The Community

American Health Information Community

January 22, 2008
8:30 a.m. - 1:00 p.m.

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

TABLE OF CONTENTS

American Health Information Community

January 22, 2008

8:30 a.m. - 12:45 p.m. (EST)

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*

8:50 a.m. **Comments** – *Kerry Weems, Vice-Chair, Acting Administrator*
Centers for Medicare and Medicaid Services

9:00 a.m. **Comments** – *Robert M. Kolodner*
Office of the National Coordinator for Health Information Technology

9:15 a.m. **Health IT Physician Adoption Survey Update**

- *David Blumenthal, Massachusetts General Hospital*
- *Karen Bell, Office of the National Coordinator for Health Information Technology*

9:45 a.m. **Update: Revised 2006 and Recently Approved 2007 HITSP Interoperability Specifications**

- *John Loonsk, Office of the National Coordinator for Health Information Technology*
- *John D. Halamka, Chair, HITSP*

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

10:30 a.m. **Workgroup Presentations**:

Population Health/Clinical Care Connections Workgroup Recommendations

- *Leslie Lenert, Centers for Disease Control and Prevention, Co-Chair*

Population Health/Clinical Care Connections Workgroup Roadmap & Timeline

- *Leslie Lenert, Centers for Disease Control and Prevention, Co-Chair*

Electronic Health Records Workgroup Recommendations

- *Jonathan Perlin, HCA, Inc., Co-Chair*
- *Karen Bell, Office of the National Coordinator for Health Information Technology*

11:45 a.m. **Findings from the *Enhancing Data Quality in EHRs Report*: Recommendations Update**

- *Jonathan Perlin, HCA, Inc., Co-Chair, EHR Workgroup*
- *Deven McGraw, National Partnership for Women and Families, Co-Chair, CPS Workgroup*

12:15 p.m. **Workgroup Recommendations Status Report:**
Consumer Empowerment Workgroup – January 2007 Recommendations

- *Nancy Davenport-Ennis, Co-chair*

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

12:45 p.m. **ADJOURN**

Meeting Report
American Health Information Community
November 13, 2007

The American Health Information Community (AHIC), a federally chartered commission formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within 10 years, held its 17th meeting on November 13, 2007, at the Sheraton Chicago Hotel and Towers/Cityfront Center, Ballroom 6, 301 East North Water Street, Chicago, IL 60611.

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 U.S. Department of Health and Human Services (HHS) on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting focused on: (1) an update on Nationwide Health Information Network (NHIN) trial implementations, (2) an update on the Certification Commission for Healthcare Information Technology (CCHIT), (3) a discussion of a health information technology (HIT) physician adoption survey, (4) a presentation on advancing the national framework for uses of health data, and (5) recommendations to HHS on a data stewardship framework.

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

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

Call to Order

Joining Secretary Leavitt around the table were:

Robert Kolodner, MD, National Coordinator for Health Information Technology

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

Scott Serota, President and CEO of the Blue Cross Blue Shield Association

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

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention

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

Kevin Hutchinson, CEO of SureScripts

Craig Barrett, PhD, Chairman of the Board, Intel

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

Dan Green, Deputy Associate Director, Office of Personnel Management (Mr. Green represented Linda Springer, Director of the Office of Personnel Management)

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

S. Ward Casscells, MD, Assistant Secretary for Health Affairs, Department of Defense

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

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

Jason Mitchell, MD, Assistant Director, Center for Health Information Technology, American Academy of Family Physicians (Dr. Mitchell represented Douglas Henley, MD, Executive Vice President, American Academy of Family Physicians)

Cita Furlani, Director Information Technology Laboratory, National Institute of Standards and Technology, U.S. Department of Commerce (also represented by Bettijoyce Lide, Scientific Advisor for Health Information Technology, NIST)

Introductory Comments

HHS Secretary Michael O. Leavitt
Secretary Leavitt opened the meeting by thanking participants for either coming to Chicago to participate in person, or for joining the meeting via Webcast/teleconference. He announced that through the Centers for Medicare and Medicaid Services (CMS), HHS put forth a proposal to adopt new standards for aspects of e-prescribing under the Medicare prescription drug benefit. This development is an important initiative tied to AHIC activities. The Secretary noted that implementation of the first set of e-prescribing standards began last year. At that time, a pilot was launched to involve providers, pharmacies, and plans to test these standards. Through the pilot, lessons were learned regarding the strengths and weaknesses of that first set of standards; these lessons were incorporated into the new proposed set of e-prescribing standards. All providers and pharmacies transmitting prescriptions electrically for Medicare will have to comply with these new CMS standards. The Secretary commented that adopting this rule will move closer to the connective system that AHIC is working towards, and will represent an improvement in the safety and quality of health care that all of patients receive.

Next, Secretary Leavitt informed the Community that 2 weeks ago, a new Medicare demonstration program was announced that promotes adoption of HIT. The demonstration will award providers who use certified EHRs to develop high-quality care in small- to medium-sized practices across the country. This is where most Americans get their health care, and it is also where there are the lowest adoption rates of HIT. Under the demonstration, Medicare will pay higher rates of reimbursement to physicians who use certified EHRs. The demonstration will involve 1,200 small- to medium-sized physician practices and reach as many as 3.6 million patients, making this a significant step forward. Many private insurance companies have, since the announcement, indicated that they plan to take similar, parallel actions.

The Secretary thanked the CCHIT for their work in creating the standards for certified EHRs. This is the designation that will be used to determine those practices that are qualified for this demonstration. Last

year, the CCHIT certified roughly 75 percent of the EHR products that are now being used by doctors. Secretary Leavitt reported that the products already certified by the Commission account for approximately 25 percent of those used in hospitals. The percentage of certified hospital EHR systems will increase fairly quickly, just as the percentage of outpatient systems has; Secretary Leavitt noted that momentum in this area is growing.

Secretary Leavitt noted that he would not be announcing the AHIC 2.0 award at this meeting as had been planned. Agreements are still being finalized, and the Secretary intends to announce the award before the next AHIC meeting. A broad coalition of significant players has been created that will convene in an aggressive effort to ensure that the AHIC 2.0 deadline is met.

FCC Chairman Kevin Martin

In introducing Federal Communications Commission (FCC) Chairman Kevin Martin, Secretary Leavitt explained that the FCC is working to fund the delivery of broadband connectivity to rural and underserved communities, placing a particular emphasis on health care providers. The Secretary thanked Chairman Martin for attending this AHIC meeting, and commented that there is not another part of the U.S. economy in which the government could invest in the development of this type of infrastructure that will have more rapid or lasting social and economic benefits.

Chairman Martin acknowledged the importance of the role that the FCC is playing in its efforts to deploy the infrastructure that can make some of AHIC's goals possible. He also characterized the work that AHIC is doing as not only important for health care, but also for the overall economy. Chairman Martin has made broadband deployment the FCC's top priority, given that broadband technology is a key driver of economic growth, productivity, and innovation. In April of 2004, the President issued an Executive Order to provide leadership for the development and nationwide implementation of an interoperable HIT infrastructure, and a key goal of AHIC is to help Americans obtain access to electronic medical records (EMRs). To receive the benefits of EHRs, Chairman Martin explained, health care providers must have access to underlying broadband infrastructure. Without this underlying infrastructure, efforts to implement EHRs cannot succeed (this also is why creation of the NHIN is a key element in the national HIT agenda, which the FCC supports).

It is the FCC's vision to see that every health care facility in the nation is connected to each other with broadband access. To that end, on September 26, 2006, the Commission launched a rural health care pilot program to provide funding for up to 85 percent of an applicant's cost of deploying a dedicated broadband network for connecting health care providers in rural and urban areas with a state or region. It also provides for funding of up to 85 percent of the applicant's cost of connecting the state or regional network to Internet2 and/or National LambdaRail, the dedicated national backbones, as well as the public Internet. In an overwhelming response, 81 regional and state health networks across the country have submitted applications. The FCC is preparing to dedicate significant funding to spur the deployment of broadband networks for these health care facilities.

Chairman Martin has proposed dedicating more than $400 million over the next 3 years to the construction of broadband networks for statewide and regional health care networks in 42 states and 3 U.S. territories, all connected to the national backbone providers. The FCC, through this funding, will connect more than 6,000 health care providers across the country, including hospitals, clinics, public health agencies, universities and research facilities, behavior health sites, community health centers and others. These networks will support telehealth, telemedicine, clinical care, consumer and professional health education, public health, health administration, research, and EMRs. The pilot program is structured to encourage applicants to aggregate the needs of health care providers in both rural and urban areas and select the most efficient technology based upon their network needs. For example, the pilot program encourages multiple health care providers in a state or region to join together, allows flexibility

and network designs that will be able to meet the specific needs of health care providers, encourages the creation of self-sustaining networks, and encourages broadband connections (particularly for rural health care providers).

Chairman Martin commented that this program aligns with the goals of the HHS and AHIC, which is why he believes it is important that the organizations participating in this pilot program use their resources in a manner consistent with the HIT initiatives being promoted by HHS. This includes the implementation of interoperable HIT systems and the use of certified HIT products. Additionally, the participants are expected to coordinate with HHS and the Centers for Disease Control and Prevention (CDC) during public health emergencies such as pandemics and bioterrorism events.

Discussion Highlights

"This is a potentially powerful energizing opportunity for the creation of our network…There is a need for us to make certain that the standards that we're developing for health information technology records are incorporated. How do we actually go about assuring that those standards are built in? Would there be opportunities for these grants to be conditioned upon their acceptance of those standards?"
– Secretary Leavitt

"I don't think that we're able to explicitly condition it on having … the records, but we have conditioned it on trying to coordinate with HHS and CDC, and [applicants] actually are required to have meetings to understand both the process and opportunities, and the best way that we could end up coordinating them. Now, the grants, themselves: because they are through the Telecommunications Act, which has a different standard, we can't explicitly condition on the grant of coming into compliance with the work of another agency, but I think that we're going to be able to accomplish the same goals by the close coordination and requiring them to at least go through the processes of meeting with HHS." – Chairman Martin

"We had a very effective program to connect schools and libraries throughout the country using broadband, but on the health care side, we've actually had a significant amount of money that's gone underutilized or not fully utilized. And I think the key to trying to unlock that was actually to try to think about this in terms of networks of networks, where we're trying to connect rural health care facilities back to the urban facilities, and paying for that—for those regional networks as opposed to just individual grant applications." – Chairman Martin

"[VHA has] over 600 small and rural hospitals in our network. And I'm curious, just as a practical application, how we could be supportive of the implementation of the pilot. We can perhaps take it offline, but I have to tell you, this is really exciting for our rural providers." – Ms. Gelinas

"I appreciate it, and we should end up following up on how you can end up being most supportive and seeing which ones of those clinics that you're talking about may actually already be implemented in one of the different networks that we're trying to provide." – Chairman Martin

CMS Acting Administrator and AHIC Vice Chair Kerry Weems

Mr. Weems announced that this morning, proposed standards for e-prescribing and for formulary and benefits and medication history were put on display in the *Federal Register*. The availability of a standard for formulary and benefits will enable the prescriber to see upfront which drugs are covered under a beneficiary's drug plan—in this case, Medicare—as well as a list of alternative drugs that would allow the provider to substitute a generic drug. Mr. Weems noted that this type of information will streamline prescriber workflows, eliminating calls to the plans, as well as callbacks from pharmacies. Although e-prescribing is voluntary under Medicare, if prescribers and pharmacies transmit subscriptions for Medicare-covered drugs electronically, they are required to comply with any standards that are in

effect. Four more standards are still being considered, and Mr. Weems expressed hope that the normal commenting process will occur quickly so that these rules can be in place soon.

Mr. Weems also described the Medicare demonstration project. The focus over the next several months is going to be on recruiting 12 communities; then CMS will work with those communities to recruit 100 participating physicians. By early winter, it is hoped that the criteria will be in place for "wired for wellness" communities. Bonuses will be paid to physicians who use EHRs: initially for reporting on quality standards, and then later, on pay for performance. This demonstration serves as a reminder that an EHR is not an end in itself. The end is patient safety and overall performance of the health care system.

National Coordinator for Health Information Technology Dr. Robert Kolodner
Dr. Kolodner welcomed new AHIC member Cita Furlani, who is representing the Department of Commerce and is the Director of the Information Technology Laboratory at the National Institute of Standards and Technology (NIST). He also announced that Dr. Chuck Friedman has joined the Office of the National Coordinator (ONC) as the new Deputy National Coordinator.

Dr. Kolodner noted that the Community received the requested report from the Institute of Medicine (IOM) that evaluated standards-setting activities and highlighted some of the issues related to pacing, depending on the complexity of the standards that the Community will be considering. In its report, the IOM recognized that ONC and HHS have advanced the national HIT agenda over the last 3 years and have accelerated the development and advancement of standards. The report also acknowledges that AHIC has helped to launch several standards related to organizations, has established a process that did not previously exist for harmonizing and identifying those standards, and has taken a full cycle of standards development into the implementation process. Dr. Kolodner announced that Secretary Leavitt is scheduled to recognize the first set of interoperability standards in December of 2007, before the next AHIC meeting. These standards will then be incorporated into the ambulatory and the inpatient certification criteria starting in mid-2008. In addition, the IOM recommended that the ONC develop a strategic plan to guide the national HIT agenda, and develop a security and privacy framework. Both of those recommendations are now being acted on.

Dr. Kolodner also noted that the Community received a report in September from the Population Health and Clinical Care Connections Workgroup with some recommendations that are still being considered and will be discussed at the January AHIC meeting.

Approval of September 18, 2007, Meeting Minutes

Minutes from the September 18, 2007, AHIC meeting were distributed, reviewed by Community members, and approved unanimously with no changes.

NHIN Trial Implementation Update

Dr. John Loonsk, Director of ONC's Office of Interoperability and Standards, reported that the awards for the first nationwide health information network exchanges (NHIEs) that will be participating in the NHIN cooperative have been announced. The following health information exchanges (HIEs) have been awarded and are participating in this process:

- New York E-health Collaborative (New York State)
- Lovelace Clinic Foundation (New Mexico)
- West Virginia Health Information Network (West Virginia)
- North Carolina Health Information and Communication Alliance (North Carolina)
- MedVirginia Health Information Exchange (Central Virginia)
- Delaware Health Information Network (Delaware)

- Long Beach Network for Health (Long Beach and areas of Los Angeles)
- CareSpark (tricities region of Eastern Tennessee and Southwest Virginia)
- Federal NHIE (DoD, VA, DHHS, others including participating Indian Health Service regions).

Others also have indicated an interest in participating, according to Dr. Loonsk.

The NHIN is currently identifying the specific core services (i.e., that minimal set of national standards that need to be advanced to have a network of networks) and has identified, through the course of the prototype work from last year, four basic standards that need to be advanced to support networks working together. Dr. Loonsk explained that many of the HIEs have rightfully been thinking about activities in their own jurisdictions, and the NHIN is trying to create a single set of standards that would:

- Identify the services for looking up patient data across HIEs.
- Support the retrieval and delivery of that data.
- Standardize consumer access controls, so the consumer can have a say in who can access their personal health information, and whether they choose to or not choose to participate in the electronic network exchange.
- Create guidelines for reporting and other uses of electronic data.

Dr. Loonsk stressed that this is a network of networks, not a central infrastructure. By the end of this first year's performance, it is hoped that the technical obstacles for health information exchange between the participating HIEs have been removed. Some critical leadership roles for the HIEs have been identified. The Core Content Working Group is being led by the representatives from the Lovelace Clinic as well as the New York Healthcare Information Collaborative. The Core Technical and Security Working Group has Co-Chairs from West Virginia and from the federal health NHIE. The Data Use Working Group is being led by representatives from the North Carolina Health Information and Communications Alliance and MedVirginia. Testing is being advanced in conjunction with representatives from NIST, as well as the Indiana University and the Indianapolis Health Information Exchange.

Dr. Loonsk explained that the Centers for Disease Control and Prevention (CDC) is another partner in the project that will help advance the vision of a reusable foundation, an infrastructure that can be used to advance public health needs even beyond creating a method for provider information exchange in individual health information access.

Liesa Jenkins of the CareSpark Health Information Exchange explained that CareSpark started approximately 4 years ago and was one of the early participants in the e-Health Initiative. The goals for their community and region align very closely with the e-Health Initiative goals (engaging the clinicians, engaging the patients, working on public health, and aligning financial incentives). It has been important for CareSpark to stay connected with activities at the federal level, because the organization straddles state lines of not only Tennessee and Virginia, which is where the bulk of their providers are, but also North Carolina, West Virginia, and Kentucky. That is why CareSpark participated in the first round of the NHIN prototypes. Ms. Jenkins indicated that it was a challenge for many of their small, entrepreneurial organizations with few resources to learn how to work with a large corporation and federal contracts. However, the group has been successful in its demonstration.

Ms. Jenkins explained that the process was valuable because CareSpark and others in the region would not otherwise have had the ability to keep up to date with the standards that were being defined, much less have a voice in their development and contribute to them. Secondly, it allowed CareSpark to connect with other communities engaged in similar activities, which allowed them to build not just a technical network, but the human infrastructure and connections between people that Ms. Jenkins believes are key to success. Third, the initiative brought awareness and education about HIT to their region. Ms. Jenkins

has seen an increase in adoption of EMRs among physicians in CareSpark's rural area, and a growing awareness about issues of privacy and security among citizens in the community.

The initiative has educated local elected officials as well. CareSpark worked with Virginia and Tennessee (the Governor of Tennessee serves as the Co-Chair of the National Governor's Association State Alliance for e-Health). Their involvement in NHIN1 and now NHIN2 has helped them serve as a conduit for those state officials to align what they are doing, what CareSpark is doing, and what is happening at the national level. Ms. Jenkins also noted that CareSpark is very interested in how it connects with the regional Veterans Administration (VA) medical center, which is an important partner in this process.

Maggie Gunter, CEO of the Lovelace Clinic Foundation, explained that her organization is devising solutions to improve health care quality, cost effectiveness, and efficiency, and is pioneering the sort of disease management that is integrated into group practices every day. Lovelace applied for Agency for Healthcare Research and Quality (AHRQ) implementation funding to create a means for sharing information across its community. The resulting grant was in the form of matching funds, so that the community was required to support and participate in the project. Intel participated as well, demonstrating that the Lovelace Clinic Foundation felt that employers had a critical role to play, not just health care organizations.

Ms. Gunter reported that after three years, the Lovelace Clinic Foundation has made significant progress in establishing the community governance and trust necessary, given that the field of providers are in some cases competing with each other and have diverse points of view and motivations. The Foundation has established the basic technology infrastructure and conducted some pilot information exchange programs. There also have been collaborative efforts with the New Mexico Department of Health, and with New Mexico Governor Bill Richardson, who is trying to pass legislation to reform health care in the state and increase uninsured coverage. The state is putting a plan together to require participation in EHRs and HIE as a way to increase efficiency and to cover more uninsured patients. Ms. Gunter noted that New Mexico is one of the poorest states and has one of the highest levels of uninsured and Medicaid recipients.

In terms of progress, Ms. Gunter indicated that the community collaboration and matching funding have not yet been as extensive as hoped. Plans called for a community-wide disease management system and a fully operational exchange to provide comprehensive information across various health settings, available to the physician at the point of care. It was also hoped to have had a patient portal developed by now, especially for patients with asthma and with chronic diseases like diabetes, so that they could better self-manage their own illnesses. Ms. Gunter emphasized that Lovelace has not given up on accomplishing these goals or on the importance of a health information exchange. She did acknowledge that building HIE is more about the sociology than the technology, and that innovation is challenging, especially when it requires reaching consensus among many different community organizations with diverse and sometimes competing interests.

Ms. Gunter noted that regional health information organizations (RHIOs) across the country are taking longer than expected to develop into fully operational systems with solid business cases. Federal grants and contracts alone are not the answer, but because of the expense involved and the technology required, federal support is critical for moving RHIOs towards solid business models.

Ms. Gunter characterized the project's aggressive one-year timeline as both scary and wonderful. The timeline allows participants to show the nation that HIE both within and across states is feasible; it also requires them to quickly come into compliance with standards. This timeline is only achievable through a very collaborative effort that allows participants to share their expertise, which is helpful because each individual participating practice has limitations and constraints in personnel and expertise. Another

significant strength in the project's model is that each site is required to create its own business model depending on the needs of its community, which will ensure that the interoperability that has been created is sustainable after the project's grant funding is over. Ms. Gunter stressed that is essential to engage both large national employers and local employers in these projects, given how much U.S. employers have at stake as health care costs continue to escalate. Some companies are unable to compete in the global market because of the enormous amounts of money that they must spend on health care. Corporate participation is also important because corporations have expertise in the area of business models.

Secretary Leavitt noted that Google and Microsoft, among others, are beginning to develop platforms for personal health records. He asked Dr. Loonsk for an update on progress in the ability to send data for health exchanges like the ones being created through the NHIN projects to such private platforms. Dr. Loonsk indicated that this has been part of the NHIN vision from the start. With the connectivity and the single set of standards being created through the NHIN projects, the private "health vaults" will have access (with the appropriate controls) to all the networked hospital and ambulatory care data. Without that access, the health vaults will not be as valuable. Dr. Loonsk also noted that the importance of the standards being developed will become self-evident to companies like Google and Microsoft.

Discussion Highlights

"When I talk to legislators and citizens about this, they kind of nod and say, 'That's really important. I know how frustrated I am. I can never get all my records wherever I go,' and mostly, they're surprised and dismayed that this doesn't already occur. [They say] 'Well, I just supposed that we already had this kind of linkage across places. We have it with Jiffy Lube. Why don't we have it with our health care data?'" – Ms. Gunter

"If the health records bank is the model, our region is quite likely to fall even farther behind than we are now, because we have a lot of folks who really don't have the education, the income level, the computer access, and all the other things it would take to manage that. So we're literally building on the relationship between the clinician and the patient to figure out how to integrate that information from the patient and the clinical setting." – Ms. Jenkins

"What are you doing, within your programs, to engage consumers as you're building the networks, and in trying to measure with consumers and patients, what are they looking for specifically at the end of the day so that they do want to become engaged, and they do feel comfortable with the process?"
– Ms. Davenport-Ennis

"We have been very publicly now, for almost five years, talking to this about our community in the media, in presentations to everything from civic clubs to seniors groups to Sunday school classes…We've done fairs and focus groups, and solicited input from people in our community…about what benefits would this bring to you, what risks do you perceive, what kind of information would you be willing to share, with whom, for what purpose…So we have been very, very public in about what we're doing."
– Ms. Jenkins

"We have taken a much more active consumer role in the last year, as we have understood that the concerns nationally about privacy are very substantial. It is not only what you can do from a HIPAA standpoint, but what is wise to do from a consumer standpoint…We're working with lots of different stakeholder groups, consumers, about privacy; but trying to find a way to balance the needs of privacy…And every one of us in our family has somebody that probably has a mental illness or AIDS or something of that sort, where there is a great concern that they have about having their data shared."
– Ms. Gunter

"There were a lot of comments made by other networks, RHIOs, and HIEs about the value of NHIN2 in moving their own strategies forward, and whether or not they could be supportive of participating in the trial implementations in the next phase, given the pressures they're under from a business perspective, as well as the demonstrations and the implementation of the standards that they feel they need to move forward with. What made these two organizations or other organizations feel differently to participate in these implementations, which we all feel are very important?" – Mr. Hutchinson

"I think we also have a philosophy of collaboration, and we know that it takes work at various levels, but even more importantly for us are really kind of two things. Number one was probably timing...[we had] done a lot of the planning and tracking along pretty closely, so the timing for us was a good match with what NHIN2 was proposing. The other thing was…my board and volunteers and partner organizations were very adamant about this, too: only if it meets the needs and priorities for our community. The outcomes that we know we need to get in health improvement and cost savings, those use cases have to line up with our needs. If they don't, it's just a distraction for us to work on something that's not that important to us. Those were really the criteria." – Ms. Jenkins

Certification Commission for Health Information Technology Update

Dr. Mark Leavitt, Chair of the CCHIT, announced that one week ago, the first inpatient EHR products were certified. Last year, the CCHIT worked on ambulatory products for physicians' offices, and this year they have started working on products for hospitals. Certifications are announced on a quarterly basis, and six hospital EHR products have now been certified. Four are full certifications, meaning they are existing products already in use in the market. Two of them are what CCHIT terms "pre-market certifications," meaning that they are new products. The Commission will wait until these new products have been in use with at least one customer for 45 days who will verify it. Then, CCHIT will issue a full certification.

