The Community

American Health Information Community

December 12, 2006
8:30 - 11:15 a.m.

U.S. Department of Health and Human Services

A G E N D A

Tenth Meeting of the
American Health Information Community

December 12, 2006

8:30 - 11:15 a.m. (EST)

- Web cast: **www.eventcenterlive.com/cfmx/ec/login/login1.cfm?BID=67**
- Enter your name and email address as requested.
- Room Number: **82899**

If you cannot hear the streaming audio during the event, you can listen via telephone by dialing the toll free number that will be posted within the Web cast interface.

Note: you must log onto the Web cast to access the toll free number.

8:30 a.m. **CALL TO ORDER** – *Secretary Leavitt*

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

8:40 A.M. **Comments** – *David Brailer*

- *Update on Personalized Healthcare Workgroup – Charges and Members*

8:45 A.M **State Health Information Exchange Steering Committee Recommendations**

- Overview – Linda Kloss
  FORE / American Health Information Management Association
- State-Federal Coordination – Donald T. Mon
  FORE /American Health Information Management Association
- Role of Medicaid – Shannah Koss
  Avalere Health
- Quality and HIE Coordination – Linda Kloss
  FORE /American Health Information Management Association

9:45 A.M. **NHIN Update**

- John Loonsk
  Office of the National Coordinator for Health Information Technology (ONC)
- Simon Cohn
  National Committee on Vital Health Statistics (NCVHS)

10:45 A.M. **Update on Standards**

- John Loonsk
  Office of the National Coordinator for Health Information Technology (ONC)

11:00 A.M. **Public Input**

11:15 A.M. **Adjourn**

Meeting Report

American Health Information Community
October 31, 2006

The American Health Information Community (AHIC), a federally chartered commission formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within 10 years, held its ninth meeting on October 31, 2006, at the Department of Health and Human Services (HHS), 200 Independence Avenue, SW, Washington, DC, 20201.

The purpose of the meeting was to bring together Community members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to HHS on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting's discussions focused on: (1) an overview of personalized health care, (2) overviews of population health and health information technology (HIT) as well as clinical research and HIT, (3) a discussion of Health Information Technology Standards Panel (HITSP) standards and interoperability specifications, (4) a presentation on a biosurveillance minimum data set, and (5) AHIC Workgroup perspectives on visioning and 2007 priority areas.

HHS Secretary Michael O. Leavitt chairs the Community. The remaining 17 members, selected by Secretary Leavitt, are key leaders in the public and private sectors who represent stakeholder interests in advancing the mission of the Community and who have strong peer support. Members serve two-year terms.

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

Call to Order

Joining Secretary Leavitt counterclockwise around the table were:

David Brailer, MD, PhD, Vice Chairman, AHIC

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

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

Kevin Hutchinson, CEO of SureScripts

Leslie Norwalk, Acting Administrator, Centers for Medicare and Medicaid Services (CMS)

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

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (Dr. Gerberding was represented by Dr. Ed Sondik, Director of the National Center for Health Statistics, for part of the meeting)

William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs (Dr. Winkenwerder was represented by Stephen Jones, DHA, Principal Deputy Assistant Secretary of Defense for Health Affairs, for part of the meeting)

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

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

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

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

Colin Evans, Director, Policy and Standards, Digital Health Group, Intel (Mr. Evans represented Craig Barrett, PhD, Chairman of the Board, Intel)

Stephen Finan, Senior Economist, U.S. Treasury (Mr. Finn represented Nada Eissa, Deputy Assistant Secretary, U.S. Treasury)

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

Rosi Sweeney, American Academy of Family Physicians (AAFP) (Ms. Sweeney represented Dr. Douglas Henley, Executive Vice President, AAFP)

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

Introductory Comments

Secretary Leavitt was absent for the start of the meeting; in his absence, Dr. Brailer served as Chair and welcomed Community members to the meeting. After reviewing the agenda, Dr. Brailer recognized Dr. Robert Kolodner, who was named as the Interim National Coordinator for Health Information Technology.

Approval of September 12, 2006, Meeting Minutes

Minutes from the September 12, 2006, AHIC meeting were distributed and reviewed by Community members. A motion to accept the minutes with no changes was made, seconded, and approved unanimously.

Overview of Personalized Health Care

Dr. Brailer introduced this panel by reminding Community members that there has been tremendous growth in personalized medicine and genomics towards bringing information that is necessary for patient care in the future. How does this affect the investment that is being made in HIT? At the same time, how

does the investment made in the nation and HIT help advance both the development and application of personalized medicine? Dr. Brailer asked Community members to consider whether AHIC should charter a workgroup in this area, and if so, what direction that workgroup would take. He also asked members to suggest ways in which AHIC as a whole can address the concept of personalized medicine within the context of the Community's mission. Following these comments, Dr. Brailer introduced the panel's Chair, Dr. Gregory Downing, Program Director, Personalized Health Care, HHS.

Dr. Downing reminded Community members that this panel was convened in response to initial discussions on the subject of personalized health care that took place at the previous AHIC meeting. There is abundant evidence on the horizon that the rapid advances in the scientific understanding of disease and health at the genetic and molecular levels will provide new opportunities to improve the quality of health care at the individual/patient level. Some of the advances that are enabling this future include the completion of the human genome project; the advent of molecularly targeted therapies and drugs aimed at specific genes and proteins; and advances in technologies for imaging, drug development, and diagnostics. This progress has fostered new approaches for predicting disease risk, enabled early interventions or preemption of disease processes, and modernized approaches to disease prevention and the development of highly effective therapies. Dr. Downing added that the future of personalized health care holds promise for addressing disparities in health outcomes and providing for a safer health care system by anticipating adverse health events on the basis of a biological response. This future will not be achievable, however, without the enabling factors that HIT provides.

Dr. Downing noted that one of the keys to understanding the impact and future direction of personalized medicine is through the EHR, explaining that organized, consistent, and structured approaches to information management can present data in an interpretive fashion that answers questions rather than leaving more to chance. The successes that AHIC has achieved in other areas of HIT can have a direct patient impact through similar strategies applied to genomic test data, for example. Another important key to success is achieving and maintaining public trust. The foundation for that trust rests on the ability to use information about an individual's health care experiences in ways that benefit the health care system at many levels, yet does so in a way that does not harm that individual. Privacy, security, and confidentiality are key components of responsible stewardship of medical information that must be considered carefully.

Using Genetic Information at Ground Level: The Perspective of Primary Care

Dr. Alfred Berg, Professor and Chair of the Department of Medicine at the University of Washington School of Medicine, discussed the perspectives of primary care practice and the use of genetic tests and applications of electronic health information for clinical decision support. He noted that primary care includes family medicine, general internal medicine, general pediatrics, and obstetrics and gynecology. These areas of medicine account for more than one-half of all office visits to physicians in the United States (approximately 471,000,000 visits in 2004). Dr. Berg emphasized that whatever policies are set forth regarding HIT and genetic testing they must work in the primary care arena, because that is where most patients begin when using medical care services.

Primary care physicians see common problems and specialize in having a breadth of knowledge and expertise. They recognize the patterns that suggest the unusual, and need information systems and decision support. From the primary care doctor's perspective, a new test or intervention must: (1) be available, feasible, and acceptable to the patient; (2) do what it says it does; (3) be accurate and reproducible; (4) improve clinical outcomes that patients would notice and care about compared with current practice; (5) not increase adverse effects; and (6) be cost effective. In terms of genetic testing, Dr. Berg explained that primary care physicians are skeptical of the concept of "genetic exceptionalism" (i.e., the idea that genetic information is a different kind of information than that from other kinds of tests and

assessments). Many non-genetic tests in current use produce the same kinds of information promised by genetic tests, such as risk, prognosis, and response to drugs and other therapies. In addition, many current EHRs already can accommodate test results (genetic or otherwise), and intelligently link them to other parts of the record. Dr. Berg commented that although there is no denying the potential importance of genetic information, many in primary care have a "wait-and-see" attitude.

There are thousands of genetic tests already available—many of which are for single-gene, rare disorders that primary care physicians do not deal with. However, an increasing number of these tests are aimed at chronic, common diseases and are intended to advise on treatment for common problems. There is essentially no regulation of these tests, which are marketed using both direct-to-physician and direct-to-consumer advertising. Clinicians and consumers need good, evidence-based advice on the use of genetic tests. Dr. Berg described the U.S. Preventive Services Task Force, which for more than 15 years has been making evidence-based recommendations about preventive interventions. The Task Force uses a rigorous process that is transparent and publicly accountable, and is not tainted by conflicts of interest.

The CDC, in partnership with the Agency for Healthcare Research and Quality's (AHRQ) Evidence-Based Practice Centers, has convened a new panel, the Evaluation of Genomic Applications in Practice and Prevention (EGAPP), to develop methods that will provide similar, evidence-based advice to clinicians about genetic testing. EGAPP has just begun its third year. The panel is non-regulatory, independent, non-federal, and multidisciplinary. EGAPP currently has the following six reviews underway: (1) testing for early detection of ovarian cancer, (2) testing before placing a patient on an antidepressant drug, (3) testing for familial colon cancer, (4) testing for response to treatment for colon cancer, (5) genetic profiling for cardiac risk, and (6) breast cancer gene expression profiling. EGAPP has not yet released a recommendation, and has found thus far that the quantity and quality of evidence supporting testing in typical practice settings is disappointing. Study designs generally are weak, some potentially important data are proprietary, and there are few data on potential benefits and harms. In addition, there are no head-to-head comparisons with current practice, these tests are not evaluated in typical patient populations, and there is little information about cost and cost-effectiveness compared with current practice. Finally, there is no information regarding ethical, legal, and social implications, especially for family members.

Before ending his presentation, Dr. Berg discussed the following conclusions:

- Genetic testing to assess risk or guide therapy holds great promise.
- There is a need to recognize the importance of appropriateness in primary care settings.
- New tests and technologies must improve on what is currently available.
- There will likely be few examples of genetic tests that meet standards for common use in typical practices in the next 3-5 years.
- Many current EHRs can already link test information to other parts of the record.
- There is a tremendous need for more and better quality research on effects of testing on clinical outcomes (good and bad), with the results made publicly available.

Support for Structured Genetic Results in the EMR and Clinical Research Infrastructure at Partners HealthCare

During this presentation, Secretary Leavitt joined the meeting and resumed his role as Chair.

Dr. John Glaser, Vice President and Chief Information Officer at Partners HealthCare as well as a Senior Advisor at the Deloitte Center for Health Solutions, discussed the use of EHRs as a means to accelerate the transition and integration of genomic discovery science into health care. He described Partners Healthcare as a large, integrated delivery system that has a fairly substantive biomedical research enterprise. Dr. Glaser commented that it is clear that understanding a patient's genome and the way that it interacts with a wide variety of variables is a critical contributor to both advances in biomedical research as well as to efforts to ensure that physicians continue to make sound and safe diagnostic and therapeutic decisions.

Dr. Glaser presented a list of research questions for which the genome appears to play a significant role. Examples of research questions include: (1) Why do some patients with asthma respond to steroid treatment while others do not? (2) Why do some patients with diabetes have few complications even with "poor" control whereas others with "good" control have severe complications? Examples of clinical questions include: (1) Can a patient lower their cholesterol through diet alone, or should they start on an anticholesterol drug immediately? (2) Should a 40-year old with mild heart failure be put on the transplant list right away because he has a genetic cardiomyopathy that will worsen rapidly?

Dr. Glaser explained that supporting Partners Healthcare's research and clinical activities is a diverse IT foundation. At the core of this foundation is a collaborative effort between Partners IS Department and the Harvard Medical School Partners Healthcare Center for Genetics and Genomics (HPCGG). This collaboration undertakes work to help investigators understand the genomic basis of disease to the degree that it exists, and understand how a certain set of genetic variants interacts or works to create a disease or manifestation of a disease. The collaboration also includes a series of laboratory activities designed to carry out the genetic tests (both those being ordered by the investigator, and those being ordered by the clinician) to produce an actionable result. Those results then are incorporated into electronic medical records (EMRs) that guide primary care physicians and specialists in ongoing treatments to manage patients' illnesses. The Partners/HPCGG collaboration also includes creation of databases that bring together phenotypic data, genotypic data, and tools to allow investigators to understand why this approach does or does not work, as well as to pursue a series of biomedical research questions and questions based on the outcomes and quality of care delivered.

Dr. Glaser described the HPCGG IT infrastructure as well as the patient genetic profile module in the EMR. Within the EMR, identified variants are represented in the CDR in structured form. Reference information related to the test performed also is retained. Dr. Glaser and his colleagues currently are working on establishing clinical decision support rules targeting this information.

Dr. Glaser noted that the NIH has authorized seven national Centers for Biomedical Computing. One of them, the National Center for Biomedical Computing's Informatics for Integrating Biology at the Bedside (i2b2) is devoted to understanding the IT infrastructure necessary to support investigators examining the genomic basis of disease and the informatics for integrating biology in the bedside. i2b2 is creating an infrastructure for a merged genomic and phenotypic data repository and analyses tools.

Dr. Glaser described a number of challenges associated with IT support of personalized medicine. In terms of infrastructure and applications, there are a number of issues, such as: (1) To what degree can patient care data be leveraged to support research on the genomic basis of disease? (2) How does one structure, store, and "operate" genomic and proteomic data and transactions? (3) What are the methods

needed for processing these data? (4) How different will clinical systems be in 10 years? Similarly, with regard to implementation and care improvement, there are a number of questions, such as: (1) What is the impact on the safety, quality, and efficiency of care? (2) Will the discovery process be accelerated significantly? (3) What steps are needed to manage privacy? (4) What are the new issues in approaches to practice?

Dr. Glaser closed his presentation by noting that Partners Healthcare has formed a collaboration with the University of Utah to develop some of these technologies. Partners also is collaborating with HL7 to begin work on the transaction standards for the exchange of genetic test results. Other collaborative endeavors with industry and payers also are underway.

Department of Veterans Affairs Genomic Medicine Database: First Steps in Implementation of a Major New Initiative

Dr. Joel Kupersmith, Chief Research and Development Officer at the Department of Veterans Affairs (VA), discussed planning for the adoption of genomic test data into VA's EHR system. He explained that the VA system is large, with a $34.7 billion budget and 5.3 million patients seen last year. The system has 7.6 million enrollees, and at least 1,400 sites of care. Dr. Kupersmith noted that academic affiliations are the underpinning of care at the VA, and clinician scientists are the backbone of VA clinical care, research, and culture. The VA's patient population is older, sicker, poorer, and loyal compared with other patient populations. The system also has less turnover than private health plans and demonstrates good adherence to clinical trials.

Dr. Kupersmith discussed the need for a genomic population cohort project. It has generally been considered that the implementation of a large genetic population cohort will considerably advance the field of genomic medicine. This advance likely would be accompanied by a move towards use in everyday practice. The VA has the capacity to create such a cohort for the benefit of veterans and the nation, and it intends to collect genetic information from all consenting veterans and link it to their EHRs. This activity has been proposed by a number of individuals, and was printed in an article appearing in the journal *Nature* (*Nature*, 429:475-477; May 2004). The VA has a number of attributes making it attractive for creating this cohort, including: (1) a health care system with a large population treated in a variety of settings, (2) a research network integrated into the health care system, (3) an unrivaled EHR, (4) vehicles for and considerable success in translation of research findings directly to clinical care, and (5) the provision of state-of-the-art care.

The first step in implementing this program is establishing governance. The VA is guided in these efforts by a federal advisory committee, the Genomic Medicine Program Advisory Committee. Internally, the VA has created the Genomic Medicine Management Committee. Other various committees are contributing as well. There is a pilot project underway via the VA's Cooperative Studies Program (VA's major clinical trials program). More than 30,000 specimens have been collected, and there is capacity to bank approximately 100,000 specimens. The pilot project is ready to be expanded beyond the Cooperative Studies Program.

The VA is looking to enlarge its capacity in genomics, and has pharmacogenomics laboratories through a pharmacogenomics Request for Applications (RFA). The VA also has issued methodology RFAs and is examining other research funding measures. A central institutional review board is being developed and should be in operation within 1 year; this board will provide assistance with multicenter trials. The VA is developing the computational capability to incorporate genomic data into EHRs while assuring security. The Department also is providing for the educational needs of its professionals and of veterans through continuing medical education-type ventures, and is beginning to look at the possibility of using the EHR to provide information in the form of guidelines (e.g., decision tree nodes with advice, literature

references, etc.). Additionally, there are open discussions ongoing with potential collaborators and the broader communities moving in the same direction.

Dr. Kupersmith noted that a significant challenge tied to these implementation steps are ethical and privacy standards. Maintaining high ethical standards and beneficence is critical, as is holding open discussions with stakeholders. Communication with veterans themselves also is key to these efforts. Dr. Kupersmith concluded his remarks by stating that the VA's practical needs for these kinds of answers may serve as a precedent-setting construct for others.

Integration of Genomic Technologies in Clinical Practice: Development of Standard Controls and Best Practice Guidelines

Dr. Janet Warrington, Vice President of Emerging Markets and Molecular Diagnostics at Affymetrix, Inc., addressed the need for standards and emerging medical opportunities for applying technology in genomic-based diagnostics. She noted that there are examples of personalized health care in practice today. In many instances, treatment decisionmaking (e.g., dosing and timing) is based on information collected using either clinical chemistry or molecular information. In addition, a number of treatments currently in use are based on genomic technology.

Dr. Warrington noted that Affymetrix and its diagnostic partners treat genetic information the same way they treat other information—with clinical utility. She described the process for developing genetic-based diagnostic tests, using the example of the Roche Amplichip™, the first U.S. Food and Drug Administration (FDA) cleared microarray-based diagnostic test. The test provides clinically useful information from a genomic assay, with an automated analysis that includes a quality check with standard controls. The test features automated interpretation by signature comparison to a controlled reference database, with XML output that provides categorical with probability information to the end user.

