office of the National Coordinator:

- Karen Bell

Chronic Care Workgroup Overview

Broad Charge:

Make recommendations to the Community to deploy widely available, secure technologies solutions for remote monitoring and assessment of patients and for communication between clinicians about patients.

Specific Charge:

Make recommendations to the Community so that within one year, widespread use of secure messaging, as appropriate, is fostered as a means of communication between clinicians and patients about care delivery.

Use Case Development: Secure Messaging

- **<u>Recommendation 1.0:</u> Given that the HITSP interoperability standards and certification criteria for secure messaging and advanced electronic technologies for clinical monitoring have not been included in the development of either of the first two sets of use cases and that interoperability between patient and clinician electronic health products is critical for improving quality of care, the Secretary should make a use case for interoperability with respect to remote care a top priority.**
  - **Accept**
  - **Table**
  - **Reject**

Business Case Alignment

- **<u>Recommendation 2.0:</u> In order for a clinician to be reimbursed by Medicare for providing services delivered through advanced electronic technologies, current statute requires the patient to be in a specific clinical setting. The Secretary should develop legal guidance that defines the clinical setting by the information collected, diagnostic services performed and treatments rendered. This guidance should take into account potential concerns with fraud and abuse, violation of Stark laws, HCPCS codes, and other possible mitigating factors.**

  - **Accept**
  - **Table**
  - **Reject**

Business Case Alignment

- **<u>Recommendation 2.1:</u> The Secretary should conduct demonstration projects to determine the value of telehealth services in clinical settings beyond those listed in Federal statute in order to make informed decisions about expansion of that list.**

  - **Accept**
  - **Table**
  - **Reject**

Business Case Alignment

- **<u>Recommendation 3.0:</u> The Secretary should evaluate the benefits of remote store and forward technology as currently employed in Alaska and Hawaii to determine if these services should be expanded beyond these two states.**

- **Accept**
- **Table**
- **Reject**

Business Case Alignment

- **<u>Recommendation 4.0:</u> The Secretary should conduct demonstration programs through the Special Needs plans and Medicare Advantage plans that specifically evaluate the use of home based, remote care monitoring for the management of specific chronic conditions by clinicians of record.**

- **Accept**
- **Table**
- **Reject**

June 12, 2007

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

Dear Mr. Chairman:

The Chronic Care (CC) Workgroup was formed in January 2006 to address both the broad and specific charges formulated by the AHIC:

> **Broad Charge for the Chronic Care Workgroup:** Make recommendations to the Community to deploy widely available, secure technology solutions for remote monitoring and assessment of patients and for communication between clinicians about patients.
>
> **Specific Charge for the Chronic Care Workgroup:** Make recommendations to the Community so that within one year, widespread use of secure messaging, as appropriate, is fostered as a means of communication between clinicians and patients about care delivery.

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

- HHS should develop and regularly update the evidence base for informed reimbursement of secure messaging between clinicians and patients.
- HHS should compile and assess the effect of various reimbursement methodologies for secure messaging on clinician workflow.
- Public and private payers, including the Centers for Medicare & Medicaid Services (CMS), should contribute to the evidence for and information base on reimbursement strategies through direct reimbursement, pilot of demonstration studies or coverage analysis for Internet-based patient/clinician encounters.
- HHS should convene the appropriate State agencies and professional societies to develop and adopt new licensing alternatives which will address the ability to provide electronic care delivery across State boundaries while still ensuring compatibility with individual State requirements.
- ONC should direct HITSP to define standards for secure patient-clinician messaging transactions so that they may be interoperable with EHRs.
- ONC should direct CCHIT to establish certification criteria for system interoperability with patient-clinician secure messaging.
- AHRQ should conduct a synthesis of current knowledge from existing studies of HIT use by elderly, ill, and underserved populations including an analysis of barriers and drivers.

- HHS should work with appropriate organizations to report on secure messaging availability via broadband to providers across the country and report on a plan and timetable to make secure messaging through broadband available uniformly.
- AHIC should create a consumer empowerment subgroup comprised of privacy, security, clinical, and technology experts from each AHIC workgroup. The subgroup should frame the privacy and security policy issues relevant to all the Community charges and solicit broad public input and testimony to identify viable options or processes to address these issues that are agreeable to all key stakeholders.

We are pleased that you have been able to move forward on most of these recommendations. We note that a pilot demonstration for reimbursement of secure messaging will be awarded this summer to address the first three recommendations. AHRQ has put out a request for proposal for a synthesis of knowledge relating to HIT use by frail and underserved populations. The Confidentiality, Privacy and Security (CPS) Workgroup was convened in 2006 and is currently in operation as an independent AHIC workgroup. The Federal Communications Commission (FCC) has a plan to make broadband available nationwide. And the National Governors Association (NGA), through a contract with ONC, is addressing the issues related to state based licensure, and will have a recommendation ready in August of this year.

However, we note that the use case for secure messaging which will lead to HITSP interoperability standards and inclusion in the certification process for EHRs is yet to be developed. Secure messaging was not included with other specific charge recommendations on the first round of use case development, and was not prioritized among the top three in the second round of use case development. The ability of patients to communicate electronically with their health care clinicians about their health is critical to improving the quality of care and to encouraging the widespread adoption and use of electronic health information. Our first recommendation, therefore, is as follows:

Recommendation 1.0: Given that the HITSP interoperability standards and certification criteria for secure messaging and advanced electronic technologies for clinical monitoring have not been included in the development of either of the first two sets of use cases and that interoperability between patient and clinician electronic health products is critical for improving quality of care, the Secretary should make a use case for interoperability with respect to remote care a top priority.

Since last May, the Chronic Care workgroup has widened its scope of activity to encompass the broad charge and has continued to be heavily engaged in hearing and synthesizing testimony about the value of remote health care and telehealth as well as the barriers to and enablers of wider adoption and utilization.

In addition, the Workgroup participated in a visioning exercise which led to a presentation to the AHIC on October 31, which articulated person-focused healthcare in the future:

1. Care available in home, work, or school -- anywhere, anytime --- through use of remote, virtual technologies to assess and support patient care.
2. New reimbursement systems supporting virtual care outside of the clinical setting.
3. Care coordinated across multiple providers through access to electronic information.

The Chronic Care Workgroup has structured its effort to support access to remote care services along the following five key areas and will continue to do so as it works in the future to refine further recommendations for using health information technologies to achieve optimum coordination of care.

- Business case alignment
- Workflow/cultural concerns
- Medical-Legal issues
- Privacy and Security
- State of the Technology

After many hours of public testimony, however, it became clear that many of the issues with respect to remote access to care were addressed by the previous set of recommendations. The primary remaining barrier to widespread adoption and use of remote care technologies is lack of reimbursement for time and expertise expended by professionals outside of the office setting. The workgroup therefore presents this set of recommendations in the area of federal reimbursement, particularly since the majority of care associated with chronic conditions is covered by the federal sector, and subject to federal statute and regulation.

