The Community

American Health Information Community

February 26, 2008
10:15 a.m. - 4:00 p.m.

HIMSS Annual Conference
Rosen Center Hotel
Salons 9 & 10
9840 International Drive
Orlando, FL 32819

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10:15 a.m. - 4:00 p.m. (EST)

HIMSS Annual Conference
Rosen Centre Hotel – Salons 9 and 10
9840 International Drive, Orlando, FL 32819

10:15 a.m. **CALL TO ORDER –** *Secretary Leavitt*

10:20 a.m. **Introductory Comments** – *Secretary Leavitt*

10:30 a.m. **Comments** – *Kerry Weems, Vice-Chair, Acting Administrator*
Centers for Medicare and Medicaid Services

10:35 a.m. **Comments** – *Robert M. Kolodner*
Office of the National Coordinator for Health Information Technology

10:45 a.m. **AHIC 2.0 Successor – Update**

- *Mark McClellan, The Brookings Institution*
- *S. Lawrence Kocot, The Brookings Institution*
- *Arthur S. Hamerschlag, LMI Consulting*

11:15 a.m. **Chartered Value Exchanges**

- *Carolyn Clancy, Agency for Healthcare Research & Quality*

11:45 a.m. **An Overview of Results of 2007 Survey on Health Information Exchange**

- *Janet Marchibroda, eHealth Initiative*

12:15 a.m. **BREAK**

1:30 p.m. **Nationwide Health Information Network: Update**

- *John Loonsk, Office of the National Coordinator for Health IT*
- *Steven Gravely, MedVirginia*

2:00 p.m. **New Workgroup Recommendations for Discussion:**
Personalized Healthcare Workgroup

- *Douglas E. Henley, American Academy of Family Physicians, Co-Chair*
- *John Glaser, Partners HealthCare, Co-Chair*

Confidentiality, Privacy & Security Workgroup

- *Deven McGraw, National Partnership for Women and Families, Co-Chair*

3:00 p.m. **Enhancing Data Quality Recommendations**

- *Jodi Daniel, Office of the National Coordinator for Health IT*

3:15 p.m. **AHIC Priorities/Use Case Options**

- *John Loonsk, Office of the National Coordinator for Health IT*

3:45 p.m. **Public Comment**

4:00 p.m. **ADJOURN**

Meeting Report

American Health Information Community
January 22, 2008

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 ten years, held its 19th meeting on January 22, 2008, at the Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW, Washington, DC.

The purpose of the meeting was to bring together Community members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to the Department of Health and Human Services (HHS) on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting focused on: (1) an update on the Health IT Physician Adoption Survey; (2) an update on revised 2006 and recently approved 2007 Healthcare Information Technology Standards Panel (HITSP) interoperability specifications; (3) recommendations from the Population Health/Clinical Care Connections (PHCCC) Workgroup; (4) a roadmap and timeline for the PHCCC Workgroup; (5) EHR Workgroup recommendations; (6) findings and recommendations from the *Enhancing Data Quality in EHRs Report*; and (7) Consumer Empowerment Workgroup recommendations.

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

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

Call to Order

Joining Secretary Leavitt around the table were:

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, At-Large AHIC member; former 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

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

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

Cita Furlani, Director, Information Technology Laboratory, at National Institute of Standards and Technology, Department of Commerce

Les Lenert, Director, National Center for Public Health Informatics, Centers for Disease Control and Prevention (Mr. Lenert represented Dr. Julie Gerberding, MD, CDC Director)

Introductory Comments – Secretary Leavitt

Secretary Leavitt noted that AHIC began meeting just over two years ago; Community members share a vision of creating a system of electronic health care rather than a paper-based one, as well as a basic understanding of the barriers that stand in the way of that vision. AHIC recognized that a lack of harmonized standards represented the major barrier to electronic health care. In the past two years, the group has much to show for its work towards harmonized standards. To date, the Secretary has officially recognized 34 interoperability standards that lay the foundation for standards-based health information exchange (HIE). These standards have been the work of literally hundreds—possibly thousands—of volunteers across the country.

Secretary Leavitt explained that the number of use cases has grown, starting with three in 2006, four in 2007, and what will be six in 2008. To date, the Certification Commission for Health Information Technology (CCHIT) has certified roughly 75 percent of the outpatient EHR systems or products that are being used by doctors, and more than one-third of the vendors for systems used in inpatient settings. A trial implementation of the Nationwide Health Information Network (NHIN) has been launched to demonstrate the possible configurations for securing interoperability.

To move these efforts along more quickly within HHS, AHIC has relied heavily on Medicare, announcing in October a new Medicare demonstration program that will provide an incentive to small and medium-sized physicians who adopt interoperable EHRs. Medicare will reimburse physicians at a higher level if they use certified EHRs to deliver health care to their patients. By involving up to 1,200 of these practices in the demonstration program, it is expected that 3.6 million Americans will receive better health care. Many private insurance companies have announced plans to take similar steps.

In November 2007, AHIC proposed a new standard for aspects of e-prescribing under the Medicare prescription drug benefit. The Community has worked hard to have e-prescribing tied as a condition to a number of areas related to physician reimbursement.

Secretary Leavitt announced that the grant to convene AHIC 2.0 has been awarded to LMI Consulting, in collaboration with The Brookings Institution. The Secretary praised The Engelberg Center for Healthcare Reform at Brookings for its sterling reputation for objective thought leadership. He explained that LMI Consulting is a not-for-profit organization based in McLean, VA, with 50 years of experience in managing government contracts. LMI will be providing management and logistical support to the group. Secretary Leavitt commented that it has always been AHIC's intent to establish a successor organization as a partnership between government and the private sector to keep its work going. Awarding this grant is an important step in protecting and perpetuating AHIC's progress.

Approval of November 13, 2007, and November 28, 2007, Meeting Minutes

Minutes from the November 13, 2007, AHIC meeting and the November 28, 2007, teleconference were distributed, reviewed by Community members, and approved unanimously with no changes.

Introductory Comments - Dr. Kolodner

Dr. Kolodner, National Coordinator for Health Information Technology, reminded Community members that LMI and Brookings were selected through a competitive process. Their application included a broad engagement of stakeholders from across the spectrum of health care, including providers (individual practitioners as well as institutions), insurers, employers, consumers (including consumers representing underserved or disadvantaged populations), communities abroad, health information technology (HIT) organizations, and others. LMI and Brookings plan to broaden their outreach in a series of activities to further engage stakeholders.

In addition, the Office of the National Coordinator for Health Information Technology (ONC) is working on a draft strategic plan, which is undergoing various clearance processes—Dr. Kolodner anticipates sharing this strategic plan with the Community in the near future.

Dr. Kolodner also reminded the Community that at its September 2007 meeting, the group indicated that the formation of a Clinical Decision Support *Ad Hoc* Workgroup should proceed. This newly formed entity is comprised of representatives from AHIC's five standing workgroups and had its first meeting on January 16, 2008. At that meeting, Clinical Decision Support *Ad Hoc* Workgroup members developed a series of draft recommendations that will be vetted through the other AHIC workgroups.

Secretary Leavitt has recognized a set of interoperability specifications relating to EHR laboratory results reporting that allows providers to review results for biosurveillance and monitor an existing public health event. Specifications relating to consumer empowerment, which will allow consumers to view medications, also have been recognized. A notice in the *Federal Register* will be published shortly.

HIT Physician Adoption Survey Update

Dr. David Blumenthal of Massachusetts General Hospital's Institute for Health Policy provided the Community with updated information related to an ongoing survey of physicians in the United States concerning their adoption of EHRs. The preliminary numbers, which were reported at an earlier AHIC meeting, have not changed significantly with an increased sample size. The mail survey's sample frame

includes 5,000 currently practicing physicians randomly selected from the American Medical Association's Master file and has a target sample size of 3,000 physicians for analysis at the subgroup level and 1,500 physicians for a stable national analysis. The field period began in July 2007 and is ongoing. Participating physicians have been sent two questionnaires. Participants were directed to complete the "physician" instrument and forward the second questionnaire to the person most knowledgeable about the practice characteristics and HIT use. To date, approximately 1,500 responses have been analyzed.

Dr. Blumenthal reminded AHIC members that the data presented represents adoption of EHRs in terms of three definitions: (1) the historical National Ambulatory Medical Care Survey (NAMCS) definition ("does your main practice use an electronic health record system [not including billing records]?"); (2) a minimally functional EHR (based on a set of functionalities used in 2005 and 2006 to encompass a minimum set of functionalities); and (3) a functional EHR (definition developed by an expert consensus panel based on the Institute of Medicine [IOM] framework). Dr. Blumenthal then discussed the differences in these definitions, with distinctions shown associated with selective functionalities in health information and data, order entry management, results management, and decision support.

Forty-three percent of physicians responded that they used electronic health care according to the historical NAMCS definition. Approximately 23 percent indicated that they used completely electronic systems; 20 percent reported using part-electronic, part-paper systems. In terms of the slightly more ambitious definition of the minimally functional EHR, 14 percent of the sample—an identical proportion to that which was previously reported to AHIC from a smaller sample size—indicated that they had a minimally functional EHR. Four percent reported having a fully functional EHR system.

Dr. Blumenthal commented that the most-reported barrier to adoption is a lack of capital, followed by finding a system that will meet the respondent's needs, uncertainty about the return on investment, fear that the system would become obsolete, fear of loss of productivity, concerns about the capacity to implement, and generalized physician resistance to adoption. When asked what incentives would have an impact on their likelihood of adopting, the most common responses by participating physicians were monetary incentives for purchase, additional reimbursement for the use of electronic records in the process of care, protection against legal liability that might arise from having EHRs, published certification standards, and the threat of legal liability if a practice did not have an EHR system.

Discussion

"While the CCHIT process has allowed folks to purchase EHRs, they're using them in a minimally functional capacity. The technology already has the switches and the bells and whistles to be a functional EHR. They just haven't turned the switches on yet because of the confusion and chaos of change within a practice." – Dr. Henley

"New products have entered the market in the last two years. And at least for our members, the cost barrier is much less important than it was two years ago. It's still important…but it's somewhat less of a challenge than it perhaps has been in the past because of some new products." – Dr. Henley

"We just need to keep the pressure on the adoption…the fact that we've seen essentially a 50 percent increase, between 2006 and today, tells me we're starting to see some action." – Secretary Leavitt

"When you break it down, do you have the sample size to enable you to [determine] what the difference is between the younger doctors and the older doctors, not only in their adoption rate, but also in their interest in help with the initial capital investment versus the payment on a per-use basis? One would think they're

more interested in the long-term investment, if they're at a younger stage in their practice, and that they are more technology oriented." – Dr. Casscells

"Previous studies by NAMCS and other groups have shown that young physicians, not unexpectedly, are much more likely to adopt than older physicians, as are physicians in groups, especially groups of 11 or more. They're four times as likely in a group of 11 or more to have an electronic health record, as in solo practice. That's probably the most distinctive and predictive attribute of adoption group, being part of an institution." – Dr. Blumenthal

"We still have a huge education problem. If you look at those that don't have an EHR, and the perception of the barriers, and those that do have the EHR, and what they're receiving from it, whether it be from an ROI standpoint, or they are finding the systems that meet their needs, or the functions that are in the systems that meet their needs, it seems that those that have gone through it, have, obviously, a very different opinion than those who have not gone through it." – Mr. Hutchinson

"The numbers who have adopted are a relatively modest sample group, they're at most 15 to 20 percent, and they are the early adopters…They're also likely to be in groups where they have technical assistance and leadership, who help them make decisions. They don't have to pick the system, the system is purchased by an organization and put on their desk, and then they get technical assistance. So I think that it's hard to interpret the gap. The gap may represent something of a gap of perception, but also a gap of reality in that the challenges you face when you're in a group of one or two physicians are objectively different than the challenges you face when you're in a group of 50 to 100 physicians." – Dr. Blumenthal

"Understanding how nurses act in the technological environment, both in inpatient settings and outpatient settings, getting data on that would, I think, be helpful…engaging the nursing profession would be a worthy thing for us to do." – Mr. Roob

"Can I ask about the final report…I assume that you intend to continue to measure this over time?"
– Secretary Leavitt

"I think…that the National Ambulatory Medical Care Survey will adopt some of our core questions, and that it is an ongoing and institutionalized survey of the department and the federal government, and we'll continue to provide comparable data over time." – Dr. Blumenthal

Update: Revised 2006 and Recently Approved 2007 HITSP Interoperability Specifications

Dr. John Loonsk, Director of ONC's Office of Interoperability and Standards, reminded the Community that Secretary Leavitt recognized the first set of interoperability standards in January 2008. Round two includes security and privacy standards, with three use cases being presented to AHIC at this meeting for recommendation to the Secretary. Round three consists of six draft use cases that currently are in the second round of public comment. Dr. Loonsk explained that the priorities of AHIC and its workgroups are advanced as use cases to the HITSP. HITSP, through thousands of volunteer hours, works through recommended standards to address those priorities and presents interoperability specifications. These specifications are brought forth to the AHIC, and the Community recommends them to the Secretary for acceptance. Following a year of testing and implementation, the interoperability standards are recognized and then implemented in the NHIN activities. It is expected that these interoperability standards will be implemented in federal systems and contracts that are for new systems/upgrades to existing systems. There is also an expectation that those interoperability standards become part of the process for all recognized certification bodies.

Dr. Loonsk indicated that the numbers of "named standards" suggested (about 700 in the first round compared with approximately 200 in the second round) points to the fact that industry is getting a better sense of the types of standards that are to be used. In the first round, HITSP harmonized those roughly 700 named standards down to about 30. In this second round, there are 31 named standards with substantial overlap—about 80 percent of those are named standards that have already been used in the first round. HITSP is also developing a set of constructs that specify how those named standards are to be used. There were about 20 of these constructs in the first round; there are 29 in this second round, with an overlap of approximately 50 percent.

Dr. John Halamka, HITSP Chair, then described the Panel's 2007 efforts. Most important, the group created a set of security constructs that support all current and future work. Dr. Halamka noted that these standards provide the security constructs to support policy and to respect patient preferences, whatever that policy may be. This security framework is included in every one of the interoperability specifications being described. These constructs were approved by HITSP in October of 2007. He reminded Community members that HITSP worked on three specifications in 2007 (tied to the Emergency Responder EHR, Consumer Empowerment, and Quality Use Cases). 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.

Dr. Halamka then described in more detail the privacy and security technology constructs. The scope of work provides implementation guidance to address security and privacy use case requirements (e.g., collect and communicate security audit trail, consistent time, secured communication channel, access control, etc.). This framework provides an initial standards infrastructure that can be used to support different methodologies and approaches that are currently employed in different states. It will continue to be used for future use cases.

Dr. Halamka explained that throughout hospitals and other facilities, there are many different ways to authenticate to a network. Users may type in a user name and password, or they may use a FOB or secure ID card, or they may have a smart card. Rather than specifying a particular method of authentication, HITSP created a set of standards, regardless of the method of authentication. The standards developed are a result of the Panel's harmonization of 249 standards originally identified as candidates to meet the security requirements from the 2006 EHR-Laboratory, Consumer Empowerment, and Biosurveillance Use Cases. HITSP chose to put these efforts into a technical note rather than an interoperability specification because it is foundational to all future HITSP work.

Next, Dr. Halamka described the Emergency Responder EHR Use Case, noting that this was a complicated endeavor because of all of the parties involved (e.g., a first responder, a doctor and nurse, an emergency department physician, hospital records). HITSP was tasked with creating an entire ecosystem of data being exchanged so that the patient receives the best care. He then described the harmonization results associated with creation of this specification, explaining that the 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. The use case defines enables the use of multiple documents throughout the patient encounter in the emergency department—standardization must support three heretofore separate affinity domains connected through the emergency department space.

Dr. Halamka explained that with this standard, it would be possible to access a continuity of care document (CCD) on a network or via transportable media, to be used in a first responder situation. Then the hospital could coordinate all aspects of that patient's care from first contact in the field to the final

discharge. Such a patient summary would include a full medication list with dosage, prescribing physician, associated problems, active diagnoses, and the last set of laboratory test results. Armed with this information, any doctor in the field in an emergency situation would have a record rich enough to deliver appropriate care to refill the medications and to avoid drug-drug interactions and errors. The summary record that is to be used for emergency cases is exactly the same summary record in the Consumer Empowerment Use Case, so whether it's in a doctor's office, a hospital, a personalized health record (PHR), or an insurance company, the standard is exactly the same.

Dr. Halamka then discussed the Consumer Empowerment Use Case. He described the new products and services that are evolving, such as Microsoft Health, and the rumored introduction of health records by Google, among others, that will enable patients to become the stewards of their own data. Patients would visit a secure web site and identify themselves. The process of determining who the patient is, and making sure that everything is appropriately private and secure, is an important component of such a service. As part of the use case, once a patient authenticates, he or she can get their data from their doctor's office, hospital, laboratories, or pharmacies. They can keep it in a PHR, apply privacy flags to it, and then share that data with providers as they see fit. Patients may choose to share different data with different providers, depending on the provider or the context. HITSP has created, with this expanded set of standards, a very robust way for a patient to now be the steward of their own data, as new products are created, and data can be self-populating. Dr. Halamka explained that patients would not have the ability to modify data from a medical provider. Instead, there will be the equivalent of an electronic "yellow sticky note" that can be added by the patient. Use of portable media (e.g., CD-Rom, USB flash drive) was introduced as the exchange mechanism.

Dr. Halamka then discussed the measurement of quality in EHRs. To create the Quality Interoperability Specification, the Panel worked with the Healthcare Information Technology Expert Panel to review the IOM's high-priority diseases and the associated quality measures, and then to create those standards that could represent an individual's measures.

In concluding his remarks, Dr. Halamka, on behalf of HITSP, asked that the AHIC recommend the following to Secretary Leavitt for acceptance: (1) TN900 (v1.1) - Security and Privacy Technical Note; (2) IS04 (v1.1) - Emergency Responder Electronic Health Record; (3) IS03 (v3.0) - Consumer Empowerment and Access to Clinical Information via Networks; (4) IS05 (v1.0) - Consumer Empowerment and Access to Clinical Information via Media; and (5) IS06 (v1.0) – Quality.

Every item was formally accepted by consensus of the Community and forwarded to the Secretary.