At present, Affymetrix alone has more than 20 microarray-based diagnostic products in the pipeline; evidence of the need to act now in fostering the integration of these technologies in clinical practice. These products bring with them an increased awareness of the value of harmonization of terminology, controls, protocols, best practice guidelines, and electronic information management systems. Unless the same terminology and metrics for performance are used, it will be very difficult for the end user to interpret and understand the information gained from these various tests. There is an increasing amount of clinically relevant genomic information, an increasing cost of development, and an increasing recognition of the need to work together to develop standard controls and best practice guidelines.

An example of an initiative to form collaborations to develop these standard controls and best practice guidelines is the External RNA Controls Consortium, which includes 175 stakeholders from 92 organizations in 14 countries. There is no regulatory recommendation or requirement for this initiative; however, four Divisions of the FDA are participating in the Consortium, as are the CDC and National Institute of Standards and Technology. In addition, regulatory bodies from Europe, China, and Japan are participating. The External RNA Controls Consortium is focused on developing well-characterized, standard control materials for RNA-based expression assays. The Consortium's goals are to: (1) develop well-characterized standard controls for multiple genomic technology platforms (e.g., reverse-transcriptase polymerase chain reaction); and (2) develop protocols for multiple applications, research, and clinical laboratory use. The Consortium's first deliverable was a guideline document on the use of external RNA controls published in August 2006 by the Clinical and Laboratory Standards Institute.

A similar activity underway is the Clinical and Laboratory Genomic and Genetic Standards Initiative—a volunteer organization with 70 participants from 50 organizations in 19 countries who represent industry, government, and academia. This Initiative has the following goals: (1) make recommendations for

qualification of performance controls for microarray-based DNA genetic tests, and (2) develop a forum for driving consensus on characteristics and output of algorithms for microarray DNA-based genomic tests.

Dr. Warrington reminded AHIC members that widespread adoption of integrated EMRs requires consensus on standard controls and best practices. She emphasized that now is the right time to establish a standardized EMR infrastructure as well as the required standard controls and guidelines for these genomic-based assays. She noted that harmonization benefits patients, physicians, test and drug developers, regulatory bodies, and trade and commerce. Creating standards early in the process accelerates development; development dollars in turn are more efficiently spent when standards are in place.

Policy Priorities for Personalized Medicine

Dr. Kathy Hudson, Director of the Genetics and Public Policy Center at Johns Hopkins University, discussed aspects of public concern and interest associated with personalized health care, including privacy and security issues. She explained that the Genetics and Public Policy Center at Johns Hopkins conducts research, legal, and policy analysis to facilitate sound, evidence-based policy in the area of genetics. The following are prerequisites for personalized medicine: public confidence, a robust research pipeline, quality assurance for genetic tests and paired treatments, providers equipped with tools, quality linked to payment, outcomes tracked over time, and strong privacy protections.

In terms of public confidence, Dr. Hudson stated that large majorities of the American public approve of genetic testing and technologies for health-related applications, despite the fact that there is a relatively low level of genetic literacy among the public. Few data exist on how much the public needs to know about the science to make informed health decisions and on the correlation between literacy and support. Dr. Hudson commented that Americans expect that the government ensures the safety and accuracy of genetic tests. The large majority of Americans feel that insurers and employers should not have access to genetic information, principally out of fear that their information will be misused. There are issues related to trust, both from the public's perspective as well as from the scientists' viewpoint.

Dr. Hudson discussed the issue of genetic testing quality. The regulatory status of these tests varies greatly. The FDA has reviewed and approved only a handful of genetic testing kits, and recently asserted its authority over a subset of laboratory-developed kits, which caused some consternation, because the CMS is responsible for laboratory quality, and that would assure the analytic validity of laboratory-developed tasks. Dr. Hudson commented that current CMS oversight of genetic testing in laboratories is inadequate.

The Genetics and Public Policy Center recently conducted a survey of genetic testing laboratories in the United States and found that overwhelmingly, most genetic testing laboratories are Clinical Laboratory Improvement Amendments (CLIA) certified, but 16 percent overall, and one-third of the highest volume genetic testing laboratories, do not have a specialty certification. Dr. Hudson explained that there is no genetic testing specialty presently, and therefore, no ability to tailor rules for quality assurance over and above the minimum standard required under CLIA. Interestingly, she and her colleagues found that a large majority of the genetic testing laboratory directors support the creation of a genetic testing specialty at CMS. This is also supported by a number of other organizations, such as the Personalized Medicine Coalition, the American Society of Human Genetics, three advisory groups to HHS, and more than 100 companies, including Affymetrix, patient groups and provider organizations. Despite reiterating its commitment to create a genetic testing specialty for almost a decade, CMS made a decision in July 2006 not to pursue creating a genetic testing specialty.

There are more than 1,000 genetic tests clinically available today, with many more under development. Despite their utility in aiding clinical decisionmaking, relatively few guidelines for genetic testing have been developed by health care provider organizations. There is a need to increase the evidence base for many tests, and a sustainable system of supporting health professional organizations is needed to develop evidence-based guidelines (e.g., for tests reviewed by EGAPP).

In terms of privacy, Dr. Hudson suggested that the approach taken under the Health Insurance Portability and Accountability Act be adopted (i.e., provide the same level of protections for all information, irrespective of whether it is genetic information or non-genetic information). There are some new challenges to privacy, particularly where clinical information and research information intersects, especially in light of the proliferation of biobanks storing vast numbers of genetic samples that are linked to clinical information. Under the current guidelines for the ethical conduct of research, de-identified samples and records can be used in research without expressed consent. Strong statutory protections are needed for genetic information.

Dr. Hudson closed her presentation by suggesting the following next steps:

- Earn public confidence by demanding transparency and encouraging engagement.
- Create a CLIA genetic testing specialty.
- Rationalize FDA's role in genetic testing.
- Create a funding mechanism for organizations to develop evidence-based practice guidelines.
- Enact statutory protections against discrimination.
- Carefully re-review policies governing use of de-identified samples.

Discussion Highlights

"This is very much part of the future. As we begin developing an infrastructure for standards on electronic health records, we need to be contemplating this in the context of where we're going to be ending up…it would be a shame if we did not anticipate this in our work." – Secretary Leavitt

"What is your view of the current state of standard setting with respect to electronic health records as it relates to the collection and storing of this kind of data? That's the first question. The second is: what must we do to integrate it into our larger effort?" – Secretary Leavitt

"The conclusion, that I've drawn and other people in the community I've worked with have drawn, is that this is the perfect place for the government to lead. It would be very difficult for any one individual in industry to really pull together the people who need to be pulled together to make this happen."
– Dr. Hudson

"There's a wide range of places you can apply standards…it's not just the data; it's the transaction that comes in from another genetic testing lab to our place and it will affect our care. So it's the transactions for moving these results back and forth…I think the timing is terrific to go out and do this." – Dr. Glaser

"We are just starting in these efforts in setting up our own internal mechanisms to look at standards as well as the ethical privacy issues and doing this in a beneficent way…I think that we can certainly enter

into some very interesting and significant discussions on this, since we are ahead in some ways, and we are catching up in others." – Dr. Kupersmith

"From the primary care perspective, many of the medical records that we already have have the capability of recording information that intelligently allows us to link test results to a clinical decision. The problem we have is that we don't have test results yet that can reliably be linked to clinical decisions that improve outcomes without increasing adverse effects." – Dr. Berg

"Is there a survey that has been completed or that is underway of the various standard-setting activities in the government or in the private sector regarding genomics information? Has this been undertaken? Do we have something we can look to that can help guide thinking about how this gets set up for future evaluation?" – Dr. Brailer

"We hosted a meeting so that we could inform ourselves and meet the people who are the experts who are driving this…we found that there were lots of activities going on, but no collective information, no report, survey… one of the outcomes of that meeting…was the request and the desire for even a single Web site that people could go to to find out what's going on in the standards community, what initiatives are underway and how people could participate in those initiatives…just as a place where people can go to get this information or people can deposit their information about their standard-setting initiatives." – Dr. Warrington

"At this point there are no high-quality randomized trials showing that the average patient entering that clinical decision-making cascade can be relatively certain of a better outcome." –Dr. Berg

"We are actually going to be starting a trial on SSRI dosing, and largely to see whether we can use the chip set to get to a more stable, initial dose faster, and avoid some of the bouncing around that can occur in the clinical setting." – Dr. Glaser

"We seem to disconnect between the clinical medical record and…in getting that data into the mental health care record…this panel or some other panel might want to look at how you get that kind of information into the mental health care record where it seems to be a generation or two behind where we are in this committee." – Mr. Roob

"Could any of you comment with respect to any policies that you're aware of in any of your organizations or for those of you particularly that are maintaining databases with respect to the retention or destruction of information of the personalized information?" – Dr. Winkenwerder

"Our policy is we do not destroy, ever. And largely for research purposes to the degree that an investigator wants to go back perhaps over very long periods of time and do this. That is probably not standard practice if you leave outside the academic health center realm. But in this case we keep it in perpetuity." – Dr. Glaser

"We don't destroy things either. But the technology moves so very quickly that there is a real problem—many of the tests that have entered the research literature are no longer being provided by the manufacturers. So, that by the time we get it into the record, it quickly becomes outdated." – Dr. Berg

"What I'm hearing…is the emergence of four different areas that need to be addressed…We need to have more research and evidence about the practical value of the genomic tests in clinical practice…We have got to have quality checks regarding the test methods because we need to make sure when a test result is reported, that it is reproducible and, in fact, means the same thing each time. Then further down the

technology scale is having to have standards for storing and representing that data…And then finally, overarching all of this [are] the policy and privacy issues that need to be dealt with." – Dr. Kolodner

"We have a Privacy and Security Workgroup that is looking at crosscutting privacy and security issues…Should we charge the existing group to look at genomic questions, or would a Genomics Personalized Medicine Workgroup want to take these up on their own right?" – Dr. Brailer

"I think the privacy considerations need to be considered throughout all of the Workgroups. I would argue that we don't want to segregate, or treat differently, genomic information. What we're really leaning towards here is trying to integrate this information into medical care. And so, I think we need to keep it as a part of the routine medical record." – Dr. Hudson

"The point of concern in primary care is the family members. Especially in family medicine where we often see all family members. What do you do with a genetic test performed on a family member that may have implications for another family member, where there's some disagreement about whether to share the information? It's a significantly different problem than sharing other kinds of medical information. That's one of the unique things, I think, about genetic testing." – Dr. Berg

"The medical professional groups have looked at the issue of what is the responsibility of the individual healthcare provider when he or she knows something that may affect family members. And they have created guidelines for that." – Dr. Hudson

"I appreciated what Dr. Berg said about not having genetic tests exceptionalism. And it's a little confusing to me why this wouldn't already automatically be part of HITSP. Is there something about these genetic data different than the current charge in authorities that HISTP has on its plate?" – Dr. Gerberding

"I think the question is one of: is there a set of standards organizations that are working on genetic information that can be standardized? It's both the maturity of the standards themselves and also whether or not those organizations are subject to the jurisdiction of HITSP. I don't think we can answer that question here. But an appropriate next step might be to look at that and determine what those roles should be." – Dr. Brailer

"I think consumers do indeed have a sense of concern that for themselves, if they've been personally diagnosed with an illness, having the genetic information is very important for them as it relates to future treatment and protocol options. But at the same time there is a concern about their heirs and the other family members and likewise a genuine concern of how is the genetic information going to be used in terms of secondary research and processes." – Ms. Davenport-Ennis

"Our work at AHIC would not be complete, in fact, it would be hampered in the future by not beginning to contemplate these issues as a significant part of our work. I would be inclined to see AHIC form a Workgroup that could begin to deal with issues and incorporate the work of other groups that are already engaged." – Secretary Leavitt

"It seems to me that there are five points a Workgroup could pursue…First, is to survey existing efforts that are developing standards, or that are influencing the standards for genomics and genetics information…Secondly, to propose a role for HITSP and the other related health IT mechanisms that have been established…Thirdly, to determine and develop a plan for how genomics information standards could be deployed over the next 2 years…Fourth, to evaluate the privacy and security considerations, and to work in collaboration with the Privacy and Security Workgroup in carrying those forward…And finally, two proposed use cases to actually come forward after this process that can help us begin the

process that has worked relatively well for the Workgroups, to focus on a few specific things that can help move this agenda forward." – Dr. Brailer

"I'm very concerned about us investing incredible resources, efforts, and energies into developing protocols and standards without looking at what the end game is here. What will ultimately be the use of the information? Who do we expect to use it? I would argue that primary care physicians would be the first line of folks that we need to have the ability to use this information. And ensure that whatever we're developing and designing is going to have ultimate utility to that group…I think we need to structure standards and structure protocols in such a fashion that they will have immediate utility to the primary care physicians rather than structure all of this and then go to the primary care physicians and say 'okay, we have this, now how are you going to use it?'" – Mr. Serota

"I'd like to suggest in the interest of time, that we ask the ONC staff to bring back to our next meeting a fleshed-in proposal as to what this should look like…it appears to me that…there would be no objection to the development of such a Workgroup. Hearing no objection, I'm going to declare a consensus on that point, and we'll direct staff as indicated and in our next meeting, we'll be in a position to finalize its development, but we'll clearly move forward in that direction." – Secretary Leavitt

Overview of Population Health and HIT

Interagency Health IT Policy Council Population Health Workgroup – Priority Areas

Dr. Terry Cullen, Chief Information Officer for the Indian Health Service, noted that population health is contained in many of the activities already being discussed by AHIC in the use cases and priority areas. She explained that HIT-enabled population health activities will permit more complete, efficient, and timely: (1) improvements in population health status through clinical performance measurement using longitudinal health data linked with external data sources; (2) measurement and reduction of health care disparities; (3) identification and management of emerging health conditions; (4) assessment, intervention, and evaluation of the impact of appropriate interventions for populations at increased risk for certain disorders; (5) clinical performance improvement; (6) population health research; and (7) dissemination of population health information. Dr. Cullen reminded AHIC members that at the last Community meeting, Dr. Michael Painter discussed sustainable, high-value care for all and acknowledged the need for many health data sets from a population perspective that currently are not available within the majority of the EHR solutions within the United States. One major reason for this is the fact that the focus of EHRs has been, appropriately, primarily on the provider and the patient at the current time.

Current HIT use for population health management typically is limited to information obtained from registries. As such, data populates an EHR, in most cases it is passively pulled into a registry, and at that point queries are done on the registry. However, the limitation imposed by solely using data fields that currently exist in registries means that the robust functionality being embedded in to the current EHR solutions are eliminated. Improving the health status of American populations requires a robust HIT solution that supports population health management—Dr. Cullen explained that it is critical to engage and ensure that the design of current EHRs facilitates the ability to do population health activities and embed population health knowledge within the context of the individual patient.

Dr. Cullen described the following benefits of using HIT:

- Facilitate identification of at-risk patients/populations.

- Facilitate monitoring of population health status and population health prevention and improvement.

- Enable information exchange between appropriate partners.

- Identify HIT requirements needed for population health management.

- Increase effectiveness and efficiencies of population health management in federal and private sectors.

Dr. Cullen concluded her remarks by identifying near-term opportunities in a number of areas, including: patient/population identification, identifying crucial data elements, privacy and security, storing and/or retrieving longitudinal patient data, de-identifying and reusing data, data mapping, integrating other data, and multi-directional reporting.

Overview of Clinical Research and HIT

Dr. Anthony Hayward, Director of the Division for Clinical Research Resources at the National Center for Research Resources, NIH, discussed the relationship between clinical research and health HIT, and why it is important to continue integrating the two. Dr. Hayward emphasized that clinical research improves health care, and defined clinical research as the study of a drug, biologic, or device in human subjects with the intent to discover potential beneficial effects and/or determine its safety and efficacy. Clinical research has yielded enormous benefits, and is the basis for all improvements in treatments, both preventive and symptomatic. Examples include antihypertensives reducing stroke risk, and the drugs Taxol and Gleevec improving patient outcomes among those with breast cancer and chronic myeloid leukemia, respectively.

The expenditures associated with clinical research are very high. In 2004/5, biomedical research expenditures in the United States were approximately $96.2 billion. Roughly one-half of that is spent on human subjects research (i.e., clinical research). These costs are minute compared with the cost of delivering health care. Dr. Hayward noted that NIH Director Dr. Elias Zerhouni has estimated that the cost savings from reductions in mortality from coronary artery disease exceed $2.6 trillion.

HIT already has brought enormous resources and benefits to bear on clinical research, foremost among them being the creation of standards that allow for structured data flow across both the research and care process. HIT also provides for communication among providers, patients, and researchers that partially support outcome and adverse event reporting (although much of this is still paper based). Existing databases serve as data warehouses for clinical findings and laboratory results, and for patient, family, and medication histories. However, the data need to be standardized to be comparable across clinical sites and across the research community.

Opportunities for health information technology in clinical research include:

- Facilitating patient access to clinical trials.

- Supporting better baseline data for comparisons.

- Increasing the speed of adverse event identification and reporting.

- Tracking human subject consents.

- Establishing common vocabularies and anonymization of human subject information.

Dr. Hayward concluded by noting that although clinical research has made tremendous contributions and advances to health care, investments will be much more productive if HIT is used to integrate the research process with the delivery of clinical care.