Alignment of Business Case for Remote Care

A. Evidence for Benefit

Over the past 12 months, the Chronic Care Workgroup heard from a number of individuals and programs that have implemented various forms of telehealth care. These private and public programs, generally in large integrated delivery systems or disease management companies, have uniformly demonstrated that, in their settings and situations, home based monitoring and care leads to decreases in hospital and ER utilization and improved patient quality of life -- in as little as four months.

The Workgroup also heard testimony from the technology sector, and learned that the options for virtual care are expanding dramatically. Visual technology can be superior to direct eye contact through its ability to magnify. Audio technology can now allow for remote auscultation. Wave form transmissions can provide critical EKG information. Data from analyses of blood and urine can be transmitted electronically to providers. Weight and other vital signs are being captured on site and transmitted remotely.

The time is ripe to address a set of laws and regulations dating back to the days of mimeograph machines and typed carbon copies.

B. Medicare Statutes that Govern Reimbursement for Telehealth

The Social Security Act, section 1834(m), governs Medicare payment for telehealth services. It is amended regularly in response to the passage of new bills relating to Medicare.

The 1997 Balanced Budget Act authorized federal reimbursement for telehealth services. The Act permitted the Health Care Financing Administration (HCFA) to reimburse physicians or practitioners for select consultative telehealth services provided to Medicare beneficiaries living in rural areas. Medicare's payment policy was developed to replicate a standard consultation as closely as possible and required a provider or practitioner to "present" the patient from a list of specified clinical settings, thus requiring a "face to face" examination of the patient via telecommunications systems.

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) further amended §1834 of the Social Security Act to provide for an expansion of Medicare payment for telehealth services to include office visits, individual psychotherapy, and pharmacologic management provided in an "approved" setting delivered via a telecommunications system. In addition, eligible geographic areas were expanded beyond rural health professional shortage areas to include counties outside of metropolitan statistical areas (MSA). The Act also allowed for annual updates in the Medicare Reimbursement Policy with respect to the facility fee payment for telehealth services and gave the Secretary the authority to consider adding additional services and settings to the list of approved telehealth services.

The Medicare Modernization Act (MMA) of 2002 required a review of the value of telehealth in skilled nursing facilities (SNFs) and gave authorization for approval of SNFs as originating sites based on the results of the evaluation. The results of this evaluation are still pending.

In summary, Medicare statute currently limits reimbursement for telehealth services to:

1. Specific non-metropolitan geographic areas
2. Care provided when the patient is physically situated in one of a list of approved clinical settings as originating sites: physician offices, hospitals, rural health clinics, or Federally qualified health centers
3. A specific list of clinicians: physicians, nurse practitioners, clinical nurse specialists, physician assistants, nurse midwives, clinical psychologists, clinical social workers, registered dieticians, and nutrition specialists
4. A specific list of services identified by HCPCS codes.

These limitations undercut the ability for professional clinicians to provide remote monitoring and assessment of patients since clinicians cannot currently be reimbursed for their time and expertise in providing these services. We therefore make the following recommendations as short term solutions to the problems posed by Federal statute.

<u>Recommendation 2.0:</u> In order for a clinician to be reimbursed by Medicare for providing services delivered through advanced electronic technologies, current statute requires the patient to be in a specific clinical setting. The Secretary should develop legal guidance that defines the clinical setting by the information collected, diagnostic services performed and treatments rendered. This guidance should take into account potential concerns with fraud and abuse, violation of Stark laws, HCPCS codes, and other possible mitigating factors.

<u>Recommendation 2.1:</u> The Secretary should conduct demonstration projects to determine the value of telehealth services in clinical settings beyond those listed in Federal statute in order to make informed decisions about expansion of that list.

D. Medicare Regulations.

As noted above, the BBA gave the Secretary regulatory authority to further specify the scope of reimbursable telehealth services within the limitations of statute. The Secretary also has authority to conduct demonstration projects to determine if coverage for certain telehealth services would be cost effective.

Examples of Medicare regulation include (but are not limited to):

- Excluding teleradiology from the definition of telehealth (thus excepting teleradiology from statutory limitations.
- Defining telehealth as being live, interactive face to face video conferencing technologies, thus precluding coverage for store and forward technologies, except in Hawaii and Alaska.

A significant amount of data from multiple years' experience of store and forward technology in Alaska and Hawaii is available for analysis. We therefore recommend:

<u>Recommendation 3.0:</u> The Secretary shall evaluate the benefits of remote store and forward technology as currently employed in Alaska and Hawaii to determine if these services should be expanded beyond these two states.

Medicare Advantage plans cover approximately 19% of all Medicare enrollees. The Centers for Medicare & Medicaid Services (CMS) operates the Medicare Advantage plans under capitated arrangements that are established through a competitive bidding process. Plans are required to cover all Part A and Part B services. The cost of these services as proposed by the plan is then compared to the average cost of offering these services under fee-for-service in the same geographical area. A portion of this difference is then awarded to the Medicare Advantage plan to be used to provide supplemental health benefits. Medicare Advantage plans must outline these supplemental benefits up front and they are not subject to the federal statutory limitations on reimbursement for telehealth which restrict the Fee-for-Service benefit of Parts A and B.

<u>Recommendation 4.0:</u> The Secretary should conduct demonstration programs through the Special Needs plans and Medicare Advantage plans that specifically evaluate the use of home based, remote care monitoring for the management of specific chronic conditions by clinicians of record.

Thank you for the opportunity to submit this second set of recommendations that address a core barrier to the broad charge of remote care adoption and utilization. We look forward to discussing them with you and the members of the American Health Information Community on June 12th.

Sincerely yours,

Craig R. Barrett
Co-chair, Chronic Care Workgroup

American Health Information Community

Electronic Health Records Workgroup

Recommendations

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

June 12, 2007

Workgroup Member List

Co-Chairs:

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

Members:

- Carolyn Clancy - Agency for Healthcare Research and Quality
- Bart Harmon - Department of Defense
- John Houston - NCVHS
- Charles Kahn - Federation of American Hospitals
- Mark Lewis - EMC Corporation
- George Lynn - American Hospital Association
- Alan Mertz - American Clinical Lab Association
- Blackford Middleton - HIMSS
- Pam Pure - McKesson
- Robert Smith - Department of Veterans Affairs
- Barry Straube - Centers for Medicare and Medicaid Services
- John Tooker - American College of Physicians

Office of the National Coordinator:

- Karen Bell

Electronic Health Records Workgroup Overview

Broad Charge:

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

Specific Charge:

Make recommendations to the Community so that within one year, standardized, widely available and secure solutions for accessing current and historical laboratory results and interpretations is deployed for clinical care by authorized parties.