In speaking to the vendors, the CCHIT learned that this certification initiative was a primary driver in the decision to invest in new product development. Mr. Leavitt commented that the Commission is actually encouraging capital investment in health information technology. In the ambulatory sector, in the first four quarters, the CCHIT certified 44 percent of the vendors who deliver the product used by more than 75 percent of the doctors using EHRs. There were about 200 vendors of ambulatory care EHR products.

Mr. Hutchinson explained that in the hospital market, there are only about 25 vendors, so the six certified vendors represent 24 percent of the total. So in the first quarter, the CCHIT is ahead of the pace it set in the ambulatory area, in terms of the percentage of vendors involved. Applications were being accepted for the next round until November 14, 2007, and several applications have already been received. In the ambulatory sector, the CCHIT updated the criteria in 2007. In particular, standards-based e-prescribing is required. Nine products have been certified, and about six more are in process. The total number of ambulatory products now certified is nearly 100.

Mr. Hutchinson then updated the Community on the development work for 2008 standards. In e-prescribing, standards will also include medication history and formulary checking beginning in July 2008. The Commission is adding four new domains this year—the HIEs or networks, plus three areas which the marketplace requested of the CCHIT (emergency department systems, child health care, and cardiovascular medicine). The CCHIT received about 1,000 public comments to the environmental scans, which is the first step in drafting the criteria. Mr. Hutchinson expects the first draft to be released on November 21, 2007, followed by a 30-day comment period.

To ensure that interoperability testing is carried out thoroughly, The CCHIT announced a collaboration with the MITRE Corporation, a nonprofit, federally funded research and development organization. The

MITRE Corporation will be the technical lead on the project to develop testing tools in open source code. A kickoff teleconference announcing this project was scheduled for November 15, 2007.

Mr. Hutchinson summed up the progress in accelerating HIT adoption by pointing to the financial incentives that are starting to emerge from both public and private payers—particularly the announcement made earlier from the CMS about their pilot project. States and regions are working with the CCHIT to develop their initiatives. Finally, the Certification Commission is working with Ms. Karen Bell at the ONC to examine the possibility of malpractice premium discounts for physicians using EHRs.

Discussion Highlights
"Tell us about volunteer fatigue. How are we doing on that?" – Secretary Leavitt

"We're actually doing okay on it. We became aware of the issue fairly early on, because so many initiatives started and they all depended on volunteers. So we added staff this year, last July, so that the volunteers didn't have to do quite as much homework. And we also added new areas so that people could focus on what they cared about most. A new privacy and compliance group, for example. Volunteers are the key resource of CCHIT, and you really have to monitor how happy they are…It's not easy, but we're not hearing that they're fatigued." – Mr. Leavitt

"Our goal has been to get through three complete turns of the crank from use case all the way to [the CCHIT] where it comes together. Could you give us an assessment of where you think we are right now? Can we get the three turns of the crank if we just keep turning? Are we pushing too much material through it? What about our pace and productivity?" – Secretary Leavitt

"I think actually the pace now is right. The start was [challenging], because we tried to start things in parallel that people thought should be sequential, but you couldn't make them sequential. But actually it's lined up very much now. So the use cases coming out of the Community now are the ones that are real practical things that we can drive a standard into the HIT systems about. And so I think that 2008 is the year that you'll actually see all the pieces." – Mr. Leavitt

"I asked the NHIN panel about the number of new large technology players who are seeing an opportunity in the personal health records space. In my judgment, that will be the energy that ultimately drives this whole thing. But they have to have the ability to populate those electronic health records, or personal health records with data coming from the 98 systems that you have now certified. Could you elaborate some on just how much work are you seeing between those systems and those large technology providers, and the extent to which this system of standards is necessary to enable that?"
– Secretary Leavitt

"The system of standards is needed, not only to enable it, but to make sure that patients have freedom of choice. So we wanted to actually energize competition between providers for not just quality and safety, but [also convenience]…You really want those standards now, because you don't want it to evolve into a proprietary world, where it's not as competitive. So I think we need them very much." – Mr. Leavitt

"I'm still looking at all of the data that suggests that thousands or tens of thousands of people in this country are impacted each year because we don't have 100 percent e-prescription. And so my question is, this is the 17th meeting of this body. We've discussed this at meetings number one, two, three, four, then we went dark, and now we're back at [meeting] 17. Where are we?" – Dr. Barrett

"Right now we don't require it as a condition of writing a prescription, but if you write an electronic prescription, then you must use our standards. And certainly, there is a considerable push out there to do

that…We are not completely deaf to those exhortations, but we're not yet in a position to require it." – Mr. Leavitt

"[the IRS and EPA] don't seem to hesitate to put requirements in without the necessary base involved. I go back continually to the issue of patient safety as our highest priority. This is an obvious issue, and we seem to just be moving ever so cautiously and slowly on it when we could make a giant leap and perhaps facilitate the movement of the infrastructure and the capability." – Dr. Barrett

"As good as something might be as an idea, until you have a base in there that in some cases may be up at the 30 or 40 percent range, you haven't worked through all the issues. And if you put an arbitrary date in before having that, at least in the health care arena, it has sometimes caused a problem. Now, the question is how you put incentives in, so you can get to that more quickly rather than starting with the stick." – Dr. Kolodner

"In terms of individual physicians, you're not going to get to 40 percent in this century unless you require it, frankly. You're not going to get to 50 percent. You're not going to get to 20 percent. So I think it's really the only way to go. You're going to have some use, but it's not going to happen until you just tell people. And I think this is one area where if you tell them, I think they're going to have to do it." – Mr. Kahn

"We stand today with 40,000 of the 55,000 pharmacies in the United States live on the network and ready to do electronic prescribing, and that continues to grow. There is an average of about 100 physicians a day that are logging on to the network and registering to get the network to do electronic prescribing…But we're not seeing the utilization that we would expect to see. It's still very much in a pilot mode. Even those physicians that are coming onto the network are processing maybe 10 to 15 percent of their total prescriptions electrically, and still picking up the pad. And we go back to this issue of the DEA. We have to solve this DEA issue…on controlled substances for schedule two through fives, because it causes physicians confusion and concern about when they can write electrically and when they can't." – Mr. Hutchinson

"The one number I would remind everyone…when we get to the tipping point, is about a 30 or 40 percent range, but it's not about 30 or 40 percent of physicians. It's about 30 or 40 percent of the volume. And 30 percent of the physicians of the United States write 80 percent of the prescriptions. So if you've automated 80 percent of the prescriptions of the United States going electrically, you have, in fact, improved enormously patient safety, and it's those 30 percent of physicians writing 80 percent of the volume that we really need to get to." – Mr. Hutchinson

Health IT Physician Adoption Survey

Dr. Jane Sisk of CDC's National Center for Health Statistics presented the current statistics regarding EHR adoption in physician's offices, gleaned from the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey. These surveys reach 3,350 office-based physicians, which will grow in 2008 to an additional 2,000 when a mail survey is added. Additionally, the surveys include 500 hospitals. In both surveys, representatives conducted in-person interviews, followed by medical record abstractions. There was approximately a 63 percent response rate in offices, and a 92 percent response rate among hospitals. EHR use has been increasing, and in 2006, an estimated 29 percent of physicians reported using either full or partial electronic medical record systems, a significant increase from 2005.

The surveys defined the percentage of office-based physicians using various EMR features, and also showed how these features correspond with the features that were identified in another study as being

necessary for minimally functional systems: clinician notes, prescription orders, test orders, and imaging results. About 12 percent of the physicians surveyed reported that they had those minimally functional selected features in their EHRs. Findings indicate that the more physicians there are in a practice, the greater the reported adoption rate. Physicians in health maintenance organizations reported a significantly higher rate, as did those in the west compared with doctors in other regions of the country. About 34 percent of all physicians in this country are solo physicians, accounting for about two-thirds of the practices. Their reported rate of any use is 24 percent, and of the minimally functional features, about 7 percent.

2005 data show that the number of patients having access to practices using EHR systems in urban areas was significantly higher than in rural areas. Privately insured patients are more likely to have them than are Medicaid or Medicare patients. Hispanic patients were significantly less likely to be visiting practices with EHRs than non-Hispanic black or non-Hispanic white patients. There was no significant difference between the two non-Hispanic categories, whether black or white.

Dr. David Blumenthal of the Massachusetts General Hospital Institute for Health Policy then discussed an ongoing survey on HIT adoption that was mailed to about 5,000 currently practicing physicians randomly selected from the American Medical Association master file. It is expected that responses from about 3,000 will be collected, for a target response rate of about 60 percent. Dr. Blumenthal indicated that the results he presented to the Community were taken from a sample of only 400 physicians and may not be representative of the final numbers.

Dr. Blumenthal presented the definitions of an EHR. The historical definition has allowed providers themselves to define an EHR (excluding billing records). Then there is the minimally functional, or selective EHR, which encompasses a set of minimal functionalities. Finally, there is a functional EHR, which fully encompasses the basic functionalities that should characterize an EHR. The minimally functional EHR has six of the 17 functionalities that a fully functional EHR would have. About 39 percent of physicians answer positively to the historical NAMCS definition. They indicate that they have an EHR system, without the surveyors defining it for them. About 14 percent have minimally functional EHRs, and about five percent have fully functional EHRs.

Dr. Blumenthal presented the following barriers to EHR adoption as indicated by preliminary survey data: (1) lack of capital (70%), (2) finding a system that meets their needs (56%), (3) uncertainty about the return on investment (55%), (4) fear of systems becoming obsolete (47%), (5) loss of productivity (39%), (6) capacity to implement (37%), and (7) physician resistance (33%)

Discussion Highlights

"The best information available suggests that there are some gains to physicians, but they are very small compared to the gains that are realized by other parties that participate in the health care system. And the parties that gain most are insurers and ultimately, employers…if you're looking for rapid adoption, the major incentives will be felt by groups that have internalized the financial gains." – Dr. Blumenthal

"Monetary incentives or pay for adoption is clearly a key component, and I would just like to hear a little bit about that, why it's not a part of this conversation here…We absolutely have to overcome this particular aspect, so I would love to hear what the survey said in terms around incentives." – Ms. Gelinas

"We have some information that wasn't presented here that looks at incentives reported by physicians that we queried. And the top two are financial. One is the availability of capital. The other is additional compensation for care rendered. So it's pay for performance or pay for use of the electronic health record. And a third, which has also come to light here, and been mentioned, is relief from fear of liability." – Dr. Blumenthal

"We have tried on numerous occasions to give away practice management technology to physicians, and they won't take it. So it's not simply that they can't afford to pay for it, it's more like they don't want to change the pattern of practice that they have in order to adopt the technologies that are required. And I also raise a little bit of concern, as you might expect, to the comment that insurers and employers are the ultimate beneficiaries. Patients are the ultimate beneficiaries of this. The objective of the electronic health record is to improve the quality of care. The economics will follow, because high quality care is more cost effective." – Mr. Serota

"How do we construct a business model that will motivate change, or at least complement our need to change in other ways? We may have to say 'Society demands this occur, and we're going to demand that it occur in the following ways.' But somehow we've got to make this business model transition so that some of the savings that comes from quality finds its way into the pocket of the physician."
– Secretary Leavitt

"At some point, we need to use the purchasing power of the federal government. And I expect that it's at a point where when it's done, the private insurers will begin to do the same thing, where we say 'It's now an expectation, if you're going to do business with us, that you use these.' Where we are on this process of tipping is an important thing that this group could give me some advice on." – Secretary Leavitt

"Everybody finds these current commercially available systems still frustratingly slow. It still interrupts the doctor/patient relationship…the speed of the systems is still frustrating….You know that it's going to improve your quality of care, and the patient is going to benefit, and you, as the doctor, are going to look better and [have] less chance for a malpractice lawsuit. But somehow, it just still grates on doctors to have a machine questioning their judgment." – Dr. Casscells

"One of the big problems is that when you document things, which is critical for quality of care…the malpractice risk is still overwhelmingly weighted towards things that you do, rather than things that you fail to do. So a lot of these people just feel safer by not documenting—the less they put down, the better they feel…You have to be reimbursed that week for the notation that the colonoscopy was scheduled or was declined, because we still are so underpaying for preventive care and paying for procedures to a large extent." – Dr. Casscells

"If you have more data on physician resistance, and on this question of loss of productivity, if you can give us more breakdown…that would be very helpful, because we're redrafting policies for our 10 million beneficiaries now in defense. And that alone would be a big service to us." – Dr. Casscells

"We will be able to get you additional data, perhaps not all the data you'd like in terms of motivation, and psychology, and physician attitudes, but we will be able to get you more data about some of these barriers and incentives in our next presentation." – Dr. Blumenthal

"I tried to prescribe a sulfa drug to a patient who was allergic to it, and the [electronic] record said, 'You can't.' And that was, to me, a seminal moment in my use of the record. It didn't endear the record to me when it also prevented me from ordering a stress test on a patient who wanted it, because it said the indications weren't there, but I think you take the good with the bad in these things." – Dr. Blumenthal

"There may be some parallels in some other aspects of business. For example, Congress passed something called Sarbanes-Oxley. Every public corporation in the United States had to immediately change the way it did business, had somebody looking over its shoulder, public auditors, public reports about how you did this, how you did not do it. It cost us all millions of dollars….This is not a new issue. Every other business in the United States has done this. As I keep trying to remind this audience, I know

that medical care is different. Everybody says their industry is different, but there are innumerable instances where massive changes have taken place almost overnight in the way we do business. Somehow, we're more resistant in this area than every other business that I know of." – Dr. Barrett

"All of the data is there that suggests that all of the parties that are participants in this process benefit from it. Some would say, 'Well, then why are the physicians bearing all of the cost of this?' And that's not true. The physicians aren't bearing all the cost of this. The pharmacies have borne a lot of cost in implementing and upgrading all of their systems to support these standards that have been required by HHS with NCPDP script standards…I think there is recognition that all parties benefit from the process. The question becomes, how we should incentivize the physicians to adopt, whether it be through positive incentives or negative." – Mr. Hutchinson

"I was intrigued when Kevin said that 30 percent of physicians represent 80 percent of the prescriptions…So if 30 percent have the large majority, what's the cost to get the 30 percent automated? And I don't think we've ever approached it that way before, because then you're really reaching the tipping point. Do we have a handle on that number or not?" – Ms. Gelinas

"I'm looking for ideas for a kind of demo we can do. It may be that a year from now, the Navy doctor or Air Force doctor doesn't get their check on time, until they get their certain percent of prescriptions done electronically…I don't want to suggest anything we do is really going to be very instructive to the larger group of physicians. But I do think a clear demonstration of these kinds of microeconomic incentives that the Secretary mentioned is necessary." – Dr. Casscells

"I did take the liberty of checking with counsel, and that points to one of the great differences between business and government, and why we have government and why we have business. And that is that it would require a change in the statute for us to compel this. So it's not within our means. Certainly it is within our means to ask the legislature for that change." – Mr. Weems

"I don't need to see any more data. I've got data everywhere. I don't need to have people waste more time, doing more research, doing more surveys. We know the answer. And maybe we, as AHIC, need to collectively put pressure on Congress through a letter to the Secretary, through a letter to the leadership and Congress to say 'We have studied this until we're blue in the face, and there is only one solution, and that is to mandate compliance with electronic prescribing.'" – Mr. Serota

"I am very sensitive to the physician's practice disruptions. I resisted e-mail and all those things, too, but eventually you got to do it. And now I don't know how I existed without it. And I suspect once we get over the hump of 'I didn't really want to do it,' once the practices go electronic, they'll wonder how they ever operated with paper and pencil before." – Mr. Serota

Advancing the National Framework for Uses of Health Data

Dr. Don Detmer, President and CEO of the American Medical Informatics Association (AMIA), explained that AMIA's goal is to make IT work effectively for health professionals. The Association has approximately 4,000 members from 53 nations. Two-thirds of the members are involved in clinical health care and in informatics. About a quarter of the members are in public health or population health, and the rest are in translational bioinformatics. AMIA started with some colleagues from Pfizer Pharmaceuticals in 1985 with the support from a variety of corporate supporters. Its first conference was held in 2006 with about 30 experts.

Dr. Charles Safran, Associate Clinical Professor of Medicine at Harvard Medical School, explained that AMIA's research starts from the premise that use of health data is a good thing, and that more of it would be better, under appropriate conditions. AMIA wants to facilitate more and better use of health data information to: (1) enhance experiences for individual citizens, (2) expand the knowledge about disease and treatment, (3) strengthen the understanding and effectiveness and efficiency of the health system, (4) support public health and homeland security, and (5) help businesses meet the needs of their customers. AMIA published a framework that was provided to AHIC in January of 2007, and convened a second conference in June of this year. The Association has presented to AHIC's Consumer Empowerment Working Group, testified before the National Committee on Vital and Health Statistics (NCVHS) in July of 2007, and submitted its taxonomy to NCVHS in September. It also has submitted a consumer checklist to Dr. Kolodner and the Office of the National Coordinator.

The 2006 AMIA meeting provided a great deal of useful information. AMIA found that the uses of health data were very widespread, sometimes beyond the existing policy and legal framework. Issues of privacy dominate the public policy discussion. In addition, technology and business development outpace policy and practice. AMIA uncovered businesses whose fundamental business case was that they were operating beyond the HIPAA framework. The organization grew concerned that that the emerging RHIOs would eventually discover that perhaps they could resell their data, and that this might be a part of their evolving business model. AMIA also felt that it was not productive to talk about data ownership, and that to forward a policy discussion, it was perhaps important to put forward the idea of stewardship. AMIA also identified the need for more leadership at the national and state levels. Dr. Safran commended the Secretary, Dr. Kolodner, and others for pushing these issues forward on a national scale.

Dr. Safran reiterated that his use of the phrase "reuse of health data" refers to data that are being collected for or used for reasons other than those for which they were originally collected. These data are valuable for reasons of quality, safety, public health, payment, business operations, research, provider certification, accreditation, post-marketing surveillance, and a variety of appropriate business uses. The reuse of health data introduces the issue of what are questionable or inappropriate uses of data.

AMIA has defined a framework for reuse of health data in the following six dimensions:

- **Accountability.** The levels of sanctions or penalties for disclosure or inappropriate use of patient health data, transparency, the extent to which the practices governing the use of patient's health data are known and understood by those who disclose or use patient data, and to the patients whose data are subject to use.

- **Transparency** – the extent to which the practices governing the use of patients' health data are known & understood by those who disclose or use data and to the patients whose data are subject to use

- **Patient Consent/Notification.** The opportunity offered to patients to allow or permit the use of their health data. Notification refers to the mechanism by which patients are informed of their right to consent.

- **Cost (Resources Required) of Re-Identification.** A proxy for the nature, complexity, & extent to which patients can be re-identified in a database(s)

- **Oversight.** The extent to which the entity is subject to governance or supervision, including the ability to impose remedies for breaches.

- **Regulatory/Law.** The framework for regulations and law that governs the use of health data, including penalties and enforcement guidelines.

Within that framework, AMIA created a consumer checklist for awareness about personal health information, how it was being used, and how policy might be devised, particularly for non-Health Insurance Portability and Accountability Act (HIPAA) covered entities. The checklist indicates that a data reuse policy should:

- Be prominently posted, with an effective date
  - Written in clear understandable language
  - Identify contact to resolve privacy issues
  - Describe any and all uses of health data and any sharing of data with other organizations, whether you can be identified or not
  - Describe how personal data are protected
  - Describe how to receive a free report of who has accessed your data, and when.
- Describe how your permission is obtained to share data with others
  - Decisions to opt-out of data sharing should not result in denial of services
  - Provide advance notification of any changes
  - Allow termination, without penalty, if you do not agree with the changes.
- Describe whether, upon termination of the agreement, you can remove your data & prevent further disclosure, whether identifiable as yours or as part of a group.
- Describe how your data are handled if the organization is sold, merges with another organization, or files for bankruptcy.

Dr. Detmer explained that AMIA thought it was important to define the language that is used when discussing issues and creating policy. To that end, the Association created a taxonomy that identifies possible uses of personal health information to clarify societal, public policy, legal and technical dimensions. AMIA is proposing the concept of "data stewardship." The idea is that certified data stewards (however those are defined) would be able to transact with other certified data stewards under the same umbrella, so that citizens would trust that the people or the entities to whom they are handing their data would abide by the same rules and philosophy and policy of the original entity to which they contributed their data.

There is a need for a standard set of data analytic principles to be used with EHRs for the following reasons:

- A statistically sound approach is necessary for analysis of large clinical practice data sets.
- Random analysis or unstructured data mining could yield associative conclusions and potentially introduce false positive associations.
- Standard data analysis principles provide a framework for sound studies with credible and reproducible results, and for minimizing errors possibly introduced during analysis.
- Data analysis principles mitigate the risk of false positives that could cause misidentification of a safety problem.
- They provide a grounding for multiple parties such that analyses can be more readily compared.