Discussion Highlights

"I would like a little better understanding of what is meant by "population health." Are we talking about populations based on race, sex, age? Clinical or chronic disease? Income? National origin? All of those things? And if so, in order for an EHR to be useful, you have to capture that information, obviously, in the EHR. Some are obviously available." – Mr. Green

"The answer would hopefully, in the long-term be yes. What we know is that the indicators of health are affected by many things that traditionally have gone beyond what we currently collect. As I call it, the 'beyond hemoglobin A1C phenomena.'" – Dr. Cullen

"The category of population health seems to me to fit a lot in what we're doing around biosurveillance, in the sense that biosurveillance could be even a subset of population health, because you're looking at the same entities that are needing to exchange information….I can see where those two things are aligned with one another from the organizations that are involved and the need for the exchange of information… What I like most about the clinical research and clinical trial category being included, either as a focused part of EHR Workgroup or as a focus of our Chronic Care Workgroup is that it brings a whole new audience to the table that could be a driver for adoption of EHRs." – Mr. Hutchinson

"More or less as we would consider structuralizing these directions, I've heard you say that perhaps biosurveillance could be expanded to include a broader population on health perspective, one element of which is biosurveillance. But secondly that clinical trials be incorporated into each of the Workgroup's domains rather than creating a subgroup unto itself for that. Is that fair?" – Dr. Brailer

"It is. I see it across a couple of groups, Chronic Care as well as EHR are two that come to mind." – Mr. Hutchinson

"I do think that clinical research has a unique focus to it. It's the need for two-way data flow. And above all, the need to see clinical research as permeating most clinical care so that the efficiency of the research process can be improved. I wouldn't have thought that diluting it out amongst all Workgroups would necessarily be the ideal way to proceed. I think that certainly the impact is going to be felt across all Workgroups. But one might do better to have at least a community that was focusing primarily on clinical research." – Dr. Hayward

"I think we have some real overlap coming here…I think the Biosurveillance Workgroup needs a new name. Because if you look at the near-term projects, even besides the ultimate vision, some of the things Terry mentioned are already on our agenda and it really is sort of a public health-clinical care interface Workgroup in terms of the kinds of projects we're talking about…in terms of a good bit of what Terry covered, that's really covered, to some extent, by our near-term and long-term agenda in the current Workgroup. But we'd have to sort of array everything to see where other issues would fall." – Mr. Kahn

"I think there may indeed by an opportunity to look at data fields such as family histories and life style choices, that we do see have a particular bearing and a very high incidence of certain types of diseases in certain special populations…As we look at Alaskan Natives, many who are being treated for chronic, debilitating and life-threatening conditions are required to leave communities, travel great distances, and

live in secondary locations for extended periods of time. And have a very diverse group of caregivers and medical providers during that process. If there is any population that can really be advantaged by a strong EHR and PHR system that is one of those populations." – Ms. Davenport-Ennis

"One of the hopes of the extrapolation of HIT throughout the health care system is to have research in more different practice-based settings to get better outcomes, so I think it's a very important point, and I'm not sure it should be in all the Workgroups but maybe it merits one on its own, so I look forward to the staff work. I think it's very important that the group looks at it." – Ms. Sweeney

Comments From the Secretary, HHS

Secretary Leavitt was not present for the opening portion of the meeting, and took a few moments to provide his introductory comments following the discussion related to population health and HIT. He first acknowledged Dr. Kolodner, who has moved from serving as a Community member to Interim National Coordinator for Health Information Technology. Secretary Leavitt noted that AHIC is pushing the horizon of what it has accomplished beyond where it was originally set, as evidenced by the fact that new Workgroups are being formed and the work is being expanded. The Executive Order that established AHIC set forth a 2-year cycle that is renewable—Secretary Leavitt indicated that he is confident that this renewal will occur by the end of the first 2-year cycle. He also reminded Community members that part of AHIC's charge includes the development of an ongoing business model that allows for AHIC's continued function outside of the government. Secretary Leavitt also noted that as of this meeting, there are 812 days left in the current administration. He expressed his resolve to have three more rounds of standards pass through the Community with the refinement of a well-established process that can continue outside of the government and not rely solely on the government to oversee it.

The Secretary acknowledged the hard work being done by others outside of AHIC, particularly by those associated with HITSP, which is developing a national health standards harmonization process that involves more than 260 health care organizations. HITSP volunteers have sifted through 700 possible standards, and after examining, testing, and documenting them, have identified 30 standards that will move this field closer to full-scale interoperability. More than 12,000 volunteer hours have been given to this effort so far. Secretary Leavitt also recognized the time and contributions of AHIC members and the staff of the Office of the National Coordinator for Health Information Technology, thanking them for their expertise, dedication, and efforts.

First Round of Standards Harmonization: HITSP Interoperability Specifications

In discussing the first round of standards harmonization results, Dr. John Loonsk, Office of the National Coordinator for Health Information Technology, first described the context of the work that HITSP has carried out, including the interoperability specifications, the HITSP process, what standards were chosen, and next steps. The context for HITSP was set by the breakthroughs that came from AHIC. These breakthroughs were converted into use cases, which were an attempt to specifically set the context, describe the processes, and describe some of the data needs necessary for data and technical standards in moving forward with interoperability for HIT systems. HITSP itself has been working towards the following three goals: (1) harmonization of standards to use in the context as defined by AHIC use cases, (2) identify gaps and needs, and to begin working with standards development organizations and other members of industry to address those gaps, and (3) develop the specificity necessary to use those standards specifically to achieve interoperability.

In describing the standards harmonization process, Dr. Loonsk noted that HITSP represents a partnership of public and private stakeholders operating through a neutral and inclusive governance model. HITSP utilizes a bylaw-based, consensus-based process. A consensus process is used with success for the majority of HITSP Technical Committee decisions—a voting process is used only when the consensus process fails—when voting is used, a quorum consists of 50 percent of the voting Technical Committee members, and 66 percent of those casting a vote must agree for a vote to pass. One vote is allowed per institutional member "representative on record" or regular participant. Dr. Loonsk noted that there are 261 registered HITSP organizations, and re-emphasized the importance and value of the estimated 12,000 volunteer hours contributed by HITSP members to date.

Dr. John Halamka, HITSP Chair, reminded Community members that about 13 months ago, HITSP was assigned use cases. Over those 13 months, HITSP has developed a process including a large group of disparate organizations that includes payers, providers, standards development organizations, employers, privacy advocates, and the general public. The first set of standards were processed through HITSP in just under one year, implying that two more rounds are possible during the current administration. Dr. Halamka reviewed the following eight major harmonization process steps developed and utilized by HITSP: (1) receiving a harmonization request; (2) conducting a requirements analysis; (3) identifying candidate standards; (4) resolving gaps, duplications, and overlaps; (5) selecting standards; (6) constructing interoperability specifications; (7) conducting an inspection test; and (8) releasing and disseminating interoperability specifications.

The standards required to support each major use case event were organized within an agreed-upon standards taxonomy. The standards selected for inclusion in the pool were examined using "HITSP-approved" tier 1 harmonization readiness criteria. Standards in the pool then were considered for inclusion in the interoperability specifications by application of the tier 2 harmonization readiness criteria. The tier 2 standards readiness criteria include five components: (1) suitability, (2) compatibility, (3) preferred standards characteristics, (4) standards development organization and process, and (5) total costs and ease of implementation.

Following these comments, Dr. Halamka described the scope, standards, and issues/remedies associated with the following three use cases:

Consumer Empowerment – Registration and Medication History

- Scope: As part of a personal health record, this interoperability specification addresses two key areas: (1) the patient's registration data, and (2) their medication history.

- Standards: Thirteen "named standards" were identified to support this interoperability specification, and five separate constructs were developed. Approximately 170 pages of implementation-level guidance were developed to support the specific use of these standards to achieve interoperability.

- Issues and Remedies: There is a need for a patient summary record within the technical environment of care providers, pharmacies, and health plans. Steps to address this include: (1) supporting and leveraging the existing HL7-ASTM harmonization initiative, (2) introducing new electronic links without replacing the existing links, and (3) promoting architectural independence.

Electronic Health Records - Laboratory Results Reporting

- Scope: This interoperability specification is relevant to clinical care providers who wish to have laboratory test results and laboratory interpretations electronically available for patients for whom they are providing care.

- Standards: Ten "named standards" were identified to support this interoperability specification, and 12 separate constructs were developed. Approximately 250 pages of implementation-level guidance were developed to support the specific use of these standards to achieve interoperability.

- Issues and Remedies: There is a lack of harmonization among data interoperability standards, including vocabulary, laboratory, and other messaging standards. Steps to address this include: (1) accommodating both laboratory message transaction and document sharing approaches, and (2) selecting standards with wide coverage to address gaps and provide mapping between standards to address overlaps.

Biosurveillance

- Scope: This interoperability specification includes the transmission of essential data from ambulatory care and emergency department visits, utilization, and laboratory result data from electronically enabled health care delivery and public health systems in a standardized and anonymized format, to authorized public health agencies with less than one day lag time.

- Standards: Twenty-four "named standards" were identified to support this interoperability specification, and 16 separate constructs were developed. Approximately 400 pages of implementation-level guidance were developed to support the specific use of these standards to achieve interoperability.

- Issues and Remedies: There is a need to maximize data sources and provide stringent data management to ensure proper routing, security, privacy, and timely reporting. Steps to address this include: (1) supporting any variant of architectural environments, and (2) selecting full options of standards to maximize data and information exchange.

Dr. Halamka summarized that in the last year, 700 possible standards were considered by 261 stakeholder organizations. Representatives from these organizations spent about 12,000 volunteer hours on these three use cases, and have reduced the 700 possible standards to 30. He emphasized the large degree of consistency across the three use cases.

Dr. Halamka stated that HITSP has approved three Version 1 sets of standards and implementation guidance (or interoperability specifications). He noted that the Panel now calls on industry to begin the implementation process for these interoperability specifications, during which HITSP will work with implementers to test the specifics of the implementation guidance. HITSP also has asked that AHIC recommend these standards and implementation guidance to Secretary Leavitt. HITSP will return to AHIC at least yearly with updates to the interoperability specifications. Because HITSP just released the Version 1 interoperability specifications, HITSP will return to AHIC no later than April 2007 with Version 2 updates for recommendation to the Secretary. Dr. Halamka explained that in the coming months, HITSP will seek to include a harmonized summary record standard into the interoperability specifications. HITSP also will work with the Certification Commission for Healthcare Information Technology (CCHIT) to establish interoperability specifications in the CCHIT criteria via the joint CCHIT/HITSP Working Group.

Discussion Highlights

"I don't have words to tell you how profoundly important I think this is in the process. I do have a question: as you see more use cases, will there be an adoption curve here where they get easier because you've got standards that you've agreed upon, that you can now build on? Will this get any easier as you go?" – Secretary Leavitt

"Absolutely. And so recognize that the greatest accomplishment of the last year was developing a process. That process is now in place [and] will continue to be refined. But because that engine is there it does make this work much more repeatable. If you look at the way we divide up these interoperability specifications into…these transaction packages, I think we'll discover, for example, for clinical research, wouldn't it be great if the laboratory transaction package that we use for doctors and patients was also used by researchers? And so one would hope there's going to be a very high degree of reusability across these new use cases and that we'll we will be able to accelerate this work." – Dr. Halamka

"You pointed out that touchstone of what you're doing was to point to standards that came from standards development organizations… But I think you also pointed to areas where no standards exist…I would suggest that those areas that clearly came from an SDO should be marked as such…You should indicate which do and don't." – Mr. Evans

"Typically, we think of a base standard as coming from an ANSI-accredited standards development organization…but we also had to consider sometimes there are implementation guides that take those standards as they come from SDOs and constrain them, because there may be too much ambiguity in a standard as it's published. So we also included in our set of base standards implementation guides from organizations like IHE, and IHE does not suggest that it is an ANSI-certified SDO, it's not creating standards at the base level. It is creating implementation guidance." – Dr. Halamka

"Where there are differences of opinion between standards development organizations and implementation guidance that is provided by non-SDOs…we will leverage the strengths of the SDOs, take work products from industry, and bring them in to technical committees where they can openly vetted, and by consensus, choose the best of what we get." – Dr. Halamka

"This is incredible work. But when we get down to the individual details and now that we're making recommendations for the passage of Version One, my concern is we actually would be recommending an implementation approach that has not been vetted through an ANSI-accredited standards organization." – Mr. Hutchinson

"I think you'll find the panel is quite good at vetting these particular decisions… We've created some foundation committees, we're calling them, to work on some of these basics of how as a whole environment of people working on standards, SDOs, implementation guide writers, and industry, do we ensure that good coordination. HITSP has a very important role in not only creating these, but ensuring they're maintained going forward." – Dr. Halamka

"I think it's fair to say that the industry is trending towards standards development organizations, or their like, managing this level of implementation guidance. So I think that this is an important step…The role that HITSP is taking here is really ensuring that it's available, though it will readily step out of the infinite detail work of implementation guidance where they are available and readily usable. And I think that's the direction the industry will head." – Dr. Loonsk

"HITSP, itself, of course does want to be an SDO. And when we can look to an SDO and say 'we need this particular use case satisfied, you maintain it, and we will reference it in an implementation guide,' that's really the best approach." – Dr. Halamka

"We did have a Working group on business sustainability… and asked the question how can HITSP continue on past a 100% government funding kind of resource set? We asked the question, given the harmonization that we've described in those multiple steps, how can we be the most efficient about it? And of course, we worry about volunteer burnout; 12,000 volunteer hours, companies that gave up employees for weeks at a time, will that be sustainable? The end result, as the model suggests, is that it will be a balance between funding by government and nongovernment entities." – Dr. Halamka

"We'll be much more efficient than we have in the past because we will have defined a lot of the processes… one hopes that we will be able to define, say, a 6 month to year-long turn of the crank process by which we can deal with two or three use cases and do that in a sustainable way. And my prediction is it will be an ongoing process that will last many years. We'll do it faster; we'll do it cheaper. But it will not be done in my lifetime, because there are so many domains to explore." – Dr. Halamka

"The standards development community has contributed substantially to this effort and has also thought about how they will play in the future. And I think as they accept some of the activities including implementation guidance, development, and such that we can see an expansion of scope of accomplishment, of throughput, even if HITSP's role may become smaller in terms of more of a coordinating role and less of the 'doing' role." – Dr. Loonsk

"One of the aspects of the implementation guides is that they constrain variability. You take an SDO's whole standard, and…these pieces implemented as such are what constitute interoperability specification, so they are all subsets. It requires that the SDOs have much better coordination amongst themselves and the stakeholders and we believe that HITSP can serve in that coordination role." – Dr. Halamka

"In the life cycle of a standard, one releases the standard, and of course it's used by industry, and then that implementation guidance about the standard is refined. So we are bringing these to you today, as I say, Version One, they're going out to the industry to begin implementation with the notion that come April, we will have refinements based on their early experiences." – Dr. Halamka

"I wasn't sure what the response was about making the distinction between those that have gone through an SDO and those what have not. Because I think that's very important. This is embryonic work in the HIT area…And I think we'd feel more comfortable if there were an understanding that the goal was for standards to go through SDOs. And I understand the need to get these out there now in a quick timeline. But we're really not comfortable, not having that distinction made and not having that ultimate goal that we do want an SDO process." – Ms. Sweeney

"This is a very important point. There are 30 standards that are being proposed here and the sense that I've gotten through my background in due diligence and or discussions is that these is standards are set and we don't expect that implementation testing will in any way change the bundle of standards you've come back to us with. The implementation guide itself may change as we get better evidence about what works and where it's ambiguous or silent. So the standards, the 30 standards have all come from standards development organizations?" – Dr. Brailer

"That is correct." – Dr. Halamka

"Are there circumstances under which you would bring back to us a named standard that did not come from SDO?" – Dr. Brailer

"There are no such circumstances." – Dr. Halamka

"We urge adoption of these standards today, and moving forward. But I do want to echo the concern about the need to do some testing over a period of time. We don't anticipate that being a long period of time, but just to have an effective implementation from the federal side." – Dr. Winkenwerder

"The President's Executive Order does contemplate that need. And in terms of its implementation I acknowledge it. I think all of us are saying we will move forward. This is a function of not 'if,' it's a matter of what the process is and we will work that out internally. Hearing no objection, but a good comment, I will declare a consensus and these will be advanced for Department's assistance."
– Secretary Leavitt

Biosurveillance Minimum Data Set Presentation

Dr. Arthur Davidson, a family physician and public health practitioner from Denver Public Health, a vertically integrated safety net organization in Denver, CO, noted that the Biosurveillance Data Steering Group's broad charge was to make recommendations to the Community so that within one year, essential ambulatory care and emergency department visits, utilization, and laboratory result data from electronically enabled health care delivery and public health systems can be transmitted in a standardized and anonymized format to authorized public health agencies within 24 hours. The Steering Group's specific charge was to identify the requirements for data from ambulatory care, emergency departments, and laboratories necessary for multijurisdictional biosurveillance programs. These requirements will build upon previous work completed by the AHIC Biosurveillance Workgroup and the HITSP Biosurviellance Technical Committee (HITSP-TC). Recommendations that specify these requirements also will refine and supplement the work of the HITSP-TC.

Dr. Davidson described the process used by the Biosurveillance Data Steering Group to build the minimum biosurveillance data set. He emphasized that the group focused solely on biosurveillance as defined by the Association of State and Territorial Health Officials. Biosurveillance is not the comprehensive package of disease control and reporting activities that happens every day in communities across America—any biosurveillance system will be insufficient to replace those activities. The task of the Biosurveillance Data Steering Group was to find the minimum data necessary to detect an event, create situational awareness, and support outbreak management and countermeasure and response administration. The minimum biosurveillance data set is much less inclusive than data required for routine public health surveillance, case reporting, and crucial disease control activities carried out daily in local and state jurisdictions.

The Biosurveillance Data Steering Group has recommended adoption of 58 valuable data elements, with the realization that not all of the data elements can be easily obtained. Given the group's feasibility estimates, it is believed that 31 of the 58 data elements will be available in the short term (defined as being available in 25 percent of all reporting sites in less than one year). Although collecting these data is feasible, a short-term implementation plan is needed, and many factors need to be more fully understood to make this practical and valuable at all jurisdictional levels.

Dr. Davidson discussed the following recommendations from the Biosurveillance Data Steering Group:

- Recommendation 1.0: The Secretary of the U.S. Department of Health and Human Services should adopt the minimum biosurveillance data set to guide data collection in biosurveillance programs that

involve the simultaneous sharing of clinical data from health care providers to authorized local, state, and federal public health agencies.