Business Case Alignment

<u>Recommendation 1.0:</u> As the Federal Government develops language in its contracts with health plans and insurers to support the widespread adoption of HITSP interoperability standards, this language should foster, to the maximum extent possible within existing authority, the use of financial incentives or Pay-for-Use programs to incent the adoption and effective utilization of CCHIT certified EHRs. Structural measures should be included in these programs, which may be limited to a specific time frame with the ultimate goal of using process and outcome measures to assess performance.

- **Accept**
- **Table**
- **Reject**

Business Case Alignment

<u>Recommendation 1.1:</u> These Pay-for-Use programs should use reliable, standardized and validated tools which are currently available to assess structural measures: for example, the NCQA's Physician's Practice Connections or CMS' publicly available Office System Survey. When the National Quality Forum endorses a set of structural measures, these should be employed by these programs.

- **Accept**
- **Table**
- **Reject**

Business Case Alignment

<u>Recommendation 1.2</u>: HHS should evaluate Pay-for-Use programs with respect to quality, cost and adoption.

- **Accept**
- **Table**
- **Reject**

June 12, 2007

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

Dear Mr. Chairman:

The Electronic Health Records (EHR) Workgroup presented recommendations to the AHIC during the April 24, 2007 meeting. Recommendations 1.0, 1.1, and 4.0 received considerable discussion and were sent back to the workgroup for additional discussion, clarification and detail. We are pleased to present you with updated versions of Recommendations 1.0 and 1.1. Additionally, we have added another recommendation, 1.2, in support of Pay-for-Use program evaluation. With regard to Recommendation 4.0, the Workgroup will continue to have deliberations and elicit public input, and will bring this recommendation back to the AHIC later this year.

RECOMMENDATIONS

Recommendation 1.0: As the Federal Government develops language in its contracts with health plans and insurers to support the widespread adoption of HITSP interoperability standards, this language should foster, but not mandate, the use of financial incentives or Pay-for-Use programs to incent the adoption and effective utilization of CCHIT certified EHRs. Structural measures should be included in these programs, which may be limited to a specific time frame with the ultimate goal of using process and outcome measures to assess performance.

Recommendation 1.1: These Pay-for -Use programs should use reliable, standardized and validated tools which are currently available to assess structural measures: for example, the NCQA's Physician's Practice Connections or CMS' publicly available Office System Survey. When the National Quality Forum endorses a set of structural measures, these should be employed by these programs.

Recommendation 1.2: HHS should evaluate Pay-for-Use programs with respect to quality, cost and adoption.

Thank you for the opportunity to resubmit these recommendations which begin to address the broad charge of widespread EHR adoption. We look forward to discussing them with you and the members of the American Health Information Community.

Sincerely yours,

Jonathan B. Perlin, M.D., Ph.D., Co-chair, Electronic Health Records Workgroup

Lillee Smith Gelinas, R.N., M.S.N., FAAN, Co-chair, Electronic Health Records Workgroup

April 24, 2007

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

Dear Mr. Chairman:

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

> **Broad Charge for the EHR Workgroup:** Make recommendations to the Community on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers.
>
> **Specific Charge for the EHR Workgroup:** Make recommendations to the Community so that within one year, standardized, widely available, and secure solutions for accessing current and historical laboratory results and interpretations are deployed for clinical care by authorized parties.

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

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

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

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

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

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

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

RECOMMENDATIONS

I. Business Case Alignment

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

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

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

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

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

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

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

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

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

2. Workflow and Culture

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

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

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

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

3. Medico-legal concerns

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

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

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

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

OVERARCHING RECOMMENDATION:

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

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

The workgroup is therefore recommending for consideration of the AHIC:

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

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

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

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

Sincerely yours,

Jonathan B. Perlin, M.D., Ph.D.
Co-chair, Electronic Health Records Workgroup

Lillee Smith Gelinas, R.N., M.S.N., FAAN
Co chair, Electronic Health Records Workgroup

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

American Health Information Community

Confidentiality, Privacy, and Security Workgroup

Recommendations

Kirk Nahra, Chair
Wiley Rein LLP

June 12, 2007

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

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

CPS Workgroup Overview

Broad Charge:

Make recommendations to the AHIC regarding the protection of personal health information in order to secure trust, and support appropriate interoperable electronic health information exchange.

Specific Charge:

Make actionable confidentiality, privacy, and security recommendations to the AHIC on specific policies that best balance the needs between appropriate information protection and access to support, and accelerate the implementation of the consumer empowerment, chronic care, and electronic health record-related breakthroughs.

CPS Recommendation

All persons and entities, excluding consumers, that participate directly in, or comprise, an electronic health information exchange network, through which individually identifiable health information is stored, compiled, transmitted, modified, or accessed should be required to meet enforceable privacy and security criteria at least equivalent to any relevant HIPAA[1] requirements (45 CFR Parts 160 and 164).

[1] Health Insurance Portability and Accountability Act of 1996

CPS Recommendation (Continued)

Furthermore, any person or entity that functions as a *Business Associate* (as described in 45 CFR §160.103) and participates directly in, or comprises, an electronic health information exchange network should be required to meet enforceable privacy and security criteria at least equivalent to any relevant HIPAA requirements, independent of those established by contractual arrangements (such as a *Business Associate Agreement* as provided for in HIPAA).

- **Accept**
- **Table**
- **Reject**

Next Steps

- Answer two key questions moving forward.

1. What constitutes a “relevant” HIPAA requirement for particular “direct participants” in the network?
   - Some persons or entities may have an appropriate reason for not needing to meet a particular requirement.
   - Evaluate the need for exceptions based on testimony, workgroup discussion, and responses to questions posed in the Federal Register.
2. What, if any, additional confidentiality, privacy, security protections may be needed beyond those already contained in the HIPAA Privacy and Security Rules?
   - Consider whether there are important differences in the operation of health information exchange networks that require a baseline standard that is more stringent than the existing HIPAA Privacy and Security Rules.

June 12, 2007

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

Dear Mr. Chairman:

The American Health Information Community (AHIC) has identified and prioritized several health information technology applications, or "breakthroughs," that could produce specific and tangible value to health care consumers. To address these breakthrough areas, the Confidentiality, Privacy, and Security Workgroup (the CPS Workgroup) was formed and given the following broad and specific charges:

> **Broad Charge for the Workgroup:** Make recommendations to the AHIC regarding the protection of personal health information in order to secure trust, and support appropriate electronic health information exchange.
>
> **Specific Charge for the Workgroup:** Make actionable confidentiality, privacy, and security recommendations to the AHIC on specific policies that best balance the needs between appropriate information protection and access to support, and accelerate the implementation of the consumer empowerment, chronic care, and electronic health record related breakthroughs.