Discussion

"When we think of KatrinaHealth [which] was created using the databases largely of payer and claims around medications, this is a much richer dataset that would follow that same kind of construct. The continuity of care document contains a problem list, a medication list, an allergy list, histories of encounters, and some lab data. And so it would be that very rich clinical dataset from doctors' offices and hospitals that would be available." – Dr. Halamka

"At the vendor level, there is quite a lot of discussion, for example, in the Electronic Health Record Vendor's Association, of putting these standards into the products of our electronic health records. I've talked to several personal health record vendors, and they also recognize that this continuity of care document, as an emerging standard, is going to be very important to include in their products."
– Dr. Halamka

"This is a set of new, very advanced standards that we hope will become very commonly used over the next year. The personal health record vendors will only move as fast as the data is available from the EHRs, so that they can become auto-populating PHRs. So certainly, look very forward to a 2008 where this becomes the reality of how data is exchanged, and then the PHR vendors follow quickly." – Dr. Halamka

"Who owns my records? And what right do I have as a consumer, even if the technology exists, for my doctor to transmit it to me and populate my record? What are the policy areas that we need to begin to pursue in order to enable or to clarify that issue, so that if I have the technical capacity, and I have the transmission issues or the transportability issues resolved, that I can have an expectation that my physician will make them available to me?" – Secretary Leavitt

"HIPAA mandates that a patient has access to their records, but it does not mandate the form in which those records are accessed." – Dr. Halamka

"If that record is electronic, it becomes a slam-dunk in terms of the office's capability to transmit electronically to whatever the receiver is for the patient, whether it's their PHR or CCD document or whatever. It should occur very seamlessly without any significant thought." – Dr. Henley

"I hear from practitioners that they have concerns about the comments in notes that they might put in the record, that they may not want to transmit those to patients." – Mr. Serota

"In the spirit of transparency, there should not be that concern…the patient should always have the capability to add the post-it note about their interpretation of what the physician may have stated, if there is a contrary thought about that. Not to modify, but to add to [it]." – Dr. Henley

"Some of these things are going to get really hung up in the General Counsel's office at the hospital, in terms of what actually goes in the record and in terms of hospital policy…There are hospitals that are resistant, or I think will be resistant to interoperability, because of concern about responsibility for what other people do." – Mr. Kahn

"I also think that there is, unfortunately, probably at least in the near term, an issue of competitiveness and some proprietariness, not necessarily a particular record, but of the capability of some systems to have certain kinds of records versus others, which may inhibit interoperability." – Mr. Kahn

"People who are interested in narcotics and things of that nature can be very creative in how they would hack a record. So [there are] concerns about protecting the information and ensuring that it's accurate…a physician will probably want to verify before they act based upon the record. Then physicians will say, 'Given the fact that I have to re-verify everything I've got, what's the benefit of getting it?'" – Mr. Serota

"I would suggest further direction for expansion of the standards, because perhaps when we introduce a fact into this electronic record summary, it should be annotated with who made the observation, and who has confirmed it…If a fact has been confirmed by several medical providers over time, it would be more accepted than the first time it was entered or observed. Perhaps this personal record standard could be expanded in that direction." – Dr. Lenert

"Recognize, especially in the Electronic Health Record Emergency First Responder Use Case, the standards to actually document a nursing note, a triage note, some of the things that were required by the use case, were not commonly used standards. We actually had to look across the entire industry, grabbing standards that were either just recently created, or in the process of creation, because it was a very unique use case with quite a lot of detail." – Dr. Halamka

"Would you say there was a consensus by the panel and your group on these recommendations?" – Mr. Hutchinson

"Each of the recommendations I brought you today was adopted by consensus without objection." – Dr. Halamka

"What recommendations would you have to AHIC 2.0 that would accelerate the work even more?" – Secretary Leavitt

"We really look forward to working with AHIC 2.0 on the prioritization, because that's what's been so key and focused us. However, one thing that use cases have not done for us, is taken every aspect of an entire domain…A risk we may have is we will end up with many use cases that are slices of entire domains and we leave gaps. Internally, what HITSP has started to look at is when we get the use cases, are there obvious aspects of the work flow among payers, providers, patients and employers, that haven't been addressed by the use cases, at a more domain level. We, therefore, reorganized some of our committees internally to actually have this larger view, using the use cases to focus us, but not forgetting that there is work flow that needs to be supported through standards." – Dr. Halamka

"It's really also a time now, with these standards coming forward, to look at implementation and to taking the standards [and] ensuring that they're properly implemented in systems and verifying, via certification and score carding in the federal sector, that one implementation works with another implementation. And that's what's going to get us to the interoperability that's going to carry us forward." – Dr. Loonsk

"The need to create standards in the 21st century on an efficient and rapid basis will define the new frontier of human productivity. And the fact that we're able to start and get better at it tells me we can continue to get better at it…and that it's crucial, not just in health care, but these skills that we're developing, this process, the rules, the acquaintance with the means by which people can drive or protect their equities." – Secretary Leavitt

"I think this is a very large social change. And it reminds me, again, that it's not the technology that limits us. It's the sociology and all of this is about not just inventing the technology, but managing the sociology. You've done a wonderful job, and there's lots of work to do, but I want to thank you for what you've done, and to commend the thousands of people who have participated in this, in this process." – Secretary Leavitt

Population Health/Clinical Care Connections Workgroup Recommendations

Dr. Leslie Lenert, Director of CDC's National Center for Public Health Informatics, began his presentation by reminding The Community of the urgently needed ability for public health to transmit information interoperably across jurisdictions in managing outbreaks. He provided an example of a salmonella outbreak at the Department of Public Health in the State of Illinois, highlighting the difficulty of communicating across state lines to try to identify what was going on, and to find the particular source of the outbreak. This episode illustrated the need for data exchange among public health organizations, and the lack of resources that are generally available for it.

The Population Health/Clinical Care Connections (PHCCC) Workgroup developed a series of recommendations that was submitted to the Secretary in September 2007. The Workgroup was asked to revisit some of the recommendations and develop a roadmap to implement these recommendations. Dr. Lenert explained that the PHCCC Workgroup's recommendations have been revised and call for the

ability, within one year, for essential ambulatory care and emergency department visit, utilization, and laboratory result data from electronically enabled health care delivery and public health systems to be transmitted in a standardized and anonymized format to authorized public health agencies within 24 hours.

Dr. Lenert then presented the PHCCC Workgroup's following recommendations:

- **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.

- **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 that programs be able to combine funds from individual programs to support integrated efforts at public health architecture and interoperability.

- **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 a systematic method for communication among systems. Specifically this would include standards identification in development of an open outbreak and event management system that would be extensible by public health partners, and dissemination of this open outbreak and events management system among the partners.

- **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. 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.

- **Recommendation 4.0: Laboratory Response.** CDC, in collaboration with the Association of Public Health Laboratories (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, speed the integration of public health laboratories with the NHIN, and facilitate 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.

- **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.

- **Recommendation 4.2: Laboratory Response.** By December 2009, CDC, in collaboration with 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.

- **Recommendation 5.0: Countermeasure Allocation, Distribution, Administration.** 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.

- **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.

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

- **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.

- **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.

- **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.

Discussion

"On Recommendation 4.1, is that different than [the creation of] the national provider ID, the unique identification of medical service providers?" – Mr. Hutchinson

"It is different, because some of the public health laboratories don't have a national service provider ID because of their function. So it's an expansion of that idea. The national service provider ID could readily be used for that, but there are other entities in public health communications that aren't covered by that." – Dr. Lenert

Population Health/Clinical Care Connections Workgroup Roadmap and Timeline

Dr. Lenert presented the following recommendations that relate to the PHCCC-proposed Roadmap and Timeline:

- **Recommendation 1: Public Health Informatics Training.** A coherent national policy to meet informatics needs for public health at state, local, and tribal levels. This includes:
  - 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 and continues training of PhDs 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, and tribal public health departments for 2-year fellowships.

Dr. Lenert noted that Recommendation 2.0 is largely a policy recommendation; execution of this recommendation has been left to the Office of the National Coordinator (ONC).

- **Recommendation 3: Outbreak and Event Management.** In order to harmonize the functionality and interoperability of OEMS applications, CDC seeks to have:
  - An open source interoperable OEMS team with independent governance and full state, local, territorial, and tribal participation
  - National prototypes and 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.

Dr. Lenert explained that Recommendation 3.1 addresses interoperability of these systems, where the initial task is to develop detailed use cases and define the interoperability criteria, in collaboration with HITSP and CCHIT. There is an existing OMS 1.2 system that is a base for the CDC's efforts, and several states have existing systems. A detailed architectural analysis is needed to move those systems forward; and this activity is currently funded, but in the latter stages of 2009, additional resources will be needed.

- **Recommendation 4: Public Health Lab Data Exchange.** 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 and a process for certification
  - Grants program to upgrade public health laboratories to ensure that 50 percent of public health laboratories can exchange messages.

- **Recommendation 5: Countermeasures.** In order to harmonize the functionality and interoperability of CRA applications, CDC seeks to have:
  - An open source interoperable CRA team with independent governance and full state, local, territorial, and tribal participation
  - National prototypes and demonstration projects to illustrate how to build interoperable CRA systems
  - CRA interoperable systems installed in 40+ states and/or territories
  - Certification criteria for COTS CRA and to have multiple CRA's systems certified, giving states choices in implementation.

- **Recommendation 6: Automated Integration With Registries.** 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 and tribal participation
- National prototypes and demonstration projects to illustrate how to build interoperable OEMS
- Compatible public health registry systems interoperating across states, laboratories, and CDC
- Certification criteria for COTS registries and certification of multiple systems, giving states choices in implementation.

Dr. Lenert discussed the estimated cost associated with implementing each of these recommendations (with the exception of Recommendation 3), both in 2009 and 2010. The overall cost is estimated at $32,765,000 in 2009, and $32,441,000 in 2010—the costs likely would decline somewhat after 2010. Most of the costs are linked to grant programs for states, or other programs that might be necessary to sustain certain activities. Dr. Lenert then described CDC activities related to this agenda that require no additional funding. In 2008, CDC will: (1) complete an environmental scan of current public health workforce needs using data collected by survey, (2) initiate a professional-level distance learning certificate program at an initial cohort of training sites, (3) initiate meetings with relevant stakeholders to begin to develop requirements and identify standards for OEMSs, (4) develop a national network of OEMS programs through creation of a governance structure and specific use cases for interoperability of OEMSs, (5) begin efforts to develop interoperability among public health laboratories by developing an initial clinical reference data model, (6) hold discussions regarding private-sector resources for CRA systems and how those would fit into a national CRA network, and (7) convene state and local public health chronic disease registry experts to identify populations of interest for registry integration with the NHIN. In 2009, the CDC will test and validate the NHIN-compatible clinical reference data model and fund OEMS development for the first quarter of 2009.

Dr. Lenert commented that the PHCCC Workgroup believes this roadmap to be a comprehensive plan for providing the nation with the capability it deserves for outbreak management response, and the state and local public health organizations the capability to address these types of difficult situations.

The Community accepted each recommendation by consensus and moved them forward for the Secretary's review.

Discussion

"The President will put forward his 09 budget on the fourth of February, I believe, and this comprehensive picture will not be represented, as such, in that budget. But I think it is a very important contribution as we begin to look forward to not only 09, but also in future budgets, as well as just getting a picture of what such a system could look like in a more comprehensive way." – Secretary Leavitt

"This does not include a proposal for CDC's overseas laboratories. Our focus was on enhancing state… and local capabilities to respond to outbreaks. And that was really the charge that was given to the PHCCC [Workgroup], which was not really looking at the whole world, but looking at the United States and how public health could fit into the NHIN in creating…an NHIN for public health." – Dr. Lenert

"We have a lot of people overseas…so whatever we can do to share information there, we would like to do." – Dr Casscells

"While we did ask them to provide us with a financial picture, it is not AHIC's role to be recommending budgets to the Secretary, and I know you all understand that. It's a very important part of the picture, but it's not necessarily something that I'm receiving as a formal recommendation, as a budget request." – Secretary Leavitt

Electronic Health Records Workgroup Recommendations

Dr. Jonathan Perlin, EHR Workgroup Co-Chair, began by reminding Community members that the EHR Workgroup's broad charge is to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers. The Workgroup's specific charge is to 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. Recent EHR Workgroup activities include: (1) broadening its focus and membership to include the inpatient arena (summer 2007); (2) receiving testimony from three hospital systems to gain perspective on inpatient HIT adoption experiences (July 2007); (3) from this testimony, learning that having an HIT trained and competent workforce was essential for HIT adoption, successful implementation, and effective utilization; and (4) focusing future activities on discovering and addressing the HIT workforce needs. Dr. Perlin explained that some very specific issues were highlighted through the hospital testimony (e.g., issues related to education and training, and tracking individuals as they enter careers, health disciplines, and career paths in public, private, and academic sectors). He then presented the following EHR Workgroup Recommendations, which focus on 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.

- **Recommendation 2.0:** HHS should work with the Department of Labor to develop occupational classifications for HIT professionals.

- **Recommendation 2.1:** HHS should encourage the Office of Personnel Management to recognize health informatics professionals in the federal professional series.

- **Recommendation 3.0:** HHS should support funding for additional research within specific Federal agencies to create HIT career pathways (including occupational series and 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.

- **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.

- **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.

- **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

- **Recommendation 8.0:** The Office of the National Coordinator should work with the states to encourage governors to increase recognition of HIT workforce needs and suggest ways to address them. This could include health professional licensing activities.

The Community accepted all of the Workgroup's recommendations and moved them forward to the Secretary for consideration.

Discussion

"I think [these recommendations are] well needed in our own industry. We have it in other industries where we recognize various different levels of mechanical engineers, and structural engineers, and other types of careers, and in health IT, this is something that we have always struggled with, on coming up with a standardized leveling of certain positions and recognition of that. So I'm all for it."
– Mr. Hutchinson

"When you begin to take everything we do, and if you strip it down to its basic core element, you find that the world of medicine is run by medical coders. And that's the place where it all happens. And yet there is no career path for them, and no way to systemically develop them." – Secretary Leavitt

"This speaks to a much larger deficiency in the way we have gone about training health workers and professionals, for that matter. We have created large institutions that depend on the system of accreditation that measures time, not competency. And what I hear your group recommending is that we begin to look at ways of identifying the competencies that are necessary, assuring that those competencies exist, certifying and allow people to move through those competencies as rapidly as they can from whatever source they learn it." – Secretary Leavitt

"Is there any way of either establishing or widening the CME credit guidelines for your Recommendation 7.0, for people that are actually on the front lines providing the care, who want to learn more? Time is already a factor in their lives." – Mr. Devore

"Recommendation 7, as with many of the recommendations, is framed within the context of the Federal Advisory Committee Act, and it places limits on how directive we can be, but you are 100 percent on target in terms of the vehicles that the group had envisioned to create the momentum that the Secretary just described." – Dr. Perlin

"As you implement these systems, the people that come forward to do this are from all walks. They're from pharmacy, laboratory, health information management, physicians. So it's really a variety of base disciplines from which—that it really makes a richer environment for implementation." – Ms. Graham

"I'm not sure that [Recommendation 2.1], as it's worded, is both general enough or specific enough, or maybe too specific in terms of getting to the issues and addressing them. I'm not sure that when all is said and done, that creating or recognizing a new professional series, or whatever was entailed, is going to solve the issues that you were discussing here…we can go forward with that recommendation, but I'm not sure that that ultimately will be what the objective will be." – Mr. Green

"It's also difficult in the hiring process, because you can't identify these people. They don't necessarily fit into a slot that you need, because they're pretty regimented from a historical perspective. So I think looking at your different hiring authorities and within the classification systems, and recognizing this as a professional classification, really would go a long way to enhancing the Federal workforce…I think it would go a long way to support informatics being identified in the private sector as well." – Ms. Graham

"I know that in the past year, the government has been working on new standards, including educational standards and those sorts of things for acquisitions professionals, and there is a home for that. There is an interagency group that oversees acquisitions in the federal government, obviously. And so that has been the champion. I think that's what needed, and maybe it's the policy council that we currently are all part of." – Mr. Green

"Maybe we can take it back to the HIT Policy Council, see if it fits their grade. If not, we'll work with the representatives to find a home for it…One of the things we have been dealing with in the course of the AHIC is that we're now expanding informatics not to be just the coding in the revenue, but pervasive throughout the very infrastructure of care delivery." – Dr. Kolodner

"When I was dealing with this in a more detailed way, our thought was 'Let's identify the categories, and then identify methods of accrediting competency in those areas'. And it was evident to me that it was everything from an entry-level coder to a Ph.D. that could fit along that spectrum. It's a wonderful career, but it's failed to become a career…if you're in academics, you can get a bachelor's degree, a master's degree and a PhD, and you're considered competent. But in this area, there is no way beyond those, and those don't fit very well." – Secretary Leavitt

"I would be interested, by our next meeting, to see if we couldn't begin to frame up at least what that would look like, and what group of people would need to be brought together to begin to do it, and then how could we use the Office of Personnel Management, the Department of Labor, and HHS, not to prescribe what they are as much as to adopt them and…collaboratively develop the basic point, and then adopt the outcome." – Secretary Leavitt

Findings From the *Enhancing Data Quality in EHRs Report*: Recommendations Update

Dr. Perlin presented the findings of the Model Requirements Executive Team (MRET) from the *Enhancing Data Quality in EHRs Report*. MRET members presented to the EHR Working Group on December 4, 2008, and the Workgroup was asked to comment on recommendations for initial EHR requirements to increase documentation accuracy and fraud management within the health care system. Discussion within the EHR Workgroup emphasized the acceleration of implementation, the ability to improve the quality of the coding, and removing many of the inefficiencies associated with this part of the care delivery process.

He went on to discuss the following "requirements":

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

Dr. Perlin explained that the Workgroup supported the general intent of MRET, which is that the clinical care should drive the documentation and should drive the coding. The Workgroup did not, however, agree with the reciprocal: that coding should necessarily drive the documentation, and thus, the clinical care. That distinction is particularly important, Dr. Perlin commented, in light of the opportunities to advance the technology to create a more coherent electronic health record. The EHR Workgroup deliberated and supported Requirements 5 and 6 as desirable to advance both broad and narrow charges, and offered no specific modifications. In terms of Requirement 5, The Workgroup hopes that this work will continue in the area to be utilized and ultimately specified so that it can inform bodies such as CCHIT, but it recognizes that there is some continuing controversy around the direction or the complexity of this requirement's apparent prohibition on an auto-prompting provider for items that may be clinically omitted. With regard to Requirement 6, the Workgroup suggested that there be greater specificity in terms of the administrative entities that might have appropriate access to view records, but not the need or authority to modify records.

AHIC also requested that the Confidentiality, Privacy, and Security (CPS) Workgroup review the MRET Requirements germane to its scope. Ms. Deven McGraw, CPS Workgroup Co-Chair, described the CPS Workgroup's reaction to the following:

- **Requirement 8: Auditor Access to Patient Record.** CPS Workgroup Assessment: The CPS Workgroup believes that Requirement 8 would benefit from further specificity. In doing so, it is expected 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).

Ms. McGraw noted that the Workgroup did not have any concerns about Requirement 8, but did believe that its three components could be enhanced by some greater specificity. To clarify, Ms. McGraw reminded the Community that 8.1 requires auditors to be a supported class of users within the EHR, 8.2 requires facilities to limit access to what would be pertinent for the audit, and 8.3 stipulates that access remains controlled by the facility (there would be different types of auditors and different reasons to access the EHR). Ms. McGraw commented that from a confidentiality, privacy and security standpoint, these recommendations would benefit from being more granular.

The Community proposed one modification of Requirement 5.2, which was accepted by consensus. The modified requirement now reads as follows:

- ***Requirement 5.2.*** *Prompts that are driven by E&M administrative processes shall not explicitly or implicitly direct a user to add documentation for the purposes of achieving a higher level code. This does not apply to prompts for additional documentation for E&M levels already achieved, for medical necessity, for quality guidelines/clinical decision support, or for previously documented clinical information.*

Mr. Weems requested that the complete set of requirements be presented at the next AHIC meeting with a recommendation for their dispensation. Dr. Kolodner agreed.

Discussion

"There is a body of evidence to show that particularly in patients that have multiple chronic conditions or multiple problems in a single visit that are attended to, the number of problems or conditions that are addressed are more than what's documented, and are more than what's coded for." – Dr. Henley

"If a physician is actually documenting care and they code for it…and they click it's a level three visit, and that's going to go over to the billing system in the EMR, and an alert pops us and says 'You don't have enough documentation for a level three,' is that violation of 5.2?" – Mr. Hutchinson

"Well, it's getting into an area beyond my level of expertise, but my understanding is that applications of that sort should offer the clinician the ability to realize that they don't support a higher level of E&M code, but they're not meant to drive additional documentation toward the point of achieving a higher E&M code." – Dr. Perlin

"The verbiage [prior to rewording Requirement 5.2] seems to suggest that control of the patient record, which then becomes a billing record, would remain more in the control of the physician or hospital than frankly it's been interpreted…we believe that once the care is rendered, that that billing record is pretty much ours for looking at and interpreting and reviewing. It makes us, as your agent, a visitor as opposed to [having] more of an ownership perception." – Mr. Roob

"I'm not sure that ownership is important, as long as there is still clear access to it. And that the auditor has a right to it." – Mr. Weems

"When this first came out, there were some people who saw it as opening up the flood gates for auditors, and I think the CPS Workgroup was able to clarify that was not what it was meant to do, but it was…meant to provide them access to everything that they should have access to, but also, to put a limit around that."—Dr. Kolodner

"As you know, Secretary Leavitt has periodically been involved in activities to identify the fraud that is going on, and wastes of hundreds of millions or billions of dollars that are diverted and aren't used for the care of individuals that need that care. And the question is: how the EHR can serve as a tool to help us to prevent the fraud, but for the provider, not to be a watch dog as much as a support. And that is alerting them that if they have the ability to stay within the boundaries that are provided by the EHR…they will have the proper documentation and they will actually almost have a protection, because we know that the vast majority of clinicians are not trying to commit fraud."—Dr. Kolodner

"This will cause some degree of up-coding. We are collectively willing to accept that, perhaps, but let's not pretend it won't happen, one. Secondly, I think there needs to be a timeline on how long that prompt comes back to. If it's not been recognized overtly by a physician for some number of months or years, it ought not come back."—Mr. Roob

"This is a real problem. Because on the one hand, pregnancy after a certain age is unlikely to recur. On the other hand, a melanoma may recur 20 years later, and if a doctor was reminded about it, it might make a difference in life and death, and actually, that's a common problem. Melanoma is a real common problem that comes back, the doctor doesn't pick it up." – Mr. Kahn

Workgroup Recommendations Status Report: *Consumer Empowerment Workgroup—January 2007 Recommendations*

Nancy Davenport-Ennis, Co-Chair of the Consumer Empowerment Workgroup, noted that the following two CE Workgroup recommendations have been completed:

- **Recommendation 1.0.** HITSP should identify the technical and data standards to enable the availability of a core registration dataset and medication history.