- Recommendation 1.1: By September 2007, the U.S. Department of Health and Human Services, in collaboration with state and local governmental public health agencies, should work with clinical care partners to implement the short term minimum biosurveillance data set and enable simultaneous data access to local, state, and federal public health entities for biosurveillance purposes.

- Recommendation 1.2: By March 2007, the U.S. Department of Health and Human Services, in collaboration with state and local governmental public health agencies, and clinical care partners, should evaluate implementation models, costs, and determine availability of resources and establish a plan to effect a short-term minimum biosurviellaince data set implementation.

- Recommendation 2.0: Public health agencies and partners who implement the short-term minimum biosurveillance data set should filter out some components of the following data elements as appropriate: date of birth, age, zip code, and diagnosis/injury code.

- Recommendation 3.0: CDC should, no less than annually, involve local, state, and federal public health agencies and clinical care partners in a minimum biosurveillance data set monitoring process for biosurveillance usefulness, and make appropriate modifications as evidence develops to support such modifications.

Discussion Highlights

"We really do appreciate the time and energy, and the thought of everyone that contributed. And I think it's a terrific starting place. It's realistic, it's doable. I think we can move ahead as you've suggested in the timeline that you've proposed…How is this biosurveillance initiative, which is really a subset of population health data requirements, going to link to the other Workgroups?...While this happens to focus on some specific utilities that are of an urgent nature, the transactional nature is basically the same. And so should we be thinking about these more as parallel processes rather than two separate streams of activity?" – Dr. Gerberding

"We look at biosurveillance as a subset of population health measures…Until we try to leverage all the local resources toward this improved interoperability across those communities and with federal agencies, we're going to lose the real sense of commonality. I think that's what we want to happen at the local level…We really want these to converge." – Dr. Davidson

"Upon this report, this Workgroup actually sunsets. It is done with its very specific charge. We didn't view this Workgroup having a life after this, unless it made a recommendation that it continue to do this work." – Dr. Brailer

"[This] was the Biosurveillance Workgroup's way of responding to the Secretary's concern that he needed certain kinds of information fast and we needed to be able to facilitate that through our process here, and that's why they were tasked as they were. And now I think that we've got this great, sort of, body, we can sort of figure out how it flows back in. But I think it was incredibly important that they worked as fast as they did, and I think we achieved your objective that you set out." – Mr. Kahn

Comments From the Interim National Coordinator for Health Information Technology

Dr. Kolodner noted that a key step toward achieving the goal of having most Americans with an EHR by 2014 is the development and nationwide implementation of the interoperable HIT infrastructure, which has been a major focus of AHIC, ONCHIT, and HHS. He added that AHIC now will place a major emphasis on what needs to be done to push the second round of standards through HITSP's process. Working with HITSP to facilitate a continuous flow of activities and manage a growing volume of standards also is a priority. Most important, Dr. Kolodner indicated, AHIC needs to ensure that the activities it focuses on are the ones that provide the most leverage. AHIC's activities should represent a floor, not a ceiling, for the efforts that are related to the interoperable HIT infrastructure. The importance of including all stakeholders in AHIC's common agenda to achieve this interoperable transformation of health care is well recognized. Dr. Kolodner indicated that his emphasis with ONCHIT will be to build the broad, inclusive alliances with other stakeholder organizations to enable continued success in their national initiatives—these alliances include AHIC's work with the private sector, with other internal HHS agencies, and across the federal government.

Visioning and 2007 Priority Areas – Workgroup Perspectives

Dr. Brailer introduced this series of presentations by explaining that each of the AHIC-chartered Workgroups was asked to come to this meeting having thought out their substantive recommendations, their priority areas, and how they fit into each Workgroup's respective vision. Leaders from each of the Workgroups were asked to present these findings, which should help move from narrow breakthroughs to a much broader vision. In addition to these Workgroup reports, ONCHIT staff undertook a separate level of analysis to look across workgroups to understand the clusters of areas that cut across the various Workgroups.

Electronic Health Record Workgroup

Community member Ms. Lillee Gelinas, Vice President and Chief Nursing Officer for VHA, Inc., noted that the EHR Workgroup heard a great deal of public testimony from multiple stakeholders, including those who have built, researched, and/or used EHRs in practice. A future priority of this Workgroup is to examine consumer perception. Ms. Gelinas reminded Community members that the broad charge for the EHR Workgroup is to make recommendations to the Community on ways to achieve the widespread adoption of certified EHRs, minimizing gaps in adoption among providers.

This Workgroup's vision of the future includes: (1) a person-centric health care system, (2) widespread use of interoperable HIT, and (3) new reimbursement systems that support improved outcomes achieved through virtual care. Today, however, there is a provider-centric health care system, low levels of EHR adoption, minimal interoperability, a low demand for HIT, and employer-based/public fee-for-services reimbursement. Ms. Gelinas commented that the low level of EHR adoption today may actually be a positive, from the standpoint that with the HITSP work that was presented earlier during this meeting, there is now the opportunity to accelerate interoperability and adoption.

In 2014, Ms. Gelinas explained that the Workgroup envisions an interim state that has a provider-centric health care system, although one with widespread adoption of EHRs with incremental availability of interoperable health information, a strong demand for HIT functions, and incentives or new models of reimbursement. The Workgroup identified 10 types of clinical information that were considered to be most important with respect to health information exchange among clinicians. Those types of information are: (1) patient identification, (2) medication list/allergies, (3) laboratory results, (4) problem

list, (5) clinical/encounter notes, (6) anatomic pathology results, (7) vital signs, (8) family history/health factors, (9) radiology reports (not including images), and (10) immunizations.

Key barriers to EHR adoption include the need for an accurate and reliable patient identification system and relief from current restrictive laboratory results data sharing under current CLIA and state laws. Additional barriers include preserving the clinical context and structuring data to be machine readable and interoperable as related to clinical encounter notes, radiology reports, and anatomic pathology results; and creating policies and guidance related to immunizations for secondary uses of data for public health policies.

Ms. Gelinas described five critical elements for reaching the interim state she touched on previously. Those elements will be the focus of a set of five recommendations that the EHR Workgroup will present to AHIC early in 2007. Those elements are:

- Creating a financial/business model that supports physician and hospital adoption and the maintenance of EHRs.

- Fostering incremental technological progress towards interoperability and usability.

- Mitigating of the medico-legal liability that rises from accessing and maintaining large amounts of clinical information.

- Establishing confidentiality, privacy, and security guidelines.

- Promoting organizational and cultural change in both the workforce and in patient populations with respect to new and different approaches to the use of HIT.

Chronic Care Workgroup

Colin Evans, Director of Policy & Standards, Digital Health Group at Intel, presented in place of Dr. Craig Barrett, Co-Chair of the Chronic Care Workgroup. Mr. Evans noted that the broad charge of the Chronic Care Workgroup is to make recommendations to the Community to deploy widely available, secure technology solutions for remote monitoring and assessment of patients, as well as patient-related communication between clinicians. He noted that there are two primary drivers pushing concern in the area of chronic care. One is that 80 percent of spending in the health care system occurs in the area of chronic care. The second is that 90 percent of that care is essentially self-administered. The Chronic Care Workgroup's efforts have been focused on the technology that puts patients in different settings outside of the clinical setting, and facilitating efficient patient-doctor communications.

The Workgroup's vision for the future involves a person-focused health care system that involves care available anywhere and any time, with new reimbursement systems that support improved outcomes achieved through virtual care and care coordinated across multiple providers and provider types. Patient engagement will be integral to this envisioned care process, which should be usable by anyone and accommodate persons with disabilities, affordable, portable, compatible with provider IT systems and other devices, enhance provider/patient relationships, and provide real-time continuous physiologic information. In addition, the future system should include bi-directional communication with pharmacies, laboratories, health care advocates, and other providers, as well as provide remote monitoring of symptoms before they become chronic. Mr. Evans contrasted this vision of the future by explaining that the current health care system is provider-centric and fragmented, with: (1) care sought in offices, clinics, laboratories, and hospitals; (2) care across multiple providers that is not coordinated; (3) a lack of reliable,

secure, and affordable HIT available in the home, school, and office settings that can communicate with care providers; (4) unit reimbursement for most ambulatory services; and (5) employer-based/fee-for-service reimbursement.

AHIC member Mr. Tony Trenkle, Director of the Office of E-Health Standards and Services at CMS and Chronic Care Workgroup Co-Chair, noted that an interim state can be reached by 2014. This interim state could feature less fragmented, provider-centric health care with widespread adoption of a limited number of interoperable remote services, remote services that are reimbursable under specific circumstances, and bi-directional communication between providers and patients. Mr. Trenkle outlined the following critical components for reaching such an interim state:

- A sustainable financial/business model for provider and patient use of interoperable monitoring devices and communications between the clinician and the patient.
- Interoperable, user-friendly, secure, and affordable technologies.
- Assurances that confidentiality, privacy, and security can be preserved.
- Mitigation of medico-legal liability that may be associated with virtual/remote care.
- Organizational/workforce changes to accommodate virtual care.

The Chronic Care Workgroup identified key enablers in financial; technological; confidentiality, privacy, and security; medico-legal; and cultural areas. The Workgroup also identified near-term priorities, including: (1) improved communications between the clinician and the patient, which are critical for assuring accurate and timely guidance; (2) vital sign monitoring (e.g., for weight); (3) laboratory monitoring (e.g., for blood glucose in patients with diabetes); and device monitoring (e.g., spirometry—asthma can be managed at home, in school, and at work). Mr. Trenkle also presented some longer-term priorities in the areas of vital sign monitoring (e.g., blood pressure, cardiac rate and rhythm, and pulse oximetry); laboratory monitoring (e.g., anticoagulation levels); and other device monitoring (e.g., motion, medication adherence).

Consumer Empowerment Workgroup

Community member Nancy Davenport-Ennis, founder of both the National Patient Advocate Foundation and the Patient Advocate Foundation and Co-Chair of the Consumer Empowerment Workgroup, introduced Dr. Paul Tang, Vice President and Chief Medical Officer of the Palo Alto Medical Foundation, who presented the Consumer Empowerment Workgroup's findings. The Palo Alto Medical Foundation includes 700 multispeciality physicians, 330 of whom use EHRs/PHRs. Approximately 40 percent of all primary care patients at this facility are immediately engaged in PHRs and EHRs.

The Consumer Empowerment Workgroup's broad charge is to make recommendations to the Community to gain widespread adoption of a PHR that is easy to use, portable, longitudinal, affordable, and consumer centered. The critical components that support widespread adoption are functionality, interoperability, consumer awareness, and business models. Dr. Tang noted that very few people know about this type of technology. Up to 40 percent of patients keep personal information at home, mostly on paper—very few keep this information in an electronic form, or even know that products to do so exist. Although stand-alone PHRs are available, uptake is poor, in large part because they involve manual entry of data, lack an interface with clinical data sources, and lack communication tools. It is hoped that adoption of the

standards passed through HITSP will improve communication between patients and their health care providers.

It is hoped to create some type of comprehensive consumer experience, with the PHR serving not as an end, but as a means, so that patients can gain access to the data and the caregivers they need in order to maintain and improve their health. The end-state vision includes widespread adoption of PHRs supporting health and wellness, with: (1) a comprehensive, longitudinal "record" about an individual's health acquired from all relevant sources; (2) timely, understandable, context-sensitive health information from trusted sources; (3) tools that support an empowered consumer taking an active role in managing his/her health; and (4) tools to facilitate communication with the health care team and caregivers. This vision also includes uniform privacy protections for personal health information that follow the data and give patients control of their personal health information. The Consumer Empowerment Workgroup identified components needed to reach this end-state vision. They include interoperability technical standards, interoperable policies, widespread adoption of interoperable EHRs, and a Nationwide Health Information Network (NHIN) that facilitates sharing of personal health information to authorized users under the control of consumers.

Dr. Tang highlighted the following key enablers for accelerating the adoption of PHRs, noting that the federal government can play a significant role in helping to advance many of them:

- Public education about PHRs from trusted sources.
- Comprehensive privacy protection for portable personal health information.
- Certification for core PHR functions, interoperability, security, and access control.
- Greater adoption of EHRs and electronic prescribing systems among providers.
- Automated population of PHRs with clinical data from multiple sources employing interoperability standards.
- Development of standards for consumer-focused, evidence-based educational information and decision support tools.

Near-term priorities for driving PHR adoption can be focused in the areas of laboratory results, lists of conditions and allergies, prescription refills and renewals, administrative features, and reminders for patients. Subsequent priorities include online consultation, summaries of health care encounters, endorsed educational information, decision support, and patient health outcomes. Dr. Tang summarized by suggesting that there is a need to provide patients with tools that improve their access to data, knowledge, and the providers they need to engage in keeping healthy and overcoming illness. Immediate needs include having interoperable standards in place to move data, have privacy protections follow the data, and certifying core functions so that consumers can be protected.

Biosurveillance Workgroup

Community member Mr. Charles Kahn, President of the Federation of American Hospitals and Co-Chair of the Biosurveillance Workgroup, reminded AHIC members that the Biosurveillance Workgroup's broad charge was to make recommendations to the Community to implement the informational tools and business operation to support real-time nationwide public health event monitoring and rapid response management across public health and care delivery communities and other authorized government

agencies. Today, public health agencies are not interconnected. Only a small proportion can receive electronic data from clinical care or public health partners, and silos of data exist in clinical and public health systems. There is a poorly articulated business case for data/information exchange between public health and clinical care at present, despite legal requirements for this exchange. Furthermore, public health programs and IT support are separated in most states, and the emphasis on information systems sometimes is inadequate. Mr. Kahn noted that today, case reporting typically is manual and passive, but notifiable disease reporting varies across states. Although bi-directional communications technologies exist at present, standards and infrastructure are under development and not yet complete. In terms of response management, there are variable degrees of application use and integration, including supporting outbreak investigations, tracking countermeasures, and linking to response registries. Finally, adverse event reporting today typically is manual, voluntary, passive, and supported by disparate systems.

Mr. John Lumpkin of the Robert Wood Johnson Foundation described the Biosurveillance Workgroup's end-state vision. In this vision with regard to connectivity between public health agencies and health care systems, local, state, and federal public health agencies can share data seamlessly with clinical care and each other. Infrastructure and policies are in place to enable data aggregation at appropriate levels of public health to monitor population health trends, disease outbreaks, and medical product safety. There is rapid, standardized case reporting across states, with case criteria integrated into EHR decision support algorithms. As such, the EHR prompts clinicians when a diagnosis matches a reportable disease and sends an electronic report that is approved by the clinician. There are integrated public health and clinical care communications; public health communications deliver value to clinicians that incentivizes providers to communicate on a routine basis with public health.

Mr. Lumpkin continued that this end-state vision, as envisioned by the Biosurveillance Workgroup, includes a response management component with integrated applications to support: (1) outbreak investigation, (2) countermeasure administration and tracking, and (3) ongoing visibility of supply and demand for critical resources. There is an established linkage between the point of care EHR and registry data with emergency management systems, and improved access to and tracking of isolation/quarantine cases, patient data for those displaced from usual site of care, and disaster case management services. This vision also includes standardized and consolidated adverse events reporting as well as automated EHR prompting and report filing for medical products.

Mr. Lumpkin presented four key enablers for achieving this end state:

- Public health involvement in health information exchange (HIE) efforts.
- Leveraging work done by the Public Health Informatics Network.
- HITSP and CCHIT inclusion of requirements for public health surveillance and response.
- An open, participatory process for certification of public health information systems.

Mr. Kahn summarized by noting that the Workgroup envisions some specific projects to tie these efforts together. With regard to case of case reporting, this would involve working on national standards to develop consistent definitions. Another project would involve developing an architecture for how electronic case reporting can be done from the developing EHRs. In terms of bi-directional communications, standards are needed, as is a system for alerts going back and forth between clinical care and public health. With regard to response management, one project would involve the design of a pilot for sharing hospital utilization data, as well as how to best integrate commercial sector supply chain and distribution response in a public health emergency. Lastly, in terms of adverse event reporting, national

standards need to be developed, and candidate systems for consolidation of that information need to be identified. Mr. Kahn concluded by noting that the title of this Workgroup should be changed to reflect the group's modified focus. He suggested the name "Public Health-Clinical Care Interface."

Quality Workgroup

Dr. Carolyn Clancy, AHRQ Director and Co-Chair of the Quality Workgroup, reminded AHIC members that the Workgroup's broad charge was to make recommendations to AHIC so that HIT can provide the data needed for the development of quality measures that are useful to patients and others in the health care industry, automate the measurement and reporting of a comprehensive current and future set of quality measures, and accelerate the use of clinical decision support that can improve performance on those quality measures. The broad charge also calls on the Workgroup to make recommendations for how performance measures should align with the capabilities and limitations of HIT. The Workgroup's specific charge (i.e., what the Workgroup is trying to accomplish in the near term) is to make recommendations to AHIC that specify how certified HIT should capture, aggregate, and report data for a core set of ambulatory and inpatient quality measures. Dr. Clancy explained that the Quality Workgroup is focusing on making quality assessment and reporting scaleable while at the same time ensuring that the same functionality is used to provide clinicians and health care organizations feedback in real time.

The Quality Workgroup was chartered in August of 2006, and has held two meetings to date. Progress thus far has included an examination of the business case for quality in the current reimbursement system as well as the business case or value added for IT to make it easier to report on an improved quality of care. The Workgroup has reached agreement that the core set of starter measures will come from the Hospital Quality Alliance (HQA) and the Ambulatory Care Quality Alliance (AQA). The Workgroup also has conducted and environmental scan and has reviewed the HIT certification process.

Dr. Clancy described a series of emerging principles for the Workgroup, including:

- Identify specific solutions for data aggregation and reporting, but not prescribing these solutions.
- Apply a requirements approach focused on the standardization and discrete capture of data elements critical for reporting.
- Focus on accountability, transparency, and improvability, helping clinicians obtain feedback in real time.
- Recognize the necessity of developing an array of solutions for decreasing the burden of data collection.