INTRODUCTION:

The CPS Workgroup issues the following recommendation as a significant step in our analysis to determine what, if any, additional protections beyond those currently provided are needed to ensure the confidentiality, privacy, and security of individually identifiable health information in an electronic health information exchange environment. This letter provides context for the AHIC as it considers issuing the recommendation to the Department of Health and Human Services (HHS).

Recommendation:

> **All persons and entities, excluding consumers, that participate directly in, or comprise, an electronic health information exchange network, through which individually identifiable health information is stored, compiled, transmitted, modified, or accessed should be required to meet enforceable privacy and security criteria at least equivalent to any relevant HIPAA [FN1] requirements (45 CFR Parts 160 and 164).**
>
> **Furthermore, any person or entity that functions as a *Business Associate* (as described in 45 CFR §160.103) and participates directly in, or comprises, an**

electronic health information exchange network should be required to meet enforceable privacy and security criteria at least equivalent to any relevant HIPAA requirements, independent of those established by contractual arrangements (such as a *Business Associate Agreement* as provided for in HIPAA).

As the prevalence of electronic health information exchange increases, it is clear that the amount of readily available health information and access to it will also increase. The recommendation above began as a "working hypothesis" – a consensus-based approach used by the CPS Workgroup to prove or disprove a concept through public testimony and CPS Workgroup deliberation.

Through several meetings, the CPS Workgroup heard testimony from a variety of stakeholders in an effort to better understand the impact persons and entities in an electronic health information exchange environment could have on the current health privacy and security regulatory structure. Many of the testifiers who spoke to the Workgroup were considered to be "non-*Covered Entities*" under the Health Insurance Portability and Accountability Act (HIPAA). All of them attested to voluntarily complying with the requirements of the HIPAA Privacy and Security Rules (the Rules) in whole or in part in order to conduct business and ensure consumers that health information would be protected. When asked if being covered under the Rules or something equivalent would negatively impact their business, many believed the impact would be negligible, because they were already meeting or exceeding the requirements of the Rules.

Based on this testimony and the other information gathered by the CPS Workgroup, we are recommending that there be a minimum set of standards – a baseline – for participation in an electronic health information exchange network, regardless of a participant's "status" under the Rules. The CPS Workgroup believes our recommendation represents an important step in assessing the obligations that are appropriate for persons and entities participating in such a network that have responsibility for such valuable personal information.

The recommendation above uses the Rules as an initial measure of comparison because the Rules establish a national baseline from which to start our analysis. Our recommendation is not a critique of the Rules, but rather a platform from which the CPS Workgroup can evaluate if, in the future, the overall baseline standard for participating in these networks should be changed to a standard that is different from or exceeds the current Rules. We will be addressing issues related to this baseline in the near future. Additionally, our recommendation is not intended to interfere with or contradict more stringent state laws that pertain to the confidentiality, privacy, and security of health information.

Moreover, as a corollary to our recommendation (particularly the idea that participating entities should be required to meet the "relevant" requirements of HIPAA as a baseline standard), we plan to further refine our position through future meetings (described below in "next steps"). We will determine what, if any, regulatory or practical differences may (e.g., gaps or non-applicable requirements) exist for certain categories of participants and evaluate whether there are specific requirements of the Rules that are not directly applicable to certain entities (e.g., a privacy notice requirement for persons or entities that have no direct relationship with consumers).

RATIONALE:

"Participate Directly"

The CPS Workgroup believes it is important to distinguish between persons and entities that "participate directly" or are "direct participants" in an electronic health information exchange network, and persons and entities whose participation is indirect or tangential.

Persons or entities that "directly" participate in an electronic health information exchange network would include the network itself (or the entity/organization that runs it) and those who engage in and connect to the network for a specified purpose – to store, compile, transmit, modify or access health information from the network. "Indirect participants" contract with "directly participating" persons or entities and receive health information, without accessing the network themselves, but from these "direct participants" solely for the purposes of serving a legitimate business need of the "direct participant."

We offer for illustration the example of a large physician group practice that interacts with its patients and with other providers via a regional health information organization (RHIO). The group practice and the RHIO would be considered direct participants in the electronic health information exchange network. But if the group practice hires an audit firm to conduct an analysis of all the claims it submitted through the network over the past three months for compliance with proper billing practices, the audit firm – whose relationship to the electronic health information exchange network is solely via contract or arrangement with the group practice – would not be considered a direct participant in the exchange.

The Business Associate Model

The CPS Workgroup addressed as part of our recommendation a concern that we have with the role *Business Associates* will play in an electronic health information exchange environment. Under the current regulatory framework there are persons and entities (*Covered Entities*) directly accountable to HHS for failure to comply with the Rules, and *Business Associates* who are only accountable to the terms in their contract with a *Covered Entity*. But in this new electronic environment, some entities who currently qualify as *Business Associates* are responsible for, and directly involved in similar, if not more, activities related to health care information than HIPAA *Covered Entities.* It is the CPS Workgroup's belief that it is not in the public's best interest to hold these entities to different accountability or enforcement standards than *Covered Entities*.

In accordance with the first part of our recommendation, the CPS Workgroup believes that any person or entity whose particular role in an electronic health information exchange network would make them a "direct participant," should be held directly accountable for its actions in a manner similar to those who are *Covered Entities* under HIPAA (i.e., this accountability is independent of any contractual requirements they may have to follow). Thus, the CPS Workgroup does not believe that *Business Associate Agreements* (contracts) will hold these types of *Business Associates* to a standard level of accountability and ensure they adequately protect health information the way a *Covered Entity* must under HIPAA. While we have not at this time prescribed a method to implement the recommendation above (meaning that we have not

reviewed the question of whether this recommendation should be implemented by a new law, a revised HIPAA regulation, a new regulation or through some other means), we believe that these protections should be enforced uniformly across all "direct participants" (i.e., "direct participants" are subject to one set of rules that are enforced independent of contractual or other agreements). Our recommendation is that the same standards be applied – meaning that if some "direct participants" face potential civil or criminal sanctions, then all "direct participants" should face these sanctions.

Although the first part of our recommendation was agreed to without objection, one member of the CPS Workgroup did not share the opinion of the majority and requested that this view be noted for the record – the obligation of a *Business Associate* to comply with any confidentiality, privacy, and security requirements should be enforced through its *Business Associate Agreement* with the person or entity that directly participates in the network.

NEXT STEPS:

The CPS Workgroup considers this recommendation to be one of many confidentiality, privacy and security issues we will present for AHIC deliberation. Over the next several months our approach will consist of research and public comment and testimony to evaluate, at a more granular level, two key questions raised by the recommendation above.