- **Recommendation 3.0.** An additional AHIC workgroup should be created that would address the cross-cutting confidentiality, privacy and security issues related to all the Community charges.

Next, Ms. Davenport-Ennis reviewed two Consumer Empowerment Workgroup recommendations that are in process:

- **Recommendation 2.0.** 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.** 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.

Ms. Davenport-Ennis reported that the CMS PHR pilot began in June 2007. CMS is working with the Office of External Affairs to evaluate appropriate and effective outreach and messages. These activities are anticipated to be completed in December 2008. With regard to recommendation 2.1, Ms. Davenport-Ennis indicated that there was significant discussion within the Workgroup about what patient population should be used for the initial pilots. It was determined that those with chronic diseases have an inherent interest in moving forward with electronic health records.

Ms. Davenport-Ennis then reviewed two more completed Consumer Empowerment Workgroup recommendations:

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

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

The following recommendations are still in process:

- **Recommendation 2.4.** 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.

Ms. Davenport-Ennis indicated that preliminary research has been conducted on various state laws with respect to specifically protected information as it is used for the purpose of treatment, research, payment and public health. The initial findings show that there is great variation at the state level in terms of what kind of laws are going to govern consumer access to EHRs. The State Alliance for e-Health is developing a report that will provide clarity on the status of state laws in all 50 states.

- **Recommendations 3.1, 3.2, 3.2.1, 3.2.2, and 3.2.3.** These recommendations are concerned with an evaluation using a standardized approach for assessing PHR use and value.

Ms. Davenport-Ennis reported that a taxonomy for PHR definitions is needed, PHR definitions will be available in March 2008, and Requests for Proposals for contracts and grants will be developed. Multi-

stakeholder groups are in the process of trying to define the context in which a PHR can be defined and described. Recommendations related to these activities will be presented to the Community in April.

Discussion

"Are you including security and privacy in there? I think it's a key element, before you get to the harmonization. I can get 50 different opinions from 50 different people as to what you mean by security and privacy. I think it would be a key element, to define what we mean when we talk about those two terms." – Mr. DeVore

"The direct answer in the short term is no, that is not part of the original statement of work, but clearly, I think there are ways that can be addressed in moving forward, and we'll deliberate that and perhaps get back to you in another meeting." – Dr. Bell

"We have looked repeatedly at the definition of privacy and security, and what is that definition going to look like…There is not a universal standard across any of the 50 states, so you can't look there. There is not a federal standard that we can turn to here. And for that reason, a subgroup was created to work specifically with privacy and security…we'll certainly go back to the Privacy and Security Workgroup to say, again, 'This is an area of great importance to the members of the AHIC,' and we're going to look forward to the answers that they bring around these issues moving forward. But for the CE Working Group, it is not part of the universal definitions that we're trying to develop." – Ms. Davenport-Ennis

"From the patient perspective, providing the PHR provides us with a well-informed patient. A well-informed patient makes well-informed decisions. Well-informed decisions will reduce not only medical errors, but opportunity for duplicity and testing and therapeutic intervention, and ultimately, will be a cost savings benefit not only to the United States of America, but to the individuals who are involved in the cost shifting burden within the country." – Ms. Davenport-Ennis

Public Comment

Speaker Number 1—Richard Singerman of IBM noted that it would be useful to have CDC's more detailed analysis of some of the issues discussed during the PHCCC Workgroup's presentation made publicly available. He referenced Dr. Perlin's comments and explained that in terms of academic careers, the National Institutes of Health offers a program for accelerating translational medicine and provides clinical science and translational awards. He asked how much of a connection there is between academic careers and leveraging an already existing and growing program. Mr. Singerman also commented that it would exciting to look at the technology and policy issues associated with having laboratory data go straight to a PHR that is not tethered to a provider or a payer, in terms of promoting consumer empowerment.

Speaker Number 2—Kathryn Serkes of the Association of American Physicians and Surgeons (AAPS), noted that the AAPS is the largest organization of office-based physicians in the practice of private medicine. The Associations constituency is mostly in solo or small group (i.e., 1-10) practices. She commented that AAPS members are not the technological "laggards" they have been portrayed as. Many of these doctors are streamlining their practices for the sake of eliminating their claims and other administrative procedures within their practices. Ms. Serkes indicated that there is still a great deal of confusion in the field about terminology and definitions—for example, when many physicians hear the term "electronic health record," it represents a national database. Ms. Serkes discussed the Physician Adoption Survey and touched on a number of points contributing to physician resistance to adoption. With regard to patient privacy, Ms. Serkes indicated that there is an inherent disconnect over the AAPS

members' perception of patient privacy being maintained within the constructs of an EHR. This in turn leads to concern that adoption of EHRs or HIT will lead to a national database. Increased legal liability is another concern; doctors who have been prosecuted on billing errors because of coding mistakes or data entry mistakes have the same fears tied to EHRs in terms of documentation. The issue of clinician notes is another concern for many physicians who feel that for patient safety, not just for patient concern, there are things in the patient notes that should not be there. Ms. Serkes explained that the clinical notes are a process, so if a doctor is speculating, for example, that a patient has Huntington's disease, that should not be available to the patient until there is a diagnosis, for the safety of the patient.

Hugh Zettel, GE Healthcare, and Vice Chair of the HIMSS EHR Vendor Association, noted that the Association's membership would appreciate a full review of the *Enhancing Data Quality in the EHR Systems* that was discussed earlier in the meeting, with the opportunity to make appropriate comments.

Closing Remarks

Before adjourning the 19th meeting of the AHIC, Dr. Kolodner thanked the Community members, speakers, and participants for their attendance and participation and reminded AHIC members that the next meeting, scheduled for February 26, 2008, will be held in Orlando, FL.

American Health Information Community

LMI-Brookings Approach to Convening the AHIC Successor

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Brookings Institution

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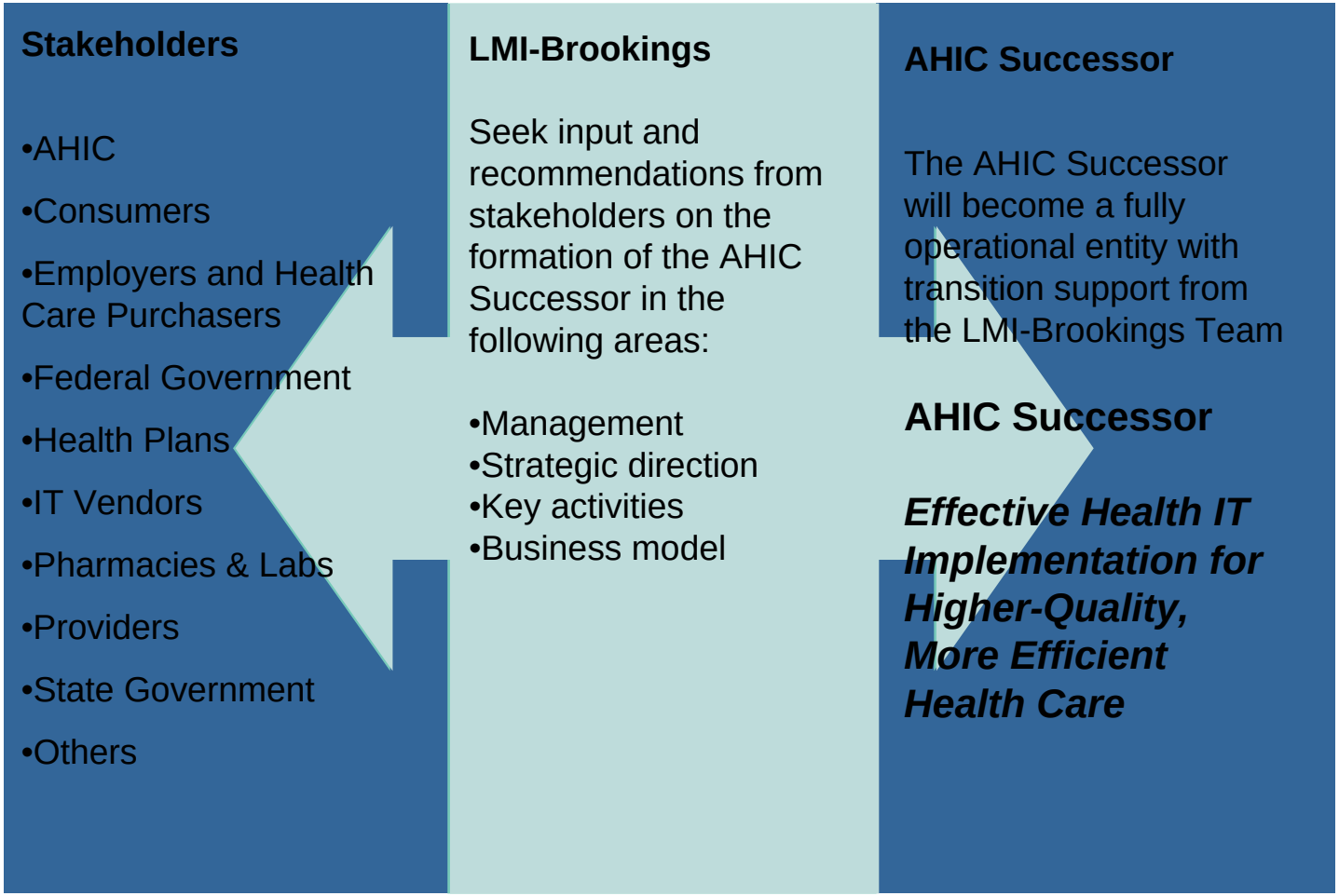
February 26, 2008

LMI-Brookings is convening stakeholders to design and establish an independent public-private AHIC Successor



02072008 control

The design of the organization will be guided by six principles

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

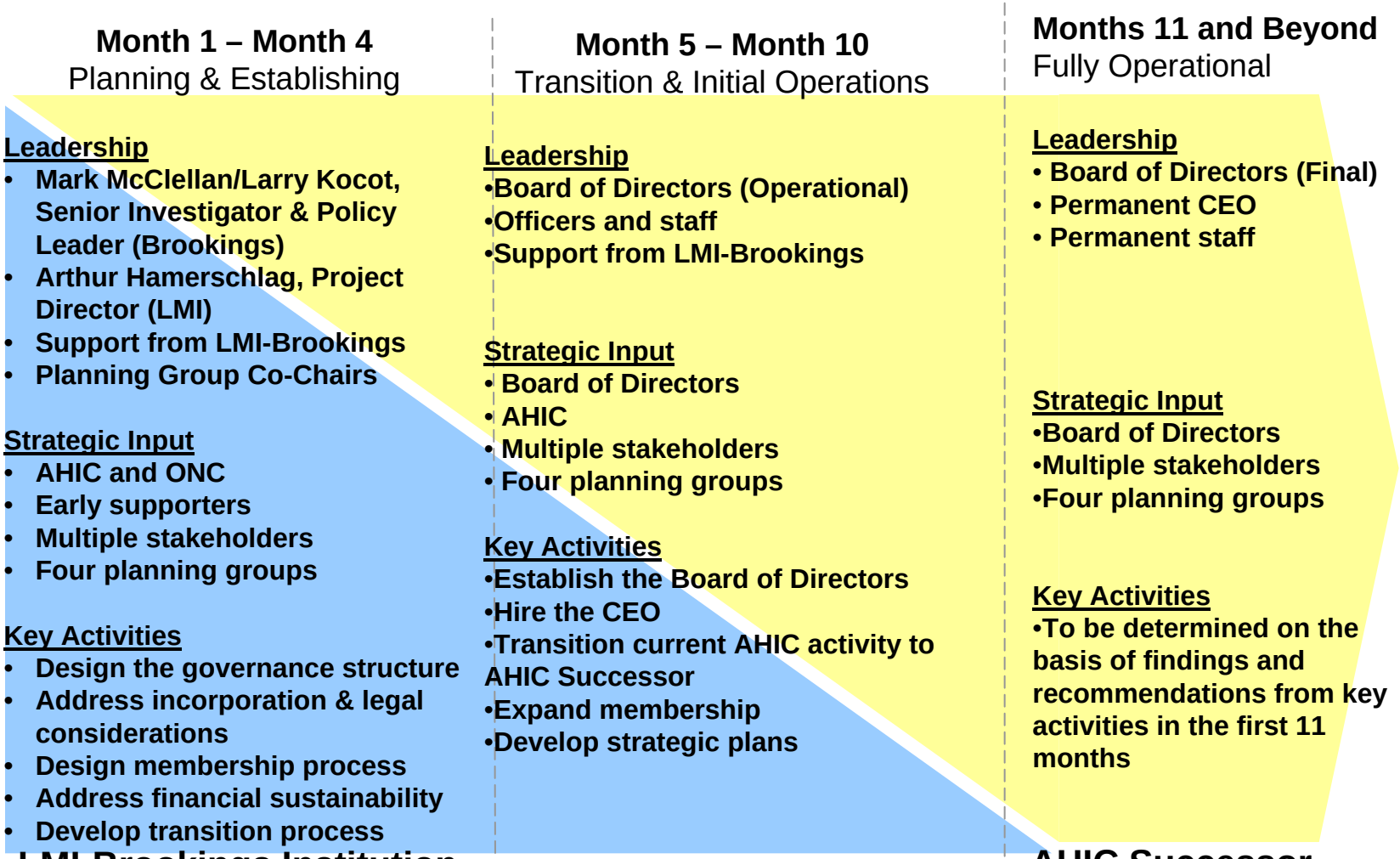
A multi-disciplinary team is needed to address all aspects of establishing the AHIC Successor

- A convener capable of drawing together stakeholders from across the health care industry
- Program management capability to manage budget and schedule and administer contracts
- Communications expertise to ensure adequate outreach for public commitment and participation
- Legal Counsel to support incorporation and develop operational bylaws
- Financial expertise to establish formal accounting
- Executive and staff development expertise to define and fill key positions within the AHIC Successor
- Management consulting to ensure an orderly transition from AHIC to its Successor

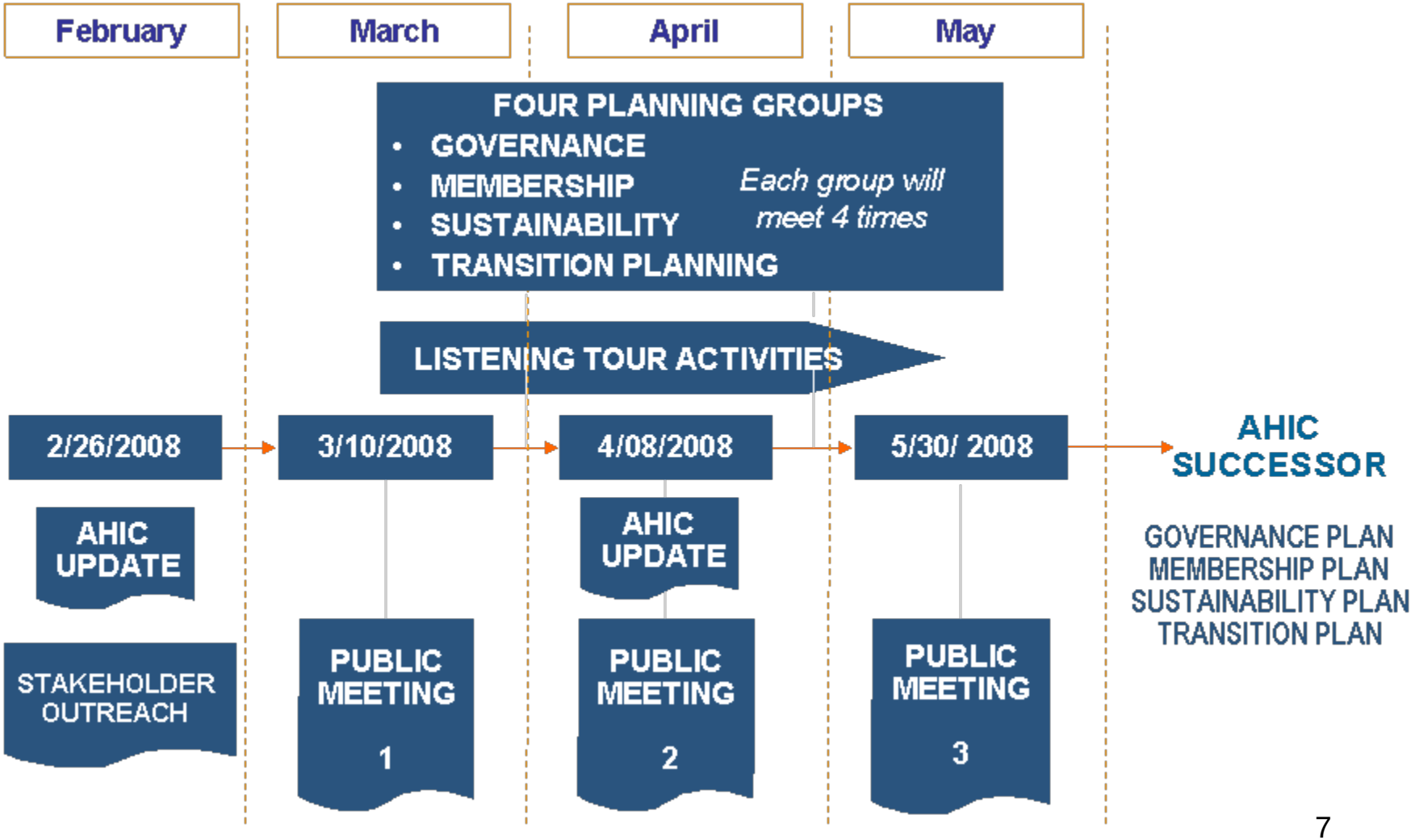
LMI-Brookings has built a team capable of convening and establishing the AHIC Successor

Organization	Primary Contributions
Brookings	• Develop and maintain stakeholder relationships required to define the Successor organization and develop consensus • Work with executive search firm to hire management team and staff
LMI	• Overall project approach and direction, integration of project work streams, oversight of sub-contracted resources • Planning group integration, grant management, contracting, invoicing, timeline and budget, risk management, reporting, meeting logistics, and website content management
Edelman and Nahigian Strategies	• Develop communications plan that includes messages, distribution channels, and collateral material to support public outreach; manage focus group activities
Sonnenschein, Nath, & Rosenthal	• Address protections, incorporation, and other legal considerations needed to establish the new legal entity
Booz Allen Hamilton	• Transition planning: baseline current AHIC activities, identify activities needing to transition, including options for HITSP, CCHIT, and NHIN

The Successor organization will be established within 4 months and transitioned to full operation after 11



The first four months of activity are focused on building commitment and defining governance



The general scope and purpose of the Successor was articulated in the AHIC Successor White Paper

- Accelerate and coordinate current AHIC interoperability initiatives, including standards harmonization and certification of health IT
  - The relationship between the AHIC successor, HITSP, and CCHIT will be determined as the organization is designed
- Prioritize stakeholder requirements for nationwide health IT interoperability
- Oversee and facilitate the Nationwide Health Information Network (NHIN)

Planning groups will convene to design key elements of the Successor organization

- Planning groups will be led by co-chairs
  - Depending on the charge, each group will have the support of legal, marketing, or accounting expertise
- Co-chairs will be identified by LMI-Brookings with input from stakeholders
- Planning group members will be selected from across the stakeholder community, including federal stakeholders
  - Target size: 20 members per planning group
- Planning group members will be identified based on suggestions from the March 10th sessions and other input

The planning groups will address the requirements for standing up a new business entity

Organization and Governance

Preliminary organizational structure for operating the AHIC Successor and the roles and responsibilities of its officers and members

Membership and Recruitment

A draft outreach plan to ensure recruitment of broad-based membership across sectors in 2008