It will be necessary to refine the data stewardship principles, which have been discussed in their broader framework. These principles include: (1) accountability (including governance, oversight, and extent and level of applicable regulations); (2) openness and transparency (including structure, processing and delivery of data, plus business processes and practices); (3) notification to patients; (4) privacy and security (including data quality, de-identification, and costs of re-identification); (5) granularity of

consent; (6) permitted uses and disclosures (including data aggregation and analyses); (7) data analysis principles; and (8) enforcement and remedies. Future activities for AMIA include the following:

- Differentiate appropriate and inappropriate use of data.
- Develop recommendations to assure maintenance of the Use Taxonomy.
- Refine the stewardship principles, including the data analysis principles.
- Publish white papers.
- Participate with AHIC, NCVHS, IOM and others, particularly with respect to negative impacts on biomedical and health-related research

Discussion Highlights

"How would you ascertain industry alignment of other major groups, in getting behind this work, endorsing it, and vetting it?" – Ms. Gelinas

"The part that was hardest for us was getting any sort of alignment around what was a use of data where there was an exchange of money. So we sort of abandoned the term 'commercial' use of data, because what it meant to be a commercial entity was a sticking point. But if you look at the uses of data around where there is an exchange of money…we need to refine the framework as it might apply to that specific area." – Dr. Safran

"The use and the rules guiding the work are totally appropriate and already safeguarded, according to the principles. The issue is, when is it inappropriate, and…how do you reach those communities and deal with that? If you have ideas for us, we would be open to it, because I think in our complex society, it's really important." – Dr. Detmer

"I'd like to challenge you to look at what is going to be available to patients in the event that their information is breached and becomes public…I'm delighted to hear that [opting out without any denial of services] is an issue that you're looking at, and one that continues to probably need discussion and review…What can be done to ensure some form of safety for consumers if there is a breach?...What are the steps that data stewards will go through to become certified, so that as we move to assist them, where perhaps we don't own data, but we become stewards of data, there is an accountability?"
– Ms. Davenport-Ennis

"To build a system where there is a chain of trust, the citizen needs to believe that the steward is, in fact, doing the things that will protect the citizen, and at the same time, that there is remedy and recourse. On the other hand, there is a concern among health service researchers and others about issues of opt-in versus opt-out, and the quality of data, and what we're going to be able to do to protect the public health and a variety of other issues." – Dr. Safran

"These are very, very tough issues, and there is not necessarily a clean, right answer. But you do need the best legal minds, I think, and the data minds, as well as the society more broadly. And really, the Institute of Medicine is probably in the best position to take on some of those kinds of questions." – Dr. Detmer

Further Discussion of e-Prescribing

Following the AMIA discussion, Mr. Serota moved that AHIC adopt a resolution requesting that the Secretary recommend to Congress that it grant CMS the statutory authority to mandate e-prescribing through the Medicare program. The motion was seconded and passed. Mr. Weems noted that he had spoken to the Secretary in anticipation of such a motion. He commented that the Secretary would be anxious to receive this recommendation, and suggested that the Community's EHR Workgroup, under the guidance of Ms. Gelinas, quickly such a recommendation. As quickly as the rules of public notice allow, a teleconference meeting of the AHIC will then be scheduled.

Dr. Kolodner requested that the record show that all Community members supported Mr. Serota's motion.

Enhanced Protections for Uses of Health Data: Recommendations to HHS on a Data Stewardship Framework

Dr. Simon Cohn, Associate Executive Director for Health Information Policy at Kaiser Permanente and Chair of the NCVHS, explained that the NCVHS is a statutory public advisory committee to HHS and the Secretary. For 58 years the Committee has advised on a variety of health information policy areas and issues, including health data, health statistics, and health information privacy. Dr. Cohn also noted the trouble with the use of the term "secondary" use of data. There is no universally accepted standard definition, nor is it always clear whether primary uses are always more important than secondary uses. In its work, the NCVHS Work Group on Health Data Uses concluded that it is best to avoid the uses of such terms as "secondary" or "reuse," and instead try to be very precise about the use being discussed (e.g., direct patient care, data for submission to public health and communicable diseases, information for quality improvement, etc.).

Dr. Justine Carr, Senior Director for Clinical Resource Management at Beth Israel Deaconess Medical Center framed listed the following reasons why it is important to address the uses of health data now: (1) electronically available health data are no longer just claims data, but include more clinically rich data; (2) electronic data can be linked more readily with other databases; (3) sources of electronic health information are expanding beyond HIPAA protections of covered entities and their business associates; and (4) electronic solutions to protect and secure data continue to evolve, including approaches to allow individual consent to follow data. She reported that there were two recurring themes heard in the testimony to the NCVHS Work Group on Health Data Uses. First, recognition of the great benefit that can be achieved by using electronic health data. Benefits include an increase in the ability of use health data to benefit health care; enhancements of quality measurement and reporting with a more real-time quality improvement cycle; support in public health surveillance and responsiveness; and an acceleration of accrual of cases for timely identification of complications that may occur from new medications or new procedures, technologies and devices. The second theme is a concern about the potential for harm. There can be erosion of trust in the health care system with potential compromise to health care when individuals do not trust that their privacy can be protected. There also is a concern about potential or actual discrimination or confidentiality violations that may occur with increased ability to collect longitudinal data, coupled with sophisticated methods to re-identify data.

Dr. Carr defined HIPAA and discussed where NCVHS perceives gaps to be. She indicated that HIPAA's focus was on the promotion of electronic exchange of data for administrative simplification. Therefore, HIPAA regulates entities that electronically transmit health information, and this includes health care payers, providers and clearinghouses. HIPAA also regulates business associates and their agents. A key concern is the fact that there are a growing number of entities that are not covered by HIPAA, including some vendors of personal health records. Another concern is the lack of detail on the expectations of HIPAA-covered business associations and their agents with regard to the ongoing uses of health information. As part of HIPAA, Congress required DHHS to adopt regulations safeguarding the privacy of individually identifiable health information (i.e., the HIPAA Privacy Rule). This covers individual identifiable health information in any form—paper, electronic, spoken, or any format held or transmitted by the covered entity. This is protected health information, but the regulations do not cover personal health information held by any organization outside the scope of HIPAA.

HIPAA requires authorization for disclosures of protected health information except for uses for treatment, payment or health care operations, or when required by law, as in public health. Health care

operations include an array of activities, such as quality assessment, competence and review, compliance activities, business planning, etc. HIPAA privacy does not protect de-identified data. The NCVHS heard concerns related to the sale of de-identified data. To begin to address this, they have created a health data stewardship conceptual framework. This framework is intended to outline how an organization may approach evaluation of intended uses of data, and recognize where it may elect to enhance data stewardship processes. The framework is as follows:

- Health data user and use profile
  - User: provider, payer, clearinghouse, business associate or agent, researcher, public health, PHR vendor, other
  - Regulatory status: HIPAA, state data statutes, IRB, FDA, VA, privacy board, other state laws, FTC, other
  - Identity status: identifiable, HIPAA de-identified (safe harbor), HIPPA de-identified (statistical), limited data set, anonymization, pseudonymization, other.
- Analysis of benefits and potential risks
  - Intended use of data: treatment, payment, health care operations, research, public health, other
  - Impact: benefits to individual and society, potential risk for harm.
- Data stewardship considerations
  - Accountability chain of trust, transparency, individual participation and control, HIPAA de-identification, security safeguards and controls, data integrity/quality, oversight of data uses.

For example, a business associate of a payer that is covered by HIPAA, who wishes to use identifiable data for quality measurement under health care operations, would describe the benefits of the use, consider the potential risks for harm, and then consider how it would address each of the data stewardship considerations. In some areas, the user may believe it provides appropriate stewardship, but in other areas, it might see an opportunity for improvement, such as improved transparency or stronger security controls. Stewardship addresses not just data collection at transmission; it also includes data aggregation and use of the data. Focus is needed on completeness and accuracy of data, and processes to assure correct application of methodologic rules, as well as valid application of the rules related to statistical significance.

The NCVHS has identified guiding principles, against which each of the recommendations on enhanced protections for uses of health data is evaluated. Protections should do the following: (1) maintain or strengthen individuals' health information privacy, (2) enable improvements in the health of Americans and the health care delivery system of the Nation, (3) facilitate uses of electronic health information, (4) not place an undue administrative burden on the health care industry, (5) increase the clarity and uniform understanding of laws and regulations pertaining to privacy and security of health information, and (6) build upon existing legislation and regulations whenever possible.

Harry Reynolds, Vice President of Blue Cross/Blue Shield of North Carolina, explained that NCVHS' draft recommendations call for enhanced HIPAA protections and data stewardship for all uses of health data by all users, independent of whether an organization is covered by HIPAA. Most of the recommendations do not require legislation, and take the form of such measures as inclusion and requirements for contractors, incentives, conditions of participation, and interagency collaboration. The recommendations, which fall under four main categories, are as follows:

Principles of Data Stewardship

These draft recommendations address the areas and the framework having to do with accountability and chain of trust, transparency, individual participation and control, de-identification, security, and data integrity, data quality. The recommendations are as follows:

- Accountability and chain of trust within HIPAA

    - Covered entities specify in business associate contracts terms that: (1) clearly describe uses of identifiable health data and de-identified health data; (2) require a contract between business associates and agents, and identification of all agents to the covered entity; and (3) include a yearly confirmation of compliance with the contract.
    - Business associates include all companies requiring access to protected health information during transmission.
- Transparency
    - Enhancements to notice of privacy practices.
    - Make information available, upon request, about specific uses and users.
    - Make information available, upon request, about specific information disclosed to other organizations, such as public health.
    - FTC uses its authority to ensure that privacy policies fully inform and do not mislead the public.
- Individual participation and control over personal health data
    - Assure authorization for personal health information uses not protected under HIPAA.
    - Evaluate technologies to manage individuals' authorization.
- De-identification
    - HIPAA definition (safe harbor or statistical process) is the only currently recognized means to de-identify protected health information.
    - NCVHS will further investigate uses of de-identified data, and potentially offer recommendations for guidance.
- Security safeguards and controls
    - Promote technical security measures and compliance with HIPAA Security Rule by all business associates and their agents.
- Data integrity and quality
    - Data for quality measurement, reporting, and improvement follow rules and guidelines to ensure precision and reliability of quality measures.

Oversight for Specific Uses of Health Data

These draft recommendations address enhanced oversight for specific uses of health data, since NCVHS recommendations also focus on uses of health data for quality measurement, reporting and improvement.

- Quality measurement, reporting, and improvement
    - Uses of health data for quality measurement, reporting, and improvement are within scope of HIPAA health care operations.
    - Use a proactive oversight process accountable to senior management and governance to ensure compliance with HIPAA.
    - Assess risk and apply further protections as appropriate when quality activities are conducted across different covered entities within an organized health care arrangement.
- Research
    - Harmonize research regulations.
    - Clarify the definition of research and provide methodologies that help differentiate research from quality.
    - Widely disseminate quality/research guidance.
    - Identify approaches to ensure that when a quality study becomes generalizable and evolves into research, that HIPAA Privacy and IRB requirements are respected.

Transitioning to an NHIN

These draft recommendations deal with evaluating new tools and technologies as the industry makes a transition to HIE and an NHIN:

- Adopt data stewardship principles in NHIN activities.

- Use NHIN trial implementations to evaluate:
  - Individual choice applications.
  - Data stewardship principles in comprehensive databases.
  - Potential new de-identification techniques.
  - Chain of trust enhancements.
  - Educational modalities to improve understanding.

Additional Privacy Protections for Health Data

These draft recommendations focus on additional legislation to broaden the scope of privacy coverage to all who may have access to personal health information, and on anti-discrimination consequences that may arise out of the wrongful uses of health data

- Address the need for:
  - More inclusive, federal privacy legislation for health data.
  - In the absence of comprehensive federal privacy legislation, an expanded definition of covered entities under HIPAA.
- Promote legislative or regulatory measures on anti-discrimination.
- Use findings from the Health Information Security and Privacy Collaboration to encourage states to map their data restriction laws to one another in order to promote interoperability.

In terms of future activities, the NCVHS will address additional public comments to finalize the draft recommendations (this presentation was part of the public comment process). The NCVHS has its full committee meeting November 27-28, 2007, and all of these recommendations will then be sent to the Secretary. Mr. Reynolds anticipates an ongoing analysis and subsequent recommendations.

Discussion Highlights
"I love the approach you're taking which is a small number of absolute principles. Those should trump all else. And if you effectively implement the principles, then you don't have to effectively go after every minute process within the system. Am I understanding correctly the direction you're taking?"
– Dr. Barrett

"Yes…and we're obviously trying to make this along the lines of best practices, model agreements, and contracts with the idea that hopefully it will lessen the administration burden." – Dr. Cohn

Public Input Session

Speaker Number 1 – Dr. Alan Zuckerman, representing the American Academy of Pediatrics, with its 60,000 pediatricians, also represents America's children on the Health Information Standards Panel and co-chairs CCHIT's Interoperability Expert Panel. Dr. Zuckerman reminded participants that he addressed the Community 2 years to state the importance of reciprocal registration, whereby providers would register with patients. This is the interoperability with personal health records that he is still seeking. Dr. Zuckerman also emphasized the importance of including children, pointing out that the EHR pilot will not include this population. He indicated that it is necessary for the Community to make a statement on the importance of including children in HIT so that there is not a repeat of what occurred at the U.S. Food and Drug Administration regarding the certification of use of drugs for children.

Dr. Zuckerman also emphasized the importance of building acceptance, adoption, and demonstration of tools such as a portable family history and immunization and response management. In addition, he discussed e-prescribing, pointing out that the use case that AHIC adopted 2 years ago, with the registration summary, could be a huge enabler of e-prescribing by facilitating work flow, enabling a

patient's usual pharmacy, their insurance, their existing medications to move seamlessly into physicians' systems. However, Dr. Zuckerman pointed out that there is very little awareness of this, and there needs to be a greater focus on the aspect of workflow facilitation.

Speaker Number 2 – Hugh Zettel of GE Healthcare serves as Vice Chair of the Healthcare Information and Management Systems Society's (HIMMS) EHR Vendor Association (EHRVA), a trade group of more than 40 EHR providers for both inpatient and ambulatory care. Recognizing the benefits of interoperability in healthcare, the HIMSS EHRVA has released a quick-start guide for the ASTM HL-7 continuity of care document standard. The organization developed the guide, which is available at no charge at www.himssehrva.org, as a resource to help speed up interoperability in health care.

Speaker Number 3 – Mr. Jackie Jacamathan, who works for a transcription service company, commented on the fact that there does not seem to be a focus on removing regulatory barriers for physicians wishing to practice in multiple states. He asked if there was any such focus on the part of the Community.

Closing Remarks

Before adjourning the 17th meeting of the AHIC, Dr. Kolodner thanked the Community members, speakers, and participants for their attendance and participation.

Teleconference Report

American Health Information Community
November 28, 2007

The American Health Information Community (AHIC), a federally chartered commission formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within 10 years, held its 18th meeting on November 28, 2007, as a teleconference from 11:00 a.m. to approximately noon.

The meeting focused on defining and approving specific recommendations from AHIC's Electronic Health Records (EHR) Workgroup to Department of Health and Human Services Secretary Michael O. Leavitt, who chairs the Community. The recommendations request that Secretary Leavitt seek authority from Congress to mandate e-prescribing pursuant to the standards defined by the Medicare Modernization Act (MMA) for e-prescribing.

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

A summary of the discussion and events of the conference call follow.

Call to Order and Roll Call

Dr. Kolodner welcomed Community members and turned the floor over to Secretary Leavitt, who reminded AHIC that at its last meeting, the EHR Workgroup was tasked with drafting recommendations to the Secretary requesting that he seek authority from Congress to mandate e-prescribing.

Joining Secretary Leavitt on the teleconference were:

Robert Kolodner, MD, National Coordinator for Health Information Technology

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

Scott Serota, President and CEO of the Blue Cross Blue Shield Association

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

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

Kevin Hutchinson, CEO of SureScripts

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

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

Dan Green, Deputy Associate Director, Office of Personnel Management (Mr. Green represented Linda Springer, Director, OPM)

Chuck Campbell, Chief Information Officer of the Military Health System (Mr. Campbell represented S. Ward Casscells, MD, Assistant Secretary for Health Affairs, Department of Defense)

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

Bettijoyce Lide, Scientific Advisor for Health Information Technology, National Institute of Standards and Technology's Information Technology Laboratory (Ms. Lide represented Cita Furlani, Director of Information Technology, NIST)

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

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

Andrea Sodano, PhD, Director of Health IT, Wal-Mart (Ms. Sodano represented John Menzer, Vice Chairman, Wal-Mart)

Discussion of EHR Workgroup Recommendations

Ms. Lillee Gelinas, EHR Workgroup Co-Chair, acknowledged the group's efforts before turning to the recommendations themselves, which were included as part of a letter to the Secretary (the recommendations also are listed at the end of this report).

Ms. Gelinas read Recommendation 1.0 and clarified with Mr. Weems that there is no condition of participation for Medicare Part B. She therefore suggested striking the phrase "as a condition of participation in Medicare Part B" from the recommendation, and there was no dissent from Community members. A number of AHIC members voiced their respective organizations' support for Recommendation 1.0.

Ms. Gelinas explained that Recommendation 1.1 was intended to ensure that the e-prescribing definition already in regulation (the MMA definition) is used and that a new definition is not created. Dr. Kolodner asked whether Recommendation 1.1 needed to be a recommendation put forward to the Secretary. Ms. Gelinas indicated that Recommendation 1.1 does not need to be submitted to the Secretary; however, Community members should be in agreement on the definition of e-prescribing from this point forward. Mr. Hutchinson noted that in the EHR Working Group's letter to the Secretary, the phrase "within Medicare Part B" should be struck from the text in the introduction to Recommendation 2.0.

Ms. Gelinas then read Recommendations 2.0 through 2.7, noting that within the EHR Workgroup, there was the least amount of controversy with regard to Recommendations 2.3, 2.5, 2.6, and 2.7. Recommendations 2.1, 2.2, and 2.4 required the most discussion on the part of EHR Workgroup members.

Dr. Henley suggested changing the word "should" in Recommendation 2.0 to the word "must," so that the recommendations put forward to the Secretary indicate that the barriers to e-prescribing (as highlighted in Recommendations 2.1 through 2.7) must be addressed. Mr. Serota disagreed and instead suggested that the words "should be met" be changed to "should be considered" in Recommendation 2.0. Mr. Serota explained that the Community should give Secretary Leavitt as much flexibility as possible as he asks Congress for authority. He added that while the barriers in 2.1 through 2.7 should and must be overcome, if Recommendation 2.0 is burdened with a series of mandatory activities that must occur prior to this recommendation taking effect, it may pose an insurmountable challenge.

Ms. Gelinas noted that some of the much-needed flexibility referred to by Mr. Serota is found in Recommendation 2.5, which is intended to help overcome the limitations tied to the following issues: (1) 30 percent of pharmacies are not able to handle e-prescribing, (2) U.S. Drug Enforcement Administration (DEA) regulations around e-prescribing and controlled substances, and (3) incentives. Dr. Henley indicated that he would not be in favor of Mr. Serota's suggested change to Recommendation 2.0, but that he would support it as written. He also added that in addition to DEA-related restrictions on e-prescribing, there are a number of other regulations that in some cases require paper-based prescriptions for controlled substances. Chaos and confusion will result if physicians must, in some cases, write both paper and electronic prescriptions. Mr. Hutchinson noted that the Senate Judiciary Committee is meeting the week after this teleconference to try to push the DEA to solve the issues related to controlled substances and e-prescribing.

At this point in the teleconference, Secretary Leavitt excused himself, thanking the EHR Workgroup and Community members for their efforts.

Mr. Weems proposed that the phrase "within Medicare Part B" in Recommendation 2.0 be stricken. All were in agreement. He also explained that his understanding of the spirit of the recommendations is that the Secretary would be seeking the appropriate congressional authority to mandate e-prescribing in instances where CMS does not already have it. Mr. Weems suggested that the phrase "with appropriate congressional authority" be included; Dr. Kolodner indicated that Recommendations 2.1 and 2.4 would be most appropriate to have this phrase included.

Mr. Serota again expressed concern about the Secretary going to Congress asking for authority to act with a number of contingencies that would restrict his ability to act. He made a motion to modify the wording in Recommendation 2.0 to change the term "should be met" to "should be considered by the Secretary." Dr. Kolodner asked for a second to the motion, but there was none, and the motion did not carry.

Dr. Henley called for a vote on Recommendation 2.0 (with the phrase "within Medicare Part B" stricken). The Community passed Recommendation 2.0 by a vote of 10-3.

Ms. Gelinas assured Mr. Weems that the EHR Workgroup acknowledges that CMS already has authority over many of the issues covered in Recommendations 2.1-2.7. Dr. Kolodner proposed a change to Recommendations 2.1 and 2.4, suggesting that both recommendations begin with the phrase "With the appropriate Congressional authority…." The Community accepted this change in wording.

Mr. Serota noted that he was pleased with the forward movement, but wanted to state for the record that he found this mechanism for discussion to be awkward and inefficient. The static and poor reception that many of the participants experienced during the conference call may have resulted in one of Mr. Serota's motions not being seconded, despite the fact that another panel member supported Mr. Serota's position on the matter a moment later. Mr. Serota commented that this teleconference approach may not be the optimal way for which the Community to consider significant recommendations.

Mr. Green expressed concern about the "absoluteness" of some of the language in the recommendations and indicated that he, like Mr. Serota, would not vote in favor of Recommendations 2.1-2.7. Mr. Serota concurred, expressing concern that the discussion language for Recommendation 2.5 includes creating processes with which to address exceptional situations. It does not mention flexibility with regard to when and how the e-prescribing mandate can be applied. Ms. Gelinas reiterated that the Workgroup intended for Recommendation 2.5 to provide flexibility across all areas of the mandate, and suggested that rewriting the language would be fine. Mr. Kahn asked if it would be possible for a "differing" opinion to be delivered to the Secretary when the recommendations are put forward. Dr. Kolodner indicated that there is precedent for passing on minority opinions, and that it would be possible in this circumstance. Mr. Weems suggested that the Secretary consider that the flexibility in Recommendation 2.5 extends to all of the recommendations; Mr. Serota agreed.

Mr. Hutchinson suggested that Mr. Serota develop a document that reflects the alternate opinions of the Community members who would not vote in favor of the recommendations. Mr. Green then suggested that Recommendation 2.5 be renumbered as Recommendation 2.1 and the discussion stricken from it. The subsequent sub-recommendations would then be renumbered (i.e., Recommendation 2.1—formerly Recommendation 2.5—becomes the recommendation concerning flexibility). Without the discussion following it, Recommendation 2.1 (previously Recommendation 2.5) provides a much wider interpretation of "flexibility." With no objections, Dr. Kolodner indicated that the Community accepted this amendment and that Recommendations 2.1 through 2.7 (with original Recommendation 2.5 moving to Recommendation 2.1) have been accepted.

Dr. Kolodner then asked for a vote on Recommendation 1.0 with the phrase "as a condition of participation in Medicare Part B" stricken. Recommendation 1.0 was unanimously approved. In closing, Dr. Kolodner thanked the EHR Workgroup Co-Chairs and members for their efforts, and for AHIC members' participation on the conference call.

Public Comment Session

There were no public comments.