First, we will examine what constitutes a "relevant" HIPAA requirement for particular "direct participants" in the network. Our current approach is to assume that all of the Rules' requirements apply to everyone who "directly participates" in electronic health information exchange networks. However, given that the Rules were written to be applicable to Health Plans, Healthcare Clearinghouses, and Health Care Providers conducting electronic healthcare transactions, we understand that some persons or entities may have an appropriate reason for not needing to meet a particular requirement. In our May 9, 2007 *Federal Register* meeting notice, we posed questions for the public in order to gain more insight into this issue. We plan to begin our discussion at our next meeting.

Second, we will analyze what, if any, additional confidentiality, privacy, security protections may be needed beyond those already contained in the Rules in order to ensure trust in an electronic health information exchange environment. Specifically, we will be addressing whether there are important differences in the operation of health information exchange networks that require a baseline standard that is more stringent than the Rules.

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

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

Sincerely yours,

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

FN1 Health Insurance Portability and Accountability Act of 1996

June 6, 2007

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

Dear Secretary Leavitt:

On behalf of the American Health Information Management Association (AHIMA) and the American Medical Informatics Association (AMIA) we would like to endorse the recommendations being presented by the American Health Information Community (Community) Confidentiality, Privacy, and Security (CPS) Workgroup on June 12, 2007, dealing with privacy and security requirements related to the electronic health information exchange network. These recommendations state:

- *All persons and entities, excluding consumers, that participate directly in, or comprise, an electronic health information exchange network, through which individually identifiable health information is stored, compiled, transmitted, modified, or accessed should be required to meet enforceable privacy and security criteria at least equivalent to any relevant HIPAA[FN1] requirements (45 CFR Parts 160 and 164).*

- *Furthermore, any person or entity that functions as a Business Associate (as described in 45 CFR §160.103) and participates directly in, or comprises, an electronic health information exchange network should be required to meet enforceable privacy and security criteria at least equivalent to any relevant HIPAA requirements, independent of those established by contractual arrangements (such as a Business Associate Agreement as provided for in HIPAA).*

AMIA and AHIMA have long advocated for confidentiality of health records and personal health data and are pleased that leaders from our Associations are serving on the CPS Workgroup. We believe the CPS workgroup has taken the time and steps necessary to provide a sound recommendation to the Community and yourself.

As our two Associations noted in our previous letter to you (March 7, 2007), and in our recent statements on health information confidentiality and personal health records (attached), is it essential that personal health information be fully protected no matter with whom or where it might reside or be transmitted, be it an electronic health record, a personal health record, a health information network, or in some other form. While the CPS recommendation recognizes the floor established by the relevant

HIPAA requirements it cites, it nonetheless establishes a baseline that can built upon to develop consumer trust in the health information exchange envisioned by the President and yourself, and establishes responsibility among the entities involved in such exchange.

We applaud the accomplishments of the Community as it moves quickly forward in 2007 and we strongly support the Confidentiality, Privacy, and Security Workgroup's recommendations being presented on June 12, 2007, and hope the AHIC members will act favorably upon them.

If you have any further questions or concerns that we might address, please contact Dan Rode at (202) 659-9440 or dan.rode@ahima.org. Our thanks for your time and attention to our concerns.

Sincerely,

Bryon D. Pickard, MBA, RHIA, President, AHIMA
Paul Tang, MD, Chairman, AMIA Board
Linda Kloss, RHIA, CAE, FAHIMA, Executive Vice President/CEO, AHIMA
Don E. Detmer, MD, President and CEO, AMIA

CC: David Brailer, MD, PhD
Robert M. Kolodner, MD
Steven Posnack, ONC/HHS
Judy Sparrow, ONC/HHS
Dan Rode, MBA, FHFMA

Att: Statement on Health Information Confidentiality
Statement on Value of Personal Health Records

FN1 Health Insurance Portability and Accountability Act of 1996

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AHIMA American Health Information Management Association®

AMIA

Statement on Health Information Confidentiality
A Joint Position Statement
by
American Medical Informatics Association
American Health Information Management Association
July 2006

The American Medical Informatics Association (AMIA) and the American Health Information Management Association (AHIMA) have a long history of working to protect the confidentiality of individuals' health information and to promote fair information practices. Public confidence that privacy will be protected and that identifiable information will be used only for purposes authorized by the individual, or otherwise permitted by law are essential to ensuring trust in a nationwide health information network (NHIN that facilitates sharing of personal health information (PHI). As the United States progresses from a paper-based system of health records to an electronic environment, AMIA and AHIMA believe that the following principles should be incorporated in all rules, regulations, or laws pertaining to PHI.

Any organization that accesses or stores PHI should abide by the following principles. The organization should:

- Inform individuals, through clear communications, about their rights and obligations and the laws and regulations governing protection and use of PHI.
- Notify individuals in clear language about the organization's privacy practices and their rights in cases of breaches
- Provide individuals with a convenient, affordable mechanism to inspect, copy, or amend their identified health information/records
- Protect the confidentiality of PHI to the fullest extent prescribed under HIPAA, regardless of whether the organization is a "covered entity" as defined in HIPAA, and ensure that the organization and its employees all comply with HIPAA, state laws, and the policies and procedures put in place to protect PHI.
- Use PHI only for legitimate purposes as defined under HIPAA or applicable laws.
- Prohibit the use of PHI for discriminatory practices, including those related to insurance coverage or employment decisions
- Timely notification of individuals if security breaches have compromised the confidentiality of their personal health information.
- Work with appropriate law enforcement to prosecute to the maximum extent allowable by law any individual or organization who intentionally misuses PHI
- Continue to improve processes, procedures, education, and technology so that PHI practices improve over time.

Furthermore, because PHI is expected to flow across organizational boundaries through the NHIN, it is important that the following principles covering information when it is transferred from one entity to another also apply:

- Health information privacy protections must follow PHI no matter where it resides
- Uniform and universal protections for PHI should apply across all jurisdictions in order to facilitate consistent understanding by those covered by such laws and the individuals whose health information is covered by such laws.

About AMIA
The American Medical Informatics Association (AMIA) is an organization of 3,500 health professionals committed to informatics who are leaders shaping the future of health information technology and its application in the United States

and 41 other nations. AMIA is dedicated to the development and application of informatics in support of patient care, teaching, research, and health care administration and public policy. www.amia.org

About AHIMA
The American Health Information Management Association (AHIMA) is the premier association of health information management (HIM) professionals. AHIMA's 50,000 members are dedicated to the effective management of personal health information needed to deliver quality health care to the public. Founded in 1928 to improve the quality of medical records, AHIMA is committed to advancing the HIM profession in an increasingly electronic and global environment through leadership in advocacy, education, certification, and lifelong learning. www.ahima.org

7-31-2006

The Value of Personal Health Records
A Joint Position Statement for Consumers of Health Care
by
American Health Information Management Association
American Medical Informatics Association
February 2007

Position

The American Health Information Management Association (AHIMA) and the American Medical Informatics Association (AMIA) advocate empowering individuals to manage their healthcare through the use of a personal health record (PHR). The PHR is a tool for collecting, tracking and sharing important, up-to-date information about an individual's health or the health of someone in their care. Using a PHR will help people make better health decisions and improves quality of care by allowing them to access and use information needed to communicate effectively with others about their healthcare.