Business Sustainability

Options for obtaining financial sustainability in alignment with the organizational plan

AHIC-to-Successor Transition

Plan for identifying actions and initiatives to be transferred from the current AHIC to the new organization and a plan for the transition of these activities by Fall 2008

Public meetings will be used to engage stakeholders in the process of determining the Successor's design

- Provide a formal setting within which to raise awareness of the Successor's development and activities
- Establish the Successor as separate from the AHIC
- Present opportunities for assessing the current environment through public input
- Allow public comment
- Support transparency of process
- Seek commitment for supporting the new legal entity

March 10	April 8	May TBD
Approach & Timeline	Progress Report	Results & Next Steps

Save the dates

Improving Quality and Value: Measure Nationally, Act Locally

Carolyn M. Clancy, MD

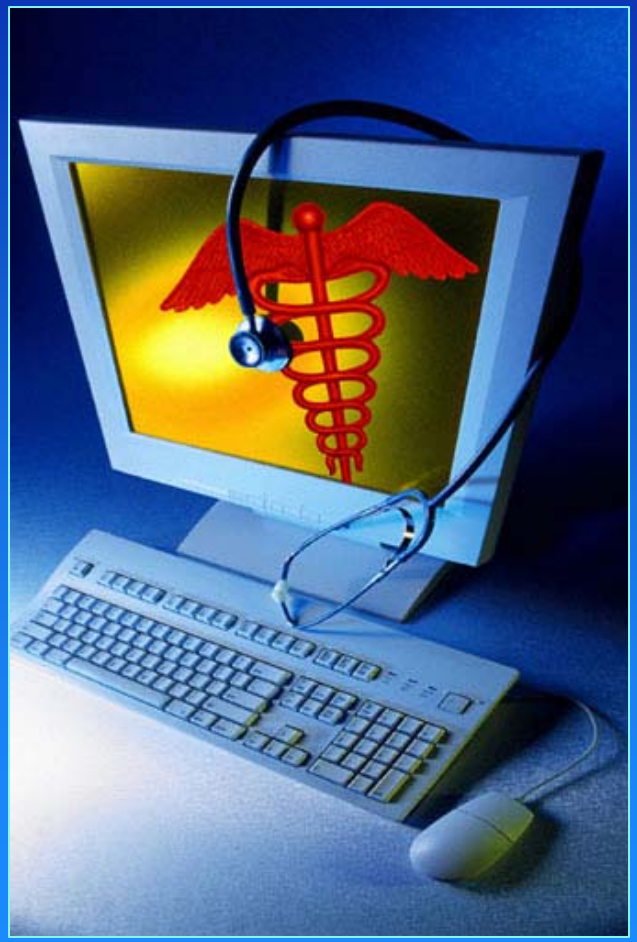
Director

Agency for Healthcare Research and Quality

American Health Information Community

Orlando – February 26, 2008

Improving Quality and Value



- Current Health Care Landscape
- The National Quality Measurement Enterprise
- Getting to Value-Driven Health Care
- The Role for Communities and Community Leaders
- Q & A

The Future

Surgical Care Consumer Guide

Search Results: **Hip Replacement**

What's included in the cost?

Summary

Average Cost in Network Facility: $11,249 - $15,895
Out of Network Facility: $18,889 - $23,460

Results sorted by: Distance **Sort by:** Quality GO

Key

Quality: ★★★★ Highest | ★ Lowest **Cost:** $ Least Expensive | $$$$ Most Expensive **Patient Assessment:** ★★★★ Highest | ★ Lowest

Distance (Miles)	Facility Name	Patients per year	Quality	Cost Estimate	Insurer Pays	Patient Pays	Patient Assessment of Care
6.2	Clearwater General 14280 Bay Drive Clearwater, FL 22131	400	★★★	$$ $15,895	85% ($13,511)	15% ($2,384)	★★
13.2	All Saints Medical Center 123800 All Saints Drive Tampa, FL 22122	86	★★★★	$$$ $20,700	80% ($16,560)	20% ($4,140)	★★★
25.6	Good Samaritan Hospital 11111 E. Samaritan Drive Tampa, FL 22222	232	★★★★	$$ $15,895	90% ($14,306)	10% ($1,590)	★★★★
26.3	Tampa Hip Hospital 1400 East Tampa Boulevard Tampa, FL 22211	170	★★★	$$$ $20,700	75% ($15,525)	25% ($5,175)	★★★
27.3	Orthopedic Clinical Hospital 1444 Goodie Drive St. Petersburg, FL 22113	432	★	$ $11,600	70% ($8,700)	30% ($2,900)	★
33.2	Valley General Hospital 1400 Tampa Bay Way Tampa Bay, FL 22031	310	★★★	$$ $16,230	85% ($13,796)	15% ($2,434)	★★★

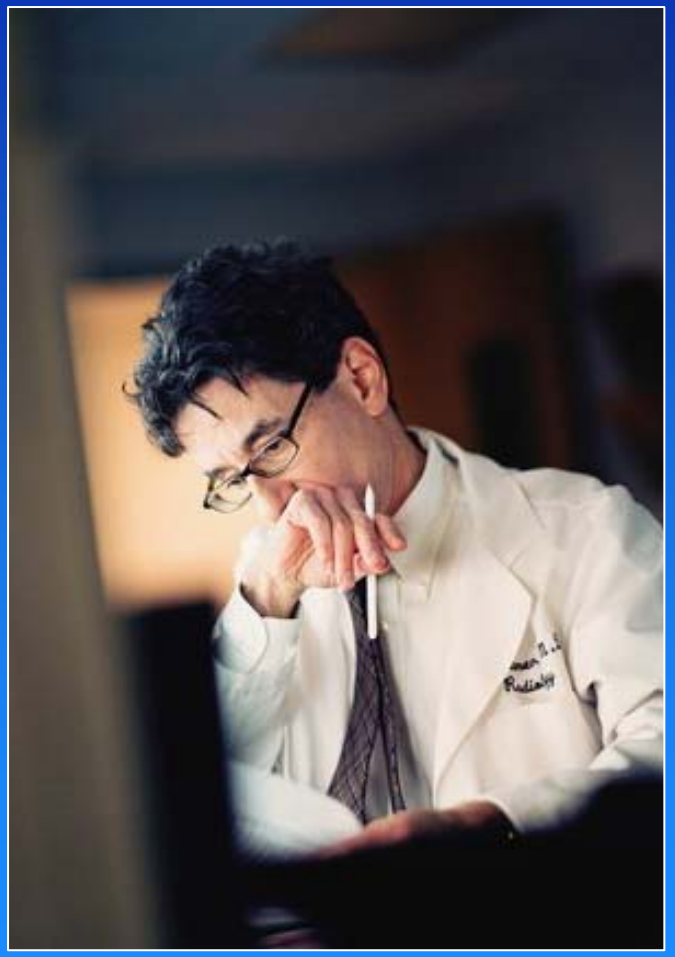
Measure Nationally, Act Locally

"All health care is local, and we need cooperative local action just as we need common national goals."

Michael O. Leavitt, Secretary
U.S. Department of Health and Human Services

Current Landscape

- Increasing demand that providers demonstrate quality
- Public reporting of performance leads to improvement
- Disparate performance monitoring initiatives
- Initiatives that link payment with performance have proliferated



A Growing National Commitment

- Hospital Quality Alliance
- AQA
- Quality Alliance Steering Committee
- CMS-Premier P4P Demonstration Project
- Leapfrog Group
- And much much more!

Many groups working toward same goal, collaboratively

Cornerstones of Value-Driven Health Care

Quality Standards

Design systems to collect quality of care information and define what constitutes quality health care

Price Standards

Aggregate claims information to enable cost comparisons between specific doctors and hospitals

Interoperability

Set common technical standards for quick and secure communication and data exchange

Incentives

Reward those who provide and purchase high-quality and competitively priced health care

National Framework for Quality and Cost Transparency for High-Value Care

What Will This Take?

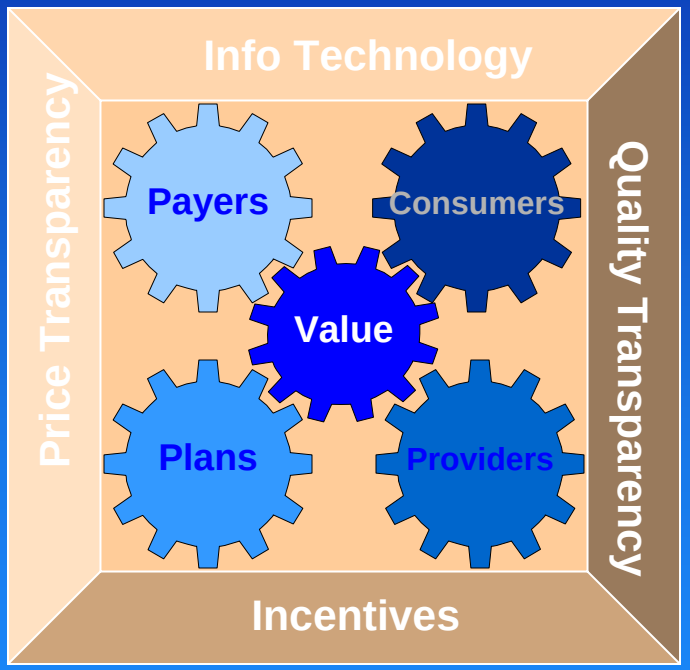
- Good measures and data
  - Local data, but national benchmarks
- Strong local coalitions
- Evidence-based reporting, payment strategies
- Evidence, tools, strategies for improvement
- Collaboration across sites

Encouraging Local Collaboration

What is a Value Exchange?

A local organization of health care stakeholders recognized for meeting the following criteria:

- Engagement with Payers, Plans, Providers, Consumers
- Non-profit entity
- Focused on improving value through the Four Cornerstones



Encouraging Local Collaboration

What does a Value Exchange do?

Serves as a hub for stakeholder engagement and information sharing

Uses standardized performance information to:
1) Partner with providers in care improvement
2) Facilitate consumer decision making through public reporting
3) Promote effective payment policies that create more value for patients

Participates in a Value Exchange network to further promising practices/lessons learned and continually refine efforts

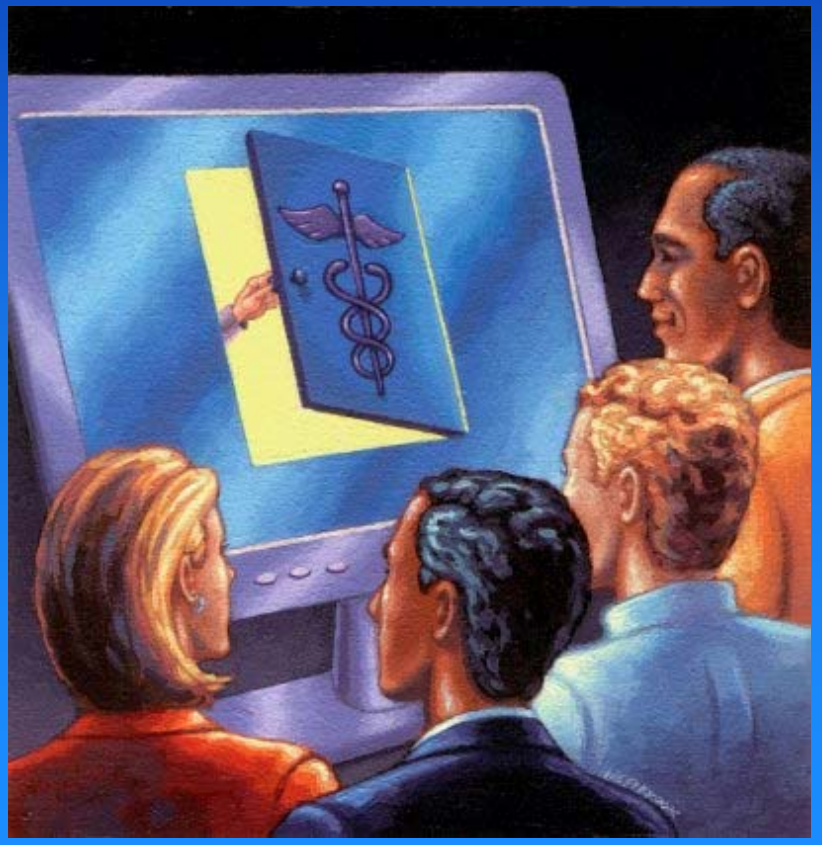
Serves as a hub for stakeholder engagement and information sharing

Uses standardized performance information to:
1) Partner with providers in care improvement
2) Facilitate consumer decision making through public reporting
3) Promote effective payment policies that create more value for patients

Medicare Data

Medicare Performance Data to Be Made Available at Community Level

- Release of physician performance information supports Value-Driven Health Care Initiative
- CMS to “crunch the numbers,” Value Exchanges will disseminate results
- Combining public and private data to provide a comprehensive picture of physician quality



Chartered Value Exchanges

AHRQ Learning Network for Value Initiative

- Encourage sharing of experiences and lessons learned
- Identify and share promising practices that improve health care value
- Identify gaps where innovation is needed
- Provide face-to-face and virtual opportunities for peer-to-peer sharing of experience
- Identify interventions or tactics that yield the best outcomes
- Translate interventions into adaptable change strategies
- Create a user-friendly, Web-based knowledge repository
- Goal: have all Community Leaders become or join Chartered Value Exchanges

Measurement *Data aggregation* *Report Cards* *Provider Incentives* *Consumer Incentives*

Issues and Challenges

- Do consumers have the information they need to make choices?
- Are providers given the tools they need to improve?
- What is “value”?

Call to Action: The Role of the AHIC/Health IT Enterprise

- "Information governance" is essential to Value-Driven Health Care
- Quality enterprise is dynamic – big opportunities to get implementation right
- Relationships between Chartered Value Exchanges and HIE's a work in progress
- Keeping consumer's needs front and center is essential

Your Questions?

American Health Information Community

An Overview of Results of 2007 Survey on Health Information Exchange

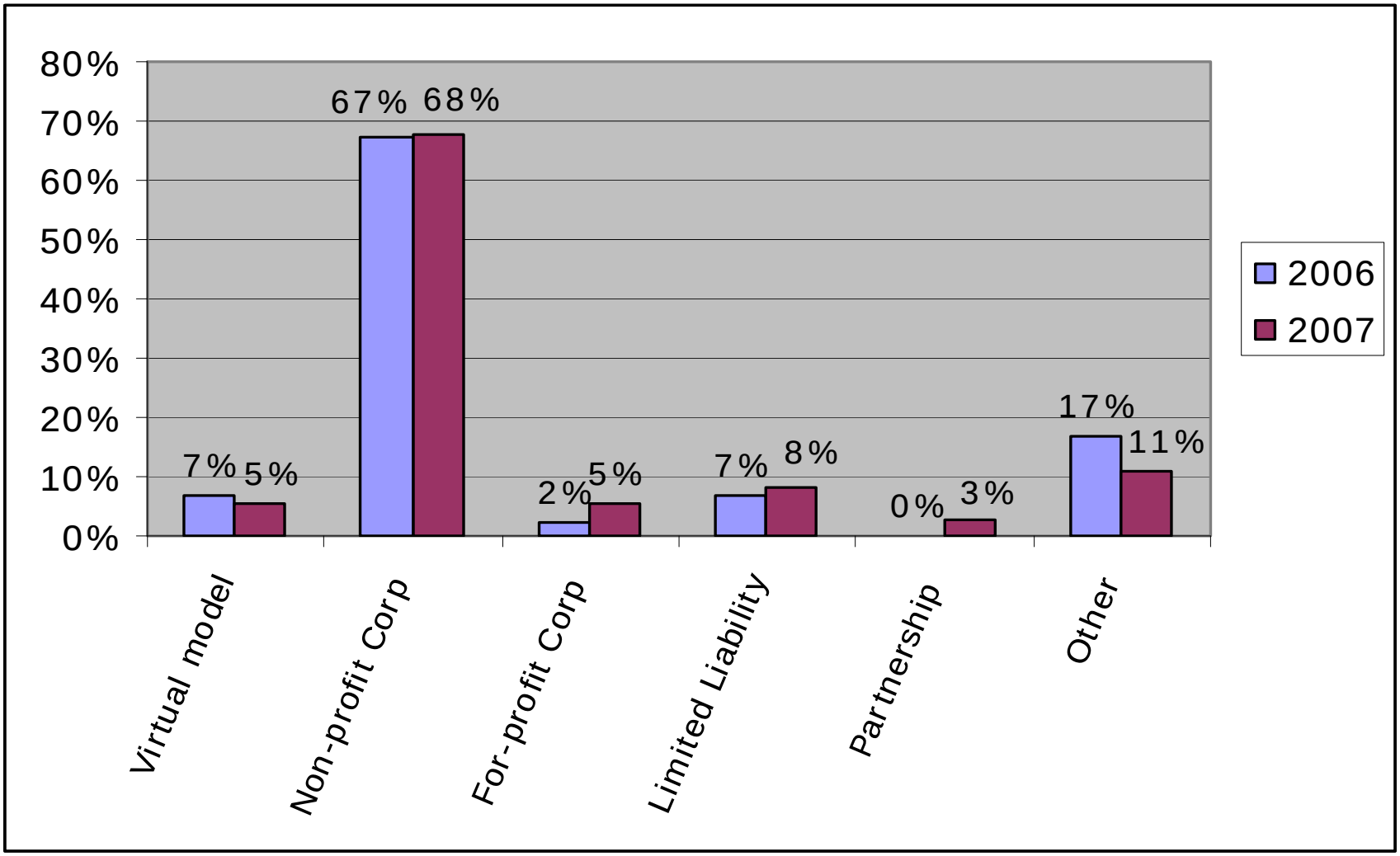
Janet M. Marchibroda
eHealth Initiative

February 26, 2008

Top Level View

- Fourth Annual Survey of Health Information Exchange at the State, Regional and Community Levels, Conducted by the eHealth Initiative Foundation
- 130 initiatives responded to survey:
  - 20 are just getting started (stage 1 or 2)
  - 68 are in the process of implementation (stage 3 or 4)
  - 32 are operational (stage 5, 6 or 7)
  - 5 are no longer moving forward
  - 5 organizations did not respond to stage of development question
- Thirty of the 2006 respondents reported an advancement in their stage of development
- Most important drivers:
  - Improving quality (94%)
  - Improving patient safety (80%)
  - Addressing inefficiencies experienced by providers (61%)
  - Addressing rising health care costs (59%)

Legal Structure: All 2007 Respondents



Sources of Upfront Funding: All 2007 Respondents

Source of Funding	2007	2006
Hospitals	53%	24%
Federal Government	44%	42%
State or Local Grants and Contracts	43%	29%
Payers	32%	12%
Philanthropies	31%	23%

Taking a Closer Look at the 32 Operational Initiatives Offers Insights

- Definition of Operational (Stage 5, 6 or 7): Fully operational health information organization, transmitting data that is used by health care stakeholders
- Three quarters are no longer dependent on “non-operating revenues” (e.g., grants)
- All operational initiatives reporting in 2006 are still operational

32 Operational Initiatives: Types of Data Exchanged

Data Type	2007	2006
Outpatient Episodes	84%	70%
Laboratory	73%	70%
Inpatient Episodes	64%	65%
Radiology Results	63%	61%
Enrollment/Eligibility	62%	75%
Dictation/Transcription	58%	61%
Pathology	58%	48%
ED Episodes	58%	77%

32 Operational Initiatives: Services Offered

- Results Delivery (75%)
- Clinical Documentation (63%)
- Consultation/Referral (54%)
- Enrollment or Eligibility Checking (54%)
- Alerts to Providers (48%)
- Electronic Referral Processing (35%)
- Reminders (33%)
- Disease or Chronic Care Management (32%)
- Quality Improvement Reporting for Clinicians (29%)
- Public Health Reporting (Lab) (28%)
- Quality Performance Reporting for Purchasers or Payers (26%)
- Public Health Surveillance (24%)
- Disease Registries (24%)
- Public Health Case Management (21%)
- Patient Access to Information (12%)

32 Operational Initiatives: Sources of Start-Up Funding

Funding Source	2007	2006
Federal Government	52%	44%
Hospitals	48%	17%
Private Payers	30%	24%
Philanthropies	30%	32%
State Government	30%	21%