Recommendations

The recommendations discussed and amended (and renumbered, in the case of Recommendations 2.1-2.7) during this conference call are as follows:

- **Recommendation 1.0:** The Secretary of Health and Human Services should seek authority from Congress to mandate e-prescribing pursuant to standards defined by the Medicare Modernization Act (MMA) for e-prescribing. This authority should be specific to e-prescribing and not extend to other health care processes.

- **Recommendation 2.0:** Prior to exercising authority to mandate e-prescribing, the following requirements should be met:

  - **2.1:** Flexibility must be maintained, since mandated e-prescribing may not be applicable to all patients, all prescriptions, and all circumstances.

- **2.2:** With appropriate Congressional authority, all pharmacies and pharmacy benefit managers must participate in such mandatory e-prescribing.

- **2.3:** All prescriptions must be electronically transmissible to the pharmacy of the patient's choice.

- **2.4:** The Certification Commission for Healthcare Information Technology (CCHIT) should develop a certification process for e-prescribing systems that are: (i) interoperable with certified EHRs; (ii) include clinical decision supports to improve safety, efficacy, and efficiency; and (iii) can be extended to integrate with fully functional EHR systems, thus assuring that the e-prescribing investment is a step towards adoption of certified EHRs.

- **2.5:** With appropriate Congressional authority, CMS should develop and institute incentives for both physician/clinician and pharmacy adoption of certified EHRs and/or certified e-prescribing systems early in 2008 before authority to mandate e-prescribing can be granted and exercised.

- **2.6:** Continue the successful pilot work undertaken by CMS to make ready important emerging standards, and supplement that work to address sustainability issues such as practice workflow, usability, clinical decision support, and safety surveillance.

- **2.7:** Pursuant to Patient Safety legislation of 2005, the Agency for Healthcare Research and Quality (AHRQ) should designate Patient Safety Organizations to monitor and address possible patient issues that may arise as a result of e-prescribing, and patient safety criteria should be included in an e-prescribing certification process.

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

American Health Information Community

A National Survey of Electronic Health Record Adoption in the United States

David Blumenthal

Massachusetts General Hospital's Institute for Health Policy

January 22, 2008

Methodology

- **Mail survey**
- **Sample frame: 5,000 currently practicing physicians randomly selected from the AMA Masterfile**
- **Target sample size: 3,000 physicians to analyze at subgroup level; 1,500 physicians for stable national analysis**
- **Field period: Began in July 2007, currently in the field**
- **Physicians were sent two questionnaires. They were directed to fill out the "physician" instrument and to give the second questionnaire to the person most knowledgeable about the practice characteristics and HIT use.**
- **Current analysis: N > 1500**

Definitions of an EHR

- **Historical NAMCS Definition**: "Does your main practice use an electronic health record system (not including billing records)?"
- **Minimally Functional EHR**: Based on a set of functionalities used in 2005 and 2006 to encompass a minimum set of functionalities.
- **Functional EHR**: Definition developed by our Expert Consensus Panel based on the Institute of Medicine framework.

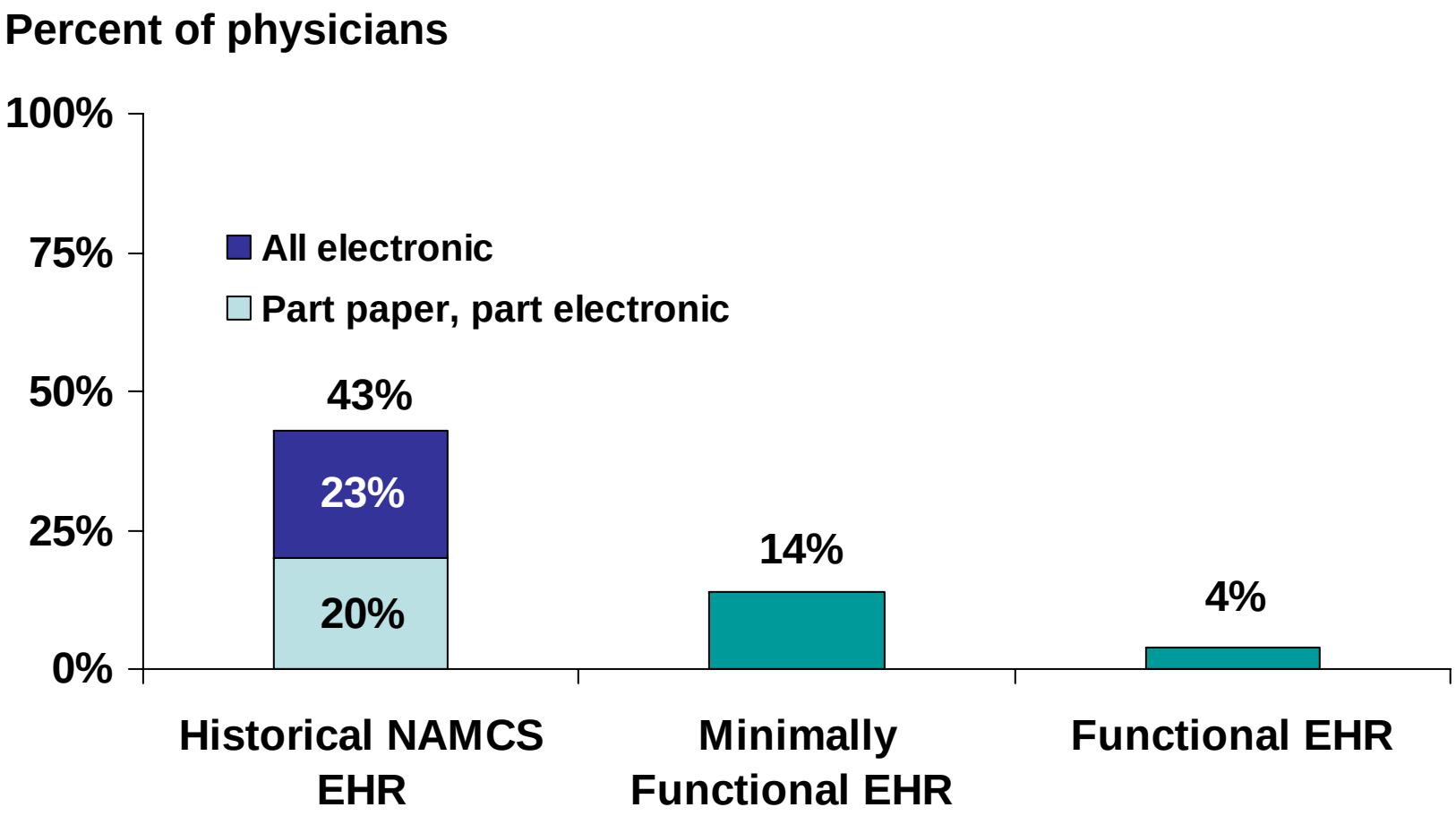
Definition of a EHR – Minimally Functional and Functional

	Minimally Functional EHR	Functional EHR
Health Information and Data		
Patient demographic information		✓
Patient problem lists		✓
Patient medication lists		✓
Clinical notes	✓	✓
Notes include medical history and follow up notes		✓
Order Entry Management		
Computerized orders for prescription	✓	✓
Computerized orders for labs	✓	✓
Computerized orders for Radiology	✓	✓
Orders sent electronically for prescriptions		✓
Orders sent electronically for labs		✓
Orders sent electronically for radiology		✓

Definition of a EHR – Minimally Functional and Functional (con't)

	Minimally Functional EHR	Functional EHR
Results management		
Viewing lab results	✓	✓
Viewing imaging results	✓	✓
Electronic images are returned		✓
Decision Support		
Warnings of drug interactions or contraindications are returned		✓
Out of range lab levels are highlighted		✓
Reminders for guideline-based interventions and screenings		✓

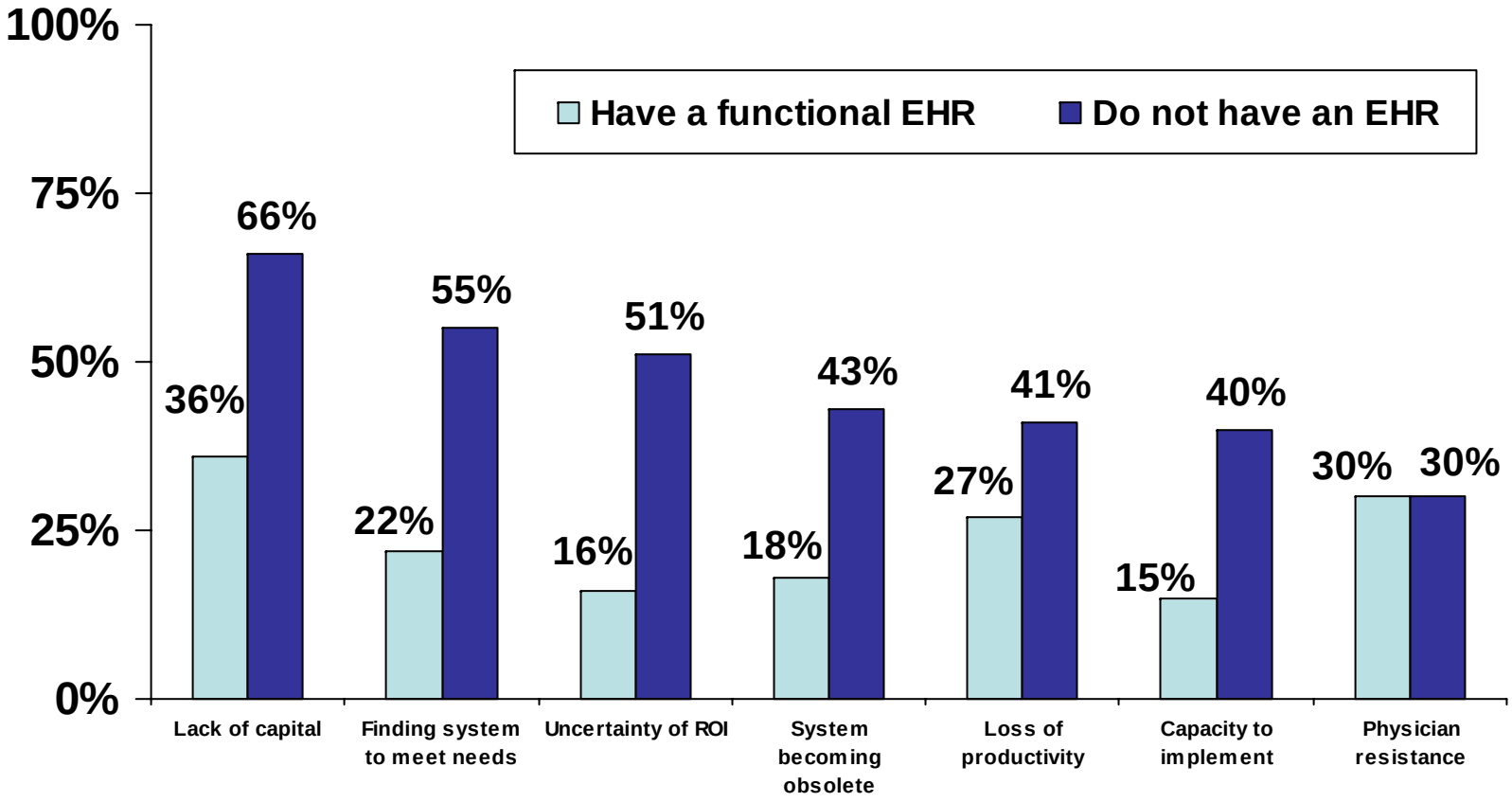
Availability of an EHR Varies By Definition



Source: MGH Institute for Health Policy, George Washington University and RTI, A National Survey of Health Record Keeping among Physicians & Group Practices in the United States, Preliminary Data

Major Barriers to EHR Adoption

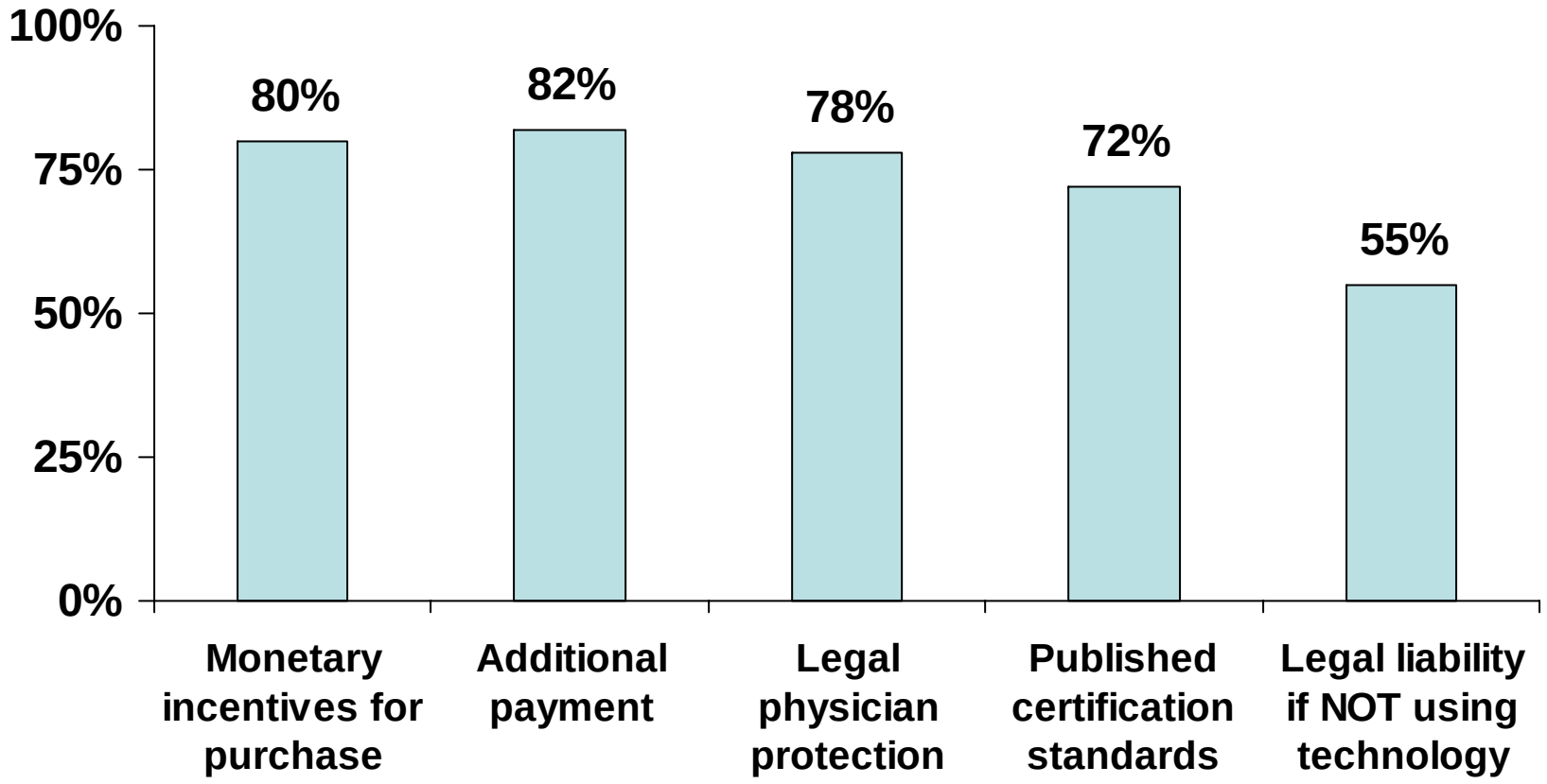
Percent of physicians reporting a "major barrier"



Source: MGH Institute for Health Policy, George Washington University and RTI, A National Survey of Health Record Keeping among Physicians & Group Practices in the United States, Preliminary Data

Incentives for EHR Adoption

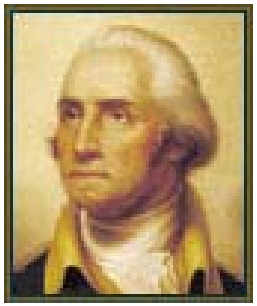
Percent of physicians reporting incentive would have an impact



Source: MGH Institute for Health Policy, George Washington University and RTI, A National Survey of Health Record Keeping among Physicians & Group Practices in the United States, Preliminary Data

Research Team

Mass General Hospital's Institute for Health Policy	George Washington University
Harvard School of Public Health	RTI



IOM Criteria and IHP/GWU Criteria for a Functional EHR

IOM Core Functionalities	Functional EHR
Health Information and Data	Patient Demographics, Clinical Notes, Notes Include Medical History and Follow Up, Medication Lists, Patient Problem Lists
Order Entry Management	Orders for Prescriptions, Labs, and Radiology Tests, Orders sent Electronically
Results Management	Viewing Lab and Imaging Results, Electronic Images Returned
Decision Support	Warning and Contra-indications Provided for Prescriptions, Out of Range Levels Highlighted, Reminders for Interventions and Screening Tests
Electronic Communication and Connectivity	
Patient Support	
Administrative Processes	
Reporting and Population Health Management	

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

American Health Information Community

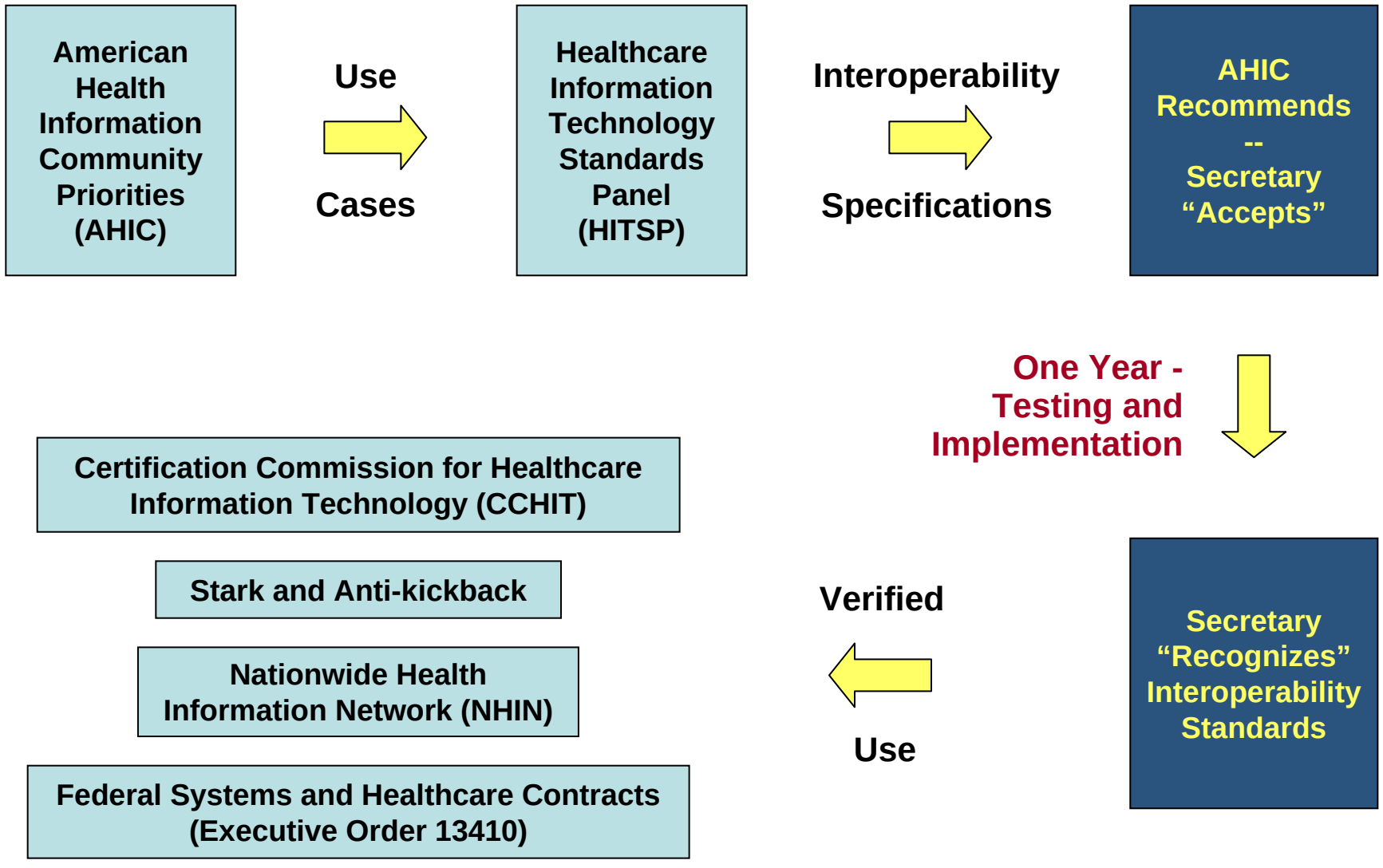
Standards Update

John Loonsk
Office of the National Coordinator

John D. Halamka
Healthcare Information Technology Standards Panel (HITSP)

January 22, 2008

Standards in the National HIT Agenda



Standards in the National HIT Agenda

- Round #1
  - Interoperability standards recognized by Secretary – January, 2008
  - Exceptions: lab message guide and HAVE standard, plan to recognize in June, 2008
- Round #2
  - Security and privacy, three use cases – presented today for AHIC recommendation to Secretary
  - Exception: Medication management use case standards to be available in March, 2008
- Round #3
  - Six draft use cases out for second round of public comment

Interoperability Standards

- Many “named standards” suggested
  - Round #1: ~700
  - Round #2: ~200
- HITSP harmonizes to minimum necessary “named standards”
  - Round #1: ~30
  - Round #2: ~31 (some overlap with round #1)
- HITSP identifies “constructs” to specify “named standards” transactions and use in implementation guidance
  - Round #1: ~20
  - Round #2: ~29 (some overlap with round #1)
- Interoperability standards (named standards and constructs) are accepted, implementation tested, and then recognized

HITSP Interoperability Specification 2007 Overview

- In 2007 HITSP developed Security & Privacy constructs
  - TN900 (v1.1) – Security and Privacy Technical Note
  - This Technical Note and the associated constructs were approved by the Panel in October 2007
- In 2007 HITSP also completed 3 new Interoperability Specifications and updated the existing IS03
  - IS04 (v1.1) - Emergency Responder Electronic Health Record
  - IS03 (v3.0) - Consumer Empowerment and Access to Clinical Information via Networks
  - IS05 (v1.0) - Consumer Empowerment and Access to Clinical Information via Media
  - IS06 (v1.0) - Quality
  - These Interoperability Specifications were approved by the Panel in December 2007

HITSP Interoperability Specification 2007 Overview

- These Interoperability Specifications include a suite of documents (including Transactions, Transaction Packages, and Components) that define selected standards and provide implementation level guidance to satisfy the requirements imposed by a given Use Case
- It is important to understand that the selected standards are defined within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts
- As used by HITSP, the term “standard” refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles

TN900 – Security and Privacy Technical Note

- Scope of work provides implementation guidance to address Security and Privacy Use Case requirements
  - Collect and Communicate Security Audit Trail
  - Consistent Time
  - Secured Communication Channel
  - Entity Identity Assertion
  - Access Control
  - Non-repudiation of Origin
  - Manage Consent Directives
  - Manage Sharing of Documents
- Provides an initial standards infrastructure that can be used to support different methodologies and approaches that are currently employed in different states
- Will continue to be reused for future Use Cases

TN900 – Security and Privacy Technical Note

- Harmonization Results
  - Originally 249 standards (including reference documents/guidelines) identified as candidates to meet the security requirements from the EHR-Lab, Consumer Empowerment and Biosurveillance 2006 Use Cases.
  - Final selection:
    - 8 Composite Standards
    - 20 Base Standards
    - Includes some standards previously selected and incorporated into the 2006 Interoperability Specifications
  - The HITSP Security and Privacy constructs are currently integrated into all of the 2007 Interoperability Specifications

HITSP IS04 Emergency Responder Electronic Health Record (ER-EHR)

- Scope of work is the deployment of standardized, widely available and secure solutions for accessing and exchanging current and historical patient-specific health information in both small and large scale incidents
- Harmonization Results
  - Defines and enables the use of multiple documents throughout the patient encounter in the Emergency Department (ED)
  - Standardization must support three heretofore separate affinity domains connected through the ED space. Standards selected:
    - ED Encounter Summary using IHE EDES
    - Patient summaries using CCD
    - Encounter Summary Document using IHE XDS-MS
    - ED Triage Note using IHE XDS-MS
    - ED Nursing Note using IHE XDS-MS
    - ED Physician Note using IHE XDS-MS
    - Data exchange using HL7

HITSP IS04 Emergency Responder Electronic Health Record (ER-EHR)

- Harmonization Results – Summary Document
  - Worked across the HITSP Technical Committees to develop an expanded Summary Document (HITSP\C32) with new additional content modules from the base standard (CCD)
    - Medication History
    - Allergies
    - Encounters
    - Problems and Conditions
    - Immunizations
    - Key Laboratory Test Results
  - Removed most content module requirements so that the Interoperability Specification may specify optionality
  - This promotes reuse of the Summary Document across current and future Interoperability Specifications

IS03 (updated) - Consumer Empowerment

- Scope of work is the support of consumer interactions with healthcare systems via networks
  - Consumer establishes an account to host a patient registration summary & clinical information (including medication history, allergies, encounters, problems & conditions, immunizations, and discrete lab results)
  - Consumer provides registration summary and self-entered/externally sourced clinical information during visit with Healthcare Providers
  - Support is provided for authorized Healthcare Provider review of a patient's clinical information
  - Support is provided for electronic distribution of clinical information and lab results by Healthcare Provider to patient

IS03 (updated) - Consumer Empowerment

- Key Requirements/Functionality Enabled by the IS
  - Reconciling identifiers for the same consumer/patient and querying other organizations for data for that individual
  - Accessing, viewing, and sharing registration summaries and clinical information
- Harmonization Results
  - Utilization of singular medical summary content (HL7 CCD) and support for uniform patient registration information (CAQH CORE)
  - Equivalent lab result content as deployed for other clinical scenarios (Care Delivery, Biosurveillance, etc)
  - Uniform clinical content for both network and media-based exchange
  - Security and privacy (S&P) requirements satisfied by HITSP S&P constructs and uniformly applied across clinical scenarios

IS05 - Consumer Empowerment

- Scope of work and harmonization results is essentially the same as the updated IS03, except…
  - IS05 introduces the use of portable media (CD-R or USB key) as the exchange mechanism. These are widespread, highly interoperable file systems
  - Patient identification reconciliation and most Security and Privacy requirements accomplished via human-to-human interaction
- Both the 2006 Consumer Empowerment Use Case and the 2007 Consumer Access Use Case are supported by the updated IS03 and the new IS05 – but distinguished by mode of exchange

IS06 - Quality

- Scope of work enables interoperable, electronic quality (eQuality) monitoring by providing implementers with a set of standards and workflows
  - Supports both electronic (automated) and manual data collection processes
  - Supports the initial set of quality measures selected by the Health Information Technology Expert Panel (HITEP)
  - Introduces patient-level quality measures in both messaging and document formats
- Harmonization Results
  - Data capture standards (IHE Retrieve Form For Data Capture, IHE Query for Existing Data (QED), IHE XDS)
  - Message-based and document-based approaches
  - Communications options (Traditional HL7, Media IHE XDM, Reliable Messaging IHE XDR)

IS06 - Quality

- Harmonization Results (continued)
  - Aligned with new IHE Quality TC, leveraging approaches defined in 2007
  - Anticipate leveraging ongoing work in HL7 and IHE Quality
  - Need for structured measures to be defined using the selected vocabularies
  - Need to be able to express logic of the measure
  - Need for on-going alignment of AHIC Expert Panel timelines with IS requirements specification timeline

Next Steps

- HITSP is asking that the AHIC recommend this work to the HHS Secretary for his acceptance / recognition
  - TN900 (v1.1) – Security and Privacy Technical Note
  - IS04 (v1.1) - Emergency Responder Electronic Health Record
  - IS03 (v3.0) - Consumer Empowerment and Access to Clinical Information via Networks
  - IS05 (v1.0) - Consumer Empowerment and Access to Clinical Information via Media
  - IS06 (v1.0) - Quality

January 22, 2008

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

Dear Mr. Chairman:

The Population Health and Clinical Care Connections Workgroup (PH/CCC) encompasses a broad perspective of population health and is described using five interrelated domains: Public Health Surveillance and Response; Health Status and Disease Monitoring; Population Based Research; Population Based Clinical Care; and Health Communications/Education.

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

Broad Charge for the Workgroup: Make recommendations to the Community that facilitates the flow of reliable health information among population health and clinical care systems necessary to protect and improve the public's health.

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

- Public Health infrastructure at the local, state and federal levels needs to be modernized to meet current and emerging threats by increasing the flexibility, functionality, and interoperability of systems that support public health.

While public health has made progress in the last several years toward developing information systems to support program specific needs, many of these systems have followed a pattern of categorical program-specific funding that constrained the scope of the solution (e.g., HIV surveillance systems cannot be easily adapted to serve other communicable disease surveillance needs). These resulting categorical public health programs solutions are now "siloed" and unable to accommodate large, complex outbreaks and events. As evidenced in the last decade alone – SARS, monkeypox, anthrax, and natural disasters such as hurricanes Katrina and Rita, public health emergencies that transcend geopolitical boundaries are becoming more routine. Testimony has shown that point or targeted solutions built in response to an emergency, often relying on inexpensive and readily available technologies such as Microsoft Access and/or Microsoft Excel scale poorly in these large emergencies that require complex contact tracing, data or information sharing across jurisdictions, and cross source data linking. Robust, scalable solutions that integrate local and state detection and response

while also accomplishing notification to national authorities are largely unavailable to public health agencies; resulting vulnerabilities could be mitigated by a thoughtful development of a strong cross-jurisdictional public health infrastructure founded on interoperable systems that support routine use yet are designed to scale and adapt to all hazards. A strong public health infrastructure available across all jurisdictions and levels of public health, regardless of size, strongly coupled to a robust private-sector healthcare information network, will go far toward reducing the wide variation in deployment of information technology that exists in public health today.

However, before interoperable systems are developed, functional, security, and interoperability criteria must be in place. The lack of criteria for public health systems is the next key issue.

- Functional, security and interoperability criteria will establish the basis for developing flexible, information systems that can be certified for functionality to support public health activities.

Public health agencies at different jurisdictional levels have disparate business needs and different capacities. Across state and local health departments there are significant capacity disparities. Large municipal health departments may have substantially more resources than their smaller rural counterparts or than some of the smaller states, yet each are expected to provide similar services. Activities supported by information systems differ across public health jurisdictional levels. For instance, outbreak investigations are comprehensively carried out and conducted at the local or state setting, with federal assistance being requested when needed. Key functions at those levels (e.g., case triage and management, epidemiologic investigation, contact tracing and tracking of laboratory diagnostics) must be incorporated into information system solutions. All levels of public health should collaboratively define criteria for interoperable systems to effectively support public health functions.

Variable organizational responsibilities across public health jurisdictional levels complicate efforts to standardize communications. While functional requirements may differ across jurisdictional levels, common data needs exist for all levels: a key difference is in how data are used and analyzed by each level. Data standard requirements are necessary to ensure semantically understandable content and secure transmission uniformly exists across all organizations involved in public health. Our goal is to limit the variation in capacity across similar jurisdictional levels while promoting interoperability across all levels.

- Public health has as a goal the development, endorsement and consistent implementation of nationally recognized data standards, common vocabulary standards and definitions, and systems available to support response.

Standards to support public health functions related to response should be prioritized for harmonization by the Healthcare Information Technology Standards Panel (HITSP) while respecting the unique business aspects of public health. Certification criteria should be

established to evaluate software solutions for functionality that support public health regarding both software and implementations. This reinforces recommendations 1.1 and 1.2 submitted to American Health Information Community (AHIC) by the PH/CCC Workgroup and accepted in March 2007[1]. These recommendations commit to the development of an approach, including development of additional and more detailed use cases to support standards identification and methods to measure certification criteria. There is insufficient emphasis and resources within public health to support the HITSP and certification processes to ensure there is capacity to harmonize standards and develop certification criteria for AHIC population health use cases. Software developed for public health response would need to adhere to HITSP harmonized standards, and meet certification criteria. This would promote standardized, interoperable solutions suitable for broad use and should curtail current redundant development pathways.

- The value to clinical care for including public health as an integral partner in health information technology (HIT) should be clearly articulated and broadly communicated.

This issue reiterates the need for a public health business case as indicated in recommendation 1.0 of the PH/CCC March 2007 letter to AHIC[1]. Public health should be considered as more than just a recipient of clinical information but also as a bi-directional source of information to clinical care. Clinical care provides case reports, adverse event reports and clinical data to appropriate public health entities, as well as providing updates to registries (such as immunization registries). Public health adds value to data derived from multiple sources (e.g., clinical care, veterinary, Food and Drug Administration, environmental sources), and makes this information available to clinicians to assist them in decision-making. Treatment recommendations, guidelines, assistance during vaccine shortages as well as updates to case definitions and the notifiable conditions list are examples of information provided back to clinical care.

The business case should encompass integration with clinical decision support (CDS) tools in electronic health records. The integration would not only prompt for reports to be sent to public health, but also provide clinical reminders from public health such as treatment recommendations and guidelines or vaccinations that are due. The AHIC CDS Planning Group focuses on CDS integration, and the PH/CCC Workgroup supports these and the other national efforts that exist in this space.

This letter provides both context and recommendations for how these issues can be addressed to implement informational tools and business operations to support real-time nationwide public health event monitoring and rapid response management. The first two overarching recommendations strive to address the key issue of strengthening the public health infrastructure. These are followed by area specific recommendations that are aimed at addressing the key issues of defining criteria and standards for information systems that support public health. These are presented in two parts: first, a section on what area needs are; and second, a section describing a timeline to meet those needs while developing a sound scientifically formed structure to ensure interoperability continues as the systems evolve.

BACKGROUND AND DISCUSSION

The threat of significant naturally occurring or man-made health events is a critical issue for the nation. Once an event has been detected, the ability to manage the event, determine the appropriate response, quickly mobilize resources and administer countermeasures can save lives.

Real-time nationwide public health event monitoring and rapid response management is addressed through four underlying priority areas. These priority areas were defined and ranked by the Workgroup based on an iterative process in 2006. The prioritization was followed by a visioning exercise to baseline the current state, and establish mid-state (by 2010) and end-state (2014 and beyond) visions for each priority area. After biosurveillance, the PH/CCC Workgroup defined and recommended the implementation order for the following priority areas:

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

Recommendations in the priority areas of Case Reporting and Bi-directional Communications were made to AHIC in March, 2007. The Workgroup then turned deliberations to the priority area of Response Management. The recommendations in this letter are based on Workgroup input, and informed by testimony given on March 29th and June 15th, 2007. Testimony and the resulting recommendations focus on four interrelated aspects of response management:

1. Outbreak and event management
2. Laboratory response
3. Countermeasure allocation, tracking, distribution and administration
4. Automated integration with registries

The overarching recommendations and the recommendations in the four aspects of response management are aimed at addressing the key issues described in this letter. As stated earlier, the key issue around a business case for data/information exchange between public health and clinical care has been covered in the March 2007 recommendation letter.

These current recommendations seek to increase the adoption and modernize public health information systems by making them fully functional (certified), and interoperable (standards compliant), in order to support the business processes required by local (~ 3000), state, tribal and territorial (~ 57) and federal (CDC and other) governmental public health authoritities.

RECOMMENDATIONS

1. Overarching Recommendation on Education in Public Health Informatics

The PH/CCC Workgroup endorses the effort to train 1,000 public health informaticians by 2010 and provide informatics leadership training to an additional 1,000 public health executives. The Workgroup endorses the concept of and placement of chief public health informatics officers in each state health department. To meet workforce shortages the PH/CCC recommends the following:

Recommendation 1.0: CDC, in collaboration with academic partners, professional societies, and public health associations should develop a program to enhance the number of professionals with informatics training who are in public health practice. This will be a three-pronged approach and include professionals who will become informaticians/scientists, those who will not be informaticians but would like to increase their understanding of public health informatics, as well as continuing education in informatics for existing public health practitioners. The public health informatics curriculum should include both didactic and a field (or lab) experience, and should include the following:

- **CDC, in collaboration with partners such as ASTHO and NACCHO, should conduct an annual assessment of informatics educational needs of public health practitioners and leaders and adapt its programs accordingly.**
- **By June 2008, CDC should develop professional level certificate training in informatics for public health professionals in informatics using distance-learning techniques and content adapted from AMIA's 10X10 program or another program as based on results from the needs assessment (outlined in the previous bullet). Experienced public health professionals and public health educators should play a key role in helping to create a competency-based curriculum based on public health needs.**
- **By June 2009, CDC should develop a program for curriculum development grants in public health informatics and also provides incentives for schools of public health to partner with schools of information science or informatics to establish new programs in public health informatics.**
- **By June 2008, CDC should expand its own public health informatics fellowship training program with dedicated funding for informatics fellows and an enhanced competency-based curriculum for fellows, to be included with other fellowship programs, such as the Epidemic Intelligence Service (EIS) program.**
- **By June 2008, CDC should work with the National Library of Medicine (NLM) and the Robert Wood Johnson Foundation to enhance graduate level training public health informatics, by expanding the supplemental funding of this activity within the NLM's graduate biomedical informatics training program.**
- **By June 2009, CDC, in collaboration with partner organizations such as ASTHO and NACCHO and the Joint Task force for Public Health Informatics should develop a comprehensive informatics program to build capacity for informatics at the state, local and tribal health department level. This program would create incentives and provide resources for informatics training and to attract and retain informatics professionals at the state and**

local health department levels. CDC should explore with HHS the ability to provide reimbursement of education loans and the provision of stipends and scholarships for those willing to practice informatics at the state and local levels.

2. Overarching Recommendation on Program Metrics

The second recommendation provides clarification for, and endorses use of, preparedness and other funds for building infrastructure in public health agencies and laboratories. This recommendation strives to move away from funding by program function, which has exacerbated the diversity seen in existing systems, and move toward an informatics capacity by building modular systems that adhere to common interface specifications.

Recommendation 2.0: HHS should work with CDC, the Health Resources and Services Administration (HRSA), the Centers for Medicare and Medicaid Services (CMS) and other federal agencies to include language in contracts, grants and cooperative agreements that ensures:

- **Funds from a variety of programs can contribute to an informatics capacity and technical architecture that invests in advancing information systems and IT infrastructure required to support their implementation and interoperability. This language should explicitly include systems and infrastructure that support public health labs, registries, surveillance systems, outbreak management and response systems, as well as other systems that receive data used for population health purposes. Input from state and local public health agencies should be sought to help identify barriers and provide solutions for this type of cross-program capacity building.**
- **In order to meet the requirements of the Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs[2], funds can be used for technical support, to cover the cost of on-going system maintenance, and for updates and enhancements to provide functionality and adhere with interoperability specifications.**
- **Metrics should be collaboratively developed with state and local public health partners to assess the ability of public health information systems to interoperate and support public health investigation and response. These metrics should measure and monitor interoperability, usability, flexibility, quality, completeness and timeliness of data, as well as system functionality to support:**
    - **Outbreak and event management,**
    - **Countermeasure allocation, tracking, distribution and administration,**
    - **Integration of laboratory information,**
    - **Case reporting and case notification, and**
    - **Bi-directional exchange of data across clinical care and public health.**

3. Outbreak and Event Management

Outbreaks vary in size and complexity, and can extend across local jurisdictions, state lines, and national borders. The SARS outbreak in Toronto[3] and the monkeypox[4] response in the U.S. illustrate the need to have systems with the ability to identify and triage suspected cases; collect initial clinical, demographic and laboratory data on suspected cases; support laboratory diagnosis, both in the clinical and public health laboratory sectors; collect relevant epidemiologic data to identify important common exposures (such as places, persons, gatherings, conveyances, or vectors) and support contact tracing and infection control, including: tracing, monitoring and possible quarantine of individuals exposed to a person with a communicable disease. Systems must be in place to manage complex relationships across geopolitical boundaries between cases, contacts and potential exposures. Methods for real-time tracking of these linkages should provide public health authorities with the ability to know who to investigate, manage, offer prophylaxis, isolate, quarantine, and/or treat.

Testimony to the PH/CCC Workgroup expressed a common theme: systems to support outbreak and event management are needed for use by public health. Criteria for these systems should be defined collaboratively, and the solutions should be both flexible and scalable enough to be used routinely and during emergencies.

Recommendation 3.0: By March 2008, CDC with the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), the Council of State and Territorial Epidemiologists (CSTE), the Association of Public Health Laboratories (APHL) and other appropriate groups, should undertake a program that will result in:

- **Requirements gathering to define functionality that is minimal but sufficient to support the needs of managing complex outbreaks across jurisdictions.**
- **Identification of existing standards and/or definition of standards that will allow OEMS to interoperate with local, state, tribal and vendor OEMS, and other public health systems such as laboratory information systems (LIS), systems that manage countermeasures, fatality management tracking systems, and tools for monitoring of quarantine and isolation.**
- **Identification of existing standards and/or definition of standards that will allow OEMS to access interoperable clinical data from the Nationwide Health Information Network (NHIN) and CCHIT certified EHRs.**
- **The development of interoperable Outbreak and Event Management Systems (OEMS) that are based on an open architecture and comply with HITSP harmonized standards.**
- **Dissemination of Outbreak and Event Management Systems (OEMS) among state and local public health departments.**

Recommendation 3.1: CDC, with input and assistance from state and local public health should support the development and testing of software systems designed to

manage public health investigations (e.g., CDC Outbreak Management System, state or commercially-developed systems), including identification of important exposures, laboratory diagnostics, contact tracing and indication for preventive countermeasures such as infection control, isolation, quarantine, prophylaxis or treatment. CDC should create a nationwide network of interoperable OEMS's meeting the criteria of 3.0, with input and assistance from state and local public health officials, CSTE, ASTHO and NACCHO that:

- **Further refine the CDC's existing outbreak management software and make this software available for free use by public health departments by October of 2008. Interoperability features should be extended with each update of the software.**
- **Develop a detailed plan for creation of this nationwide network by October 2008.**
- **Develop detailed use cases for interoperability between OEMS systems and among OEMS and other systems, including LIS and EMRs by October 2008 building from the relevant AHIC Use Cases (i.e., Biosurveillance, Public Health Case Reporting, Immunizations and Response Management and Electronic Health Records: Laboratory Results Reporting).**
- **Develop functional specifications for OEMS software by December 2008.**
- **Identify relevant standards for vocabulary, security, data elements, and data transmission by December 2008 and advance these standards for harmonization by HITSP.**
- **Develop preliminary systems and software architecture for interoperable OEMS systems by June 2009.**
- **Develop and test prototype interoperable OEM systems by October 2009.**
- **Conduct a nationwide demonstration project linking interoperable OEM systems in multiple jurisdictions in an interoperable system of systems starting December 2009.**
- **Initiate certification of OEMS' including the definition of certification criteria through an open participatory process of certification for public health information systems as referenced in the PH/CCC Recommendations from March 2007.**

4. Laboratory Response

Laboratory testing plays an important role in multiple domains related to this report including Public Health Surveillance and Response, Health Status and Disease Monitoring and Population Based Clinical Care. While much attention has been placed on electronic laboratory reporting for notifiable diseases (ELR), the full breadth of laboratory testing from which actionable information can be derived extends to other processes associated with laboratory testing, including requests for testing services and physician orders. The ability to electronically exchange test orders and test results facilitates multiple functions, including the rapid identification of outbreaks of disease, the monitoring of the health of a population and the generation of data essential for response to a public health event and ongoing situational awareness. Testimony illustrated that during an outbreak or event; laboratory test volume can

dramatically escalate, requiring the test loads be balanced among laboratories in different jurisdictions. This was observed during the anthrax events of 2001 when the Laboratory Response Network (LRN)[5] laboratories tested over 125,000 samples representing over one million separate laboratory tests. The reporting, aggregation, and analysis of the results from the many labs performing the testing was complex and unsupported by electronic exchange between organizations involved in the response. Significant human effort was required to consolidate and reconcile data, activities that can be largely eliminated through adoption of standard approaches to electronic laboratory test ordering and reporting. The anthrax events, followed by SARS and more recently the numerous food borne outbreaks (E. coli in spinach, salmonella in peanut butter) illustrate the need to develop and broadly adopt common specifications and processes to enable specimen and results tracking and corroboration among public and private laboratories and public health partners. Infectious diseases are not the only challenges facing public health laboratories. Following the impact of Hurricane Katrina, laboratory services provided by the Louisiana Public Health Laboratory had to be shifted to other distant sites including the Iowa State Hygienic Laboratory. The testimony not only called attention to the need for collaboration among labs and public health partners, but also the need for federal agencies to coordinate and harmonize requirements across the entire United States.

Public health requires coordination of reporting requirements from clinical, veterinary, environmental and public health laboratories to state and federal agencies. Coordinated reporting requirements across all data sources will reduce the current reporting burden on labs and clear the path to define standards and vocabulary for automated exchange of test results. In June 2005, the Department of Homeland Security established the Integrated Consortium of Laboratory Networks (ICLN) with a Memorandum of Agreement to promote harmonization and coordination across multiple laboratory networks affiliated with federal agencies (LRN-B, LRN-C, NAHLN, FERN, eLRN, etc.). The ICLN includes 10 federal departments/agencies, including Agriculture, Commerce, Defense, Energy, Health and Human Services, Homeland Security, Interior, Justice, State, and the Environmental Protection Agency. The ICLN's mission is to create a U.S. homeland security infrastructure with a coordinated operational system of laboratory networks that provide timely, high quality, and interpretable results for early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response. The PH/CCC Workgroup recommends support of the interagency coordination efforts of the ICLN.