Basic Principles

- Every person is ultimately responsible for making decisions about his or her health.
- Every person should have access to his or her complete health information. Ideally it should be consolidated in a comprehensive record.
- Information in the PHR should be understandable to the individual.
- Information in the PHR should be accurate, reliable, and complete.
- Integration of PHRs with EHRs of providers allows data and secure communication to be shared between a consumer and his or her health care team.
- Every person should have control over how their PHR information is accessed, used and disclosed. All secondary uses of PHR data must be disclosed to the consumer, with an option to opt-out, except as required by law.
- PHR products should be certified by CCHIT to comply with data standards, include a minimum data set, identify each data's source, and meet security criteria consistent with HIPAA
- The operator[FN1] of a PHR must be accountable to the individual for unauthorized use or disclosure of personal health information. The consumers should be notified immediately of breeches in security that could lead to disclosure of personal health information.
- A PHR may be separate from and does not normally replace the legal medical record of any provider.
- Privacy protection of PHR data should follow the data. PHR data must not be used in any discriminatory practices.

Questions and Answers

Why should everyone have a PHR? We believe that all individuals should be able to readily access, understand, and use their personal health information. A PHR allows individuals to be more active partners in their healthcare, and gives them up-to-date information when and where they need it. A PHR provides a single, detailed and comprehensive profile of a person's health status and healthcare activity. It facilitates informed decisions about the care of the individual. It may also reduce duplicate procedures or processes – such as repeated lab tests and x-rays – saving time and money. A PHR helps people prepare for appointments, facilitates care in emergency situations, and helps track health changes.

What media should you use for a PHR? We encourage individuals to begin tracking their health information in whatever format works best for them, even if the choice is paper. We recommend that individuals use an electronic media to facilitate a timely, accurate, and secure exchange of information

across healthcare institutions and providers. PHR information should always be stored in a secure manner just as you would store other confidential personal information such as financial information.

How can an individual choose a PHR supplier? Individuals can create their own PHR, or may be offered one by a variety of sources, such as a healthcare provider, insurer, employer or a commercial supplier of PHRs. Each supplier has different policies and practices regarding how they may use data they store for the individual. Study the policies and procedures carefully to make sure you understand how your personal health information will be used and protected. Policies to look for include privacy and security; the ability of the individual, or those they authorize, to access their information; and control over accessibility by others. If the PHR contains the same information that the doctor has seen, it has more usefulness for tracking purposes than information from insurance forms. For example, insurance claims information may list the diagnosis or medication but not the details (for example, actual blood pressure reading or dose of the medication taken).

What should a PHR contain? Broader than a medical record, the PHR should contain any information relevant to an individual's health. In addition to medical information such as test results and treatments, a PHR may include diet and exercise logs or a list of over-the-counter medications. A PHR should contain the following information:

- Personal identification, including name and birth date
- People to contact in case of emergency
- Names, addresses, and phone numbers of your physicians, dentists, and specialists
- Health insurance information
- Living wills, advance directives, or medical power of attorney
- Organ donor authorization
- A list and dates of significant illnesses and surgical procedures
- Current medications and dosages
- Immunizations and their dates
- Allergies or sensitivities to drugs or materials, such as latex
- Important events, dates, and hereditary conditions in your family history
- Results from a recent physical examination
- Opinions of specialists
- Important tests results; eye and dental records
- Correspondence between an individual and his or her provider(s)
- Current educational materials (or appropriate web links) relating to one's health

Where individuals should begin: A good place to begin is with a visit to www.myPHR.com (a site provided as a free public service by AHIMA) for further information on creating and managing a PHR. We suggest that people find out if their healthcare providers, employer, insurers, or another individual or organization offers a PHR. If an individual needs to obtain copies of medical records themselves, they can contact doctors' offices or each facility where they have received treatment.

Each person can create a PHR at his or her own pace, perhaps starting with the next medical visit. The important thing is to get started.

Note: Because the use of personal health records is an issue of importance to both organizations, AHIMA and AMIA collaborated on the development of this joint position statement.

About AHIMA
The American Health Information Management Association (AHIMA) is the premier association of health information management (HIM) professionals. AHIMA's 50,000 members are dedicated to the effective management of personal health information needed to deliver quality health care to the public. Founded in 1928 to improve the quality of medical records, AHIMA is committed to advancing the HIM profession in an increasingly electronic and global environment through leadership in advocacy, education, certification, and lifelong learning. www.ahima.org

About AMIA

The American Medical Informatics Association (AMIA) is an organization of 3,500 health professionals committed to informatics who are leaders shaping the future of health information technology and its application in the United States and 41 other nations. AMIA is dedicated to the development and application of informatics in support of patient care, teaching, research, and health care administration and public policy. www.amia.org

2-1-2007

FN1 An “operator” could be a healthcare provider, health plan, commercial supplier, government agency, employer, union, fraternal order, and so forth.

Developing a Privacy & Security Framework

Robert M. Kolodner, M.D.
National Coordinator for Health Information Technology

June 12, 2007

HHS Privacy and Security Framework

Responsibilities of the National Coordinator:

*"(iv) Address **privacy and security** issues related to interoperable health information technology and recommend methods to ensure appropriate authorization, authentication, and encryption of data for transmission over the Internet."*

~ Executive Order #13335

Privacy and Security Framework Objectives

A Framework is a basic conceptual structure used to solve complex issues.

Complex Issues:

- To respond to privacy and security expectations.
- To foster adoption of privacy and security practices that promote trust.

The Objective is to build consensus around a set of privacy and security principles to guide the use and disclosure of individual health information in the public and private sector.

Recognized Privacy and Security Instruments

- **OECD:** **O**rganisation for **E**conomic **C**o-operation and **D**evelopment Guidelines on the Protection of Privacy and Transborder Flows of Personal Data.
- **FTC:** **F**ederal **T**rade **C**ommission Fair Information Practice Principles.
- **Markle:** Markle Foundation's Model Privacy Policies for Health Information Exchange.
- **Coalition of Consumer Organizations:** Health Information Technology - Consumer Principles.
- **ISTPA: I**nternational **S**ecurity **T**rust **and P**rivacy **A**lliance Common Terminology in Privacy Requirements.