Additional principles include recognizing that quality reporting is one of several secondary uses for clinical data, the solution will require the skills of many, and the development/evolution of market competition and collaboration will be a significant enabler. Dr. Clancy identified four priorities in the near term: (1) automate data capture and reporting to support a core set of AQA clinician-focused quality measures, (2) automate data capture and reporting to support a core set of HQA inpatient quality measures, (3) provide feedback to providers in real or near-real time, and (4) enable data aggregation. Next steps for the Quality Workgroup include continued exploration of the broad and specific charges, development of recommendations for the specific charge and priority areas, and taking part in a visioning exercise to guide and inform the Workgroup's future activities. Dr. Clancy concluded her remarks by presenting a Venn diagram illustrating how the Quality Workgroup overlaps materially with other AHIC

efforts relative to the Consumer Empowerment, Electronic Health Records, and Biosurveillance Workgroups.

Perspectives and Clustering of AHIC Priorities

Dr. Kolodner noted that a priority roadmap for AHIC will be developed to describe when areas and issues will be considered and to allow AHIC Workgroups to focus on their identified priorities and issues in a coordinated manner. The roadmap also will inform next steps for the different processes of the national agenda, including use cases that detail needs for architecture, data harmonization, confidentiality and security, certification, and policy consideration. Dr. Kolodner explained that many priorities have been identified by AHIC Workgroups and others—not all issues can be addressed at one time, and there is overlap and relationships between the different priorities. There is a need to avoid "stovepipe" activities where there are opportunities to share and connect. There also is a need to address process gaps with HITSP and the CCHIT.

Dr. Loonsk explained that a coordinating structure for future use cases has been developed with three high-level perspectives: (1) the consumer perspective, (2) the provider perspective, and (3) a secondary use perspective. The priorities from the existing use cases, as developed by AHIC Workgroups, have been put into this structure, in an effort to examine these priorities, their commonalities, this additional organizing principle of what the high level perspectives are, so that AHIC can make the next use cases coherent and leverage the different needs across the different activities. A spreadsheet illustrating this structure was presented and distributed to Community members. Dr. Brailer noted that there are significant value statements being made by the perspectives that are brought and how they were chosen—the attempt was not made to represent every stakeholder in health care and have their perspective, but to represent some of the key polarities that come through. He also emphasized that these are not organizational statements; rather, these are management tools to help understand where activities have been completed and where there are gaps.

On the spreadsheet, Workgroup priorities and issues are arranged in columns corresponding to each of the three AHIC Workgroups, EHRs, Quality, AHIC, CCHIT, and HITSP. Areas highlighted in yellow represent an inclusive list of priority areas and issues related to perspective (consumer, provider, or secondary use). For example, with regards to the consumer perspective, everything that is highlighted is very related to the consumers' view on this process moving forward. Areas highlighted in gray indicate priority areas and issues that are part of a perspective that AHIC will try to write up into the next step use cases. Priorities that relate to, or depend on, each other are clustered across workgroups and perspectives—clustered items may influence the importance of the priorities.

Ms. Kelly Cronin, ONCHIT, noted that there are important common issues across the Workgroups that are being considered within the context of their respective broad charges. These include the business case, work flow, legal issues, and issues related to privacy, confidentiality, and security. Some of the specific issues related to the priority areas include regulatory barriers for provider and patient access to laboratory results; EHR, PHR, remote care monitoring, and case reporting integration in work flow; and the need for clear policy and practices for secondary uses of clinical data. Ms. Cronin noted that next steps involve: (1) obtaining AHIC comments on cross-linked priorities at this meeting, (2) initiating the development of the next round of use cases, (3) continuing to have the Workgroups address important issues for their broad charges, (4) developing the high-level roadmap for infrastructure development and AHIC activities, and (5) reviewing priorities at AHIC in approximately six months.

In reviewing and discussing the spreadsheet, AHIC members were asked to consider the following discussion questions from the consumer, provider, and secondary use perspectives:

- Are the most important priority areas (highlighted in gray, bold text) captured to advance interoperability in the second round of use cases?

- Are there any important considerations for the Workgroups as they continue to address both their broad charges and these priority areas?

- Are there any highlighted gray areas that should be considered for the third round of uses cases or later in the Workgroup process?

Before opening the floor for discussion, Dr. Brailer commented that one additional purpose of this exercise to develop a roadmap is to break the mold of AHIC/ONCHIT being only one small step ahead of where they need to be for contractual purposes with CCHIT, HITSP, or NHIN. This will allow AHIC to not be dictated by the short-term needs ONCHIT has to be able to fulfill its own contract oversight. He emphasized that this is a work in progress, built on all of the Workgroup discussions that have taken place to date.

Discussion Highlights

"The resource pressure would imply that there are some ugly choices we might have to make in order to slow things down or, in fact, not take things on…I'd certainly err on the side of making what we're doing already impactful before on taking new stuff that's potentially speculative." – Mr. Evans

"With respect to the resources that are being triaged or prioritized here, it's really an unknown quantity, because while clearly ONC has resources, and the agencies have resources that apply to this, the real pool of resources that this is prioritizing is the work of volunteers. And we don't know how elastic that pool is or how expansible, but clearly, there is a real sense that we can't go radically faster or broader at the same time, without taxing the voluntary resources that you've already heard so much about." – Dr. Brailer

"There is another component, and that is external factors that have nothing particularly to do with logical sequence or way to do this. For example, Congress could pass legislation that accelerated the need for a means of collecting quality information, and it could have a timeframe on it that would be a year or less." – Secretary Leavitt

"There is really an unknown number of contingencies that aren't even stated here that could shift this, and that's why I think this is seen in the end as not a 'top down once and for all' list…but a process to be revisited." – Dr. Brailer

"This list will change in two ways. The elements on the list will change as the universe of what's considered expands…Secondly, the sense of actionability or priority will change because of reasons that you describe, the nonlinear factors or just the linear evolution...The decisions that need to flow from this will happen beginning after this meeting…I do expect that at the December 12th meeting, that the ONC staff will bring back the 'so what?' that comes from all of this discovery and say, 'here are our stated directions, here is what's underlying them, and here's how we go forward.' So this abstraction, if you would, comes down to a very concrete set of actions steps." – Dr. Brailer

"If you get into the adoption for future projects of those workflow issues or workflow groups, are we going to focus on clearing those roadblocks for adoption, like the discussion we've had previously on IRS with payer programs that are trying to distribute funds to physicians to deploy and adopt EHR systems, but aren't able to because they can't get nonprofit status?" – Mr. Hutchinson

"This effort is being driven by the charter of AHIC, which does not exclude those, but gives those a diminished status with respect to the work here…this exercise was intended to not replace the set of recommendations that are already slated to come back here from the Workgroups within the next two meetings. This was really seen as giving guidance to what happens after that, and one of the things we made very clear in this visioning exercise was to not stop, slow down, or change the short-term recommendations that are due." – Dr. Brailer

"I would like to see AHIC focus on any technical barriers to adoption. There is a robust debate that's taking place outside this room, that we're all involved in, and we all have different perspectives on, and in many cases we'll share the perspectives. But I think our focus here ought to be in eliminating technical barriers to adoption. I'm of the belief that adoption is about to see a dramatic upswing, I think in significant part, because of the work of AHIC" – Secretary Leavitt

"I have been encouraged by seeing that there is a segment in healthcare in the United States that is interoperable, and that's the Veterans Administration…I hope that our VA colleagues…are informing our work, because I have been enormously impressed in the VA system, and see that the adoption lag is really in the public sector." – Ms. Gelinas

"There are some very good examples of systems that have achieved a high level of interoperability, but only within their own system, and our job is to figure how to get the 83 percent of small practitioners, who haven't achieved that yet. Ours is to make certain that the large systems, particularly hospitals who have and now want to share that and help small practitioners, that when they do it, they do it in a way that weaves into the larger vision. So I think when we talk about the technical barriers, this is not a technology problem. It's a sociologic problem and a coordination problem. And I'm convinced with enough time and enough focus, we'll get there." – Secretary Leavitt

"One of the next things you can expect is some prototype/proto-use cases that will be high level, and the process that was engineered around the emergency responder EHR is the one that we're thinking about, where there is a high level projection of what the use case would be, and then there is an opportunity for comment." – Dr. Loonsk

"In the end, what we look at in terms of use cases or action steps might be pretty self-evident, but we felt it was very important that we not just know what we're doing, but why we're doing it, and build up a public methodology, a public legacy of process, because many people do look to the AHIC to say, make these overarching priority decisions, so the industry can work in sync as they have done in many times." – Dr. Brailer

"If there was just some way of assessing not just the financial resources, but all the resources that it would take to actually accomplish one of these things, even if we just see the plans, it gives you something to sort of get a hold on. Otherwise, it's just a value judgment of whether this or that is more important for reaching all these goals…I just wonder if there is some way to weight it so you can make some judgment." – Mr. Kahn

"The problem that we had in going through that kind of a cost analysis is depending on what the goal is, different pockets of resources become available, because so many different constituencies in the market care about some problems and not others…And so we really had a hard time trying to ultimately add up whose cost it was, and it became a really difficult exercise. But we could certainly go back and revisit that, again in the spirit of building up a methodological process to make valuable decisions." – Dr. Brailer

"We're doing something that hasn't been done before. We said we're going to be learning as we go. This was the first set of things that are through, but we're not to the point where we've finished incorporating

them into a certification process and delivering that and having them purchased. That's still a part of the learning that we haven't yet experienced." – Dr. Kolodner

"It seems a little bit dangerous to look too much at the cross-cutting [priorities], because I'd hate to be in a situation where we've actually done a fabulous job of building some horizontal capability, but actually not being able to do all of what is necessary to do any one of these Workgroup things. To me, I'd give a higher priority to picking the minimum subset of things required to make the base set of recommendations in each of the Workgroups actually get implemented rather than focus too much on the horizontal and then miss the vertical end." – Mr. Evans

"I would caution that this is not an organizational tool. We are not telegraphing a desire to change the Workgroups or their approach towards these perspectives. It's really a tool for us to try to break those assumptions and make sure that we're not relying too much upon those silos that get created. And I think one of the takeaways from this is exactly that, that, in fact, these groups are large enough that they can really get big pieces that seem to fit elsewhere into others as well." – Dr. Brailer

"I have this suspicion…that Congress is going to take actions that will make it in the financial interest of physicians to collect information, and there is going to be a substantial interest in automating that process. And when that occurs, there will be a great hunger for adoption. A lot of people are going to be buying systems, and if those systems don't do what they want, that's a problem." – Secretary Leavitt

Following these remarks, Secretary Leavitt excused himself from the meeting. Dr. Brailer served as Chair for the rest of the meeting.

"Most of you thought that it would be best to consider specific priorities within clinical research and population health during future reviews or considerations of priorities, and not now. But I think it would be best to get all of you to make a determination on what you'd like to do with respect to both clinical research and population health." – Ms. Cronin

"I would still make the strong case for clinical research, whether it is a separate group or not a separate group. It seems to be a big business driver as associated with an EHR use case or underneath chronic care or even quality. It's hard to say where it actually would fit in the structure that we have today, but I think that individual one could end up being a big business driver for driving adoption uses of health IT." – Mr. Hutchinson

"Is there objection to merging the population health topic into this…expanded Workgroup formerly called 'Biosurveillance?" If there is no objection to that, then we'll be looking for the name and charter that goes with that, and clearly, we already have a bunch of proto-use cases to feed into that…perhaps the first discovery effort should be trying to find where there is a clinical research aspect to the use cases or questions that are being contemplated within the Workgroups, and then we can come back as AHIC and decide, through the vehicle of another broad multi-person panel presentation, what [we are] missing." – Dr. Brailer

"I see the information coming from this as not solely, if you will, health care. But I think what we also get from this is health status. And when we look at it that way, then I see it as really quite critical to how we look at health, overall." – Dr. Sondik

"I will ask ONC to go back and look at the secondary uses, and to come back with something even deeper than a name change, really a rationale for why that's a management tool and how we use it, or perhaps parsing it apart more. Again, in the spirit of building a toolbox, we can manage our process. It's a good starting point, but I think your points are fair, that we need to look more deeply." – Dr. Brailer

"I'd like to see also what's in and out of secondary use. I'm not real clear on that. I get the feeling that you're talking about public health, and oversight, and management of the health care system, but do you also mean payers? Do you include the secondary consumers; parents, for instance? I would like to see a clearer definition." – Mr. Green

"The purposes of what we put together for today, we were driven by just the Workgroup charges and their deliberations, so for quality measurement and reporting, clearly the clinical data that's being captured for that would be used on a secondary basis when it's aggregated and analyzed, and then reported either back to providers or to the public." – Ms. Cronin

"I think the direction stands for ONC to come back with a more fully parsed out or rationalized classification of secondary use of data as this process goes forward." – Dr. Brailer

"I cannot tell this body of members of AHIC how exciting it was for me, representing the consumer voices in the United States, to see this body support the HITSP recommendations this afternoon. And with that support, I think that I would have also an additional invitation that I would like to extend. And that is, that while all of us may look at that and feel there are other alternatives, or perhaps different processes available, as members of AHIC, I hope that we can all set aside any personal independent views of the world and encourage our constituents to be very supportive of adopting and integrating the standards that have been established by HITSP, so that, indeed, we can have a genuine measurement opportunity for integration into the country." – Ms. Davenport-Ennis

Public Input Session

Speaker Number 1 – Mr. Alan Mertz, President of the American Clinical Laboratory Association (ACLA), commented on the ongoing work of HITSP. He suggested that although the ACLA is generally supportive of HITSP's standards harmonization efforts, some of the Panel's work is flawed. Mr. Mertz stated that by recommending standards that are not being utilized by providers today in the United States, despite the existence of other suitable standards that are more widely adopted, HITSP is sacrificing feasibility in pursuit of perceived technical progress. In particular, Mr. Mertz explained that HITSP's recommendation to utilize HITSP/IS-01, if adopted, will create new roadblocks, despite existing efforts to address the creation of uniform results for reporting standards. ACLA believes that vendors have dominated this process, and that HITSP/IS-01 reflects a specification used by vendors in Europe that do not adequately accommodate the practical realities of laboratory result reporting today in the United States.

Mr. Mertz explained that the cost and time required for health care providers to upgrade their systems and processes to the HITSP specification would be substantial, and only the largest health care providers in the United States would be capable of conforming to this standard, at a considerable cost. He indicated that the adoption of E-Links, a specification developed under sponsorship of the California Healthcare Foundation would be preferable than adoption of HITSP's recommendation for laboratory results reporting. E-Links facilitates the delivery of electronic clinical laboratory results to clinicians in the office setting by providing a precise and generally applicable laboratory reporting specification that can be adopted as an industry standard. E-Links is based on HL7 Version 2.4, while HITSP/IS-01 is based on HL7 Version 2.5, which few providers and laboratories have adopted. Mr. Mertz stated that implementing HITSP/IS-01 would be significantly more costly, take much longer to adopt, and create numerous operational difficulties for all providers.

Mr. Mertz noted that E-Links currently is being utilized successfully in the United States, while the HITSP recommendation is not. He further recommended that AHIC reject the HITSP recommendation and consider a means to leverage the E-Links specification. The Certification Commission has already recognized the use of E-Links in the initial and second drafts of the Commission's 2007 Interoperability Criteria, and Mr. Mertz urged the Community to do the same.

Speaker Number 2 – Katheryn Serkes of the Association of American Physicians and Surgeons (AAPS) emphasized that it is not as much a matter of technology holding physicians back with regard to adoption of HIT, it is more a matter of policy questions that have yet to be answered. Many AAPS members are physicians in small groups and solo practitioners, who are likely to be laggers in terms of adoption. Cost is an issue, and from AAPS's standpoint, policy should drive the technology, rather than technology driving policy. The secondary use is a primary concern for AAPS members, as is privacy—both are policy decisions. Ms. Serkes gave the example of trying to determine what information can be shared, and with whom. The technology must be in place to handle this issue, but there also needs to be policy decisions in place directing what and how much information will be made available. Many AAPS members are trying to become independent of third-party influences on the clinical practice of medicine and are concerned that the inclusion of the EHR being linked to payment will obstruct this independence.

Speaker Number 3 – Tom Leary, Director of Federal Affairs at the Healthcare Information and Management Systems Society (HIMSS), noted that given the discussion of coordinated next steps, an obvious next step for AHIC would be to more closely coordinate its efforts with the government and health sector coordinating councils around infrastructure protection. On behalf of HIMSS members, he noted with appreciation Secretary Leavitt's comments regarding volunteers, especially volunteer participation in the HITSP process. Mr. Leary commented that the issue of volunteer burnout is a reality for HIMSS members. He asked that the Secretary's comments be made available so that they can be distributed to HIMSS members who have participated in these activities but were unable to attend this AHIC meeting in person.

Closing Remarks

Before adjourning the meeting, Dr. Brailer recognized and thanked Judy Sparrow, Director of AHIC, as well as Gloria Cohen and Matt McCoy, for all of their efforts and support for the Community.