While federal agencies play an important role in confirmation and investigation of disease outbreaks or public heath events, the majority of sentinel data is generated either within the community laboratory or the local or state public health laboratory. The lack of uniform process and standards significantly hinders the ability of federal agencies to coordinate the response effort and limits efforts at the local and state levels to share information efficiently. Therefore, a significant need exists to harmonize data reporting standards and guidelines among local, state and federal agencies. Testimony expresses significant progress being made by the CDC and APHL in pilot projects directed toward achieving a uniform approach to electronic exchange of laboratory test orders and results reporting. The PH/CCC Workgroup recommends the expansion of these efforts with the goal of achieving an integrated laboratory system focused on public health.

To achieve these collective goals, the Workgroup further recommends:

Recommendation 4.0: CDC, in collaboration with APHL, CSTE, ASTHO, NACCHO and other appropriate organizations, should develop a national program to enable public health laboratories to exchange data with other public health laboratories, speeds the integration of public health laboratories with the NHIN, and facilitates data exchange between public health laboratories, state, local and nationwide public health protection entities, Nationwide Health Information Exchanges and CCHIT certified EHRs. Initial focus should be on any type of data, codes, and relationships necessary to support:

- **Test orders to and result reporting from public health labs.**
- **Coding of public health conditions in the HITSP lab message.**
- **Result reporting of veterinary and environmental data.**
- **Unambiguous linkage of laboratory data to clinical and public health records.**

To achieve this end, CDC in consultation APHL, CSTE, ASTHO, and NACCHO, and other appropriate organizations, should undertake the following activities:

- **By February 2008, launch a national effort, in collaboration with APHL, to develop a NHIN compatible reference data model for public health laboratories, standards for data exchange and protocols for data exchange. The program should include a demonstration project with two way exchange of information across a network of public health laboratories. Relevant HITSP standards should be used and standards gaps identified as part of this process should be advanced for harmonization by HITSP.**
- **By October 2009, develop a reference data model linking public health laboratory data with relevant veterinary and environmental health data.**
- **By October 2010, begin a demonstration project linking a network of public health laboratories with a network of environment laboratories for data exchange.**
- **Initiate certification for public health laboratory networks through an independent certification process for public health information systems as referenced in the PH/CCC Recommendations from March 2007.**

The scope of this effort should be inclusive of the additional public health laboratory response requirements not included in the AHIC EHR Laboratory and Biosurveillance Use Cases (e.g., orders and results for veterinary, environmental and food specimens). This effort should include, at a minimum, the AHIC Minimum Biosurveillance Data Set (MBDS) and the HITSP lab result message interoperability specification as well as the planned HITSP additions. An analysis should be done to identify possible additional domain vocabularies to support the expanded scope for public health laboratory response. CDC should identify new

priorities from this work and advance them through the PH/CCC Workgroup for incorporation into the national agenda process.

Recommendation 4.1: HHS, in conjunction with state and regional health information exchanges, public health and clinical laboratories, should develop the infrastructure and architecture for unambiguous unique identification of medical service providers in association with the Nationwide Health Information Network (NHIN) initiative. This should include ensuring that registries of medical service providers exist and that registry lookup capability is developed and available to laboratories for routing laboratory data back to the originating requestor, and to other appropriate parties, to support national electronic laboratory data exchange.

Recommendation 4.2: By December 2009, CDC, in collaboration with the Association of Public Health Laboratories (APHL), private laboratories, and other federal laboratories, should establish regional or national capabilities to receive and route public health laboratory results to all appropriate recipients simultaneously. The steps to achieve this capability would include:

- **Defining the processes and approaches for consolidated receipt and routing of laboratory results.**
- **Conducting a demonstration project illustrating efficient regional or national mechanism for the acquisition of laboratory test order information as well as simultaneous dissemination of public health laboratory test results to appropriate public health and clinical care providers.**

5. Countermeasure Allocation, Tracking, Distribution and Administration

Response Management includes interventions (i.e., isolation and quarantine) as well as acquisition and allocation of supportive countermeasures (e.g., treatments, prophylaxis, and provisions) during a public health response. Tracking activities include monitoring shortages and apportioning countermeasures during a shortage, administration management, distribution of resources, and coordination of potential assets through the commercial sector supply chain.

Some of the same issues exist in the area of countermeasures, as noted in other public health activities:

- Standards are currently incomplete or not available to support countermeasure needs across jurisdictional units. Standards should include a set of uniform minimum data elements, common vocabulary and defined relationships between the data elements; operational guidance to include system redundancy, security, and reliability; and should consider methods to handle materiel identification, such as bar coding standards.
- Information on the availability of countermeasures in the commercial supply chain is, at times, considered to be sensitive and proprietary information of commercial organizations and not readily sharable with public health.

- While countermeasure distribution systems are available for tracking and follow-up, they are not well-integrated. There are few commercial off-the-shelf (COTS) products available to support countermeasure administration and follow-up.
- Customization of a COTS product can be cost prohibitive and still not guarantee that the final product will meet the organization's requirements nor interoperate with other jurisdictions or vendor resources.
- Hospitals have developed and implemented electronic tracking systems that do not interoperate with public health resources or informational needs. During testimony, specific local health departments mentioned limited capacities to fund interfacing with community providers and partners as it would detract from capacity to provide ongoing public health services.
- Legal concerns persist regarding provision of clinical data (e.g., hospital system data) to public health officials for active surveillance.
- There is a need for obtaining as much information as possible during an outbreak or event so that you know what materials are available, who has them, and where the greatest need exists.
- Information gaps exist in the supply chain; for example, information doesn't come back from treatment centers to Point of Distribution (POD) sites.

Because outbreaks and events are not limit to jurisdictional boundaries, systems must interconnect both horizontally and vertically. During a response, secure exchange between the private sector and public health may be needed across jurisdictions and national borders. To be effective, this requires comparable growth toward integration and interoperability in both public health and the private sector -- a need in which the AHIC process strives to fulfill. Although it is recognized that data needs to be exchanged across jurisdictions during an emergency, it is also important to recognize that data must be shared on a routine basis. In 2004, 14% of the population moved domiciles at least once. In addition, annually there is a significant portion of the population that changes domiciles on a temporal basis, such as college students and "snowbirds."

Recommendation 5.0: By March 2008, CDC in consultation with ASTHO, NACCHO, CSTE, APHL, the Food and Drug Administration (FDA) and other appropriate groups, should undertake a program that will result in the requirements gathering to ensure system development and interoperability and wide-spread dissemination of interoperable systems that support countermeasure apportionment, tracking, distribution, administration, and outcomes measurement at local, tribal, state and federal levels. The program should result in:

- **Requirements that are minimal but sufficient to support the needs of managing countermeasures.**
- **The identification of HITSP standards that will allow countermeasure software to interoperate with other public health systems such as laboratory information systems (LIS), systems that manage countermeasures, fatality management tracking systems, OEMS and tools for monitoring of quarantine and isolation.**

- **Development of a free version of countermeasure software that integrates well across jurisdictions should be made available for use by public health departments.**
- **The ability to support data exchange with the private sector including vendor managed inventories, facility management tracking systems, point of distribution software and other recognized items.**
- **The identification of standards that will allow countermeasure systems to interoperate using clinical data from the Nationwide Health Information Network and CCHIT certified EHRs.**

Recommendation 5.1: By April 2008, CDC should convene a meeting to include representation from clinical partners, manufacturers and distributors to understand the resources that are available in the private sector, and at the state level, and develop strategies to exchange information on the availability of and demand for, and uses of resources at any given time.

Recommendation 5.2: To create a nationwide network of interoperable countermeasure tracking and administration systems, CDC, with input and assistance from state, tribal and local public health departments, ASTHO, NACCHO, CSTE, APHL, and other appropriate partners should:

- **Develop a detailed plan for development of the network by June 2008.**
- **Develop detailed use cases for interoperability of countermeasure systems by August 2008 that build on relevant AHIC Use Cases.**
- **Collaboratively develop requirements' gathering and functional specifications for interoperable countermeasure software by October 2008.**
- **Identify relevant standards for vocabulary, modeling, security and data transmission by December 2008 and advance these standards for harmonization by HITSP.**
- **Develop preliminary systems and software architecture plan by February 2009.**
- **Develop a reference data model for countermeasure administration linked to a public health ontology by May 2009.**
- **Develop and begin testing prototype applications that implement the proposed architecture and vocabulary standards by August 2009.**
- **Conduct a national demonstration project linking multiple countermeasure administration systems in multiple jurisdictions for data exchange starting January 2010.**
- **Initiate certification for countermeasure information systems including the definition of certification criteria thorough an independent certification process for public health information systems as referenced in the PH/CCC Recommendations from March 2007.**

Recommendation 5.3: By June 2008, HHS should facilitate development of nationwide administrative or legal approaches for routine and emergency inter-state data exchange of countermeasure and immunization information.

- **Address business propriety data concerns of relevant commercial supply chain entities.**
- **Develop a blanket agreement to provide federal support for sharing of data and resources when it is necessary.**
- **Communicate with and educate hospital risk management staff and privacy and confidentiality officers in clinical care settings to alleviate concerns about public health access to clinical data.**

6. Automated Integration with Registries

During a response, registries may be used for multiple purposes, and the potential for additional uses should be explored. Registries of emergency response volunteers, credentialing, and those responders with appropriate immunization status may be used to identify personnel prepared to participate in a response. Similarly, during a response, registries may be used to track people given countermeasures, being monitored (e.g., quarantine) and those requiring long-term follow-up. Immunization registries played a key role after hurricanes Katrina and Rita in providing vaccination records for displaced children; saving an estimated $4.6 million dollars in potential revaccination costs[6]. During deliberations, the Workgroup recognized that health information exchanges (HIEs) may eventually assume some of the functions currently handled through integration with registries. The Workgroup identified that a powerful role may be possible for HIEs in the future, and this may be an area to prioritize for future deliberations. However, this section is focused on recommendations for registries.

In the area of immunization registries, the infrastructure for these systems, known as Immunization Information Systems (IIS), is partially established. The IIS information infrastructure is in place in a number of states and includes characteristics that should be endorsed and extended. In general, registry systems should be population-based and adopt industry standards-based techniques for data communication.

Capabilities developed in more established registries, such as the infrastructure of IIS and the clinical data exchange of cancer registries, could be leveraged to improve integration with both clinical and public health registries during a response. The first step is to facilitate dialog to discover short-term and long-term benefits that could be realized from automating integration with registries. The second step is to prioritize potential advances, and communicate efficiencies that could be realized with the appropriate parties.

Recommendation 6.0: CDC should evaluate the potential effectiveness of use of state and local clinical encounter and public health registries in disaster management for use in response. This should include the following:

- **By June 2008, convene a group of state, local and other federal public health registry experts to discuss potential models for use of patient and clinical encounter or public health registries, especially those for special populations, disparate populations, and nursing home residents, in disaster response and to assess expert opinion on the potential usefulness of this information and to identify populations of interest.**
- **By August 2008, if deemed feasible by the experts in the June meeting, develop a detailed use case for healthcare related registry information beyond immunizations in disaster response with input from ASTHO, NACCHO, CMS, AHRQ and other appropriate CDC partners.**
- **Prioritize disease registries as a 2009 use case.**

Recommendation 6.1: CDC, HHS and public health partners should work to accelerate the integration of IISs with the NHIN and enhance IISs information exchange amongst each other. This should include the following:

- **By May 2008, complete the development of a detailed use case for exchange of patient data among vaccine registries and EHRs, and exchange of population data from IISs to a public health entity.**
- **By October 2008, working through HITSP, identify the relevant standards for implementation of vaccine-data-transaction use cases.**
- **By January 2009, initiate a demonstration project to test the feasibility of transmitting data between vaccine exchanges using NHIN standards and the feasibility of transmitting data between an NHIE and an IIS.**
- **By July 2009, initiate a demonstration project to test the feasibility of using NHIN standards to track the vaccination status of an individual across a wide geographic region with multiple IISs.**

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

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

Sincerely yours,

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

Sincerely yours,

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

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[1] *Population Health Recommendation Letter. Available from URL: http://www.hhs.gov/healthit/documents/m20070313/pophealthletter.html [Accessed Sep 2007]*

[2] *Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs. Available from URL: http://www.whitehouse.gov/news/releases/2006/08/20060822-2.html [Accessed Sep 2007]*

[3] *Wallington T, MD, Berger L, MD, et al. Update: Severe Acute Respiratory Syndrome --- Toronto, Canada, 2003 Morbidity and Mortality Weekly Report. 2003: 52(23);547-550*

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[6] *Urquhart, G, Williams, W, et al. Immunization Information Systems Use During a Public Health Emergency in the United States, J Public Health Management Practice, 2007, 13(5), 481–485*

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

American Health Information Community

Population Health and Clinical Care Connections Workgroup Recommendations

Leslie Lenert
NCPHI Director
Centers for Disease Control and Prevention

January 22, 2008

PH/CCC Workgroup Member List

- **Co-Chairs:**
  - John Lumpkin — The Robert Wood Johnson Foundation
  - Julie Gerberding — CDC
- **Members:**
  - Michael Barr — ACP
  - Scott Becker — APHL
  - Larry Biggio — State of WY
  - Theresa Cullen — IHS
  - Art Davidson — Denver Public Health Dept. (NACCHO)
  - Lisa Dwyer — CSTE
  - Jon Einbinder — Partners Healthcare
  - Thomas Frieden — NYC Dept. of Health and Mental Hygiene (NACCHO)
  - Angela Fix — ASTHO
  - Shawn Fultz — Dept. of VA
  - Shaun Grannis — Regenstrief
  - James Hadler — CT Dept of Health (CSTE)
  - Amy Helwig — AHRQ
  - Brian Keaton — ACEP
  - Martin LaVenture — MN Dept of Health (ASTHO)
  - John Loonsk — ONC
  - Bob Martin — CDC/CoCHIS
  - David Parramore — Dept of Defense
  - Dave Ross — PHII
  - Lisa Rovin — FDA
  - Edward Sondik — CDC
  - Paula Soper — NACCHO
- **Office of the National Coordinator:**
  - Kelly Cronin — ONC WG Director
  - Laura Conn — Senior Advisor
  - Shu McGarvey — Lead Staff, NG – Contractor to ONC

Population Health and Clinical Care Connections Workgroup Overview

Broad Charge:

Make recommendations to the Community that facilitate the flow of reliable health information among population health and clinical care systems necessary to protect and improve the public's health.

Specific Charge:

Make recommendations to the Community so that within one year, essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems can be transmitted in standardized and anonymized format to authorized public health agencies within 24 hours.

Scope of Response Management Recommendations

- Overarching – Education
- Overarching – Program Metrics
- Outbreak Management
- Laboratory response
- Countermeasure Allocation, Distribution and Administration
- Integration with Registries

Recommendation 1.0: Overarching - Education

CDC, in collaboration with academic partners, professional societies, and public health associations should develop a program to enhance the number of professionals with informatics training who are in public health practice. This will be a three-pronged approach and include professionals who will become informaticians/scientists, those who will not be informaticians but would like to increase their understanding of public health informatics, as well as those who are existing public health practitioners and would like to continue their education in informatics. The public health informatics curriculum should include both didactic and a field (or lab) experience, and should include the following:

(please find detail in notes)

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 2.0: Overarching – Program Metrics

HHS should work with CDC, the Health Resources and Services Administration (HRSA), the Centers for Medicare and Medicaid Services (CMS) and other federal agencies to include language in contracts, grants and cooperative agreements that ensures:

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 3.0: Outbreak and Event Management

By March 2008, CDC with the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), the Council of State and Territorial Epidemiologists (CSTE), the Association of Public Health Laboratories (APHL) and other appropriate groups, should undertake a program that will result in:

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 3.1: Outbreak and Event Management

CDC, with input and assistance from state and local public health should support the development and testing of software systems designed to manage public health investigations (e.g., CDC Outbreak Management System, state or commercially-developed systems), including identification of important exposures, laboratory diagnostics, contact tracing and indication for preventive countermeasures such as infection control, isolation, quarantine, prophylaxis or treatment.

Recommendation 3.1: Outbreak and Event Management (cont.)

CDC should create a nationwide network of interoperable OEM Systems meeting the criteria of 3.0, with input and assistance from state and local public health officials, CSTE, ASTHO and NACCHO that:

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 4.0: Laboratory Response

CDC, in collaboration with APHL, CSTE, ASTHO, NACCHO and other appropriate organizations, should develop a national program to enable public health laboratories to exchange data with other public health laboratories, speeds the integration of public health laboratories with the NHIN, and facilitates data exchange between public health laboratories, state, local and nationwide public health protection entities, Nationwide Health Information Exchanges and CCHIT certified EHRs. Initial focus should be on any type of data, codes, and relationships necessary to support:

Recommendation 4.0: Laboratory Response (cont.)

- Test orders to and result reporting from public health labs.
- Coding of public health conditions in the HITSP lab message.
- Result reporting of veterinary and environmental data.
- Unambiguous linkage of laboratory data to clinical and public health records.

To achieve this end, CDC in consultation APHL, CSTE, ASTHO, and NACCHO, and other appropriate organizations, should undertake the following activities:

☐ Accept ☐ Table ☐ Reject

Recommendation 4.1: Laboratory Response

HHS, in conjunction with state and regional health information exchanges, public health and clinical laboratories, should develop the infrastructure and architecture for unambiguous unique identification of medical service providers in association with the Nationwide Health Information Network (NHIN) initiative. This should include ensuring that registries of medical service providers exist and that registry lookup capability is developed and available to laboratories for routing laboratory data back to the originating requestor, and to other appropriate parties, to support national electronic laboratory data exchange.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 4.2: Laboratory Response

By December 2009, CDC, in collaboration with the Association of Public Health Laboratories (APHL), private laboratories, and other federal laboratories, should establish regional or national capabilities to receive and route public health laboratory results to all appropriate recipients simultaneously. The steps to achieve this capability would include:

- **Defining the processes and approaches for consolidated receipt and routing of laboratory results.**
- **Conducting a demonstration project illustrating efficient regional or national mechanism for the acquisition of laboratory test order information as well as simultaneous dissemination of public health laboratory test results to appropriate public health and clinical care providers.**

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 5.0: Countermeasure Allocation, Distribution, Admin.

By March 2008, CDC in consultation with ASTHO, NACCHO, CSTE, APHL, the Food and Drug Administration (FDA) and other appropriate groups, should undertake a program that will result in the requirements gathering to ensure system development and interoperability and wide-spread dissemination of interoperable systems that support countermeasure apportionment, tracking, distribution, administration, and outcomes measurement at local, tribal, state and federal levels. The program should result in:

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 5.1: Countermeasure

By April 2008, CDC should convene a meeting to include representation from clinical partners, manufacturers and distributors to understand the resources that are available in the private sector, and at the state level, and develop strategies to exchange information on the availability of and demand for, and uses of resources at any given time.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 5.2: Countermeasure

To create a nationwide network of interoperable countermeasure tracking and administration systems, CDC, with input and assistance from state, tribal and local public health departments, ASTHO, NACCHO, CSTE, APHL, and other appropriate partners should:

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 5.3: Countermeasure

By June 2008, HHS should facilitate development of nationwide administrative or legal approaches for routine and emergency inter-state data exchange of countermeasure and immunization information.

- **Address business propriety data concerns of relevant commercial supply chain entities.**
- **Develop a blanket agreement to provide federal support for sharing of data and resources when it is necessary.**
- **Communicate with and educate hospital risk management staff and privacy and confidentiality officers in clinical care settings to alleviate concerns about public health access to clinical data.**

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 6.0: Automated Integration with Registries

CDC should evaluate the potential effectiveness of use of state and local clinical encounter and public health registries in disaster management for use in response. This should include the following:

- **By June 2008, convene a group of state, local and other federal public health registry experts to discuss potential models for use of patient and clinical encounter or public health registries, especially those for special populations, disparate populations, and nursing home residents, in disaster response and to assess expert opinion on the potential usefulness of this information and to identify populations of interest.**
- **By August 2008, if deemed feasible by the experts in the June meeting, develop a detailed use case for healthcare related registry information beyond immunizations in disaster response with input from ASTHO, NACCHO, CMS, AHRQ and other appropriate CDC partners.**
- **Prioritize disease registries as a 2009 use case.**

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 6.1: Automated Integration with Registries

CDC, HHS and public health partners should work to accelerate the integration of Immunization Information Systems (IISs) with the NHIN and enhance Immunization Information Systems information exchange amongst each other. This should include the following:

- **By May 2008, complete the development of a detailed use case for exchange of patient data among vaccine registries and EHRs, and exchange of population data from IISs to a public health entity.**
- **By October 2008, working through HITSP, identify the relevant standards for implementation of vaccine-data-transaction use cases.**
- **By January 2009, initiate a demonstration project to test the feasibility of transmitting data between vaccine exchanges using NHIN standards and the feasibility of transmitting data between an NHIE and an IIS.**
- **By July 2009, initiate a demonstration project to test the feasibility of using NHIN standards to track the vaccination status of an individual across a wide geographic region with multiple IISs.**