32 Operational Initiatives: Sources of Revenue for Ongoing Operations

Funding Source	2007	2006
Hospitals	58%	54%
Payers – Private	46%	19%
Physician Practices	46%	33%
Payers – Public	38%	18%
Laboratories	33%	42%
Federal Government	29%	17%
Philanthropic Organizations	29%	21%
State or Local Government	21%	26%
Purchasers/Employers	17%	0%
Pharmacies	13%	11%
Pharmaceutical Companies	4%	6%

Key Survey Take-Aways

- Health information exchange initiatives are continuing to mature
- Some are no longer moving forward—which is expected…
- Most difficult challenge is that related to the development of a sustainable business model—current reimbursement system provides a disincentive for information sharing
- There are a number of advanced stage initiatives that are able to generate revenue to support ongoing operations through “services”
- Increasingly, hospitals are a funding source, and payers are increasing their investment as well

Key Survey Take-Aways

- Both the data and services provided by operational health information exchange initiatives indicate that such entities can support **current health care needs**, thereby creating ***near-term opportunities for a business case for the use of electronic health information***:
  - Quality improvement and performance reporting
  - Chronic care and disease management
  - Drug safety—assessing the risks and benefits of medications
  - Comparative effectiveness
  - Public health needs
  - Consumer access to clinical information

American Health Information Community

Nationwide Health Information Network:
"Data Use and Reciprocal Support"

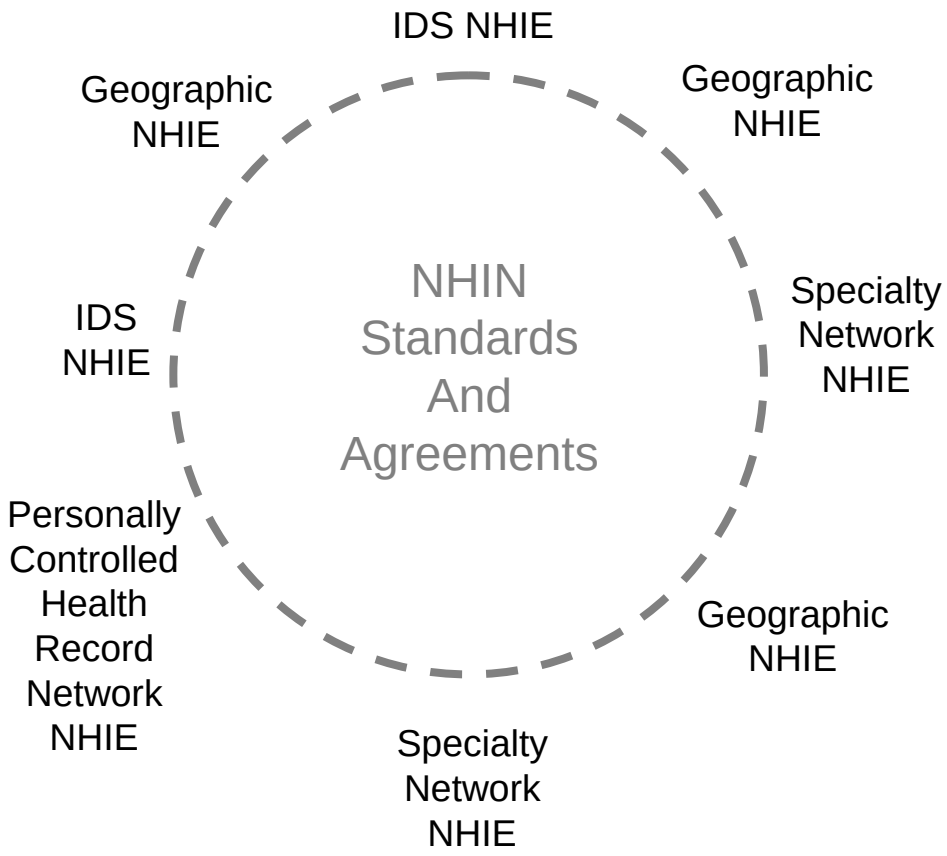
John W. Loonsk, MD
Office of the National Coordinator for Health Information Technology

Steven D. Gravely, M.H.A., J.D.
Partner and Healthcare Practice Group Leader
Troutman Sanders LLP

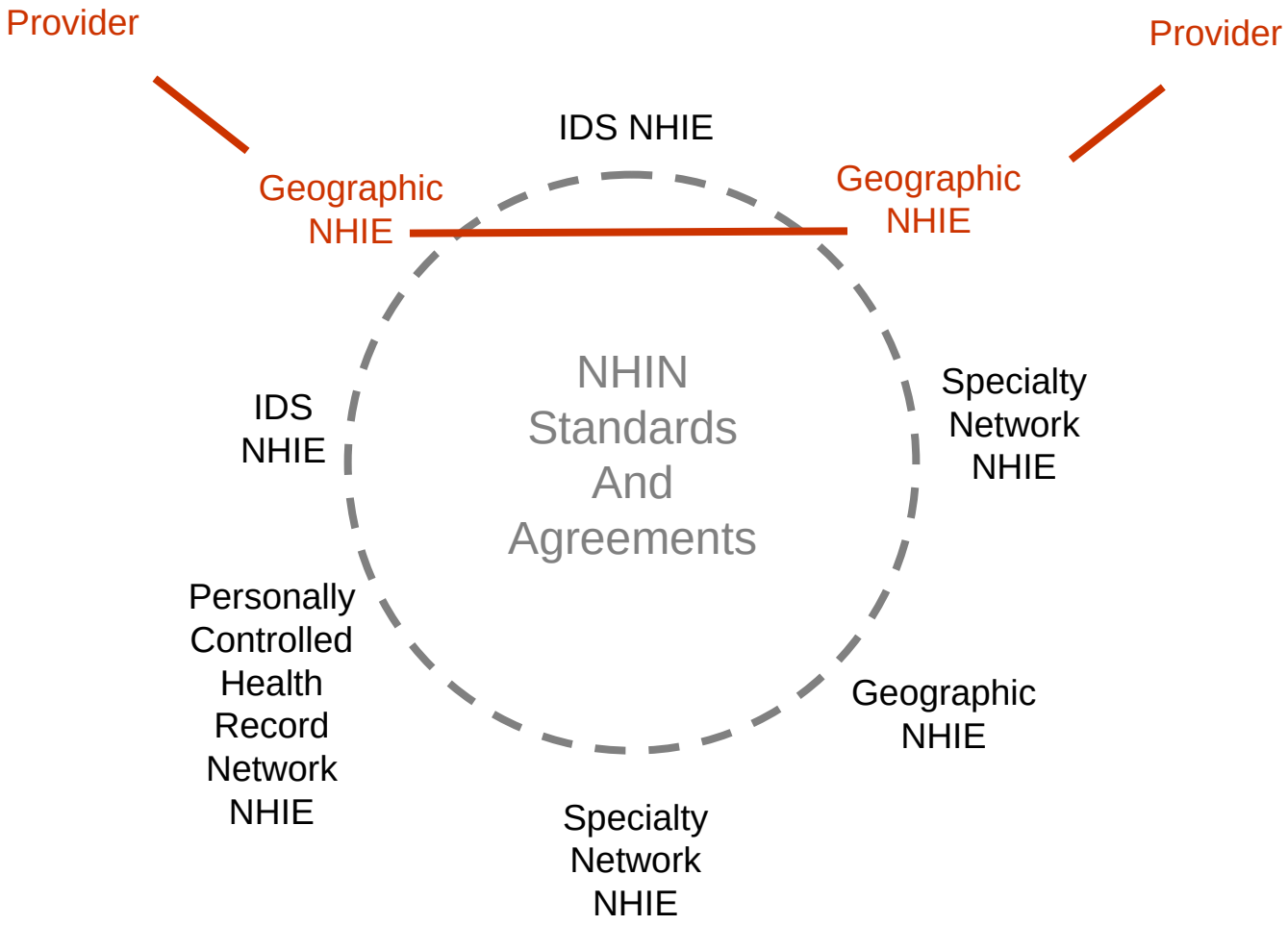
Nationwide Health Information Network (NHIN)

- Currently most electronic exchange of health data is “point to point”
  - Data originator and a data recipient – are challenges where not
  - Regulation and/or data use documents define their exchange
  - State laws and regulations can usually be applied
- NHIN is a Network of Networks
  - Each network can include multiple organizations and partners with different roles and authorities
  - Data exchange can include more than one exchange intermediary
  - NHIN data exchange may be between organizations in a region or between different regions or states

NHIN Health Information Exchanges (HIEs) – Common Trust Agreement



NHIN HIEs – Multiple Data Intermediaries (example)



NHIN - Possible Tools for Ensuring Policies and Standards

- **State and federal law and regulations**
- **Certification** (CCHIT) - common functionality, technical security, interoperability
- **Accreditation** - onsite assessment of implemented policies and practices
- **Governance** (e.g., AHIC 2.0) - ongoing leadership and supervision of participant relationships
- **Data use and reciprocal support agreement (DURSA)** - common agreement among participants

NHIN DURSAs

- Data use and reciprocal support agreement for “test data” – March 2008
- Data use and reciprocal support agreement for “live, production data” – November 2008
- Government participants have special legal considerations
- Beginning big push to work though issues in multiple federal agencies

Data Use and Reciprocal Support Agreement

- A multi-party agreement among participating HIEs that defines how the HIEs relate to each other
- Creates the legal framework within which HIEs can exchange data
- Assumes that each HIE has trust relationships in place with its participants
- Participants expect the HIE to protect their interests when exchanging data with other HIEs
- DURSA is being designed to accommodate many kinds of HIE organizations

Key Components of the DURSA

- **Privacy Protection**: HIEs will be exchanging Personal Health Information (PHI), so compliance with the Health Information Portability and Accountability Act (HIPAA) is essential
- **Reciprocal Duties**
  - Duty to only forward data in response to an authenticated request for data
  - Duty to respond to a valid request
- **Performance Specifications**: DURSA incorporates the interoperability performance specifications being developed by the NHIN
  - HIEs must comply with these specifications

Key Components of the DURSA (cont)

- **Warranty:**
  - Comprehensive representations and warranties
  - HIE warrants that it is sending complete and accurate copy of the information that it has
- **Dispute resolution**:
  - Current draft calls for binding arbitration
  - Government participants may not be able to agree to this
- **Entity Protection**:
  - Goal is that each HIE is financially and legally protected from damages caused by another HIE's breach of the DURSA
  - Challenge due to restriction on government participants' ability to indemnify private parties

Issues that Require Resolution for the Live Data DURSA

- Exchange of live data exposes all participants to significantly greater risks
- Specific issues on which we continue to work include:
  - Governing law – Each HIE is governed by the law of the state in which it operates
  - Necessary patient consent or authorization for exchange of live data under some laws and regulations
  - Reporting of suspected or actual breaches within each HIE that are unrelated to data exchange
  - How to contain liability to party that caused the breach

Issues that Require Resolution for the Live Data DURSA (cont)

- Exchange of “High Risk” data
- Evaluation of impact of federal law
  - Privacy Act
  - FOIA
  - Federal Torts Claims Act
  - Federal Information Security Management Act

American Health Information Community

Personalized Health Care Workgroup Recommendations

Douglas E. Henley
American Academy of Family Physicians

John Glaser
Partners HealthCare

February 26, 2008

Personalized Health Care (PHC) Workgroup Member List

- **Co-Chairs:**
  - John Glaser — Partners HealthCare
  - Douglas Henley — American Academy of Family Physicians
- **Staff Co-Chair:**
  - Gregory Downing — Office of the Secretary, HHS
- **Members:**
  - Carolyn Clancy — Agency for Healthcare Research and Quality
  - Beryl Crossley — American Clinical Laboratory Association, Quest
  - Paul Cusenza — Entrepreneur and Consultant
  - Andrea Ferreira-Gonzalez — Virginia Commonwealth University
  - Becky Fisher — Patient Advocate
  - Felix Frueh — Food and Drug Administration
  - Emory Fry — Department of Defense
  - Alan Guttmacher — National Institutes of Health/NHGRI
  - Kathy Hudson — Genetics and Public Policy Center
  - Betsy Humphreys — National Institutes of Health/NLM
  - Charles Kennedy — WellPoint
  - Joel Kupersmith — Department of Veterans Affairs
  - Stephen Matteson — Pfizer
  - Deven McGraw — National Partnership for Women and Families
  - Amy McGuire — Baylor College of Medicine
  - Mark Rothstein — University of Louisville
  - Steve Teutsch — Merck
  - Janet Warrington — Affymetrix Inc.
  - Andrew Wiesenthal — Permanente Federation
  - Dennis Williams — Health Resources and Services Administration
  - Marc Williams — Intermountain Healthcare

PHC Workgroup Senior Advisors

- **Senior Advisors:**
  - Mary Beth Bigley — Office of the U.S. Surgeon General
  - Greg Feero — National Institutes of Health/NHGRI
  - Joseph Kelly — Centers for Medicare & Medicaid Services
  - Muin Khoury — Centers for Disease Control and Prevention
  - Katherine Kolor — Centers for Disease Control and Prevention
  - Michele Lloyd-Puryear — Health Resources and Services Administration
  - Elizabeth Mansfield — Food and Drug Administration
  - Clement McDonald — National Institutes of Health/NLM
  - Armando Oliva — Food and Drug Administration
  - Dina Paltoo — National Institutes of Health/NHLBI
  - Jonathan Perlin — HCA, Inc.
  - Ronald Przygodzki — Department of Veterans Affairs
  - Gurvaneet Randhawa — Agency for Healthcare Research and Quality
  - Lisa Rovin — Food and Drug Administration
  - Maren Scheuner — RAND Corporation
  - Jean Slutsky — Agency for Healthcare Research and Quality
  - Reed Tuckson — UnitedHealth Group; SACGHS
  - Mollie Ullman-Cullere — Harvard Partners Center for Genetics and Genomics
  - Grant Wood — Intermountain Healthcare

PHC Workgroup Overview

Broad Charge:

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

Specific Charge:

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

PHC Vision and Priorities

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

- Four perspectives were identified as important to the vision
  - Consumer
  - Clinician
  - Researcher
  - Health Plan/Payer

- Four priority areas across each perspective
  - Genetic/Genomic Tests
  - Family Health History
  - Confidentiality, Privacy, and Security
  - Clinical Decision Support

PHC Newborn Screening (NBS) Subgroup Member List

- **Co-Chairs:**
  - Peter van Dyck — Health Resources and Services Administration
  - Steve Downs — Indiana University, Regenstrief Institute
- **Members:**
  - Beryl Crossley* — American Clinical Laboratory Association, Quest
  - Emory Fry* — Department of Defense
  - Betsy Humphreys* — National Institutes of Health (NIH)/National Library of Medicine
  - Janet Warrington* — Affymetrix Inc.
  - Cheryl Austein-Casnoff — Health Resources and Services Administration
  - Coleen Boyle — Centers for Disease Control and Prevention
  - Aaron Carroll — Indiana University, American Academy of Pediatrics
  - Mark Carroll — Indian Health Service
  - Terry Cullen** — Indian Health Service
  - Otto Del Cid** — New York City Public Health Laboratory, Association of Public Health Laboratories
  - John Eichwald — Centers for Disease Control and Prevention
  - Greg Feero — NIH/National Human Genome Research Institute
  - Alan Fleischman — March of Dimes
  - Irene Forsman — Health Resources and Services Administration
  - Roland Gamache** — Indiana State Department of Health, Association of State and Territorial Health Officials
  - Scott Grosse — Centers for Disease Control and Prevention
  - Alan Hinman — Public Health Informatics Institute
  - Rod Howell — NIH/National Institute of Child Health and Human Development
  - Christopher Kus — New York State Department of Health, Association of Maternal and Child Health Programs
  - Michele Lloyd-Puryear — Health Resources and Services Administration
  - Joe Martinec — Consumer

*Member of the Personalized Health Care Workgroup
**Member of the Population Health and Clinical Care Connections Workgroup or designee

PHC NBS Subgroup Member List (cont.)

- **Members:**
  - Mark McCann** — Minnesota Public Health Laboratory, Association of Public Health Laboratories
  - Cindy Powell — University of North Carolina at Chapel Hill, American Academy of Pediatrics
  - David Ross — Public Health Informatics Institute
  - Kathy Stagni — Consumer
  - Linda Vaughan — Maryland Department of Health and Mental Hygiene
  - Bob Vogt — Centers for Disease Control and Prevention
  - Mike Watson — American College of Medical Genetics
- **Senior Advisors / Resources:**
  - Rick Friedman — Centers for Medicare and Medicaid Services
  - Harry Hannon — Centers for Disease Control and Prevention
  - Melanie Lockhart — March of Dimes
  - Marie Mann — Health Resources and Services Administration
  - Craig Mason — University of Maine
  - Clem McDonald — NIH/National Library of Medicine
  - Michelle Meigs — Association of Public Health Laboratories
  - Carolyn Mullen — March of Dimes
  - Ken Pass — New York State Department of Health
  - Brad Therrell — University of Texas Health Science Center at San Antonio
  - Karl White — Utah State University
  - Patina Zarcone — Association of Public Health Laboratories
- **Staff:**
  - Gregory Downing — Office of the Secretary, HHS
  - Kristin Brinner — Office of the Secretary, HHS
  - Alan Zuckerman — Georgetown University, State Alliance for e-Health
  - Lauren Kim — BearingPoint

**Member of the Population Health and Clinical Care Connections Workgroup or designee

Fostering Information Exchange for Newborn Screening

- Overarching Goals:
  - Identify, develop, and encourage adoption of appropriate standards by instrument manufacturers, public health laboratories, and EHR vendors, to facilitate interoperable exchange of newborn screening test results (includes genetic, metabolic, and hearing tests)
  - Ensure timely communication among state public health laboratories and newborn nurseries doing screening and immediate follow-up, and the primary care professionals and specialists who are involved in the diagnosis, treatment, and management of the affected infants
  - Potential to support newborn screening program evaluations and quality improvement efforts

Newborn Screening Information Exchange

Recommendation 1.0: The information flows for Newborn Screening should be prioritized for Use Case Development. All of the multi-directional information flows, stakeholders, and other participants involved in the complete evaluation of newborn screening (i.e., hearing detection, dried blood spot screening, and diagnostic confirmation) should be considered so that appropriate standards and interoperability specifications can be developed to support information exchange.

☐ **Accept** ☐ **Table** ☐ **Reject**

Newborn Screening Information Exchange (cont.)

Recommendation 1.0.1: The Newborn Screening Subgroup of the Personalized Health Care Workgroup should complete development of a reference matrix of tests, analytes, conditions screened for, and associated genomic variants that are used in newborn screening programs.

☐ **Accept** ☐ **Table** ☐ **Reject**

Newborn Screening Information Exchange (cont.)

Recommendation 1.0.2: Based on the reference matrix described in Recommendation 1.0.1, appropriate codes should be identified for use in electronic reports to identify the test ordered, individual test results, and categorical results of these tests (e.g., Logical Observation Identifiers Names and Codes (LOINC), Systematized Nomenclature of Medicine – Clinical Terms (SNOMED-CT), Health Level Seven (HL7), Online Mendelian Inheritance in Man (OMIM), International Classification of Diseases – Ninth Edition (ICD-9), and ICD-10 Clinical Modification (CM)).

☐ **Accept** ☐ **Table** ☐ **Reject**

Newborn Screening Information Exchange (cont.)

Recommendation 1.0.3: Long-term maintenance of the reference matrix should be coordinated by the National Library of Medicine (NLM) in collaboration with the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC).

☐ **Accept** ☐ **Table** ☐ **Reject**

Newborn Screening Information Exchange (cont.)

Recommendation 1.0.4: For the Use Case development process, ONC should consider the need for documentation of permissions and authentications of users for access and transmittal of results, the need for ongoing collection of information for long-term follow-up, and integration of existing educational and clinical decision support information.

☐ **Accept** ☐ **Table** ☐ **Reject**

Newborn Screening Information Exchange (cont.)

Recommendation 1.1: Requirements for electronic reporting of newborn screening results should include specifications for reporting the quantitative measurements that now underpin the qualitative results and/or interpretations. Allowance should be made for accompanying qualitative and/or interpretive reports, and other test- or method-specific information that may assist in qualitative result interpretation.

☐ **Accept** ☐ **Table** ☐ **Reject**

Newborn Screening Information Exchange (cont.)