American Health Information Community

Personalized Healthcare Workgroup

PHC Member List

- **Co-chairs:**
  - Dr. John Glaser — Harvard Partners
  - Dr. Douglas Henley — American Academy of Family Physicians
- **Members:**
  - Dr. Carolyn Clancy — Agency for Healthcare Research and Quality
  - Dr. Beryl Crossley, BM BCh — American Clinical Laboratory, Quest
  - Paul Cusenza, MBA — 23andME
  - Dr. Andrea Ferriera-Gonzalez — Virginia Commonwealth University
  - Dr. Felix Frueh — Food and Drug Administration
  - Betsy Humphreys, MLS — National Institutes of Health/NLM
  - Dr. Allan Guttmacher — National Institutes of Health/NHGRI
  - Dr. Kathy Hudson — Genetics and Public Policy Center
  - Dr. Charles Kennedy — Wellpoint
  - Dr. Joel Kupersmith — Department of Veteran Affairs
  - Stephen Matteson — Pfizer
  - Dr. Amy McGuire — Baylor College of Medicine
  - Dr. John Potter — Department of Defense
  - Mark Rothstein, JD — University of Louisville
  - Dr. Steve Teutsch, MPH — Merck
  - Dr. Janet Warrington — Affymetrix
  - Dr. Andrew Weisenthal — Permanente Foundation
  - Dr. Marc S. Williams — Intermountain Health
- **Office of the National Coordinator:**
  - Dr. Gregory Downing

PHC Senior Advisors & Alternates

Senior Advisors

• Dr. Jonathan Perlin	HCA Healthcare
• Dr. Michele Lloyd-Puryear	HHS/HRSA
• Dr. Muin Khoury	HHS/CDC
• Dr. Reed Tuckson	UnitedHealth
• Dr. Alfred Berg	University of Washington

Alternates

• Lisa Rovin	HHS/FDA
• Jean Slutsky	HHS/AHRQ

PHC Charges (Proposed)

- **Broad Charge for the Workgroup:**

  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 that encourages the incorporation of interoperable, clinically useful genetic laboratory test data and analytical tools into electronic health records to support clinical decision-making for the health care provider and patient.

- **Specific Charge for the Workgroup:**

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

Initial Workgroup Activities

- Survey existing standards efforts for genomic test data and interpretation in electronic health records and evaluate their maturity
- Develop recommendations to further standards development and implementation
- Assess needs for analytical tools to support genetic-testing-based clinical decision support and identify associated EHR functional and technical requirements
- Evaluate privacy and security issues that are unique to genomic test results
- Develop use case scenarios to guide the above work

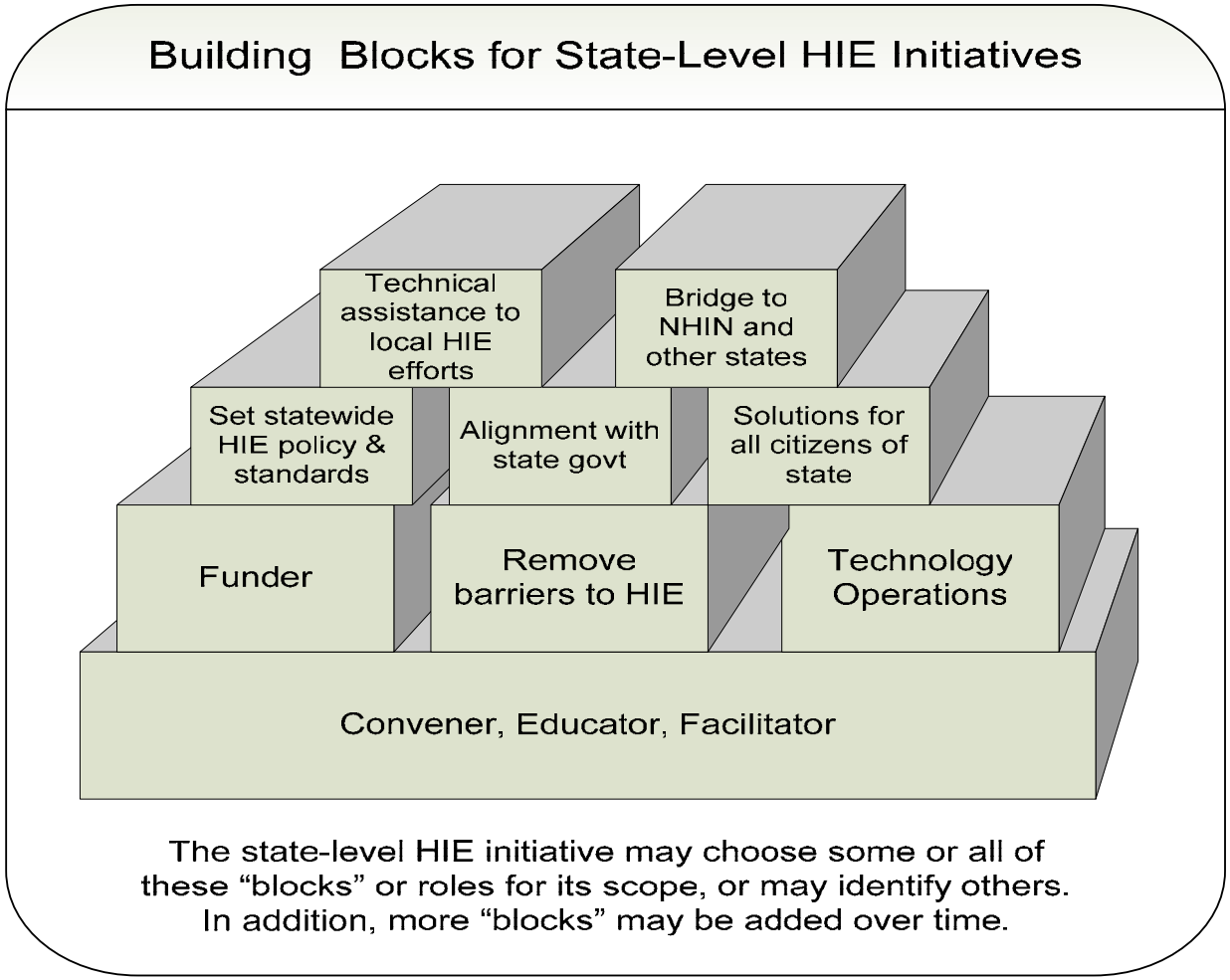
Next Steps

- Workgroup orientation conference call: December 19
- Establish first draft of charges: December 20
- Initial Workgroup meeting: January 4

State-Level Health Information Exchange Initiatives: Part II

December 12, 2006

Critical Roles for State-Level Initiatives



Part I Recommendations

- Mechanisms to promote strategic synergy among states and between state and federal efforts.
  - Coordinating body for active ongoing collaboration
  - Roadmap and explicit linkage of AHIC and ONC vision and project
- Salient financial models for sustainable HIE
- Engage and leverage public and private payers
- Advance understanding of how state policymakers and governmental agencies should be involved
- Vehicles for support and knowledge sharing among state-level HIE initiatives

Part II: Targeted studies

Organization & communication	**State-Level Health Information Exchange and Major Federal Initiatives**	**Health Information Exchange and Quality and Transparency Initiatives**
Program	**Medicaid and Health Information Exchange Initiatives**	**Financially Sustainable Health Information Exchange Services**

Steering Committee

Chair

- Molly J. Coye, MD, MPH, Founder and CEO, Health Technology Center, San Francisco, CA

Committee Members

- Laura L. Adams, President and CEO, ***Rhode Island Quality Institute***, Providence, RI
- Antoine Agassi, Director and Chair of the ***Tennessee eHealth Council***, Nashville, TN
- Ray Campbell, Esq., MPA, CEO, ***Massachusetts Health Data Consortium***, Waltham, MA
- Devore Culver, Executive Director, **HealthInfoNet**, Manchester, ME
- Lynn Dierker, RN, Director for Community Initiatives, ***Colorado Regional Health Information Organization***, Denver, CO
- Lori Hack, MBA, Interim CEO, ***CalRHIO***, San Francisco, CA
- W. Michael Heekin, Esq., Chair of the ***Florida Governor's Health Information Infrastructure Advisory Board***, Atlanta, GA
- Marc Overhage, MD, PhD, FACP, FACMI, CEO, ***Indiana Health Information Exchange, Inc,*** Indianapolis, IN
- Jan Root, PhD, Assistant Executive Director, ***Utah Health Information Network***, Murray, UT

Technical Advisors and Staff

Technical Advisors:

- John Glaser, PhD, Vice President and Chief Information Officer, Partners HealthCare System, Inc.
- Stephen T. Parente, PhD, MPH, MS, Principal, HIS Network, LLC, and Assistant Professor, Department of Finance, Carlson School of Management, University of Minnesota
- Kala Ladenheim, Program Director, Forum for State Health Policy Leadership, National Conference of State Legislatures

Task 1

Donald T. Mon, PhD - Principal Investigator, Vice President, Practice Leadership, AHIMA
Harry Rhodes, MBA, RHIA, Director, Practice Leadership, AHIMA

Task 2

Victoria M. Prescott, Esq. – Principal Investigator

Task 3

Avalere Health LLC:
Gregory Fuller, Project Manager – Senior Associate
Madeleine Konig, Senior Associate
Sheera Rosenfeld, Director, Health Information Technology Practice
Shannah Koss, Vice President

Linda L. Kloss, MA, RHIA, CEO, American Health Information Management Association
Eileen M. Murray, MM, CFRE, CAE – Executive Director, Foundation of Research and Education, AHIMA

Relationship between State-Level Health Information Exchange and Major Federal Initiatives

Donald T. Mon, PhD
Vice President, Practice Leadership
American Health Information Management Association (AHIMA)

FORE
Foundation of Research and Education of AHIMA

Project Overview

- Purpose
  - Explore potential roles/interactions between state-level health information exchange (HIE) initiatives and major federal health care and health information technology (HIT) activities

- Deliverables
  - Recommendations for establishing formal communications among states and federal agencies
  - Identification and documentation of barriers and concerns expressed by state-level HIEs that HHS/ONC and other federal agencies can constructively address and alleviate

Major Barriers – Validation of Roles

- Standards harmonized today not always the ones most urgently needed by the state-level HIEs
- State governments need to be much more involved in state-level HIE initiatives
- Financial sustainability still a top issue; strong relationship between financial sustainability and lack of alignment of incentives and sequence of activities moving HIT forward
- No consensus on how thick or thin the nation-wide health information network (NHIN) should be
- State-level HIEs may be ideal entity to aggregate secondary data for the state, but currently no business case to support it

Major Barriers – HIT Alignment/Communication

- Little sharing of lessons learned between state-level HIE and federal HIT initiatives
- State government, through the State Alliance for e-Health, should leverage but not disrupt progress on a state level
- Unclear whether the legislative branch is fully supportive of the role of HIT in improving quality of care
- No central authority accountable for
  - HIT's role in transforming healthcare
  - Making key HIT adoption-related decisions

Recommendations

- Begin transition to a public-private health information community successor to AHIC
- Community should develop transformational agenda by end of its first year
- Select, develop, and fund use cases that align more clearly with state-level HIE business cases
- Select, develop, and fund use cases that require the actual exchange of health information at the state level
- Align incentives and engage the state-level HIEs in the NHIN process
- Implement a formal communication process between the federal HIT projects and the state-level HIE initiatives

Medicaid and Health Information Exchange Initiatives

Shannah Koss, Vice President
Avalere Health LLC

Project Overview

- Explore the role of state Medicaid programs in HIE initiatives
  - Barriers and drivers to engagement
  - Opportunities for and value of Medicaid's participation
- Interviewed:
  - 9 HIE initiatives represented on AHIMA steering committee
  - 5 additional HIE initiatives
  - 2 state Medicaid officials
  - 4 representatives from a regional CMS office
  - 1 representative from Center for Medicaid and State Operations

Key Findings

- HIE initiatives see value in Medicaid agency participation and expect Medicaid interest
- Medicaid has been minimally involved with HIE
- Medicaid can play many roles in an HIE initiative
- HIE initiatives must address specific Medicaid business problems
- Vehicles exist to facilitate Medicaid's involvement
- MITA has longer-term potential to facilitate HIE for Medicaid

Perspectives Vary on Medicaid's Limited Involvement

According to HIE initiatives, Medicaid:

- Does not readily understand or see value proposition of HIE
- Functions in an administrative and political environment that limits receptivity
- Tends to conservatively interpret data sharing laws
- Operates cumbersome legacy claims systems

According to Medicaid:

- Lack of a proven HIE value proposition makes it risky for Medicaid engagement in early stages
- Priority investments focus on cost-effective program administration
- Limited state and national leadership constrains Medicaid's support of HIE
- Limited staff and financial resources inhibit participation

Recommendations

- **HIE Initiatives**
  - Demonstrate ROI showing Medicaid cost savings or efficiencies
  - Seek state political leadership and include Medicaid in HIE governance
  - Identify and engage in HIE efforts consistent with the needs of Medicaid

- **Medicaid**
  - Work with state agencies and leadership to identify shared HIE needs and value
  - Leverage contracts and purchasing (e.g., managed care, disease management, and transparency)
  - Work with Medicare to use HIE to better manage dually eligible beneficiaries
  - Engage in HIE initiatives on projects that meet program needs

- **CMS and other Federal Stakeholders**
  - Articulate support for Medicaid's involvement in HIE
  - Clarify appropriate data sharing policies
  - Create a central point of contact for Medicaid HIE issues to serve as a knowledge base and clearinghouse on best practices and successful Medicaid HIE projects
  - Help develop the business case for Medicaid HIE

Health Information Exchange and Quality and Transparency Initiatives

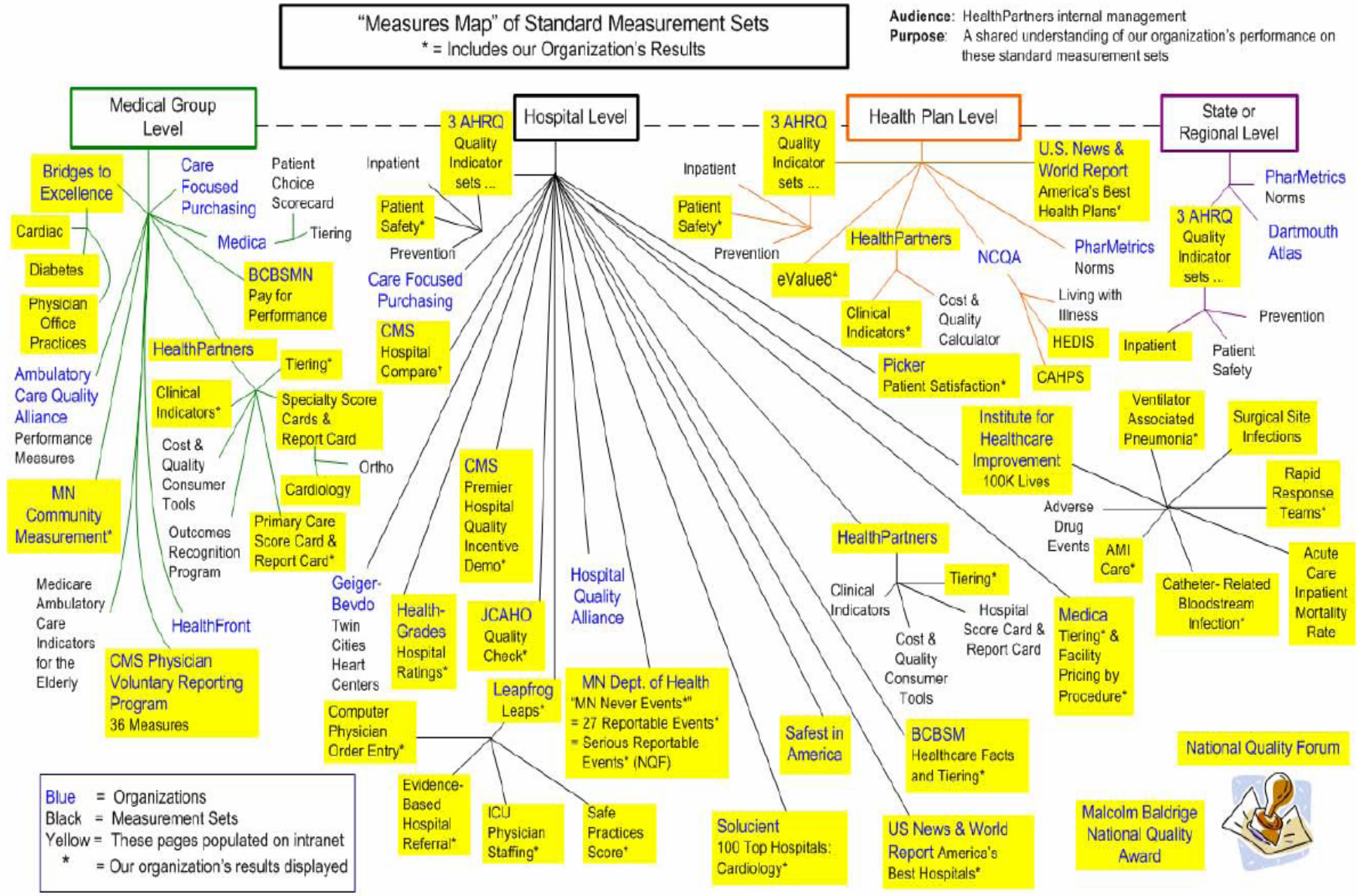
Linda L. Kloss, MA, RHIA
CEO, American Health Information Management Association (AHIMA)

FORE
Foundation of Research and Education of AHIMA

Quality improvement is mission critical state-level HIEs

- 55% - Supplier of data for performance reporting
- 33% - Disease or chronic care management
- 33% - Reporting performance to purchasers/payers
- 22% - Public reporting
- 33% - Advising and overseeing initiatives being managed by other entities