☐ **Accept** ☐ **Table** ☐ **Reject**

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

American Health Information Community

Roadmap to Achieving PH/CCC Recommendations

Leslie Lenert
NCPHI Director
Centers for Disease Control and Prevention

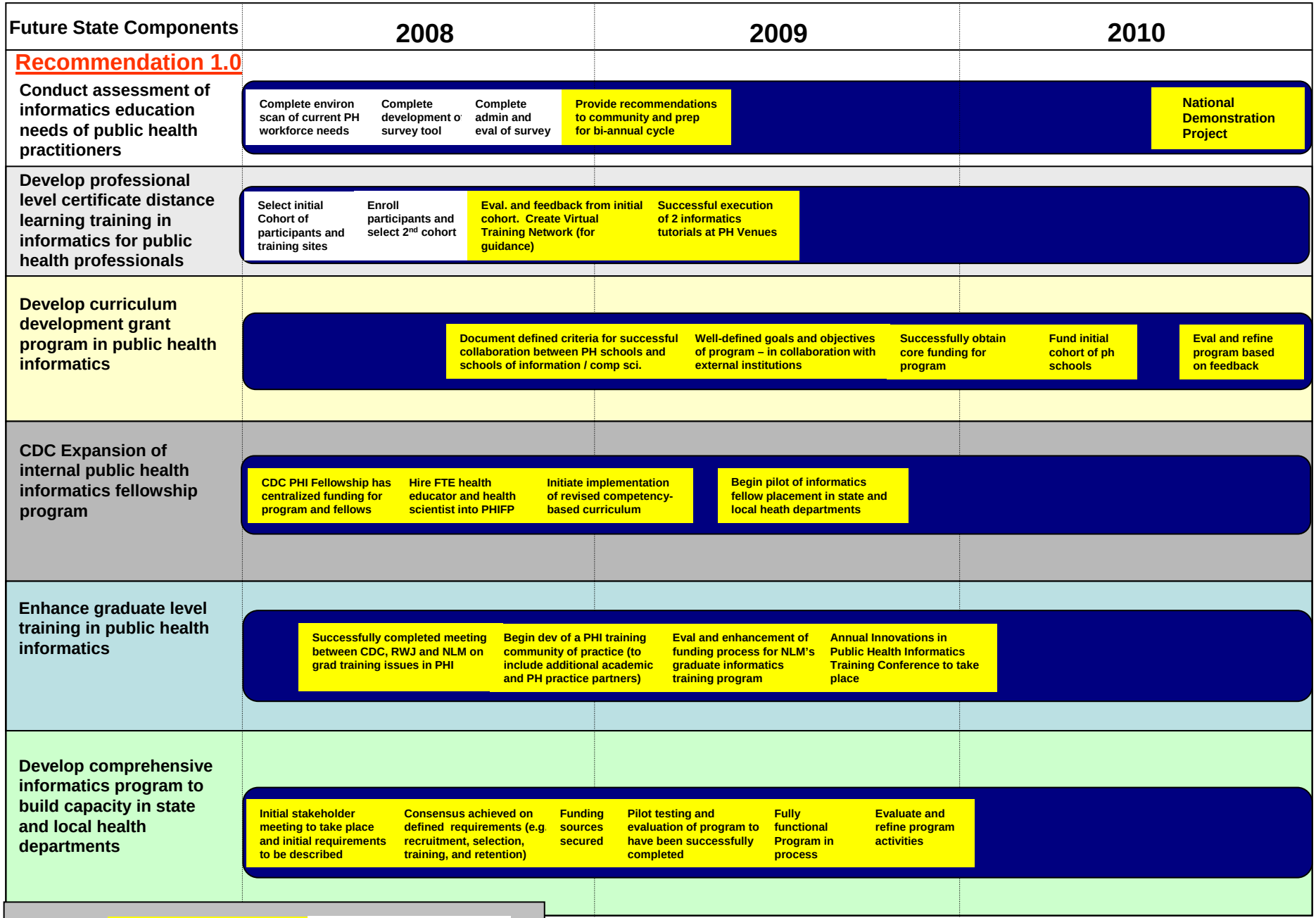
January 22, 2008

Recommendation 1: Public Health Informatics Training

Goals & Objectives

A coherent national policy to meet informatics needs for public health at state, local & tribal levels

- Distance learning program expanded to train 100 public health officials per year
- Biannual program evaluation to ensure proper focus is maintained
- Informatics tutorials will be held at most major conferences
- RWJ-NLM graduate program transitioned to CDC leadership & continues training of PhD in Informatics specializing in public health
- Six new public health schools create specialized graduate programs in public health informatics
- Six dedicated informatics fellowship slots created at CDC
- Ten trained informaticians placed in state, local & tribal public health departments for 2-year fellowships

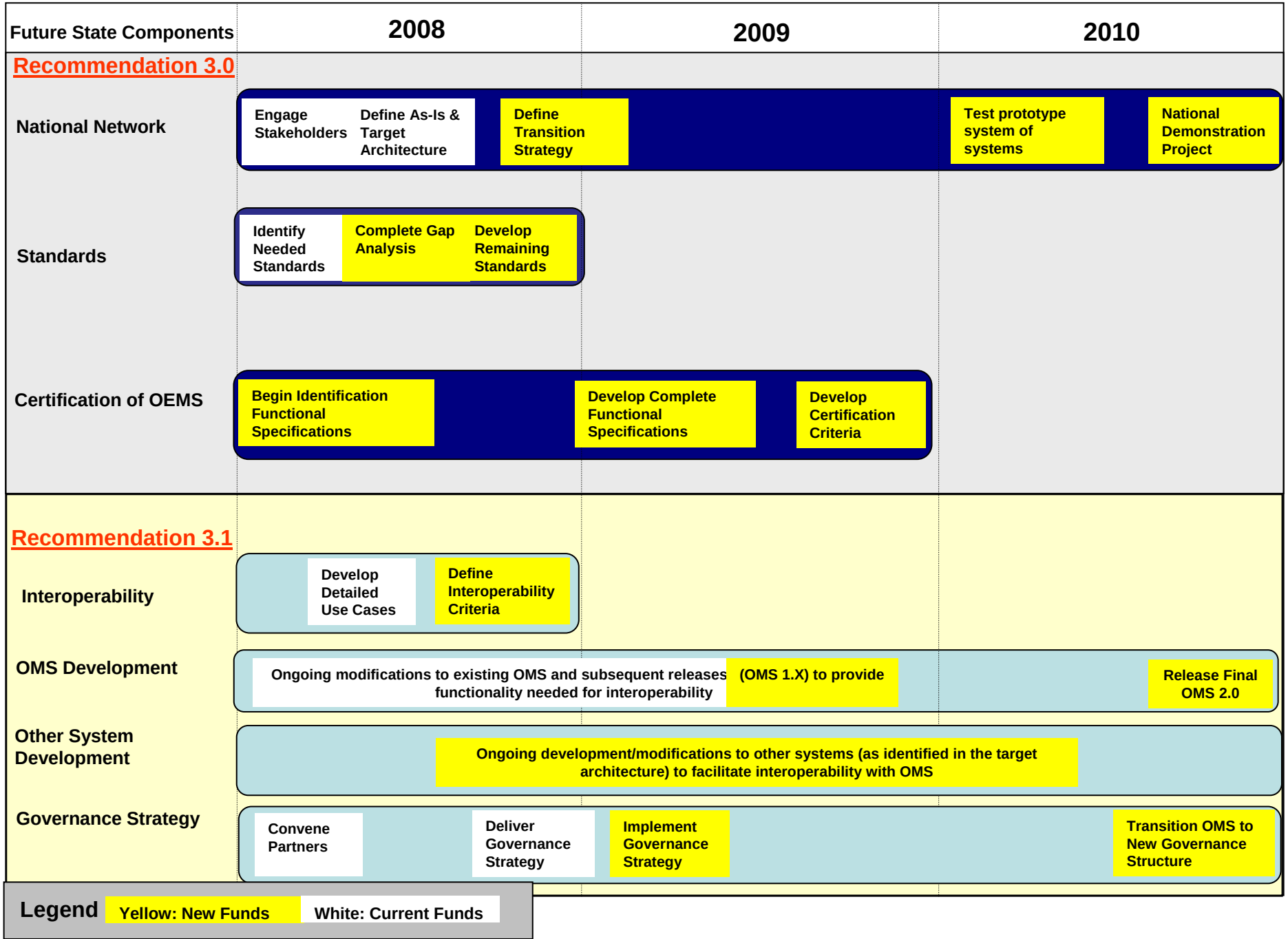

Future State Components
2008
2009
2010
Recommendation 1.0
Conduct assessment of informatics education needs of public health practitioners
Complete environ scan of current PH workforce needs
Complete development o survey tool
Complete admin and eval of survey
Provide recommendations to community and prep for bi-annual cycle
National Demonstration Project
Develop professional level certificate distance learning training in informatics for public health professionals
Select initial Cohort of participants and training sites
Enroll participants and select 2nd cohort
Eval. and feedback from initial cohort. Create Virtual Training Network (for guidance)
Successful execution of 2 informatics tutorials at PH Venues
Develop curriculum development grant program in public health informatics
Document defined criteria for successful collaboration between PH schools and schools of information / comp sci.
Well-defined goals and objectives of program – in collaboration with external institutions
Successfully obtain core funding for program
Fund initial cohort of ph schools
Eval and refine program based on feedback
CDC Expansion of internal public health informatics fellowship program
CDC PHI Fellowship has centralized funding for program and fellows
Hire FTE health educator and health scientist into PHIFP
Initiate implementation of revised competency-based curriculum
Begin pilot of informatics fellow placement in state and local heath departments
Enhance graduate level training in public health informatics
Successfully completed meeting between CDC, RWJ and NLM on grad training issues in PHI
Begin dev of a PHI training community of practice (to include additional academic and PH practice partners)
Eval and enhancement of funding process for NLM's graduate informatics training program
Annual Innovations in Public Health Informatics Training Conference to take place
Develop comprehensive informatics program to build capacity in state and local health departments
Initial stakeholder meeting to take place and initial requirements to be described
Consensus achieved on defined requirements (e.g. recruitment, selection, training, and retention)
Funding sources secured
Pilot testing and evaluation of program to have been successfully completed
Fully functional Program in process
Evaluate and refine program activities
Legend
Yellow: New Funds
White: Current Funds

Recommendation 3: Outbreak and Event Management

Goals & Objectives

In order to harmonize the functionality & interoperability of OEMS applications, CDC seeks to have:

- An open source interoperable OEMS team with independent governance and full state, local, territorial & tribal participation
- National prototypes & demonstration projects to illustrate how to build interoperable OEMS
- OEMS interoperable systems installed in 40+ states and/or territories
- Certification criteria for COTS OEMS and to have multiple OEMS certified, giving states choices in implementation

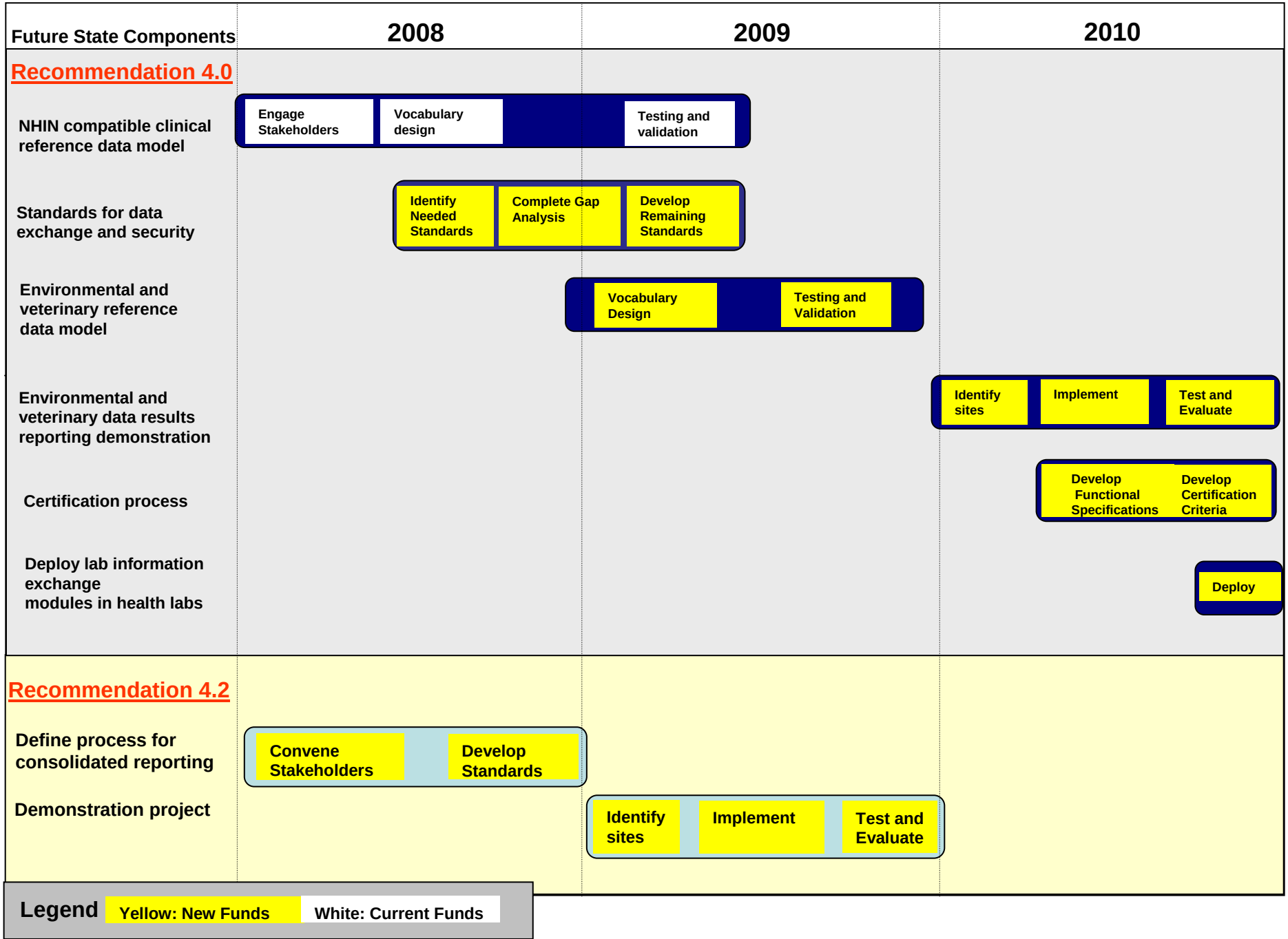

Future State Components
2008
2009
2010
Recommendation 3.0
National Network
Engage Stakeholders
Define As-Is & Target Architecture
Define Transition Strategy
Test prototype system of systems
National Demonstration Project
Standards
Identify Needed Standards
Complete Gap Analysis
Develop Remaining Standards
Certification of OEMS
Begin Identification Functional Specifications
Develop Complete Functional Specifications
Develop Certification Criteria
Recommendation 3.1
Interoperability
Develop Detailed Use Cases
Define Interoperability Criteria
OMS Development
Ongoing modifications to existing OMS and subsequent releases (OMS 1.X) to provide functionality needed for interoperability
Release Final OMS 2.0
Other System Development
Ongoing development/modifications to other systems (as identified in the target architecture) to facilitate interoperability with OMS
Governance Strategy
Convene Partners
Deliver Governance Strategy
Implement Governance Strategy
Transition OMS to New Governance Structure
Legend
Yellow: New Funds
White: Current Funds

Recommendation 4: Public Health Lab Data Exchange

Goals & Objectives

In order to develop a national program for laboratory data exchange, CDC will develop:

- Software and processes designed to allow public health laboratories to:
  - Exchange data with each other
  - Exchange data with environmental and veterinary labs
  - Exchange data with clinical care system
  - Route messages to all relevant parties in a region
- Standards to certify public health laboratory systems & a process for certification
- Grants program to upgrade public health laboratories to ensure that 50% of public health laboratories can exchange messages

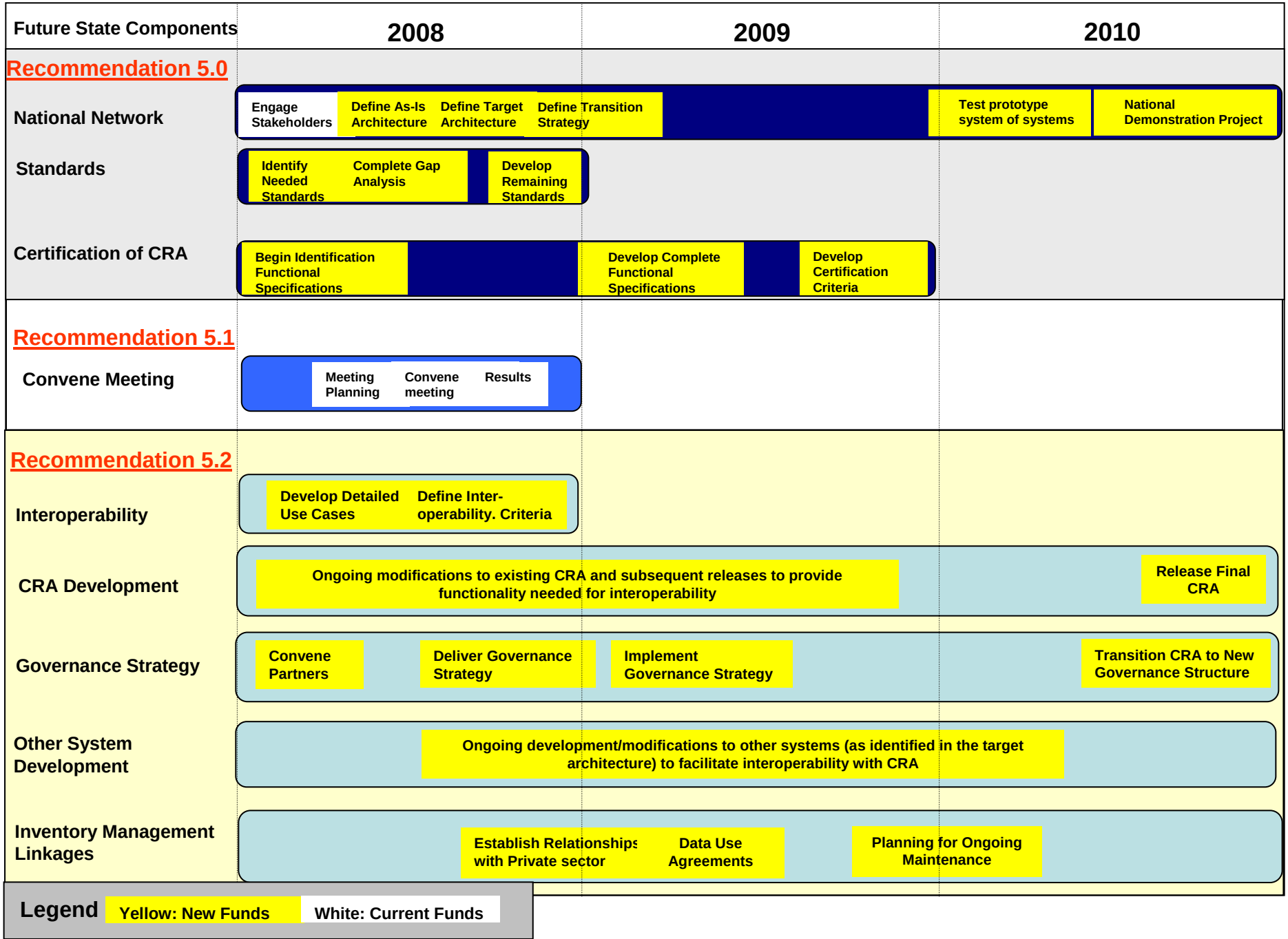

Future State Components
2008
2009
2010
Recommendation 4.0
NHIN compatible clinical reference data model
Engage Stakeholders
Vocabulary design
Testing and validation
Standards for data exchange and security
Identify Needed Standards
Complete Gap Analysis
Develop Remaining Standards
Environmental and veterinary reference data model
Vocabulary Design
Testing and Validation
Environmental and veterinary data results reporting demonstration
Identify sites
Implement
Test and Evaluate
Certification process
Develop Functional Specifications
Develop Certification Criteria
Deploy lab information exchange modules in health labs
Deploy
Recommendation 4.2
Define process for consolidated reporting
Convene Stakeholders
Develop Standards
Demonstration project
Identify sites
Implement
Test and Evaluate
Legend
Yellow: New Funds
White: Current Funds

Recommendation 5: Countermeasures

Goals & Objectives

In order to harmonize the functionality & interoperability of CRA applications, CDC seeks to have:

- An open source interoperable CRA team with independent governance & full state, local, territorial & tribal participation
- National prototypes & demonstration projects to illustrate how to build interoperable CRA systems
- CRA interoperable systems installed in 40+ states &/or territories
- Certification criteria for COTS CRA & to have multiple CRA's systems certified, giving states choices in implementation

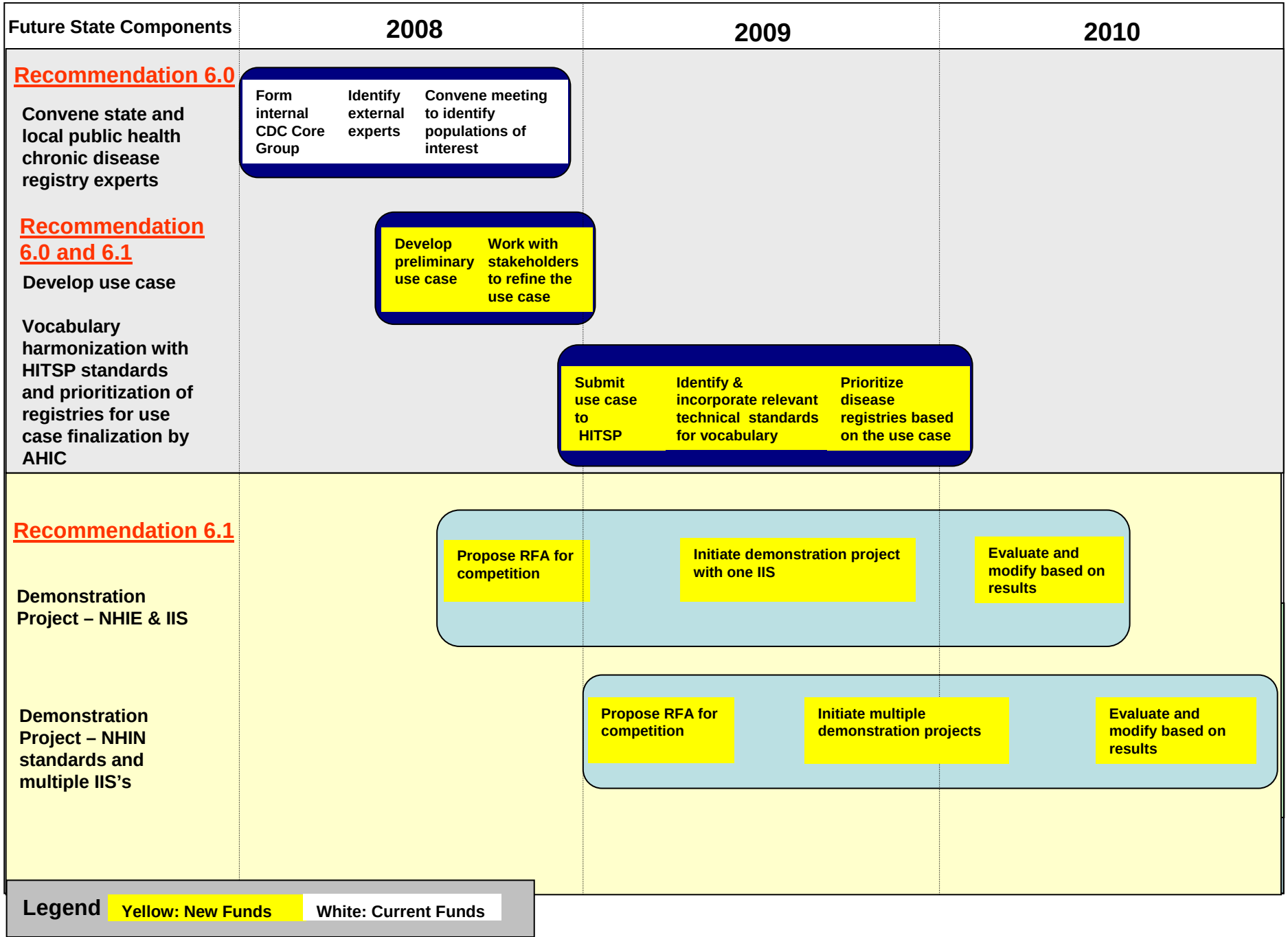

Future State Components
2008
2009
2010
Recommendation 5.0
National Network
Engage Stakeholders
Define As-Is Architecture
Define Target Architecture
Define Transition Strategy
Test prototype system of systems
National Demonstration Project
Standards
Identify Needed Standards
Complete Gap Analysis
Develop Remaining Standards
Certification of CRA
Begin Identification Functional Specifications
Develop Complete Functional Specifications
Develop Certification Criteria
Recommendation 5.1
Convene Meeting
Meeting Planning
Convene meeting
Results
Recommendation 5.2
Interoperability
Develop Detailed Use Cases
Define Inter-operability. Criteria
CRA Development
Ongoing modifications to existing CRA and subsequent releases to provide functionality needed for interoperability
Release Final CRA
Governance Strategy
Convene Partners
Deliver Governance Strategy
Implement Governance Strategy
Transition CRA to New Governance Structure
Other System Development
Ongoing development/modifications to other systems (as identified in the target architecture) to facilitate interoperability with CRA
Inventory Management Linkages
Establish Relationships with Private sector
Data Use Agreements
Planning for Ongoing Maintenance
Legend
Yellow: New Funds
White: Current Funds