Recommendation 1.1.1: HHS should work with the National Governors Association (NGA) and the National Conference of State Legislatures (NCSL) to support electronic reporting of quantitative, qualitative, and/or interpretive reports.

☐ **Accept** ☐ **Table** ☐ **Reject**

Newborn Screening Information Exchange (cont.)

Recommendation 1.1.2: HHS should convene a workgroup with participation from the Centers for Medicare and Medicaid Services (CMS), HRSA, Substance Abuse and Mental Health Services Administration (SAMHSA), Administration for Children and Families (ACF), and other agencies that provide grants or reimbursement to health care providers, in order to determine the most appropriate ways to facilitate the adoption and development of electronic systems that conform to the concepts and standards identified in the Use Case. Special attention should be given to funding opportunities provided by existing authorities associated with the Early, Periodic, Screening, Diagnostic and Testing (EPSDT) requirements under Title XIX for Medicaid beneficiaries; e.g., enhanced match for the Medicaid Management Information System (MMIS) and in a manner consistent with the emerging architectures described within the Medicaid Information Technology Architecture (MITA).

☐ **Accept** ☐ **Table** ☐ **Reject**

Newborn Screening Information Exchange (cont.)

Recommendation 1.2: An action plan, timetable, and metrics for the implementation and tracking of these recommendations should be developed by HRSA to measure uptake of electronic transmission of test results that conform to the standards identified through the Use Case development process. HRSA Newborn Screening technical support centers should conduct annual surveys to monitor the pace of implementing these recommendations, standards, and transmission of newborn tests results by electronic means (EHRs and repositories).

☐ **Accept** ☐ **Table** ☐ **Reject**

Confidentiality, Privacy, and Security Issues Specific to Newborn Screening

Recommendation 2.0: HHS should work with state stakeholders to accurately identify, analyze, and develop solutions to address any misperceptions or misapplications of state privacy laws that may affect the timely transmission of newborn screening results. This work should also include an analysis of whether clarifying guidance from HHS related to the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules, the Clinical Laboratory Improvement Amendments (CLIA), and other regulations under HHS' authority would be appropriate.

☐ **Accept** ☐ **Table** ☐ **Reject**

Reporting of Newborn Screening Results to Improve Population Health

Recommendation 3.0: A taskforce that includes representatives from appropriate federal and state agencies, professional and public organizations, and the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDGDNC) should be formed to develop a plan for and descriptions of a patient-based information registry of newborn screening data within twelve months. Public review of the findings of this taskforce will be essential to address any ethical, legal, and social implications of any proposed research that will be facilitated by the development of electronic test reporting and national standards for identifying the tests performed and results obtained.

☐ **Accept** ☐ **Table** ☐ **Reject**

Next Steps

- Ongoing and Future PHC Workgroup Activities:
  - Newborn Screening (NBS)
    - High-level use case
    - Reference matrix for standards development processes
  - Clinical Decision Support (CDS)
  - Pharmacogenomics (PGx)

February 26, 2008

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

Dear Mr. Chairman:

The American Health Information Community (AHIC) has given the following broad charge to the Personalized Health Care Workgroup:

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

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

1. Genetic/Genomic Tests
2. Family Health History
3. Clinical Decision Support
4. Confidentiality, Privacy, and Security

This letter provides both context and recommendations for how the issue of Newborn Screening (NBS) can be addressed in the next twelve months.

BACKGROUND

As one of the more common applications of genetic tests in public health, newborn screening for congenital (inherited) disorders is performed near the time of birth for nearly every newborn, accounting for more than four million infants each year. Finding these conditions in the newborn, before symptoms appear, has been shown not only to save lives, but also, for certain disorders, to save costs for the health care system. Various conditions can be screened for by collecting a dried blood spot sample on filter paper or conducting a physiologic test, as with newborn hearing screening.

Newborn screening illustrates the critical need for standardized key data elements and terminologies in order to advance our understanding of genetic and other congenital conditions on a population basis. Issues include standardization of case definitions; recognizing the relationship between screening and diagnosis; and tracking the newborn to ensure proper follow-up of out of range (abnormal) test results. Standard representations of newborn screening (and confirmatory) data must be developed to enable sharing of data with individuals involved in the infants' care, for research purposes, and for improved patient and population health.

If accepted by the AHIC, these recommendations should be considered for adoption by the Department of Health and Human Services (HHS) as HHS policy regarding current and future federal activities as they relate to the Workgroup's charge.

INITIAL RECOMMENDATIONS

I. Newborn Screening Information Exchange

The capability to exchange newborn screening test results via electronic means (interoperability) is not widespread among public health and health care providers, despite the availability and use of electronic data exchange for other types of test results. Information flows are complicated by the fact that the provider who needs to receive results and import them into an electronic health record (EHR) is not always the provider who orders them. Provision should be made to allow parents to authorize delivery of test results to any primary care provider of their choice. Additionally, results should be available from a secure web site for authorized providers who do not use an EHR and for access by hospital Emergency Department personnel who may have to evaluate an infant in crisis. Appropriate direction and exchange of screening data is crucial to ensure proper follow-up and management of affected infants. Clinical vocabularies for newborn screening tests are needed to code the tests that were performed, the categorical results produced, and the conditions that were tested. The use of existing standards and approaches for the exchange of electronic information with Certification Commission for Healthcare Information Technology (CCHIT) certified EHRs could also facilitate the inclusion of newborn screening data, but significant challenges remain at other interfaces between the public and private parties involved.

The legal issues, data flows, actors, and stakeholders for newborn screening are complex and the actions take place over a longer period of time than other types of screenings and genetic testing. The initial screening test is typically mandated by state law and often does not require patient consent. Full diagnostic test evaluation, follow-up, and treatment may take place over prolonged periods of time and involve the participation of specialists and laboratories or audiologic (hearing test) centers, as with hearing screening, not involved in the initial testing.

Many of the conditions detected by newborn dried blood spot screening are rare and seen by a primary care provider only once during his/her career. Approximately 8,000 of the more than four million infants screened each year are identified with certain medical conditions through these screening programs. Some children become acutely and seriously ill as a consequence of their disorder and are taken to Emergency Departments even before the results of newborn screening are available. Information and guidance must accompany the test results to save time by educating providers and families about the rare conditions. The ACT sheets developed by the American College of Medical Genetics[1] are an important example of this type of resource, but information regarding local resources and recommended procedures vary depending on the state screening programs. Additionally, updates to these advisory documents occur over time and it is appropriate to check for updates on an identified condition as the child grows older. Concurrent to reporting the results to the primary care provider, some states report abnormal results directly

to parents or through designated specialist centers to improve timeliness of follow-up testing or start of appropriate therapy.

Newborn hearing screening, or more commonly referred to as Early Hearing Detection and Intervention (EHDI) at the state and federal level, has proven to be an outstanding public health success story. With two to three of every 1,000 babies being born with a hearing loss, it is the most frequently occurring condition screened in the newborn period. It is estimated that more than 50% of congenital hearing loss has a genetic basis. In 1993 only eleven hospitals in the United States were screening a significant number of their newborns for hearing loss. Now, the hearing screening results of over 92% of the infants born in the U.S. can be documented. Unfortunately, a documented diagnosis cannot be confirmed for nearly two-thirds of the infants not passing their final hearing screen. Moreover, for those infants with a confirmed diagnosis of permanent hearing loss, over 20% cannot be confirmed as having obtained early intervention services. Left undetected, hearing loss in infants can negatively impact communication, social and emotional development, as well as academic achievement. If a child with hearing loss is identified early and given appropriate educational, medical, and audiological services, significant special education and societal costs savings can be realized.

Newborn dried blood spot tests and hearing screening testing often differ from other laboratory tests in the practice of reporting results as positive or negative (or in range/out of range) without specific analytical values. Current practice recognizes that these tests are a screen and generally not considered diagnostic in nature. A qualitative value is generally used at the time of assigning a diagnosis. There is also often a need for immediate and long-term follow-up testing, and reporting the quantitative measurements that now underpin the qualitative results and/or interpretative reports, and other test- or method-specific information, may assist in qualitative result interpretation.[2] As currently deployed, manufacturers of screening devices most often utilize statistical and mathematical techniques to distinguish between individuals who are likely versus those who are not likely to be identified with a target condition, rather than the reporting of quantitative data. However, the capacity to collect, transmit, and analyze quantitative data could potentially improve quality assurance measures, reduce costs, and support clinical decision making for the public health community, clinicians, and consumers.[3]

A detailed Use Case will clarify the workflows involved, guide the identification and selection of required standards, and determine the electronic reporting and tracking requirements of the entire newborn screening process. The information exchange for newborn screening serves at least two purposes: to ensure timely and accurate delivery of information for clinical decision-making and to facilitate quality assurance within the screening system. The existing Office of the National Coordinator for Health Information Technology (ONC) Harmonized Use Case for EHRs (Laboratory Result Reporting), the Consumer Empowerment: Consumer Access to Clinical Information Use Case, and the Personalized Health Care Use Case provide a foundation that will extend the scope of the existing use cases and build on prior work by including the additional data requirements and the need to share results between multiple providers and public health entities. This should also be considered in the context of the Population Health and Clinical Care Connections Workgroup recommendations regarding laboratory result reporting and a national

program to enable public health laboratories to exchange data with other public health laboratories, which were accepted by the AHIC in January 2008[4]. Additionally, work in progress to develop a Health Level Seven (HL7) Implementation Guide for Newborn Screening will also facilitate and guide development of the Use Case.

Recommendation 1.0: The information flows for Newborn Screening should be prioritized for Use Case Development. All of the multidirectional information flows, stakeholders, and other participants involved in the complete evaluation of newborn screening (i.e., hearing detection, dried blood spot screening, and diagnostic confirmation) should be considered so that appropriate standards and interoperability specifications can be developed to support information exchange.

Recommendation 1.0.1: The Newborn Screening Subgroup of the Personalized Health Care Workgroup should complete development of a reference matrix of tests, analytes, conditions screened for, and associated genomic variants that are used in newborn screening programs.

Recommendation 1.0.2: Based on the reference matrix described in Recommendation 1.0.1, appropriate codes should be identified for use in electronic reports to identify the test ordered, individual test results, and categorical results of these tests (e.g., Logical Observation Identifiers Names and Codes (LOINC), Systematized Nomenclature of Medicine – Clinical Terms (SNOMED-CT), HL7, Online Mendelian Inheritance in Man (OMIM), International Classification of Diseases – Ninth Edition (ICD-9), and ICD-10 Clinical Modification (CM)).

Recommendation 1.0.3: Long-term maintenance of the reference matrix should be coordinated by the National Library of Medicine (NLM) in collaboration with the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC).

Recommendation 1.0.4: For the Use Case development process, ONC should consider the need for documentation of permissions and authentications of users for access and transmittal of results, the need for ongoing collection of information for long-term follow-up, and integration of existing educational and clinical decision support information.

Recommendation 1.1: Requirements for electronic reporting of newborn screening results should include specifications for reporting the quantitative measurements that now underpin the qualitative results and/or interpretations. Allowance should be made for accompanying qualitative and/or interpretive reports, and other test- or method-specific information that may assist in qualitative result interpretation.

Recommendation 1.1.1: HHS should work with the National Governors Association (NGA) and the National Conference of State Legislatures (NCSL) to

support electronic reporting of quantitative, qualitative, and/or interpretive reports.

Recommendation 1.1.2: HHS should convene a workgroup with participation from the Centers for Medicare and Medicaid Services (CMS), HRSA, Substance Abuse and Mental Health Services Administration (SAMHSA), Administration for Children and Families (ACF) and other agencies that provide grants or reimbursement to health care providers, in order to determine the most appropriate ways to facilitate the adoption and development of electronic systems that conform to the concepts and standards identified in the Use Case. Special attention should be given to funding opportunities provided by existing authorities associated with the Early, Periodic, Screening, Diagnostic and Testing (EPSDT) requirements under Title XIX for Medicaid beneficiaries; e.g., enhanced match for the Medicaid Management Information System (MMIS) and in a manner consistent with the emerging architectures described within the Medicaid Information Technology Architecture (MITA).

Recommendation 1.2: An action plan, timetable, and metrics for the implementation and tracking of these recommendations should be developed by HRSA to measure uptake of electronic transmission of test results that conform to the standards identified through the Use Case development process. HRSA Newborn Screening technical support centers should conduct annual surveys to monitor the pace of implementing these recommendations, standards, and transmission of newborn tests results by electronic means (EHRs and repositories).

II. Confidentiality, Privacy, and Security Issues Specific to Newborn Screening

Secure communication is critical to the patient-family/physician relationship, contributing to the quality of care and improved health outcomes. Sharing of newborn screening results is common and necessary for effective and timely use of newborn screening results and directing appropriate responses to those results. Several aspects of the newborn screening process present unique challenges with respect to appropriate sharing and transmission of results. First, it is common that a newborn's name changes between when the test is performed and when the results need to be reported. Second, the clinician ordering the newborn screening tests is usually not the same clinician who will be acting as the infant's primary care provider. Third, situations commonly arise when infants are born in one state while their family's primary residence and the location of the primary care provider may be in a different state. Private and secure solutions need to be developed that facilitate electronic reporting of or web access to screening results by the parents, and/or parent-authorized health care providers regardless of whether they are the original ordering provider or if they practice in a state other than the one where the infant was born and the newborn screening test was conducted. While there may not be overt aspects of the various privacy regulations that appear to be an impediment, the lack of understanding amongst health care providers around their application to newborn screening results impedes timely exchange. A January 2008 analysis prepared by the HRSA-funded National Newborn Screening and Genetics Resource Center for the NBS subgroup of the Personalized Health Care Workgroup suggests that newborn screening program officials in many states are uncertain about the privacy requirements for electronic reporting of newborn screening results. While a majority of the respondents confirmed that privacy concerns are an important consideration for electronic NBS test result

reporting, almost half of the respondents were uncertain about which privacy laws or regulations are relevant to electronic reporting, and were equally uncertain if their specific states were developing new laws that would affect electronic sharing of NBS results. When considering electronic reporting of NBS results, both the need for timely communication and sharing of screening results among appropriate clinicians, and protections against inappropriate disclosure of screening results, should be considered.

> **Recommendation 2.0:** HHS should work with state stakeholders to accurately identify, analyze, and develop solutions to address any misperceptions or misapplications of state privacy laws that may affect the timely transmission of newborn screening results. This work should also include an analysis of whether clarifying guidance from HHS related to the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules, the Clinical Laboratory Improvement Amendments (CLIA), and other regulations under HHS' authority would be appropriate.

III. Reporting of Newborn Screening Results to Improve Population Health

There are several uses of patient-based informational registries and other health record systems, including research, program evaluation, and monitoring of health outcomes. Program evaluation improves the efficiency and effectiveness of newborn screening programs. Positive predictive values of similar tests may vary from state to state based on cut-off values or variations in methods that are used. The high social cost and unnecessary diagnostic testing cost of false positive results, as well as the potentially tragic costs of a false negative result, justify appropriate use of newborn screening data to improve screening programs. In parallel with enhanced infrastructure and technical capabilities for information sharing, ongoing efforts to address emerging ethical, legal, and social implications of these capabilities on newborn screening programs will need to be addressed.

Use of newborn screening data to advance population health should be facilitated to improve the efficiency and effectiveness of these tests. One example of such a project is a HRSA-funded program at the Region 4 Genetics Collaborative[5] that has been established to improve access to high-quality genetic and newborn screening services to children and families. Findings from this project's efforts include the creation of a multi-state database that could be used as a model for a national program to improve the early identification and management of infants with metabolic, genetic, and other physiological disorders. Another example is a Region 3 Genetics Collaborative[6] project that is developing a long-term follow-up information system as a resource for care coordination, research, and information among clinicians, researchers, and consumers within that region. Both the Region 4 and 3 projects necessitate the transfer of information between the public and private sectors and multiple public health and health care providers in a multidirectional fashion. The development of policies and procedures that address confidentiality and privacy issues to guide the appropriate use of patient-based informational registries and other health record systems should consider guidelines for secondary data use previously developed by

the National Committee on Vital and Health Statistics (NCVHS)[7] and the American Medical Informatics Association (AMIA)[8].

> **Recommendation 3.0:** A taskforce that includes representatives from appropriate federal and state agencies, professional and public organizations, and the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDGDNC) should be formed to develop a plan for and descriptions of a patient-based information registry of newborn screening data within twelve months. Public review of the findings of this taskforce will be essential to address any ethical, legal, and social implications of any proposed research that will be facilitated by the development of electronic test reporting and national standards for identifying the tests performed and results obtained.

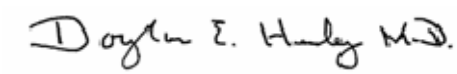
These recommendations are supported by information obtained through research and testimony to the Personalized Health Care Workgroup, which is contained in the supporting documents available at http://www.hhs.gov/healthit/.

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 Glaser, PhD
Co-Chair, Personalized Health Care Workgroup

Sincerely yours,



Douglas E. Henley, MD
Co-Chair, Personalized Health Care Workgroup

[1] http://www.acmg.net/resources/policies/ACT/condition-analyte-links.htm. ACTion (ACT) sheets describe the short term actions a health professional should follow in communicating with the family and determining the appropriate steps in the follow-up of the infant that has screened positive.
[2] Quantitative newborn dried blood spot screening reports may include numeric values that represent analytic values, percentiles, and/or ratios and should be accompanied by expected ranges. Qualitative reports may include testing observations (e.g., fluorescence or no fluorescence) and subjective evaluations (e.g., Hb FA present). Interpretive reports may include probability information (e.g., probable Hb S,S anemia), or other reporting information (e.g., T4 out-of-range, TSH out-of-range, please refer for serum testing).
[3] Quantitative newborn hearing screening reports may include data collection parameters such as type of stimulus delivery transducer (e.g., circumaural, supraaural and tubal-insert earphone), stimulus parameters (e.g., type [transient/tonal envelope], intensity [reference equivalent threshold sound pressure level], number, rate, duration, polarity), and elicited waveform response measurements (acoustic as in otoacoustic and distortion product measurement [frequency analysis, response level, baseline noise and contamination level, reproducibility, correlated non-linearity] or electrical as in auditory brainstem response [analysis of intensity, frequency, absolute and inter-peak latencies, morphology]), and test conditions (e.g., test time, signal-to-noise ratio, calibration date).
[4] http://hhs.gov/healthit/documents/m20080115/06-phccc_recs_ltr.html
[5] http://region4genetics.org/

[6] http://region3collaborative.org/
[7] http://www.ncvhs.hhs.gov/071221lt.pdf
[8] "Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper." *Journal of the American Medical Informatics Association*, Volume 14, Number 1, 2007.

American Health Information Community

Confidentiality, Privacy, and Security Workgroup Recommendations

Deven McGraw
National Partnership for Women and Families

February 26, 2008

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

- **Co-chairs:**
  - Deven McGraw — National Partnership for Women and Families
  - Kirk Nahra — Wiley Rein LLP

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

CPS Workgroup Overview

Broad Charge:

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

Specific Charge:

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

CPS Recommendation from June 12, 2007

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

[1] Health Insurance Portability and Accountability Act of 1996

CPS Recommendation from June 12, 2007 (Continued)

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

The Following Recommendations:

- Exempt HIEs from certain HIPAA notification and individual right requirements only when they do not have independent relationships with consumers or patients. Otherwise, all HIPAA requirements apply to all direct participants.

- Ensure that all rights will continue to apply in full through the entity with whom the consumer or patient has an independent relationship.

Independent Relationship

- Current HIPAA Privacy Rule requirements are dependent on a consumer or patient's relationship with a health care provider or health plan.
- Currently, few HIEs have independent relationships with patients or consumers.
- An HIE that uses or discloses health information directly to, or on behalf of, a patient or consumer rather than via other HIE participants (e.g., providers) has an independent relationship with that patient or consumer.
- HIEs that do have independent relationships with patients or consumers should be required to follow all HIPAA Privacy Rule requirements.

Recommendations: Notice of Privacy Practices

- **Recommendation 1.0:** The CPS Workgroup recommends that the HIPAA Privacy Rule requirement to provide a notice of privacy practices to consumers is *not relevant* to HIEs that do not have an independent relationship with consumers or patients. Therefore, we recommend that HIEs be exempted from this specific HIPAA Privacy Rule requirement.