Quality Measurement & Reporting – A Single Health System's Current Experience



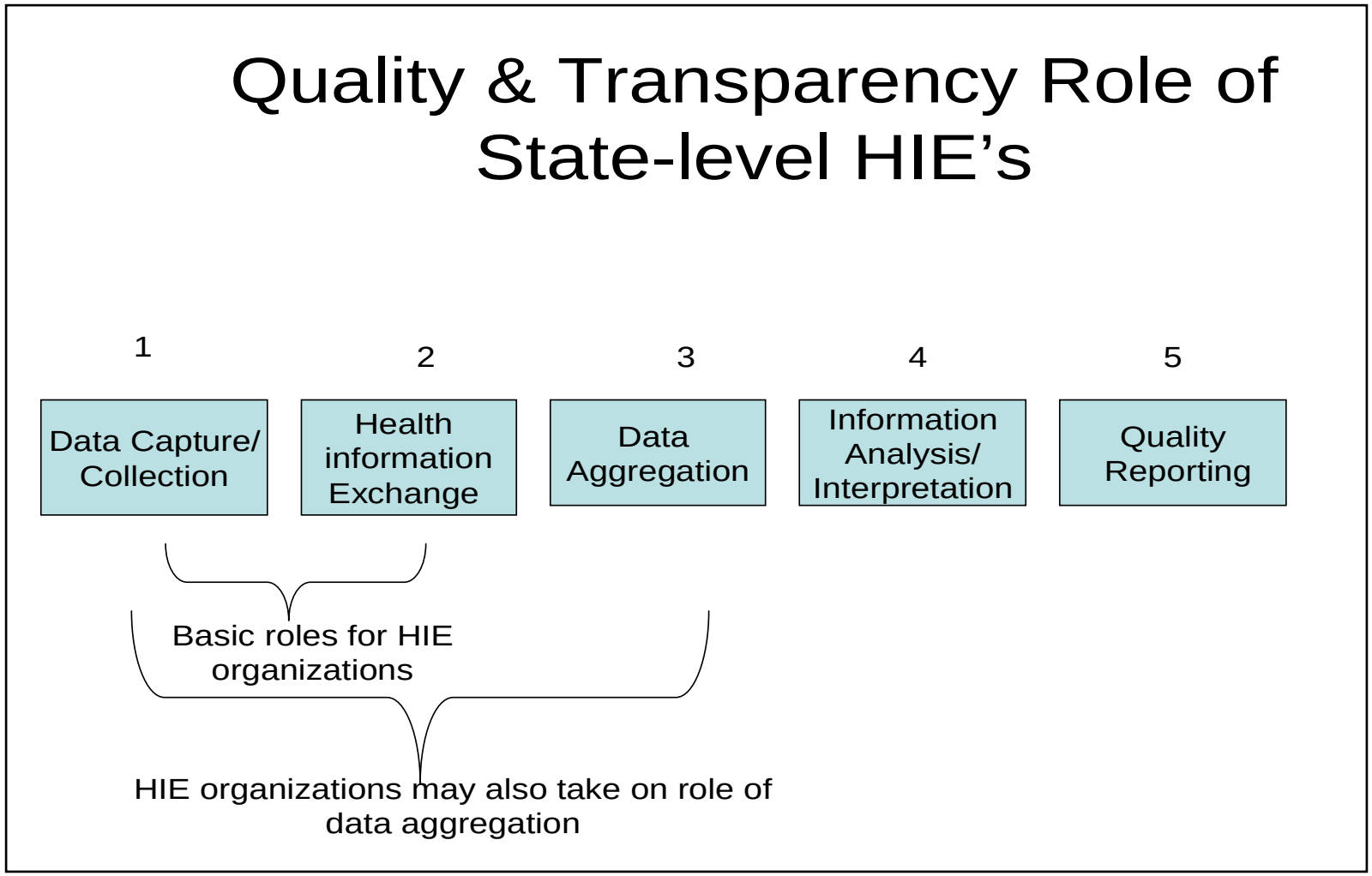
Recommendations

1. The Secretary and AHIC should clearly articulate the need for explicit coordination between state-level HIE and state quality and transparency initiatives.

2. While each state must determine its preferred model for data capture and aggregation, state level HIEs may be positioned to facilitate cost effective access to statewide data for quality initiatives. At a minimum, they should partner to
   - Assist with data standardization
   - Work to reduce duplicate data acquisition efforts

3. A more integrated model should be further developed and tested.

Role of State Level HIEs



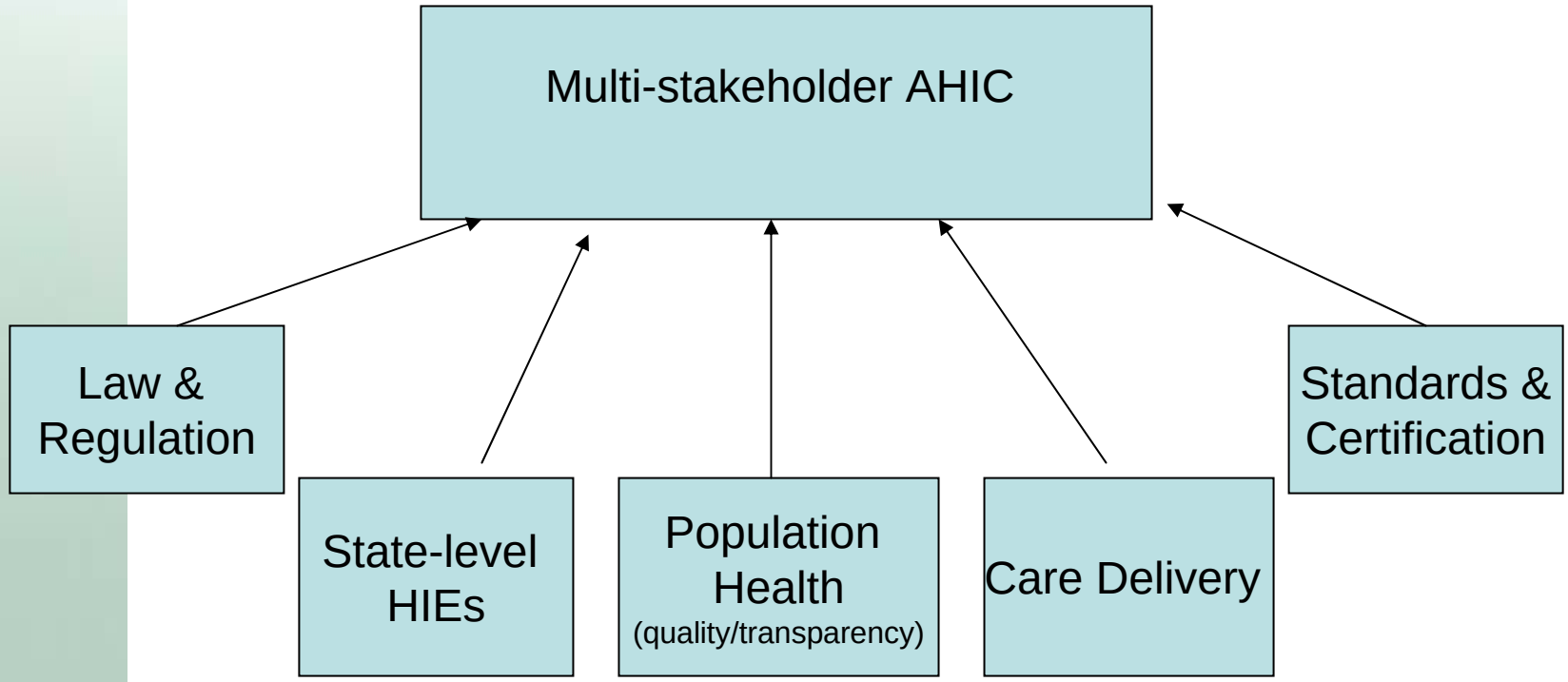
Recommendations

4. Formal and funded role to provide data services to quality measures may be critical to sustaining HIEs.

5. HIE representatives must get involved in national committees such as the NQF, AQA/HQA, AHRQ, and AHIC activities to design integrative data strategies. At the same time, they must strengthen relationships with quality organizations at the state and local levels.

6. Broader stakeholder dialogue is urgently needed:
   - Conduct an environmental scan of states that have successfully integrated state-level HIE with quality and transparency initiatives
   - Develop business models that supports state-level HIE involvement in quality and transparency initiatives, incorporating the long term cost savings due to reduced data variations and collection and aggregation burdens
   - Discuss and clarify the governance structures that are required to support the relationship between state-level HIE organizations and quality initiatives

National Coordination-Next Generation



FORE
Foundation of Research and Education of AHIMA

December 6, 2006

Michael O. Leavitt
Chair
The American Health Information Community
US Department of Health and Human Services
Hubert H. Humphrey Building, Room 615-F
200 Independence Avenue, Southwest
Washington, DC 20201

Dear Secretary Leavitt:

Attached is the contract extension report, "Development of Consensus Best Practices for State-Level Regional Health Information Organizations." In this phase, we examined three aspects of the operation of state-level Regional Health Information Organizations (RHIOs):

1. Explore the potential roles of and interactions between state-level Regional Health Information Organizations (RHIOs) and federal activities for health care and information technology.
2. Identify, examine and analyze health information exchange (HIE) projects that have achieved financial sustainability.
3. Explore the roles of public payers and their influence on state-level HIE activities

As the result of the discussion at the September 12, 2006, American Health Information Community (AHIC) meeting, we also examined the role of State-level HIEs in quality improvement and reporting.

The major recommendations from the four areas of inquiry are summarized below. The project Steering Committee also identified several important cross cutting recommendations that are outlined for you in this letter.

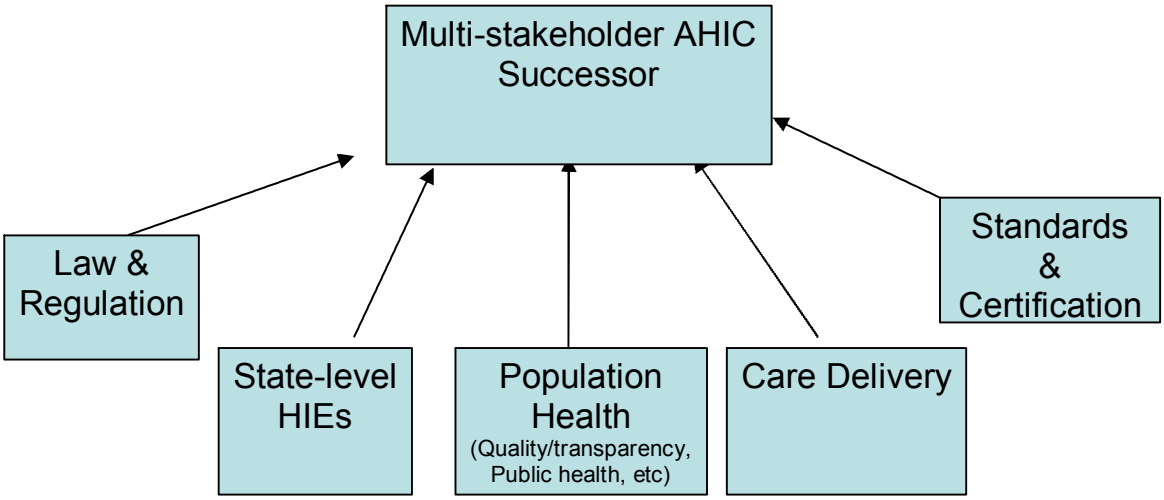
Coordinating the Change Agenda

1. The 2004 Framework for Strategic Action should be updated and reintroduced by the Office of the National Coordinator (ONC). This unifying strategic Health IT vision and plan should be refreshed to account for the role of state and local public-private HIE initiatives, the American Health Information Community (AHIC), and new strategies to advance the Nationwide Health Information Network (NHIN). While the Framework continues to be a very useful way to bolt together strategies for change, its dynamic vision has blurred with the scope and pace of change.

233 N. Michigan Ave., Suite 2150, Chicago, IL 60601-5800
phone (312) 233-1100 · *fax* (312) 233-1090 · www.ahima.org

2. Federal programs will benefit from what is being learned by states and communities. State-level HIE leaders understand how standards harmonization, certification compliance, security and privacy collaboration, and NHIN prototyping each supports the goal of accelerating HIT adoption. It is less clear, however, how the projects relate to one another and to the work of state-level HIEs. Bi-directional communication is needed to keep state and regional initiatives better informed about federal programs and projects and therefore enable meaningful input. HHS should support the formation of a state HIE learning forum to support the communication and coordination of HIE initiatives across states in an effort to ensure alignment with federal programs and create an interoperable network of networks.

3. The Secretary of HHS and AHIC should design the successor to AHIC. Multi-stakeholder coordination of health care transformation through information will be required for years to come. If planning for a sustaining body is not begun in 2007, there may be a leadership gap that could take valuable time to fill. As shown in the following diagram, standing committees can advise the coordinating body on issues such as: legal and regulatory issues (including privacy and security); care delivery; health information exchange; and population health (including quality improvement and public health),; and standards and certification. The coordinating body must have sanctioned authority to set priorities and resolve conflict to advance the national agenda.



4. Convene a State-level HIE Best Practices Steering Group to continue the best practices research work begun in this project and to serve as an advisory body for issues related to HIE. This will be an effective bridge strategy until a coordinating body with standing subcommittees as described under #3 is convened.

Leveraging State-level HIE

5. Centers for Medicare and Medicaid Services (CMS) should demonstrate strong national leadership by defining a clear position on HIE in and across state Medicaid programs, while also serving as a clearinghouse for information and guidance about the collaboration process.

6. State-level HIEs should collaborate with Medicaid to identify short-term recommendations that are well suited to the needs of both parties. The lack of a sufficient and obvious shared business proposition will require engagement and shared learning. Longer term, HIE initiatives will need to participate in state Medicaid planning activities.

7. HHS should clearly distinguish the goals of the State Alliance for e-Health project from the ongoing roles of public-private health information exchange initiatives and call for effective leverage and coordination so state-level efforts do not fragment.

8. HHS should encourage innovative and cost effective coordination between state-level HIE and state quality and transparency initiatives. Adding to "silos" of data must be avoided. Additional research will be needed to develop and demonstrate the models for data capture and aggregation; however, some state-level HIEs are positioned to facilitate cost effective access to statewide data for quality initiatives. And for these, a role in quality improvement will be a critical element of business sustainability.

Health Data and Standards

9. State-level HIEs have a role in encouraging the rapid deployment of standards from standard development organizations (SDOs) and the Health Information Technology Standards Panel (HITSP) as they are released. To be effective in this role, HIEs must have a voice in development of use cases that are relevant to information exchange. Further, State-level HIEs should have input into standards harmonization processes and plans, and development of conformance criteria for certifying networks by Certification Commission for Healthcare Information Technology (CCHIT). This can be one of the roles played by the State-level HIE Best Practices Steering Committee described under #4.

10. HIE and quality organizations must work together on national committees such as the NQF, AQA/HQA, AHRQ, and AHIC activities to design integrative strategies. At the same time, working relationships need to be strengthened at the state and local levels. The quality community must be at the table when information exchange decisions are being made and the HIE community must be at the table when decisions are being made about data capture, exchange, and aggregation of data for quality.

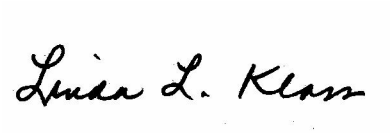
11. Sustainable business models for HIEs appear to effectively leverage investments in infrastructure and data by using them for more than one type of service. Successful HIE applications must continue to be studied and documented. This can be an additional role for the State-Level HIE Best Practices Steering Committee described under #4.

12. While each state must determine its preferred model for data capture and aggregation, research is urgently needed on how State level HIEs can assist with data standardization to reduce duplicate data acquisition efforts. HIE organizations should partner with community stakeholders to design data collection and aggregation strategies that will be capable of evolving as experience with performance measurement and information management technology improves.

13. While each state must determine its preferred model for data capture and aggregation, research is urgently needed on how to State level HIEs should assist with data standardization to reduce duplicate data acquisition efforts. HIE organizations should partner with community stakeholders to design data collection and aggregation strategies that will be capable of evolving as experience with performance measurement and information management technology improves.

We look forward to describing our work and our conclusions at the December 12 meeting of the American Health Information Community. Thank you for this opportunity to contribute to advancing health care through information.