Examples of Similarities in Principle Names

- Integrity/Security: FTC
- Security/Safeguards: OECD, ISTPA
- Security Safeguards & Controls: Markle

- Accountability: OECD, ISTPA
- Accountability & Oversight: Markle

- Notice: ISTPA
- Notice & Awareness: FTC

Alignment of Themes

- Accountability/Oversight.
- Collection Limitation.
- Data Integrity/Quality.
- Enforcement/Remedies.
- Individual Participation/Control/Access/Correction.
- Openness Transparency/Notice.
- Use Limitation/Consent/Disclosure/ Purposed Specification/Minimization.
- Security/Safeguards/Controls.

Principle Harmonization Methodology

Analysis:

- Conducted cross-instrument mapping at the specific wording level
  - while accommodating variations in wording.
- Considered each set of wording, using the source documents for context, which lead to specific concepts.
- Determined whether to include or exclude the wording/concept in a specific principle.
    - Very few exclusions.
    - Primary reason for exclusion - the wording/concept appeared in another principle and did not warrant duplication.

Principle Harmonization

Principle A						
Include	**Concept**	**Consumers**	**FTC**	**ISTPA**	**OECD**	**Markle**
yes	1st	NP	P	I	NP	I
yes	2nd	I	P	P	I	P
no	3rd	NP	NP	P	NP	NP
yes	4th	P	NP	P	NP	NP
yes	5th	NP	NP	NP	P	NP
yes	6th	I	P	P	P	P
yes	7th	I	I	P	P	P
yes	8th	P	NP	NP	NP	NP
no	9th	NP	P	I	NP	I
		NP = Not Present; **I** = Implied; **P** = Present				

Principle Development Methodology

Currently building a harmonized set of principles.

- Using the harmonized set of wording/concepts, and
- Using the source documents for context.

Federal and Private Collaboration

Next Step:

- ONC will work with public and private stakeholders to build consensus around a harmonized set of principles.

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

American Health Information Community

AHIC Recommendations-Implementation Status Report

Electronic Health Records
Chronic Care
Population Health & Clinical Care Connections

Robert M. Kolodner, M.D.
National Coordinator for Health Information Technology

June 12, 2007

Electronic Health Records Workgroup

Electronic Health Records Workgroup Recommendations Summary

Recommendation

- 1.0 (May 2006) - DONE
- 2.0 (May 2006) - Some Progress
- 2.1 (May 2006) - DONE
- 2.2 (May 2006) - Progress on Target
- 3.0 (May 2006) - Some Progress
- 3.1 (May 2006) - DONE
- 4.0 (May 2006) - DONE
- 1.0 (August 2006) - DONE

STATUS: Done

Recommended that HHS take immediate steps to facilitate the adoption and use of endorsed standards and incentives needed for laboratory data results interoperability.

Status:

- HITSP EHR-Laboratory Results Reporting Interoperability Specification V1.2 accepted by the Secretary in December 2006.
- August 22, 2006 Executive Order 13410: “Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs”.
  - Federal healthcare programs must use recognized HITSP standards in new systems, upgrades and care contracts.

Recommendation 2.0 May 2006 **STATUS:** Some progress

Recommended HITSP identify and endorse a standard for laboratory result reporting for inclusion in the CCHIT interoperability criteria.

Status:

- HITSP EHR-Laboratory Results Reporting Interoperability Specification V1.2 accepted by Secretary in December 2006.
- CCHIT and HITSP have formed a joint workgroup to plan for the incorporation of HITSP Interoperability Specifications in CCHIT interoperability certification criteria.

STATUS: Done

Recommended Federal healthcare delivery systems that provide direct patient care develop a plan to adopt the HITSP endorsed Laboratory Results Reporting Interoperability Specifications.

Status:

- Executive Order 13410 (August 22, 2006).
- Department of Defense, VA, and Indian Health Service have all submitted work plans to Office of Management and Budget for adoption of HITSP Interoperability Specifications recognized by the Secretary.

STATUS: Progress on target

Recommended that Federal Agencies and Departments with health lines of business should include/incent the use of HITSP-approved standards in their contracting vehicles.

Status:

- Executive Order 13410(August 22, 2006).
- ONC working with all agencies that contract for health care services on behalf of the federal government to assure consistent language in health plan contracts.

Electronic Health Records

Recommendation 3.0 May 2006

STATUS: Some progress

AHIC: By September 30, 2006, HHS shall issue guidance on how to achieve patient centric flow of lab results under current CLIA and HIPAA regulations. HHS shall evaluate and report to the Secretary on other changes that could be needed beyond this guidance to achieve the goal of patient-centric data in the longer term.

Status:

- ONC has worked with Centers of Medicare and Medicaid (CMS) to identify the possible models for current and historical lab results exchange. CMS and ONC will identify short and long-range solutions, and issue guidance as appropriate.

STATUS: Done

Recommended ONC contract with the NGA and other state-based organizations to identify and resolve state regulations and practices regarding electronic transmittal of laboratory data.

Status:

- National Governors Association contract initiated October 2006.
- State Alliance convened January 26, 2007.
- Three Task Forces: Health Information Protection, Health Care Practice, Health Information Communication & Data Exchange.
  - Health Care Practice Taskforce will address this issue.

STATUS: Done

Recommended creation of additional AHIC workgroup that would address the cross-cutting confidentiality, privacy and security issues related to all the Community charges.

Status:

- Confidentiality, Privacy, & Security Workgroup convened August 2006.

STATUS: Done

Recommended development of an emergency responder use case.

Status:

- Use Case developed and finalized in December 2006.
- The HITSP Requirement, Design and Standards Selection document for the ER-EHR Use Case is open for public comment until June 14, 2007.
- The HITSP ER-EHR Interoperability Specification will be finalized in November-December 2007.

Chronic Care Workgroup

Chronic Care Workgroup
Recommendations Summary

Recommendation

- 1.0 (May 2006) - Some Progress
- 1.1 (May 2006) - Some Progress
- 1.2 (May 2006) - Some Progress
- 2.0 (May 2006) - Progress on Target
- 3.0 (May 2006) - Minimum Progress to Date
- 3.1 (May 2006) - Minimum Progress to Date
- 4.0 (May 2006) - Progress on Target
- 4.1 (May 2006) - DONE

Chronic Care

Recommendations 1.0, 1.1, 1.2 May 2006 **STATUS:** Some progress

Three recommendations to develop and expand the evidence base for reimbursement of secure messaging.

Status:

- ONC to release Request for Proposal (RFP) in July 2007.
- RFP will test the value of secure messaging and assess merit of different payment methodologies.
- Award will go to three sites.
- Results expected by December 2008.

STATUS: Progress on target

Recommend HHS convene State agencies and professional societies to develop licensing alternatives that will allow the provision of electronic care delivery across State boundaries.