Recommendations: Notice of Privacy Practices

- **Recommendation 1.1:** The CPS Workgroup recommends that HIEs make publicly available on their website (or through other means) a document that reasonably and accurately describes how they use and disclose health information and their privacy policies and practices, as well as how they safeguard patient or consumer information.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendations: Individual Rights

- **<u>Recommendation 2.0:</u>** The obligation to provide the individual rights below should remain with the current Covered Entity – who today has the independent relationship with the patient or consumer – and not the HIE.
  - **Recommendation 2.1:** We recommend that HIEs that do not have independent relationships with patients or consumers be exempted from the obligation to provide them with direct access rights.
  - **Recommendation 2.2:** We recommend that HIEs that do not have independent relationships with patients or consumers be exempted from the obligation to provide them with restriction or confidential communication rights.

Recommendations: Individual Rights

- **Recommendation 2.3:** We recommend that HIEs that do not have independent relationships with patients or consumers be exempted from the obligation to provide them with amendment rights.
- **Recommendation 2.4:** We recommend that HIEs that do not have independent relationships with patients or consumers be exempted from the obligation to provide them with an accounting of disclosures.

☐ **Accept** ☐ **Table** ☐ **Reject**

February 26, 2008

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

Dear Mr. Chairman:

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

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

Background:

On June 12th, 2007, the AHIC accepted the following for recommendation to the Secretary of the Department of Health and Human Services.

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

In our June recommendation letter, the CPS Workgroup set forth two areas for additional inquiry. We expressed our intent to first examine what constitutes a "relevant" HIPAA requirement for particular "direct participants" in an electronic health information exchange

network, as that term is defined in the June letter. After determining relevancy we noted that we would focus on what, if any, additional confidentiality, privacy, and security protections may be needed beyond those already contained in the HIPAA Privacy and Security Rules (the Rules) in order to raise public trust in an electronic health information exchange environment. The recommendations in this letter focus solely on the first question: whether all requirements under the Rules are relevant to all entities who are direct participants in an electronic health information exchange network but who are not currently covered by the Rules.

Based on public testimony and CPS Workgroup analysis and discussion, the CPS Workgroup recommends that all persons and entities (excluding consumers) that participate directly in or comprise an electronic health information exchange network should be required to meet enforceable privacy and security criteria at least equivalent to the Rules, except as expressly set forth in this letter. To further clarify, with the exception of the recommendations below – which provide specific exemptions – we recommend that all of the Rules requirements apply and are relevant to other non-Covered Entities such as those offering PHRs. Our recommendations specifically pertain to health information exchanges (HIEs) and regional health information organizations (RHIOs) (collectively referred to in this letter as HIEs) that do not have "independent relationships" with patients or consumers and in our view should not be required to meet: (1) §164.520 Notice of privacy practices for protected health information; (2) §164.522 Rights to request privacy protection for protected health information; (3) §164.524 Access of individuals to protected health information; (4) §164.526 Amendment of protected health information; and (5) §164.528 Accounting of disclosures of protected health information.

The particular HIPAA Privacy Rule requirements cited above directly implicate, and are dependent on, a consumer or patient's relationship with a health care provider or health plan that is a HIPAA Covered Entity. Based on our research to date, few, if any, HIEs currently in operation or contemplated have, or will have, independent relationships with individual patients or consumers. To further clarify, we would consider an HIE that uses or discloses health information directly to, or on behalf of, a patient or consumer rather than other participants in the HIE as having an independent relationship with that patient or consumer. For example, an HIE that offers PHRs to patients or consumers would have an independent relationship, and consequently, would be expected to follow all of the HIPAA Privacy Rule requirements. Today, by contrast, HIEs typically operate as intermediaries to move health information to and from persons and entities – including Covered Entities such as health care providers. Rarely will a consumer or patient be called upon to provide information directly to or request information directly from an HIE, but they will continue to do so through their health care provider, health plan, or PHR service provider with whom an independent relationship exists.

Because we have already recommended that those persons and entities who participate directly in an electronic health information exchange network should meet requirements equivalent to these particular HIPAA rules, and HIE access to health information will be solely as an agent or Business Associate of those persons and entities, there is no need to also impose these requirements on HIEs. In fact, we have concerns that in some situations, it may be counter-productive or inappropriate for an HIE that does not have an independent relationship with the consumer or patient to have direct responsibilities for fulfilling these individual rights. But this is

a rapidly evolving environment, and as explained in more detail below, if HIEs establish independent relationships with patients or consumers, the Rules should apply equally to those entities as they do to other Covered Entities.

It is important to note that the recommendations below are neither meant to discount or detract from the privacy rights of patients or consumers, nor reduce the type of protections that should be provided in an electronic health information exchange network. Our recommendations are meant to pragmatically exempt particular entities (HIEs) from directly providing certain HIPAA Privacy Rule requirements to patients or consumers in situations where they are acting on behalf of another entity that is participating in the HIE. All rights will continue to apply in full through the entity with whom the consumer or patient has an independent relationship. Moreover, HIEs will continue – as they do today – to assist these Covered Entities as appropriate in providing individual rights pursuant to existing Business Associate Agreements.

Recommendations:

Notice of Privacy Practices

Recommendation 1.0: The CPS Workgroup recommends that the HIPAA Privacy Rule requirement to provide a notice of privacy practices to consumers is *not relevant* to HIEs that do not have an independent relationship with consumers or patients. Therefore, we recommend that HIEs be exempted from this specific HIPAA Privacy Rule requirement.

> **Recommendation 1.1:** The CPS Workgroup recommends that HIEs make publicly available on their website (or through other means) a document that reasonably and accurately describes how they use and disclose health information and their privacy policies and practices, as well as how they safeguard patient or consumer information.

The exemption of a notice requirement does not mean that HIEs can use or disclose health information in a way that a Covered Entity or Business Associate could not. Rather, it means they do not have to disseminate a notice to a patient or consumer the way a health care provider or health plan must. If, in the future, HIEs were to establish independent relationships with individuals, the CPS Workgroup would consider this requirement to be relevant to such entities and expect an HIE to provide a notice equivalent to the one required under the HIPAA Privacy Rule today.

Individual Rights

Recommendation 2.0: The obligation to provide the individual rights below should remain with the current Covered Entity – who today has the independent relationship with the patient or consumer – and not the HIE.

Testimony has suggested that many HIEs today exchange health information for a limited set of purposes under a limited set of conditions and operate in most instances without any patient or consumer interaction (i.e. a "non-independent relationship"). However, if, in the future, an HIE were to establish independent relationships with individuals, the CPS Workgroup would consider

this requirement to be relevant to such entities and expect the HIE to provide individuals rights equivalent to those required under the HIPAA Privacy Rule today. While we recommend that the responsibility for fulfilling these individual rights continue to rest with the person or entity that has an independent relationship, we do not intend this recommendation to disrupt or alter in any way the obligations of an HIE to assist in performing these rights consistent with their obligations under existing Business Associate Agreements.

Recommendation 2.1: We recommend that HIEs that do not have independent relationships with patients or consumers be exempted from the obligation to provide them with direct access rights.

Recommendation 2.2: We recommend that HIEs that do not have independent relationships with patients or consumers be exempted from the obligation to provide them with restriction or confidential communication rights.

Recommendation 2.3: We recommend that HIEs that do not have independent relationships with patients or consumers be exempted from the obligation to provide them with amendment rights.

Recommendation 2.4: We recommend that HIEs that do not have independent relationships with patients or consumers be exempted from the obligation to provide them with an accounting of disclosures.

We believe that the individual rights mentioned above are best provided by the persons and entities that have independent relationships with individuals. HIEs would still have an obligation – consistent with any existing Business Associate Agreements – to assist a Covered Entity in providing these individual rights where appropriate. For example, to assist a Covered Entity in responding to an amendment where appropriate (i.e., satisfying the "informing others" requirement within §164.526(c)(3)).

Next Steps:

As mentioned above, having completed the task of determining relevancy, we will next turn to the issue of what, if any, additional confidentiality, privacy, security protections should apply to persons and entities that participate directly in electronic exchange of health information beyond those already contained in the Rules to raise public trust in an electronic health information exchange environment. Specifically, we will be addressing whether there are important differences in this environment for HIEs and PHRs and whether those differences require standards that are more stringent than the Rules.

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

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

Sincerely yours,

/Kirk J. Nahra/
Kirk J. Nahra
Co-Chair
Confidentiality, Privacy, and Security Workgroup

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

American Health Information Community

Enhancing Data Quality Recommendations

Jodi Daniel
Office of the National Coordinator for Health IT

February 26, 2008

Background

- ONC contract – In late 2006, ONC contracted with RTI International for a project involving three tasks:
  - Develop recommendations for requirements for EHRs to enhance data quality by reducing incidences of improper payment.
  - Validate recommendations through public comment.
  - Work with HIT organizations to encourage adoption of recommendations.
- RTI formed Model Requirement Executive Team (MRET) - industry experts from various private and public stakeholders to develop recommendations.

Background

AHIC Meeting held on September 18, 2007:

- MRET presented recommendations for criteria to include in EHRs to enhance data quality.
- AHIC requested that the Confidentiality, Privacy, and Security (CPS) and Electronic Health Record (EHR) Workgroups evaluate the recommendations.

Background

AHIC Meeting held on January 22, 2008:

- CPS Workgroup reviewed Recommendation #8 (Auditor Access) and reported:
  - The recommendation is consistent with HIPAA and would not grant new rights; and
  - The recommendation would benefit from more specificity of auditor types.
- EHR Workgroup reviewed Recommendations #5 (Evaluation and Management (E&M) Coding) and #6 (Proxy Authorship) and suggested no modification to requirements in the report.
- AHIC suggest re-wording to Requirement 5.2 in the MRET Report.

Recommendation 1.0

- **<u>Recommendation 1.0</u>:** With the exceptions listed below, the recommended requirements for enhancing data quality in EHRs set forth in the RTI Report dated May 2007 should be used to inform the Certification Commission for Healthcare Information Technology (CCHIT) as it establishes plans for new certification criteria development and HHS should request CCHIT to identify how these issues fit in their roadmap. Exceptions:
  - Criteria for more specificity to the auditor role described in Recommendation #8 (e.g., government auditor vs. commercial auditor, vs. internal auditor); and

Recommendation 1.0 (Continued)

- MRET's Recommendation 5.2 should be considered with the following amendments (AHIC additions in **bold**):
  - Prompts that are driven by E&M administrative processes shall not explicitly or implicitly direct a user to add documentation **for the purpose of achieving higher level code**. This does not apply to prompts for additional documentation for E&M levels already achieved**,** for medical necessity**,** for quality guidelines/clinical decision support**, or for previously documented clinical information.**

☐ **Accept** ☐ **Table** ☐ **Reject**

May 2007

Recommended Requirements for Enhancing Data Quality in Electronic Health Records

Final Report
Executive Summary

Prepared for

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RTI Project Number 0208490.035.005

Executive Summary

ES.1 Introduction

The rising cost of health care has become a major issue in the United States. In 2005, the United States spent $1.98 trillion, or 16% of its gross domestic product (GDP), on health care. By 2016, health care expenditures are projected to surpass $4.1 trillion, or 19.6% of GDP.[1,2] In 2006, the National Coalition on Health Care (NCHC) noted that "inappropriate care, waste and fraud" were major contributors to the cost of medical care and health insurance.[3]

Electronic health record systems (EHR-S) are the key to the transformation of health care. EHR-S can

- improve the quality of care through enhanced evidence-based clinical decision support, the timely communication of clinical information, and better documentation;
- increase operational efficiency and contain costs by automating routine tasks, streamlining clinical workflow, and avoiding duplication of procedures;
- help collect data for uses other than clinical care, such as billing, quality reporting, disease surveillance, public health reporting, and fraud detection and deterrence;[4] and
- protect the privacy of health information through secure mechanisms and authorized access and control procedures.

Thus, widespread use of EHR-S has the potential to improve the quality of care, increase patient safety, reduce medical errors, and control health care costs. The notion that EHR-S can be leveraged in such a wide variety of ways is central to this project.

ES.2 Purpose and Objectives

The primary purpose of this project is to identify requirements for EHR-S that can help enhance data protections, such as increased data validity, accuracy and integrity including appropriate fraud management[1] which would prevent fraud[2] from occurring, as well as detect fraud both prospectively and retrospectively. A key component of creating these recommended requirements is to overlap whenever possible with those requirements currently in use for EHR certification. For example, authentication is required for privacy and confidentiality, but it is just as useful for preventing and detecting fraud. All of the requirements identified through this project are framed as recommendations to the industry.

The deliverables for this project are as follows:

1. A set of recommended requirements for EHR-S that will help prevent fraud from occurring, as well as detect fraud prospectively and retrospectively, with each requirement having an accompanying rationale

2. The identification of technical standards that will need to be harmonized so that the recommended requirements can be implemented in an interoperable fashion

3. A map between the anti-fraud requirements and certification criteria so that the recommended requirements can be ultimately embedded in certified EHR-S

4. Recommended next steps for education and research, as well as for implementing the anti-fraud requirements

While the focus of this project is on enhancing data accuracy, including the detection and prevention of fraud, it is important to emphasize the following points:

- By and large, clinicians are not engaged in fraudulent activities. Not all improper payments are the result of fraud, and not all unusual billing patterns are fraudulent. However, certain documentation practices, such as data errors, mistakes in coding, and confusion regarding billing codes and procedures may result in improper payments.

- The recommended requirements are aimed equally at reducing such erroneous documentation practices, preventing improper payments, and improving supporting documentation for legitimate claims submissions.

The transforming nature of EHR-S can benefit clinicians, patients, and payers by reducing human error and improper payment. EHR-S can also help detect and deter health care

[1] Fraud management is defined as the prevention, detection, and prosecution of fraud.

[2] For the purposes of this report, fraud is defined generally as a deliberately false representation of fact or a failure to disclose a fact that is material to a health care transaction. This includes but is not limited to deliberate submittal of false claims to private health insurance plans and/or tax-funded public health insurance programs such as Medicare and Medicaid. A more complete definition for health care fraud is in Appendix C.

fraud, protecting both clinicians and patients by documenting that correct procedures were used, highlighting outliers before they become serious issues, and giving patients a clearer understanding and peace of mind that their health records are being disclosed only to appropriately authorized users.

Although requirements that enhance data accuracy might overlap with current EHR certification criteria, thought must be given specifically to the criteria that will help combat both large- and small-scale suspected fraud, as well as accentuate the potential benefits of these systems with regard to reducing improper payment and human error. While a component of combating fraud is the ability to trace and audit information that may be used in prosecution, these same functionalities can be used to ensure information validity over time, which can protect both clinicians and patients. The ability to definitively show that correct procedures were used, use audit functionality as an "early warning system" to locate outliers before they become serious issues, or to provide patients with a clearer understanding and peace of mind that their records are being disclosed only to appropriately authorized users are all factors that can benefit all major stakeholders, from clinicians to patients to payers.

The Office of the National Coordinator for Health Information Technology (ONC) is responsible for overseeing activities that will realize the vision set by President George W. Bush in April 2004 to develop and implement a strategic plan to guide the nationwide implementation of interoperable HIT in both the public and private health care sectors. Through a series of initiatives, ONC has advanced this goal considerably over the past 3 years and continues to pave the way for HIT adoption across the country. In addition to moving the current directives forward, ONC is charged with planning for the future, such as anticipating the potential benefits of such a system. Designing enhanced data protections into EHR-S and the Nationwide Health Information Network (NHIN) has the potential to significantly reduce health care losses due to improper documentation and fraud.[4]

ES.3 Methodology and Rationale

In late 2006, ONC contracted with RTI International for a project involving three tasks: (1) develop recommendations for functional requirements for EHR-S that would enhance data by reducing the incidence of improper payment and assisting in fraud management, (2) validate the recommendations through public comment, and (3) work with appropriate HIT organizations to encourage adoption of the recommendations.

The basis for this project followed a subset of the 10 Guiding Principles[3] outlined in the September 2005 *Report on the Use of Health Information Technology to Enhance and Expand Health Care Anti-Fraud Activities* by the American Health Information Management

[3] The 10 Guiding Principles are listed in Appendix B.

Association's (AHIMA's) Foundation of Research and Education (FORE).[4] First, the NHIN policies, procedures, and standards must proactively prevent, detect, and support prosecution of health care fraud rather than be neutral toward it. Second, EHR standards must define requirements to promote fraud management and minimize opportunities for fraud and abuse, consistent with the use of EHRs for patient care purposes. Third, data required from the NHIN for monitoring fraud and abuse must be derived from the NHIN's operations and must not require additional data transactions. In addition to these three principles, one of this project's important decisions was that fraud management requirements also can be used to improve the accuracy and quality of documentation for the large majority of clinicians who are not involved in fraudulent activity.

The project's first task involved the creation of the Model Requirements Executive Team (MRET), which brought together industry experts from various private and public stakeholder groups with multiple backgrounds in order to develop a set of recommendations for enhanced accuracy and fraud management requirements for Electronic Health Records (EHRs). The MRET worked in two groups, one that focused on prevention functions and another that focused on prospective and retrospective functions. Prevention functions are those that occur prior to and during the documentation process in an EHR. Prospective functions are those that occur after EHR documentation occurs but before a payment is made on any claim based on the EHR documentation. Retrospective functions are those that occur after a claim has been paid. Following the Guiding Principles outlined above, all requirements were constructed based on their ability to enable prevention of fraud management rather than remain neutral toward it, their ability to do this without impeding delivery of timely services to the patient, and to the extent possible, their ability to minimize EHR software programming and administrative costs associated with the recommended functions.

The next task validated the MRET recommendations through a public comment process by which the recommended requirements were released to the public using online tools to gather feedback from all interested parties. The majority of public comments fell into one of five categories:

- Ability to Detect or Deter Fraud
- Practicality of and Timeline of Implementation
- Cost Issues
- Burden and User Issues
- Patient and Privacy Issues

In response to the public comments, the MRET eliminated or modified requirements as necessary and developed a final set of recommendations for the requirements. These

requirements were supported by the vast majority of public responders and achieved high consensus among the members of the MRET.

Finally, the project staff worked closely with the leadership of the Health Information Technology and Security Standards Panel (HITSP) and the Certification Commission for Health Information Technology (CCHIT) to determine the most appropriate procedures for considering the recommended requirements in upcoming review cycles of each group. Each organization emphasized the importance of balancing the needs of enhancing accuracy, fraud management, and risk reductions that might enhance EHR-S against concerns that might inhibit EHR adoption. Productive conversations about both the costs and benefits of the recommended requirements led to feasible and actionable solutions that encouraged strong consideration within both groups.

ES.4 Recommendations

The recommended requirements for EHR-S developed herein provide the initial building blocks for increasing accuracy and fraud management within the health care system. Great efforts have been made to ensure the privacy and security of EHR data, but a deliberate effort to build these functional requirements into EHR-S and the NHIN could also increase data quality and reduce exposure to new and ever-evolving forms of electronically enabled health care fraud.[4]

This project produced 14 recommended functional requirements that, if included in EHR-S, would increase data accuracy and would aid in fraud management:

1. Audit Functions and Features
2. Provider Identification
3. User Access Authorization
4. Documentation Process Issues
5. Evaluation and Management (E&M) Coding
6. Proxy Authorship
7. Record Modification after Signature
8. Auditor Access to Patient Records
9. EHR Traceability
10. Patient Involvement in Anti-Fraud
11. Patient Identity-Proofing
12. Structured and Coded Data
13. Integrity of EHR Transmission
14. Accurate Linkage of Claims to Clinical Records

Each of these requirements was linked to current or planned CCHIT and Health Level 7 (HL7) criteria♦ where applicable. Twenty-two percent of the recommended requirements developed by the MRET map closely to existing CCHIT criteria. Another 45% of the requirements had some foundation in the current or planned criteria, but would require additions or modifications to support an active stance against fraud in EHR-S. Finally, 33% of the recommendations were found to have no match to current or planned criteria. These findings indicate that there is a significant base in current standards and certification requirements upon which to build proactive fraud management capabilities, but further work is required. Updating these current criteria would certainly provide a significant win for reducing costs associated with this current and growing problem.

The overwhelming majority of clinicians do not commit fraud and should not be burdened by mechanisms aimed solely at the few who do. Therefore, the recommended requirements also are directed at helping the majority, as they support quality of care through reduced errors and promote good documentation practices, as well as assist in fraud management, including protections against unmerited accusations of fraud and strengthened proofs of legitimacy. It is recommended that these requirements be considered among the many other improvements to be built into the emerging generation of EHR-S that are interoperable in the NHIN.