Sincerely,



Linda L. Kloss
Chief Executive Officer

cc: Dr. David Brailer
Dr. Robert Kolodner
Kelly Cronin
Members of the Project Steering Committee

Nationwide Health Information Network Initiative - Update

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

December 12, 2006

Nationwide Health Information Network (NHIN)

2006 - Four “Prototype Architectures”

- Needed standards defined
- Functional requirements produced
- Security architectures described
- At January AHIC and NHIN public forum:
  - Present software implementations
  - Discuss cost / revenue models for network services

Nationwide Health Information Network (NHIN)

2007 – “Trial Implementations”

- New procurement to directly engage state and regional health information exchange efforts
- Will connect state and local efforts to developing expertise of health information service providers (such as prototype work)
- Initiate a collaboration environment for NHIN “network of networks”
- Interconnect EHR’s, PHR’s and other networks (including federal health systems)

The National Committee on Vital and Health Statistics
The Public Advisory Body to the Secretary of Health and Human Services

Functional Requirements Needed for the Initial Definition of a Nationwide Health Information Network (NHIN)

American Health Information Community
December 12, 2006

Simon P. Cohn, MD
Associate Executive Director, The Permanente Federation, Kaiser Permanente
Chair, NCVHS and Ad Hoc Workgroup on NHIN

Jeffrey Blair, MBA
Director of Health Informatics, Lovelace Clinic Foundation
Vice-Chair, NCVHS Ad Hoc Workgroup on NHIN

Discussion Outline

- **NCVHS and the Nationwide Health Information Network (NHIN) Charge**
- **High Level Minimum but Inclusive Functional Requirements for an NHIN**
- **Policy Issues and Recommended Next Steps**

NCVHS

NCVHS

- **Statutory public advisory body to the Secretary of Health and Human Services**
  - **57 year history of advising HHS in the areas of health data, health statistics, privacy and national health information policy**
- **18 members**
  - **16 appointed by the Secretary, 2 by Congress**
  - **Leaders and experts in their fields**
- **Reputation for open, collaborative processes and the ability to deliver timely, thoughtful, and practical recommendations**

www.ncvhs.hhs.gov

NCVHS

Work of the NCVHS

- **Congressionally-mandated role in HIPAA**
  - **Administrative and financial transactions**
  - **Code Sets and Identifiers**
  - **Privacy and Security**
  - **Report and recommendations on clinical data standards and interoperability**
- **E-Prescribing standards under MMA**
- **Privacy, including recent report on Privacy and Confidentiality and the NHIN**
- **Population Health**
  - **Shaping a Health Statistics Vision for the 21st Century**

NCVHS

NCVHS NHIN Charge

- **The NCVHS was asked by ONC to review and synthesize the results of the June 28-29 Forum and the functional requirements identified by NHIN prototype consortia contractors that will:**
  - **Define a minimum, but inclusive, set of functional requirements necessary for NHIN activities**
  - **Be wrapped in a privacy and security structure that warrants the trust of the individual whose information is exchanged**
  - **Not include architectural decisions**

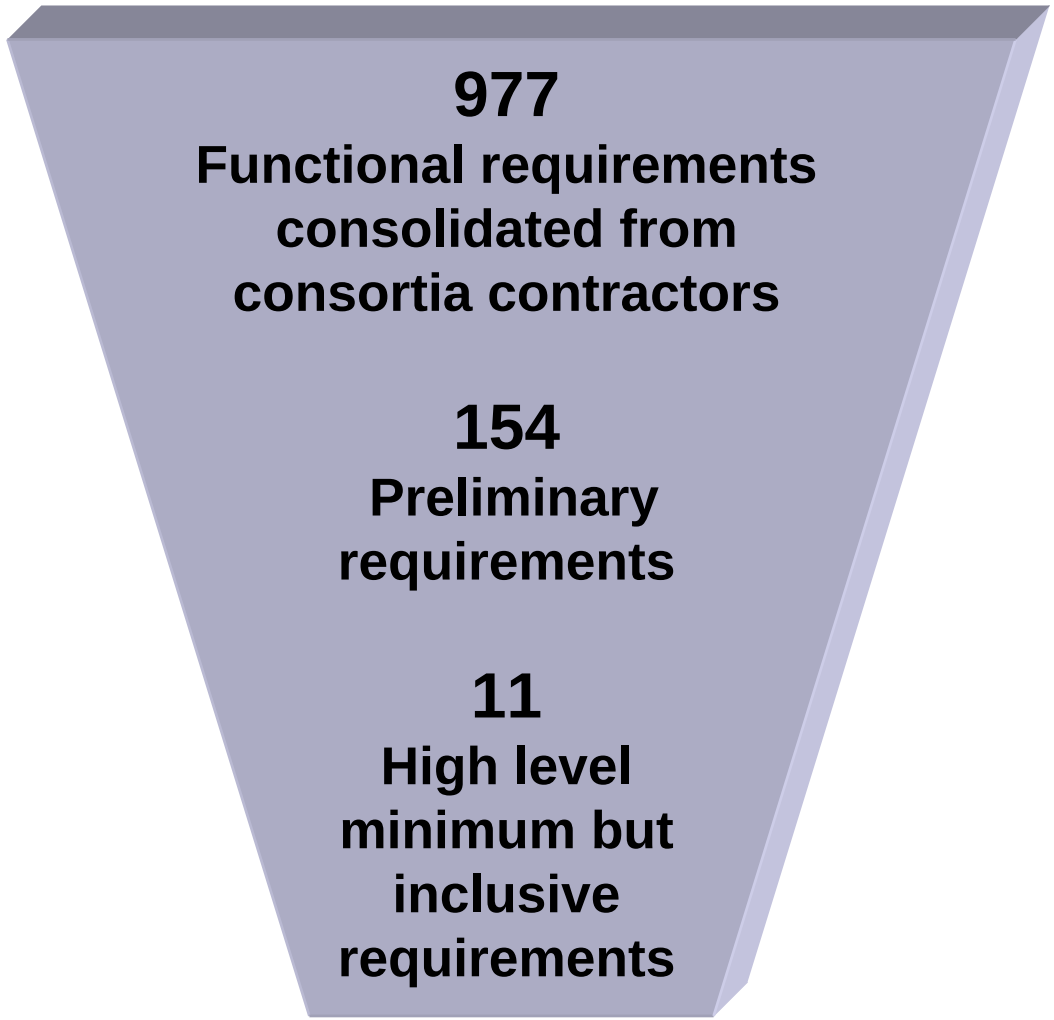
NCVHS

NCVHS Process

- Participation in ONC NHIN Forums on June 28-29, and October 16-17, 2006
- Public Hearings in Washington, DC
  - June 29, 2006
  - July 27-28, 2006
- Open public conference calls
  - August 31, 2006
  - October 3, 2006
- NCVHS Full Committee approval, October 30, 2006

NCVHS

Refinement of Functional Requirements



Observation

A nationwide health information network is not a specific entity, but a *system of systems . . .*

Functional requirements are about the entire initiative – not specific to an entity.

NCVHS

Recommendations

- **The NCVHS recommends that HHS adopt the set of minimum but inclusive high level functional requirements for the initial definition of a nationwide health information network**
  - **When variations exist and seem to be compatible with one another and do not impose an undue burden, the NCVHS includes them in the minimum but inclusive requirements**
  - **When variations exist, but appear to be incompatible or impose undue burden, the NCVHS recommends further study to reconcile incompatibilities**
- **The NCVHS also makes recommendations relative to specific gaps, policy issues, and next steps**

NCVHS

High Level Requirements

1. Certification
2. Authentication
3. Authorization
4. Person Identification
5. Location of Health Information
6. Transport and Content Standards
7. Data Transactions
8. Auditing and Logging
9. Time-sensitive Data Access
10. Communications
11. Data Storage

NCVHS

Functional Requirements

1. **Certification**
   Utilize a certification process that includes the requirements (standards and agreements) with which any entity's health information users must conform for exchange of data within a nationwide health information network.

2. **Authentication**
   Enable authentication of an entity's users (systems, software tools, and individuals) as well as independent users whenever location of information and/or data are exchanged within a nationwide health information network.

NCVHS

Functional Requirements *(cont'd)*

3. **Authorization**
   Facilitate management of an individual's permission/authorization to share information about location of health information or apply restrictions on access to specified health information.

4. **Person Identification**
   Utilize a standard person identity/information correlation process to uniquely identify an individual.

5. **Location of Health Information**
   Provide functionality that will locate where health information exists for identified individuals.

NCVHS

Functional Requirements *(cont'd)*

6. Transport and Content Standards

Transport types

- **Requests for and their responses to location of information**
- **Requests for data**
- **Data itself**
- **Other types of messages (such as notifications of the availability of new data)**

To destinations using general industry-recognized transport types and authorized recipient's specified mode

To and from electronic addresses that are unambiguously identified in a standardized manner

NCVHS

Functional Requirements *(cont'd)*

7. **Data Transactions**
   Provide functionality that will enable data transactions to occur among authorized entities and/or users upon specific trigger events, such as:

   - **Automatically sending final lab results for any previously sent preliminary results, sending any changes in medications prescribed, reporting medication errors, notifying Public Health about the occurrence of a bio-hazard event, informing individuals about the availability of a clinical trial, and determining hospital census for disaster planning**

Functional Requirements *(cont'd)*

8. **Auditing and Logging**
   Log and audit all (intentional or unintentional) connections and disconnections to network services and all network configuration changes, generating alerts/notifications for system activity outside the normal range of monitoring levels/thresholds.

9. **Time-sensitive Data Access**
   Enable time-sensitive data request/response interactions to specific target systems (e.g., query of immunization registry, request for current medication list).

Functional Requirements *(cont'd)*

10. **Communications**
    Communicate health information using HITSP-identified standard content and message formats.

11. **Data Storage**
    Enable the ability to aggregate data from disparate sources to facilitate communications.

    - **For example, temporarily hold information as it is being collected to communicate a concise summary of the information; or permanently store data from uncoordinated sources across time to support a data registry.**

NCVHS

Policy Issues

- Determining where responsibilities for the performance of various functional requirements may exist within an NHIN
- Assuring ongoing conformance of entities and their systems to the requirements for connectivity and exchange of data
- Ensuring accurate matching of individuals to their health information
  - Individual identification
  - Health information location
- Enabling communication of individual permissions or entity preferences concerning specific data

NCVHS

Policy Issues *(cont'd)*

- **Closing potential gaps**
  - **While baseline requirements for privacy, security, transactions and code sets, and identifiers are provided for by HIPAA for covered entities, equivalent requirements do not exist where there may be exchange of health information among non-covered entities or their business associates. Privacy measures, at least equal to those in HIPAA, should apply to all personal health record systems**
- **Collaborating with other public and private entities to develop a public awareness campaign**

NCVHS

Recommended Next Steps for HHS

- **Use these high level functional requirements as a way to communicate the nature of the NHIN initiative**
- **Test the functional requirements against other very common use cases, such as:**
  - **E-prescribing**
  - **Medication reconciliation**
  - **Use of clinical decision support**
  - **Chronic care, long term care, home health care, behavioral health care, and other settings for care**
  - **Reimbursement for healthcare services**
  - **Clinical research**
  - **Regulatory reporting**
  - **Selected services provided by public health departments**
- **Continue to refine the functional requirements based on NHIN prototype consortia contractors work and further industry experience**

NCVHS

Thank You for Your Attention...

Questions?

www.ncvhs.hhs.gov

NCVHS

Appendix

- **Membership of NCVHS Ad Hoc Workgroup on NHIN**
- **Detailed Functional Requirements**

NCVHS Ad Hoc Work Group on NHIN

Chair: Simon P. Cohn, M.D., M.P.H. **Kaiser Permanente**

Vice Chair: Jeffrey S. Blair, M.B.A. **Lovelace Clinic Foundation**

Vice Chair: Harry Reynolds **Blue Cross Blue Shield of North Carolina**

John P. Houston, J.D. **University of Pittsburgh Medical Center**

Stanley M. Huff, M.D. **University of Utah**

Mark A. Rothstein, J.D. **University of Louisville School of Medicine**

Paul Tang, M.D. **Palo Alto Medical Foundation**

Kevin C. Vigilante, M.D., M.P.H**. Booz-Allen & Hamilton**

Judith Warren, Ph.D., RN **University of Kansas School of Nursing**

Lead Staff: Mary Jo Deering **NCI**

Project Consultant: Margret Amatayakul

NCVHS

Functional Requirements

1. Certification: **Utilize a certification process that includes the requirements (standards and agreements) with which any entity's health information users must conform for exchange of data within a nationwide health information network.**

   1.1 Certification of an entity's ability to connect with a nationwide health information network should include a description of the level of participation for which an entity's information systems are capable. For example, a small provider may only be able to exchange data within a nationwide health information network via a gateway; another entity may only be able to exchange certain types of data electronically, or during certain hours.

NCVHS

Functional Requirements *(cont'd)*

2. Authentication: **Enable authentication of an entity's users (systems, software tools, and individuals) as well as independent users whenever location of information and/or data are exchanged within a nationwide health information network.**

2.1 Enable an entity to register (provide authorization and establish authentication processes for)[1] users to connect with a nationwide health information network in a manner consistent with all HIPAA and other applicable federal, state, and local privacy and security legislation/regulation.

2.2 Protect authentication credentials during transmission.

2.3 Provide mechanisms for non-repudiation when the policies of the parties exchanging data would require such service.

NCVHS

Functional Requirements *(cont'd)*

3. Authorization: **Facilitate management of an individual's permission/authorization to share information about location of health information or apply restrictions on access to specified health information.**

- **3.1 Enable entities and/or users to provide permissions, authorizations, and/or restrictions to share location information/data.**
- **3.2 Enable changes to be made in permissions, authorizations, and restrictions as requested by applicable entity and/or user.**
- **3.3 Allow access to location of information and/or data based only on permission/authorization status or emergency access as defined by law.**
- **3.4 Utilize standard authorization codes to convey permissions/authorizations to share data.**

NCVHS

Functional Requirements *(cont'd)*

3. Authorization ***(cont'd)***.

3.5 Enable participants in a nationwide health information network the ability to anonymize and re-link data to ensure its confidentiality, in accordance with policies of the relevant entities (e.g., public health departments).

3.6 Enable an entity to de-identify and aggregate data, for research or other purposes, upon request

4. Person Identification: **Utilize a standard person identity/information correlation process to uniquely identify an individual.**

4.1 Uniquely identify an individual through matching on a common set of various identifiers, such as last name, middle name, first name, date of birth, gender, etc.

4.2 Utilize a set of standard policies to resolve identity ambiguities, consistent with applicable tolerance levels for errors.

NCVHS

Functional Requirements *(cont'd)*

5. Location of Health Information: **Provide functionality that will locate where health information exists for identified individuals.**

5.1 **Utilize a standard, unique entity identifier (such as the ISO Object Identifier [OID] recommended by HITSP) to locate entities holding a specific individual's information.**

5.2 **Provide notification concerning location of information, pointers to the locations, metadata describing the nature of available data (e.g. radiology report, dates of service, advance directives), or the data itself to the requestor depending on the structure of the network used and agreements in place.**

5.3 **Provide information back to the authorized requestor if identity, location information, and/or data could not be determined and/or provided.**

NCVHS

Functional Requirements *(cont'd)*

6. Transport and Content Standards: **Transport requests for and their responses to location of information, requests for data, data itself, and other types of messages (such as notifications of the availability of new data) to destinations using general industry-recognized transport types (e.g., Internet Protocol Version 6 [IPv6]) and authorized recipient's specified mode (e.g., e-fax vs. transaction) to and from electronic addresses that are unambiguously identified in a standardized manner.**

6.1 Support content (vocabulary and code sets), application protocols, and message formats used for the exchange of health information within a nationwide health information network that conform to standard interoperability specifications.

NCVHS

Functional Requirements *(cont'd)*

6. Transport *(cont'd)*

6.2 Verify the integrity of data transmission using general industry recognized methods.

6.3 Enable standard information metadata (e.g., UML, XSD) to be included in message formats in order to convey, for example, sensitivity restrictions, individual permissions, and entity preferences.

6.4 Support the ability to include an error message service that notifies the requestor if authentication or authorization is not verified.

6.5 Support, based on an entity's query, the ability to temporarily hold and aggregate appropriate error messages or data until completely collected and ready for transmission to the requestor.

Functional Requirements *(cont'd)*

6. Transport ***(cont'd)***

6.6 **Support the ability to transport data, as directed, from one entity's system to another, such as from one personal health record to another personal health record, or from one provider's system to a personal health record.**

6.7 **Provide the ability to send/receive/retransmit acknowledgment of data requests or data content transmissions.**

6.8 **Enable entities and systems to transport updates, corrections, and amendments to health information in accordance with HIPAA requirements and internal policies.**

6.9 **Ensure that all parties involved in the transport of health information manage the connections with contingency plans, security incident procedures, ongoing evaluation and risk management, and retention of data and metadata (including audit logs) as required by state statutes and other requirements.**

NCVHS

Functional Requirements *(cont'd)*

7. Data Transactions: **Provide functionality that will enable data transactions to occur among authorized entities and/or users upon specific trigger events, such as to automatically send final lab results for any previously sent preliminary results, send any changes in medications prescribed, report medication errors, notify public health about the occurrence of a bio-hazard event, inform individuals about the availability of a clinical trial, determine hospital census for disaster planning, etc.**

7.1 Identify the source of any externally-provided data in whatever form the data may take (e.g., aggregated, anonymized, or identifiable).

7.2 Enable data filtering to allow for subscription and un-subscription to specified or all available future clinical events data.

NCVHS

Functional Requirements *(cont'd)*

7. Data Transactions *(cont'd)*

7.3 Enable entities to acquire data to monitor a previously detected event, generate alerts/notifications, or perform similar functions.

7.4 Enable entities to account for disclosures in accordance with HIPAA requirements if a covered entity; or provide an audit trail of accesses and disclosures if not a covered entity.

7.5 Support consistent methodology for granting and tracking access in applicable emergency situations (e.g., when normal authorizations for access are not feasible and special procedures are instituted to gain access to critical care data).

NCVHS

Functional Requirements *(cont'd)*

8. Auditing and Logging: **Log and audit all (intentional or unintentional) connections and disconnections to network services and all network configuration changes, generating alerts/notifications for system activity outside the normal range of monitoring levels/thresholds.**

- **8.1 Retain logs for period of time determined by law, accrediting agencies, marketplace, and entities.**
- **8.2 Protect audit data from unauthorized access/modification.**
- **8.3 Generate evidence to support incident management (investigations) and response processes (corrective action).**
- **8.4 Be guided in standards and policy adoption by regular risk assessments.**

NCVHS

Functional Requirements *(cont'd)*

9. Time-sensitive Data Access: **Enable time-sensitive data request/response interactions to specific target systems (e.g., query of immunization registry, request for current medication list).**

10. Communications: **Communicate health information using HITSP-identified standard content and message formats.**

10.1 **Enable mapping between versions of a standard and multiple standards, mapping terminologies and code sets, and supporting Americans with Disabilities Act Section 508 compliance.**

10.2 **Support display, entry, or retrieval of data in multiple ways as determined by the needs of the recipient.**

NCVHS

Functional Requirements *(cont'd)*

11. Data Storage: **Enable the ability to aggregate data from disparate sources to facilitate communications. For example, temporarily hold information as it is being collected to communicate a concise summary of the information; or permanently store data from uncoordinated sources across time to support a data registry.**

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

Standards - Update

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

December 12, 2006

AHIC Priorities and Use Cases

- Emergency Responder EHR Use Case is now available
- AHIC Workgroup priorities and issues into “prototype” use cases
  - Include as many AHIC priority areas as can be accommodated
  - Present a coherent approach to advancing and coordinating priorities across Workgroups
- January AHIC – discussion of different “prototype” use cases
  - Input on which use cases to use first
  - Refinement of included priorities

Standards Update

- HITSP / CCHIT joint working group established
  - Coordination of two processes
  - Recommendations for timing of HITSP “Interoperability Specifications” in certification process
- Standards to implementation
  - In general, one year is being discussed as the time between availability of implementation guidance and expectations for implementation (Executive Order and certification)

Standards Update

- HITSP and non – Standard Development Organization (SDO) content
  - HITSP “readiness criteria” seek openness in processes for included standards / implementation guidance
- SDO’s acceptance of responsibilities for implementation guidance maintenance will continue to be pushed
- As part of the review of its first year, HITSP has identified a series of steps to make it easier for small organizations to participate and work issues in the HITSP process