Status

- July 6, 2007, Health Care Practices Task Force of National Governor's Association will make recommendations to State Alliance to reduce licensing barriers to interstate telehealth care delivery.

Chronic Care
Recommendation 3.0 & 3.1
May 2006

STATUS: Minimum Progress To Date

Recommend HITSP define standards for secure patient-clinician messaging transactions & CCHIT establish certification criteria for system interoperability.

Status

- AHIC did not identify secure messaging as a priority for standards development in 2007.
- CCHIT did not identify secure messaging as a priority for certification in 2007.

STATUS: Progress on target

Recommend Agency for Healthcare Research & Quality (AHRQ) conduct a synthesis of current knowledge of health information technology use by elderly, ill, and underserved populations

Status

- AHRQ's Evidence-based Practice Center Request for Task Order: "Barriers and Drivers of Health IT Use for the Elderly, Chronically Ill and Underserved" .
- Put out for solicitation in May 2007.
- Contract award expected July 31, 2007.

STATUS: Done

Recommend HHS work with appropriate organizations to report on secure messaging availability through broadband across the country.

Status

- Federal Communications Commission (FCC) tasked with expanding broadband technology across U.S.
- Current penetration rate is 45%.
- Nationwide, 79% of households have access to high speed connections.
- President's goal is to have broadband access available to all U.S. households by 2014.

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

Population Health & Clinical Care Connections Workgroup

Pop. Health & Clin. Care Connections Workgroup Recommendations Summary

Recommendation

- 1.0, 1.1, 1.2 (May 2006) - DONE
- 2.0 (May 2006) - Some Progress
- 3.0 (May 2006) - Minimum Progress to Date
- 3.1 (May 2006) - Minimum Progress to Date
- 4.0 (May 2006) - Some Progress
- 1.0, 1.1, 1.2 (October 2006) - Some Progress
- 2.0 (October 2006) - Some Progress
- 3.1 (October 2006) - Some Progress

Pop. Health & Clin. Care Connections

Recommendation 1.0, 1.1, 1.2 May 2006

STATUS: Done

By 6/30/06, HHS, in collaboration with Federal, State, and local governmental public health agencies and clinical care partners, should establish, convene, and oversee a Data Steering Committee to carry out the following activities:

- identify the data elements and the appropriate filtering of data from ambulatory care settings, emergency departments and laboratories, as well as hospital utilization data needed to enable the key public health functions
- HITSP should identify the technical specifications for these initial data requirements by 9/30/06.
- CDC and others should provide HITSP with the public health expertise and funds needed to perform this task.
- Identify the data sources and requirements necessary to allow for collection of a more limited set of data across a broader geographic area.

Status

- Biosurveillance Data Steering Group (BDSG) chartered.
- Recommendations presented to AHIC in October 2006.

Pop. Health & Clin. Care Connections Recommendation 2.0 May 2006

STATUS: Some progress

For the purposes of the Biosurveillance Breakthrough Initiative, the CDC should establish memoranda of understanding (MOU) to enable simultaneous data flow from data providers to local, State, and Federal public health entities while preserving traditional investigation roles at local and State public health levels, whereby local and State jurisdictions continue to have lead roles in public health investigations.

Status

- MOUs in place between CDC and all data providers sending data to BioSense
- Three states/locals public health jurisdictions receiving simultaneous data flow from data providers (4 more in progress), broader implementation is in progress, but many states/local public health jurisdictions don't have infrastructure in place to accept data feed.

Pop. Health & Clin. Care Connections Recommendation 3.0 May 2006

STATUS: Minimum Progress To Date

HHS should develop sample data use agreements to facilitate the sharing of data from health care providers to local, State and Federal public health agencies. HHS should also offer practical implementation guidance to data providers and State and local public health agencies to address HIPAA concerns about transmitting data (with obvious identifiers removed) for public health purposes, to enable simultaneous data flow from data providers to local, State, and Federal public health entities while preserving traditional investigation roles at local and State public health levels, whereby local and State jurisdictions continue to have lead roles in public health investigations

Status

- No action taken.

Pop. Health & Clin. Care Connections Recommendation 3.1 May 2006

STATUS: Minimum Progress To Date

HHS, in collaboration with privacy experts, State and local governmental public health agencies and clinical care partners, should develop public communication materials to educate the general public about the information that is used for biosurveillance including the benefits to the public's health, improved national security, and the protection of patient confidentiality by 9/30/06.

Status

- Associate Director for Communication Science in NCPHI/CDC will collaborate with partners to develop communication message(s).
- CDC will convene meeting with partners in February 2008 & develop a 1-2 page communication message for use with public communications

Pop. Health & Clin. Care Connections Recommendation 4.0 May 2006

STATUS: Some progress

The CDC, State and local governmental public health agencies, and clinical care partners with firsthand experience in managing ongoing biosurveillance programs should design and conduct evaluations of the biosurveillance breakthrough. These parties should establish goals, develop outcome measures and establish metrics for evaluation of the breakthrough by 9/30/06.

Status

- The BioSense Round Table Meeting planned for June 19, 2007, will include discussions about goals, outcome measures and evaluation metrics of the biosurveillance breakthrough. Additional discussions are planned for the February 2008 meeting.

Pop. Health & Clin. Care Connections
BDSG Recommendation 1.0, 1.1, 1.2
October 2006

STATUS: Some progress

The U.S. Department of Health and Human Services, in collaboration with state and local governmental public health agencies, should work with clinical care partners:

- to implement the short term Minimum Biosurveillance Data Set (MBSD) and enable simultaneous data access to local, state and federal public health entities for Biosurveillance purposes.
- should evaluate implementation models, costs, and determine availability of resources and establish a plan to effect a short term MBDS implementation.

Status

- BDSG Recommendation 1.0 regarding the Secretary of HHS should adopt MBDS is completed.
- Significant progress made to collect the MBDS at BioSense hospitals, 365 hospitals are at some stage of implementing the MBDS.
- CDC will provide extramural funding as announced in RFP Accelerating Public Health Situational Awareness.
- CDC/NCPHI Centers of Excellence in Informatics are currently implementing the MBDS.

Public health agencies and partners who implement the short term MBDS should filter out some components of the following data elements as appropriate: date of birth, age, zip code, and diagnosis/injury code.

Status

- CDC will provide extramural funding as announced in RFP Accelerating Public Health Situational Awareness to look at appropriate methods for filtering sensitive and confidential information that may be necessary for public health use.

 STATUS: Some progress

CDC should, no less than annually, involve local, state and federal public health agencies and clinical care partners, in an MBDS monitoring process for biosurveillance usefulness, and make appropriate modifications as evidence develops to support such modifications.

Status

- MBDS will be discussed at BioSense RoundTable Meeting on June 19, 2007.
- February 2008 meeting planned with local, state, federal, and clinical care partners to discuss usefulness of MBDS.