ES.5 Moving Forward

The activities undertaken in this project are simply the latest steps in an ongoing process to develop and integrate effective anti-fraud measures in the evolving HER-S requirements. Our efforts to date were constrained by time and resources and were not intended to produce a comprehensive solution to the fraud problem. Instead, our efforts are intended to raise awareness of the need to be proactive regarding the problems of fraud, rather than neutral or passive, and to encourage a dialogue between all parties interested in enhancing the accuracy of data in EHR-S.

At the conclusion of this project, the following suggestions are provided to ensure a continual, long-term approach to ensuring the integrity, validity, and accuracy of health record data. A full supporting explanation for each suggestion is provided in Chapter 5 of the report.

1: Current processes that are shaping the direction of HIT must be guided to advance health care information validity, accuracy, and integrity protections, including health care fraud management, in order to meet their future goals and objectives.

♦ The CCHIT roadmap establishes the areas of focus for the workgroups for future certification cycles by establishing future milestones.

1.1: ONC should include fraud management as one of its basic tenets in the next version of the Strategic Framework.

1.2: ONC must articulate the need to advance health information validity, accuracy, integrity, and fraud management functionalities to the American Health Information Community (AHIC) so that the appropriate use cases may be developed for HITSP and CCHIT.

1.3: Guidelines should be developed for both vendors and users of EHR-S regarding the appropriate use of documentation techniques to ensure complete, accurate, and quality documentation.

2: Given that this project narrowly focused on anti-fraud requirements for EHR-S; fraud management requirements for HIE/NHIN infrastructure and plans for their deployment should developed.

3: Greater efforts should be made to understand the concerns and opinions of all affected stakeholder groups regarding requirements that discourage fraud within EHR-S.

4: Further analysis is required to better quantify and characterize the current fraud activity as it relates to EHR-S, either as a tool for fraud or a potential source for fraud management. This should include an investigation into ways in which the appropriate entities in health care can work with law enforcement to communicate to providers how fraud schemes and fraud “rings” operate.

5: Stimulate advancements in the data aggregation process beyond the institutional level so that advanced analytics can detect trends and anomalies.

6: Increase consumer awareness of health care fraud and the role HIT, such as EHRs and PHRs, play in its reduction.

7: Educate health care stakeholders to a greater degree on the benefits of EHR-S containing requirements on health information validity, accuracy, and integrity and the impact these requirements will have on fraud management.

8: A designated position and supporting staff within ONC should be created to:

8.1 oversee and encourage the adoption of the recommended requirements developed under this project within CCHIT, HITSP, and other organizations responsible for the evolving NHIN;

8.2 develop future contracts to evolve and refine the functional requirements; and

8.3 oversee future research and analysis in this area.

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
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American Health Information Community

AHIC 2009 Priorities and Use Cases

John W. Loonsk, MD
Office of the National Coordinator

February 26, 2008

AHIC Priorities and Use Case Roadmap

AHIC Priorities and Use Case Roadmap

2006	2007 Use Cases		2008 Use Cases	
Consumer Empowerment Use Case • Registration • Medication History	**Consumer Access to Clinical Information** • Access to Clinical Data • Provider Permissions • PHR Transfer		**Remote Monitoring** • Remote Monitoring of Vital Signs and Labs (Glucose)	**Remote Consultation** • Structured email • Reminders • On-line Consultation
EHR Use Case • Laboratory Result Reporting	**Emergency Responder EHR** • On-Site Care • Emergency Care • Definitive Care • Provider Authentication and Authorization	**Medication Management** • Medication Reconciliation • Ambulatory Prescriptions • Contra-indications	**Consultation & Transfers of Care** • Referrals • Problem Lists • Transfer of Care	**Personalized Healthcare** • Laboratory Genetic / Genomic Data • Family Medical History
Biosurveillance Use Case • Visit • Utilization • Clinical Data • Lab and Radiology	**Quality** • Hospital Measurement and Reporting • Clinician Measurement and Reporting • Feedback to Clinicians		**Public Health Case Reporting** • Case Reporting • Bidirectional Communication • Labs • Adverse Events	**Immunizations & Response Management** • Resource Identification • Vaccine • EHR Data

2009 and Beyond

CE 3.0 Administrative features
CE 3.1 Appointment scheduling
CE 3.2 Demographic profile
CE 3.3 Editing account profile
CE 3.4 Insurance eligibility & claims
CE 3.5 Financial recordkeeping & management
CE 4.0 Reminders (examples)
CE 4.1 Annual check-ups
CE 4.2 Cancer screening—mammograms
CE 4.3 Cancer screening—colonoscopies
CE 4.4 Immunizations
CE 6.0 Summaries of healthcare encounters
CE 6.1 Dates of services
CE 6.3 Procedure codes
CE 7.0 Educational information
CE 7.1 Evidence based health information
CE 8.0 Decision support
CE 8.1 Shared decision making
CE 8.2 Communications preferences
CE 9.0 Patient health outcomes
CE 9.1 Adverse events
CE 9.2 Medical errors
CE 9.3 Patient reported health outcomes
CC 3.0 Glucose monitoring
CC 4.0 Spirometery
CC 5.0 Anticoagulation
CC 7.0 Fall/motion monitoring
CC 11.0 Lesion assessment
CC 12.0 Remote monitoring for chronic conditions
CC 13.0 HIT use in specific populations
CC 15.0 Product and services certification
CC 16.1 State licensure constraints
CC 18.0 Patient identification for authorization and authentication
EHR 5.0 Clinical/encounter notes
EHR 6.0 Anatomic pathology results
EHR 8.0 Radiology reports
EHR 12.0 Machine readable and interoperable
EHR 12.1 Encounter notes
EHR 12.2 Radiology reports
EHR 12.3 Lab results

Q 3.1 Clinical decision support
Q 5.0 Clinical decision support
Q 6.0 Expanded inpatient quality measures
Q 7.0 Expanded ambulatory quality measures
BIO 1.2 Clinical symptomology
BIO 1.3 Integration with EHRs
BIO 1.4 Health alerting (HA)/email alerts
BIO 2.1 Collaborative discussions
BIO 2.2 Web pages
BIO 3.2 Chemoprophylaxis
BIO 3.3 Treatment
BIO 3.4 Isolation/quarantine
BIO 3.6.2 Disease registry
BIO 4.0 Adverse event reporting
BIO 4.1 Devices, drugs, biologic
BIO 5.0 Nosocomial infections
BIO 5.1 Medication errors
BIO 5.1.1 Ordering/ prescribing/ dispensing
BIO 5.1.2 Drug-drug, drug-allergy interaction decision support
BIO 5.1.3 Linkage to FDA structured product labeling database results
BIO 10.0 Public health information network (PHIN) can be leveraged
BIO 14.0 National notifiable disease conditions have been identified
AHIC 1.0 Labs, medications, allergies, immunizations
AHIC 2.0 Secure messaging/online consultation
AHIC 3.0 Bi-directional communications
AHIC 4.0 Adverse event reporting
AHIC 5.0 Case reporting
AHIC 6.0 Clinical decision support systems
AHIC 7.0 Identification/ authentication
AHIC 8.0 Problem lists
AHIC 9.0 Clinical encounter notes
AHIC 10.0 Family history/social factors
AHIC 11.0 Vitals signs
AHIC 12.0 Population health/ conditions
AHIC 13.0 Minimum data set
AHIC 14.0 Confidentiality, privacy, & security of patient data

AHIC 15.0 Data access/data control
AHIC 16.0 Data aggregation
AHIC 17.0 Infrastructure areas missing
AHIC 17.1 Security, network, repositories
AHIC 18.0 Vital measurements
AHIC19.0 Text documents
AHIC 21.0 Health literacy (multilingual support)
AHIC 23.0 Advance directive/living wills
AHIC 24.0 Social/family history
AHIC 26.0 Medication history
AHIC 27.0 E-prescribing
AHIC 28.0 Standardization of device interfaces
AHIC 29.0 Care plans/clinical flowsheets
AHIC 30.0 Provider list
AHIC 31.0 Adverse events
AHIC 32.0 Nosocomial infections
AHIC 33.0 Clinical data storage for surveillance
AHIC 34.0 Case reporting
AHIC 35.0 Bi-directional communications
AHIC 36.0 Lab results
AHIC 37.0 Anatomic pathology results
AHIC 38.0 Radiology reports
AHIC 39.0 Social history
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AHIC 43.0 Dental
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AHIC 46.0 Legal liability & regulatory barriers
AHIC 47.0 Consumer consent
CCHIT
CCHIT 1.0 Patient safety
CCHIT 2.0 Transfer of care
HITSP 1.1.4 Text reports
HITSP 1.1.5 Numeric results
HITSP 1.1.7 Images
HITSP 1.2 HIPAA covered entities
HITSP 1.2.1 X12 Claims attachment

HITSP 2.0 Secondary uses of data
HITSP 2.1 Clinical research
HITSP 2.2 Clinical trials
HITSP 2.3 Population health
HITSP 3.0 Quality/control measurements
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HITSP 4.0 Clinical device data
HITSP 4.1 Glucometers
HITSP 4.2 Monitors
HITSP 4.2 Smart pump
HITSP 5.0 Cross use case work on security (standards)
HITSP 5.3 Authentication models to support chain of trust data exchanges

Standards Recognized 1/08

AHIC Priorities and Use Case Roadmap

AHIC Priorities and Use Case Roadmap

2006

Consumer Empowerment Use Case
- Registration
- Medication History

EHR Use Case
- Laboratory Result Reporting

Biosurveillance Use Case
- Visit
- Utilization
- Clinical Data
- Lab and Radiology

2007 Use Cases

Consumer Access to Clinical Information
- Access to Clinical Data
- Provider Permissions
- PHR Transfer

Emergency Responder EHR
- On-Site Care
- Emergency Care
- Definitive Care
- Provider Authentication and Authorization

Medication Management
- Medication Reconciliation
- Ambulatory Prescriptions
- Contra-indications

Quality
- Hospital Measurement and Reporting
- Clinician Measurement and Reporting
- Feedback to Clinicians

2008 Use Cases

Remote Monitoring
- Remote Monitoring of Vital Signs and Labs (Glucose)

Remote Consultation
- Structured email
- Reminders
- On-line Consultation

Consultation & Transfers of Care
- Referrals
- Problem Lists
- Transfer of Care

Personalized Healthcare
- Laboratory Genetic / Genomic Data
- Family Medical History

Public Health Case Reporting
- Case Reporting
- Bidirectional Communication
- Labs
- Adverse Events

Immunizations & Response Management
- Resource Identification
- Vaccine
- EHR Data

2009 and Beyond

CE 3.0 Administrative features
CE 3.1 Appointment scheduling
CE 3.2 Demographic profile
CE 3.3 Editing account profile
CE 3.4 Insurance eligibility & claims
CE 3.5 Financial recordkeeping & management
CE 4.0 Reminders (examples)
CE 4.1 Annual check-ups
CE 4.2 Cancer screening—mammograms
CE 4.3 Cancer screening—colonoscopies
CE 4.4 Immunizations
CE 6.0 Summaries of healthcare encounters
CE 6.1 Dates of services
CE 6.3 Procedure codes
CE 7.0 Educational information
CE 7.1 Evidence based health information
CE 8.0 Decision support
CE 8.1 Shared decision making
CE 8.2 Communications preferences
CE 9.0 Patient health outcomes
CE 9.1 Adverse events
CE 9.2 Medical errors
CE 9.3 Patient reported health outcomes
CC 3.0 Glucose monitoring
CC 4.0 Spirometery
CC 5.0 Anticoagulation
CC 7.0 Fall/motion monitoring
CC 11.0 Lesion assessment
CC 12.0 Remote monitoring for chronic conditions
CC 13.0 HIT use in specific populations
CC 15.0 Product and services certification
CC 16.1 State licensure constraints
CC 18.0 Patient identification for authorization and authentication
EHR 5.0 Clinical/encounter notes
EHR 6.0 Anatomic pathology results
EHR 8.0 Radiology reports
EHR 12.0 Machine readable and interoperable
EHR 12.1 Encounter notes
EHR 12.2 Radiology reports
EHR 12.3 Lab results

Q 3.1 Clinical decision support
Q 5.0 Clinical decision support
Q 6.0 Expanded inpatient quality measures
Q 7.0 Expanded ambulatory quality measures
BIO 1.2 Clinical symptomology
BIO 1.3 Integration with EHRs
BIO 1.4 Health alerting (HA)/email alerts
BIO 2.1 Collaborative discussions
BIO 2.2 Web pages
BIO 3.2 Chemoprophylaxis
BIO 3.3 Treatment
BIO 3.4 Isolation/quarantine
BIO 3.6.2 Disease registry
BIO 4.0 Adverse event reporting
BIO 4.1 Devices, drugs, biologic
BIO 5.0 Nosocomial infections
BIO 5.1 Medication errors
BIO 5.1.1 Ordering/ prescribing/ dispensing
BIO 5.1.2 Drug-drug, drug-allergy interaction decision support
BIO 5.1.3 Linkage to FDA structured product labeling database results
BIO 10.0 Public health information network (PHIN) can be leveraged
BIO 14.0 National notifiable disease conditions have been identified
AHIC 1.0 Labs, medications, allergies, immunizations
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AHIC 4.0 Adverse event reporting
AHIC 5.0 Case reporting
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AHIC 8.0 Problem lists
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AHIC 10.0 Family history/social factors
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AHIC 12.0 Population health/ conditions
AHIC 13.0 Minimum data set
AHIC 14.0 Confidentiality, privacy, & security of patient data

AHIC 15.0 Data access/data control
AHIC 16.0 Data aggregation
AHIC 17.0 Infrastructure areas missing
AHIC 17.1 Security, network, repositories
AHIC 18.0 Vital measurements
AHIC19.0 Text documents
AHIC 21.0 Health literacy (multilingual support)
AHIC 23.0 Advance directive/living wills
AHIC 24.0 Social/family history
AHIC 26.0 Medication history
AHIC 27.0 E-prescribing
AHIC 28.0 Standardization of device interfaces
AHIC 29.0 Care plans/clinical flowsheets
AHIC 30.0 Provider list
AHIC 31.0 Adverse events
AHIC 32.0 Nosocomial infections
AHIC 33.0 Clinical data storage for surveillance
AHIC 34.0 Case reporting
AHIC 35.0 Bi-directional communications
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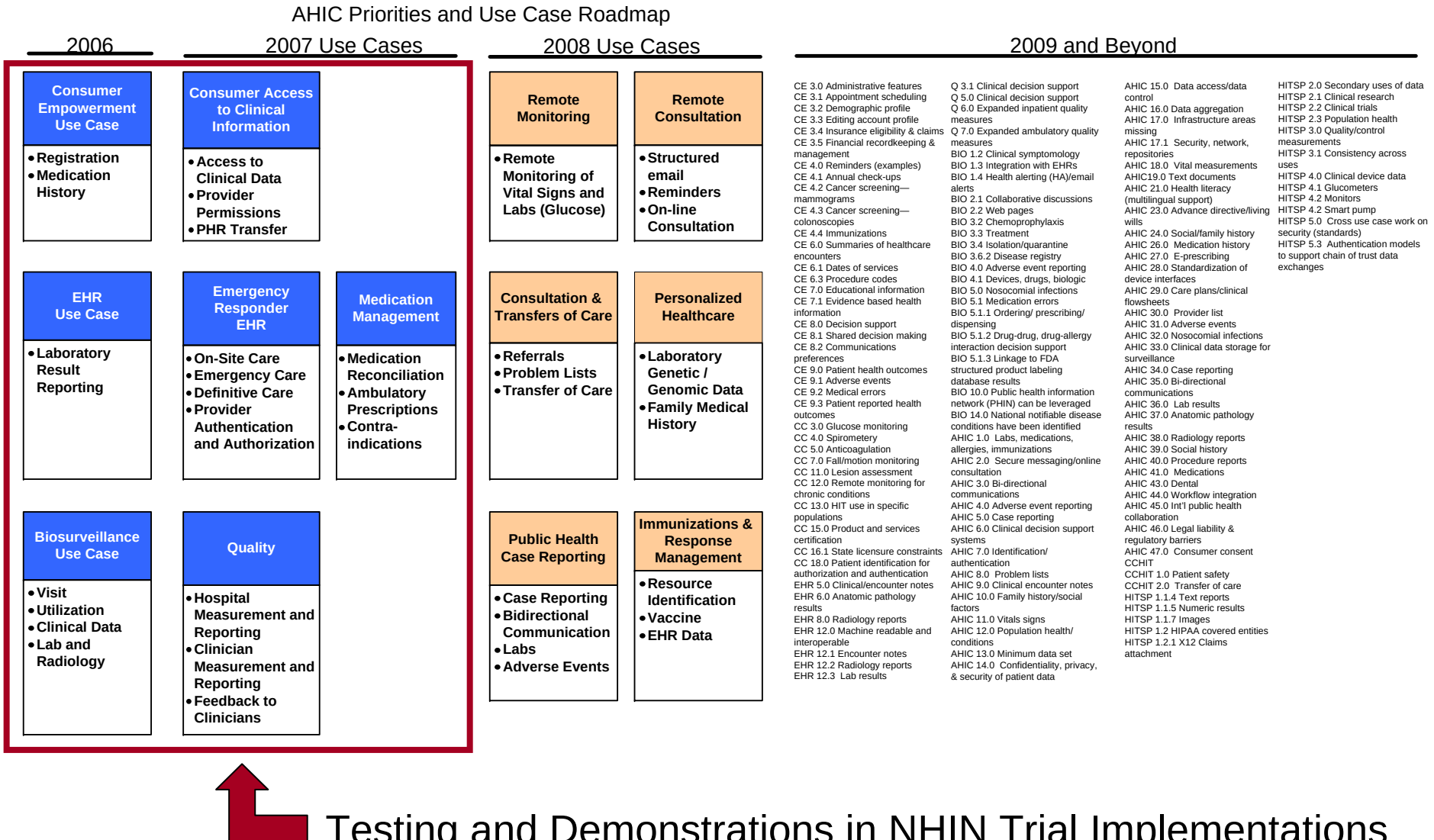
Standards Accepted 1/08, to be Recognized 1/09

AHIC Priorities and Use Case Roadmap



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Use Cases To Be Published 3/08

AHIC 2009 Priorities

- **ONC asked AHIC workgroups, CCHIT, HITSP, and the federal agencies to review and refresh the detailed outstanding priorities**
- **Some new priorities were added and some old priorities were no longer promoted**
- **ONC also received suggestions for several areas that really would represent full use cases by themselves**
- **Additional input has suggested that it would be a good time to look at “gaps” in the existing thirteen use cases**

AHIC 2009 Priorities

- **After analyzing all of the input and considering available resources, ONC recommends the following:**
  - the AHIC prioritize three new use cases for 2009
  - the AHIC help prioritize a list of smaller “gaps and extensions” which will also be put forward in detailed form for the next round of work
- **Because many of these priorities represent a balancing between workgroups, ONC will follow-up after this meeting with a process for the AHIC to determine final prioritization**

“Full” Use Cases Suggested

- Newborn Screening
- Maternal & Child Health*
- Eligibility, Prior-Authorization & Scheduling
- Disability and Other Qualification
- Authorization and Release of Information
- Medical Home and Care Coordination
- Clinical Research and Clinical Trials*
- Long Term Care and Assessment
- Store and Forward Telemedicine

*** Very large areas that would require further scoping**

2009 Priorities

- **Many of the refreshed specific 2009 priorities represent “gaps” in existing use cases**
- **Others would use an existing use case information flow, but add an additional capability or data set**
- **As an example, the EHR – Lab Reporting use case did not address “Lab test orders” because of scope issues at the time**
- **In the coming days ONC will distribute a tool for AHIC members to prioritize the choices for:**
    1. “major” use cases
    2. “gaps and extensions”

Previously Used Criteria

- **Advances the adoption of interoperable health information technology (health IT)**
- **Realizes the window of opportunity for near-term societal benefits**
- **Leverages existing health IT efforts**
- **Demonstrates the tangible benefits of health IT adoption**
- **Accelerates the vision articulated in the Federal health IT strategic framework**
- **Necessary to meet or advance other top health policy goals**