Recommendation 6: Automated Integration with Registries

Goals & Objectives

CDC's goals in automated integration with registries is to achieve the following:

- Open source interoperable public health registry team with full state, local, territorial & tribal participation
- National prototypes & demonstration projects to illustrate how to build interoperable OEMS
- Compatible public health registry systems interoperating across states, laboratories, & CDC
- Certification criteria for COTS registries & certification of multiple systems, giving states choices in implementation


Future State Components
2008
2009
2010
Recommendation 6.0
Convene state and local public health chronic disease registry experts
Form internal CDC Core Group
Identify external experts
Convene meeting to identify populations of interest
Recommendation 6.0 and 6.1
Develop use case
Develop preliminary use case
Work with stakeholders to refine the use case
Vocabulary harmonization with HITSP standards and prioritization of registries for use case finalization by AHIC
Submit use case to HITSP
Identify & incorporate relevant technical standards for vocabulary
Prioritize disease registries based on the use case
Recommendation 6.1
Demonstration Project – NHIE & IIS
Propose RFA for competition
Initiate demonstration project with one IIS
Evaluate and modify based on results
Demonstration Project – NHIN standards and multiple IIS's
Propose RFA for competition
Initiate multiple demonstration projects
Evaluate and modify based on results
Legend
Yellow: New Funds
White: Current Funds

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

Estimated Cost

	2009	2010
Recommendation 1		
Estimated Cost	$5,665,000	$5,615,000
Recommendation 2		
Estimated Cost	$3,750,000	$4,150,000
Recommendation 4		
Esimated Cost	$14,400,000	$15,300,000
Recommendation 5		
Estimated Cost	$8,950,000	$10,376,000
Recommendation 6		
Estimated Cost	$810,000	$2,075,000
Total	$32,765,000	$35,441,000

2008 and 2009 Activities Requiring No Additional Funding

In 2008, CDC will accomplish the following:

- In order to evaluate public health informatics education needs, CDC will complete an environmental scan of current PH workforce needs using data collected by survey.
- In addition, CDC will initiate a professional-level distance learning certificate program at an initial cohort of training sites.
- CDC will initiate meetings with relevant stakeholders to begin to develop requirements and identify standards for OEMSs.
- CDC will also work to develop a national network of OEMS programs through developing a governance structure and specific use cases for interoperability of OEMSs.
- Efforts to develop interoperability among public health laboratories will be started by developing an initial clinical reference data model.
- Discussions will be held regarding private sector resources for CRA systems and how those would fit into a national CRA network.
- CDC will convene state and local public health chronic disease registry experts to identify populations of interest for registry integration with NHIN.

In 2009, CDC will accomplish the following:

- CDC will test and validate the NHIN compatible clinical reference data model.
- OEMS development will be funded for the first quarter of 2009.

January 22, 2008

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 EHR Workgroup has spent more than a year and a half focused on the specific charge and the primary enablers and barriers to ambulatory EHR adoption. For the last several months the Workgroup has widened its focus to also explore the issues with regards to widespread adoption of certified EHRs in the inpatient setting. Throughout, the Workgroup continued to structure its work in the key enabling areas of:

- Privacy and Security
- Business case alignment
- Organizational
- Technology
- Medical/ legal issues

This cross-cutting recommendation letter addresses the specific workforce needs for adoption of health information technology (HIT) and is intended to be broad enough to encompass all areas of health care.

BACKGROUND AND DISCUSSION

As the EHR Workgroup broadened its focus to incorporate the inpatient environment, several changes in Workgroup membership were made to reflect this additional scope. To initiate this work, in May 2007, the Workgroup heard testimony from the American Hospital Association on their recent survey of hospitals' use of health information technology, "Continued Progress: Hospital Use of Information Technology," available at: http://www.aha.org/aha/content/2007/pdf/070227-continuedprogress.pdf. The survey

covered topics such as information technologies used by hospitals, the functions of hospitals' EHRs, information exchange, and barriers to greater adoption of information technology. Additionally, in July 2007, the EHR Workgroup was very privileged to have presentations on HIT adoption and implementation experiences from three hospital systems, Vanderbilt Health System, Geisinger Health System and Midland Memorial Hospital, and built on prior input on this topic provided by AHRQ funded research. (c.f. Blumenthal et al). These presentations were very informative, giving the Workgroup both the broad, national perspective of the state of HIT adoption in the hospital setting, but also some very focused and detailed case study experiences. The Workgroup heard and determined that a critical and potentially rate-limiting issue requiring further exploration was the necessity for an HIT trained and competent workforce throughout the health care enterprise, particularly during adoption and implementation.

As the Workgroup focused on the specific workforce needs to achieve the broad goal of widespread HIT adoption, this September the Workgroup heard testimony from industry leaders as they participated in an HIT Workforce panel discussion. Distinguished panel participants included:

- Ms. Linda L. Kloss- CEO, American Health Information Management Association (AHIMA)
- Dr. Don Detmer- President & CEO, American Medical Informatics Association (AMIA)
- Dr. William A. Yasnoff- NHII Advisors
- Mr. Don Schoen- Health Information Management Systems Society (HIMSS) EHR Vendor's Association
- Carole A. Gassert RN, PhD- representing nursing informatics education, Technology Informatics Guiding Education Reform (T.I.G.E.R) and the Alliance for Nursing Informatics (ANI).

Ms. Kloss and Dr. Detmer discussed the findings of their collaborative workforce research and recommendations emanating from their 2005 AHIMA/AMIA work force summit, "Building the Work Force for Health Information Transformation" available at http://www.ahima.org/emerging_issues/Workforce_web.pdf. Dr. Yasnoff, presented the results of his research project that was borne out of the AHIMA/AMIA workforce summit and sponsored by HHS/ Assistant Secretary for Planning and Evaluation (ASPE), entitled "Nationwide Health Information Network (NHIN) Workforce Study" http://aspe.hhs.gov/sp/reports/2007/NHIN/NHINReport.pdf. Dr. Gassert, provided data and information about the T.I.G.E.R initiative, and efforts within nursing education regarding adoption and use of HIT. She provided the Workgroup with a letter of several recommendations http://www.hhs.gov/healthit/ahic/materials/10_07/ehr/followup.html. The Workgroup found the efforts and testimony of these leaders in the area of HIT workforce extremely valuable and is reflected in the following recommendations.

RECOMMENDATIONS

As stated by the workforce panel participants, and discussed extensively during the Workgroup's deliberations, more research and evaluation of the HIT workforce needs is still required. The AHIMA/AMIA report call for this was the impetus for the ASPE workforce study, but as they and the EHR Workgroup agreed, this is just the beginning and there is considerable work ahead to determine the needs, develop an action plan and monitor the progress of workforce development in the areas of clinical, research, public health and research informatics, and translational bioinformatics.

> **RECOMMENDATION 1.0: HHS should support funding for a collaborative group to research and better quantify discipline-specific workforce deficits (calibrated to different rates of HIT implementation) and to develop an approach for supporting informatics workforce needs.**

As Recommendation 1 notes, there is a great need to continue to research and monitor HIT workforce needs. A current barrier to this necessary work, identified in testimony, was the lack of adequate occupational classifications needed to enable this research.

> **RECOMMENDATION 2.0: HHS should work with the Department of Labor to develop occupational classifications for HIT professionals.**
>
> **RECOMMENDATION 2.1: HHS should encourage OPM to recognize health informatics professionals in the federal professional series.**

Several health professions, namely Nursing and Medicine, have or are in the process of developing HIT competencies and standards of practice for their respective disciplines. Yet, many health professions and specialty areas of practice are still not engaged fully in these efforts. The identification of health informatics competencies and the development of curricula across all health care disciplines to support such education and training will be essential for the widespread adoption and effective use of HIT to improve patient outcomes. The following several recommendations reflect the Workgroup's desire to further develop, support and grow these professions.

> **RECOMMENDATION 3.0: HHS should support funding for additional research within specific Federal agencies to create HIT career pathways (including occupational series & job classifications), with particular attention to clinical informatics, research informatics, translational bioinformatics, and public health and population informatics, in support of HIT implementation; improved quality, and clinical effectiveness; systems development; and executive leadership.**
>
> **RECOMMENDATION 4.0: HHS should support Federal funding for research in health informatics (including clinical informatics, health information management and IT) which would increase attractiveness of**

academic careers in HIT and the pool of faculty for HIT curricula in health care disciplines.

<u>RECOMMENDATION 5.0</u>: HHS should work with the DOE to institute loan forgiveness programs or other incentives to attract necessary health professions trainees to HIT careers in underserved and safety net areas.

<u>RECOMMENDATION 6.0</u>: Appropriate Federal agencies engaged in HIT should identify and develop informatics competencies for health profession disciplines, and incorporate these in academic programs and mentorship/fellowship programs.

Although there is great need to "grow" the HIT workforce through additional recruitment into the professions and subsequent formal academic education, there is a considerable cultural change and training/re-training needed within the current workforce and across all health care disciplines. Those current health care workers/ professionals will need training and a transition strategy as they become the current adopters and implementers of HIT.

<u>RECOMMENDATION 7.0</u>: For the current health care worker, public or private, participation in educational and certification programs such as AMIA 10x10 program, HIM progression and certificate programs, European Computer Driver's License equivalent, and other programs for basic/core HIT competency training and evaluation should be encouraged through bonus criteria, training programs, or other means.

The EHR Workgroup recognizes that the states have significant influence and a stake in having an adequate and competent HIT workforce as they embark on local and regional HIT adoption and implementation efforts. We wish to engage the states and encourage them to determine their HIT workforce needs and develop collaborative plans to address these.

<u>RECOMMENDATION 8.0:</u> ONC should work with the states to encourage governors to increase recognition of health IT workforce needs and suggest ways to address them. This could include health professional licensing activities.

Sincerely yours,

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

Sincerely yours,

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

Electronic Health Records Workgroup

Recommendations

Jonathan B. Perlin
HCA, Inc., Co-Chair

January 22, 2008

Workgroup Member List

Co-Chairs:

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

Members:

– Bonnie Anton	University of Pittsburgh Medical Center
– Carolyn Clancy	HHS/Agency for Healthcare Research and Quality
– Laura Cranston	Pharmacy Quality Alliance
– Nhan Do	Department of Defense
– Peter Elkin	Mayo Clinic
– Linda Fischetti	Veterans Health Administration
– Richard Hays	American College of Cardiology
– Robert Juhasz	American Osteopathic Association
– Charles Kahn	Federation of American Hospitals
– Mark Lewis	EMC Corporation
– George Lynn	American Hospital Association
– Blackford Middleton	Partners Healthcare System
– Jack Price	HIMSS Analytics
– Pam Pure	McKesson
– Robert Smith	Veterans Health Administration
– Barry Straube	HHS/Centers for Medicare & Medicaid Services
– Robert Wears	University of Florida Health Center

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.

Electronic Health Records Workgroup: Recent workgroup activities

- During the summer, the WG broadened its focus and membership to include the inpatient arena
- July ’07 the WG received testimony from 3 hospital systems to gain perspective on inpatient HIT adoption experiences
- From this testimony the WG learned that having an HIT trained and competent workforce was essential for HIT adoption, successful implementation and effective utilization.
- In turn, the EHR WG focused their next piece of work and several WG meetings discovering and addressing the HIT workforce needs.

Workforce Needs

Recommendation 1.0:

HHS should support funding for a collaborative group to research and better quantify discipline-specific workforce deficits (calibrated to different rates of HIT implementation) and to develop an approach for supporting informatics workforce needs.

☐ **Accept** ☐ **Table** ☐ **Reject**

Workforce Needs

Recommendation 2.0:

HHS should work with the Department of Labor to develop occupational classifications for HIT professionals.

☐ **Accept** ☐ **Table** ☐ **Reject**

Workforce Needs

Recommendation 2.1:

HHS should encourage the Office of Personnel Management to recognize health informatics professionals in the federal professional series.

☐ **Accept** ☐ **Table** ☐ **Reject**

Workforce Needs

Recommendation 3.0:

HHS should support funding for additional research within specific Federal agencies to create HIT career pathways (including occupational series & job classifications), with particular attention to clinical informatics, research informatics, translational bioinformatics, and public health and population informatics, in support of HIT implementation; improved quality, and clinical effectiveness; systems development; and executive leadership.

☐ **Accept** ☐ **Table** ☐ **Reject**

Workforce Needs

Recommendation 4.0:

HHS should support Federal funding for research in health informatics (including clinical informatics, health information management and IT) which would increase attractiveness of academic careers in HIT and the pool of faculty for HIT curricula in health care disciplines.

☐ **Accept** ☐ **Table** ☐ **Reject**

Workforce Needs

Recommendation 5.0:

HHS should work with the Department of Education to institute loan forgiveness programs or other incentives to attract necessary health professions trainees to HIT careers in underserved and safety net areas.

☐ **Accept** ☐ **Table** ☐ **Reject**

Workforce Needs

Recommendation 6.0

Appropriate Federal agencies engaged in HIT should identify and develop informatics competencies for health profession disciplines, and incorporate these in academic programs and mentorship/fellowship programs.

☐ **Accept** ☐ **Table** ☐ **Reject**

Workforce Needs

Recommendation 7.0:

For the current health care worker, public or private, participation in educational and certification programs such as the American Medical Informatics Association's (AMIA) 10x10 program, health information management (HIM) progression and certificate programs, European Computer Driver's License equivalent, and other programs for basic/core HIT competency training and evaluation should be encouraged through bonus criteria, training programs, or other means.

☐ **Accept** ☐ **Table** ☐ **Reject**

Workforce Needs

Recommendation 8.0:

The Office of the National Coordinator should work with the states to encourage governors to increase recognition of health IT workforce needs and suggest ways to address them. This could include health professional licensing activities.

☐ **Accept** ☐ **Table** ☐ **Reject**

January 22, 2008

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

Dear Mr. Chairman:

On September 18, 2007, three members of the Model Requirements Executive Team (MRET) – brought together under a contract awarded to Research Triangle Institute International by the Office of the National Coordinator for Health Information Technology (ONC) – presented recommendations to the American Health Information Community (AHIC) on initial requirements for electronic health records (EHRs) that seek to increase documentation accuracy and fraud management within the health care system. At the aforementioned AHIC meeting, the Confidentiality, Privacy and Security (CPS) and the Electronic Health Record (EHR) AHIC Workgroups were asked to evaluate the MRET recommendations in their area of expertise, hear additional public comment, and offer additional insight from their Workgroup's perspective.

The CPS Workgroup was specifically asked to evaluate Requirement 8. This is as follows:

Requirement 8: Auditor Access to Patient Record

8.0 The system shall have the capacity to allow authorized entities read-only access to the EHR according to agreed upon uses and only as a part of an identified audit subject to appropriate authentication, authorization, and access control functionality. Such access controls shall also support the applicable release of information protocols, local audit policies, minimum necessary criteria, and other contractual arrangements and, laws, and:

8.1 Require "auditor" be a supported class of user

8.2 Limit access to pertinent functions and views only for patient records covered by the audit.

8.3 Access remains controlled by the facility and the same authentication and audit supports would apply.

8.4 Remote access may be offered if agreed to by the organization subject to the aforementioned protocols and suitable authentication

8.5 Demonstrate the ability to provide a paper copy of such information in the event access to the EHR is not possible.

The EHR Workgroup was specifically asked to evaluate MRET Requirements 5 and 6. These requirements are as follows:

Requirement 5: Evaluation and Management (E&M) Coding

5.1 The system shall be capable of prompting for omitted necessary administrative data or codes. This could include the capability to prompt a physician if the selected E&M code is not consistent with the documentation in the encounter note**.**

5.2 Prompts that are driven by E&M administrative processes shall not explicitly or implicitly direct a user to add documentation. This does not apply to prompts for additional documentation for E&M levels already achieved, for medical necessity or for quality guidelines/clinical decision support.

Requirement 6: Proxy Authorship

6.1 Retain date/time/user stamp of original data entry person when data entered "on behalf" of another author.

6.2 If an assistant is used to enter date that will subsequently be signed by a provider, retain the date/time/use stamp of the data entry person as well as the provider.

Mr. Chairman, the CPS Workgroup has reviewed Requirement 8 and offers the following response. After Workgroup discussion, we have determined that Requirement 8 is consistent with Health Insurance Portability and Accountability Act (HIPAA) requirements and does not provide auditors with any new access rights to EHRs. Dr. Reed Gelzer, a Workgroup chairman of the MRET effort and Rebecca Busch, a member of the MRET, participated in our discussion of Requirement 8 and explained the MRET made this recommendation to encourage further discussion in the area of auditor access to EHRs and to promote EHRs capable of implementing clear policies to limit auditor access to EHRs. The CPS Workgroup believes that Requirement #8 would benefit from further specificity. In doing so, we would expect that this refinement would take into account different types of auditors (8.1), their levels of access depending upon their role (8.2), and the related access controls specified by the facility (8.3).

Mr. Chairman, the EHR Workgroup was pleased to have Dr. Reed Gelzer, a MRET Workgroup chairman, lead a detailed discussion on December 4th with the EHR workgroup members regarding Requirements 5 & 6. The Workgroup deliberated and determined that Requirements 5 & 6 were beneficial and offer no suggested modifications. We are hopeful work will continue in this area and will be utilized to inform the efforts of the Certification Commission for Health Information Technology. Regarding Requirement 5.1, the Workgroup had considerable discussion on whether such a capability should be mandated or just strongly suggested using the terminology "should" rather that "shall". The EHR Workgroup finally concluded that it is appropriate to ensure systems "shall" have this prompting capability noting that enabling/ disenabling such functionality will be at the discretion of the institution and their governing policies/ practices.

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

Sincerely yours,

Kirk Nahra
Co-Chair
Confidentiality, Privacy, and Security Workgroup

Deven McGraw
Co-Chair
Confidentiality, Privacy, and Security Workgroup

Jonathan Perlin
Co-Chair
Electronic Health Records Workgroup

Lillee Smith Gelinas
Co-Chair
Electronic Health Records Workgroup

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

American Health Information Community

CPS & EHR Workgroups' Review of the "Recommended Requirements for Enhancing Data Quality in Electronic Health Record Systems"

Deven McGraw
National Partnership for Women & Families

Jonathan B. Perlin
HCA, Inc.

January 22, 2008

MRET Review: CPS and EHR workgroups

- Report presented to AHIC September 18th, 2007.
- Model Requirements Executive Team (MRET) members presented recommendations on initial requirements for electronic health records (EHRs) to increase documentation accuracy and fraud management within the health care system.
- AHIC requested that the CPS and EHR Workgroups review requirements germane to their scope and return to the AHIC with their assessment.
- MRET members participated in each Workgroup's discussion and provided insight as well as answered questions.

Requirements Evaluated: EHR Workgroup

- Requirement 5: Evaluation and Management (E&M) Coding
- Requirement 6: Proxy Authorship

- Assessment: No modifications were suggested. Regarding Requirement 5.1, the workgroup had considerable discussion on whether such a capability should be mandated or just strongly suggested using the terminology “should” rather that “shall.” The EHR workgroup finally concluded that it is appropriate to ensure systems “shall” have this prompting capability noting that enabling/ disenabling such functionality will be at the discretion of the institution and their governing policies/ practices.

Requirement Evaluated: CPS Workgroup

- Requirement 8: Auditor Access to Patient Record

- Assessment: The CPS Workgroup believes that Requirement 8 would benefit from further specificity. In doing so, we would expect that this refinement would take into account different types of auditors (8.1), their levels of access depending upon their role (8.2), and the related access controls specified by the facility (8.3).

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

American Health Information Community

AHIC Recommendations-Implementation Status Report

Consumer Empowerment

Nancy Davenport-Ennis, Co-chair

January 22, 2008

Consumer Empowerment
Recommendation 2.0 and 2.1 May 2006

Recommendation 2.0

Recommended that federal agencies sponsoring pilots for an electronic registration summary and medication history should work with appropriate private-sector health organizations to promote provider and consumer participation in a breakthrough project through a targeted outreach initiative.

Recommendation 2.1

Recommended that HHS through CMS, AHRQ, other interested Federal agencies and private sector partners should pilot programs that measure and demonstrate the value of an electronic registration and medication history to patients with chronic disease and their clinicians.

Status: Some Progress:

- CMS PHR pilot began in June 2007 in collaboration with AHIP and BlueCross BlueShield Association.
- CMS working with the Office of External Affairs to evaluate appropriate and effective outreach and messages.
- Anticipated completion date in December 2008.

Consumer Empowerment
Recommendation 1.0 and 3.0 May 2006

Recommendation 1.0

Recommended that HITSP identify the technical and data standards to enable the availability of a core registration dataset and medication history.

Recommendation 3.0

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

STATUS: DONE

Consumer Empowerment
Recommendation 1.1 January 2007

Recommendation 1.1

Recommended that HHS should promote consumer access to their personal health information in the trial implementations of the NHIN.

Recommendation 3.3

Recommended that the Department of Veterans Affairs should conduct an evaluation of the benefits of their My HealtheVet PHR in the 2007 calendar year, and report back to the Community about the status and results to date no later than December 28, 2007. Based on the evaluation, the Department of Veterans Affairs should communicate the value of their PHR to veterans and stakeholders to encourage adoption.

STATUS: DONE

Consumer Empowerment
Recommendation 2.4 January 2007

Recommendation 2.4

Recommended in its final report the State Alliance for e-Health should include information on variation in state laws with respect to consumer access to electronic health information, and any relevant recommendations to improve this access.

Status: Some Progress

- Initial research has been conducted on variation state laws with respect to specifically protected information as it is used for the purpose of treatment, research, payment and public health.

Recommendation 3.1, 3.2, 3.2.1, 3.2.2, and 3.2.3

Concerned with an evaluation using a standardized approach for assessing PHR use and value.

Status: Some Progress

- Taxonomy for PHR definitions is needed.
- PHR definitions will be available in March 2008.
- RFP's for contracts and grants will be developed.