The Community

American Health Information Community

April 22, 2008
8:00 a.m. - 12:30 p.m.

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

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April 22, 2008

8:00 a.m. - 12:30 p.m. (ET)

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

8:00 a.m. **CALL TO ORDER –** *Secretary Leavitt*

8:05 a.m. **Introductory Comments** – *Secretary Leavitt*

8:15 a.m. **Comments** – *Kerry Weems, Vice-Chair, Acting Administrator Centers for Medicare and Medicaid Services*

8:25 a.m. **Comments** – *Robert M. Kolodner Office of the National Coordinator for Health Information Technology*

8:30 a.m. **AHIC 2.0 Successor - Update**
– *Mark McClellan, The Brookings Institution*

9:00 a.m. **AHIC Priorities/Use Case Options**
– *John Loonsk, Office of the National Coordinator for Health IT*

9:45 a.m. **Workgroup Presentations**

Quality Workgroup Recommendations
– *Carolyn Clancy, Agency for Healthcare Research & Quality, Co-Chair*
– *Richard Stephens, The Boeing Company, Co-Chair*

Joint Consumer Empowerment-EHR-Personalized Healthcare-Population Health-Quality Workgroups' Recommendations on Clinical Decision Support
– *John Glaser, Partners HealthCare, Chair*
– *Charles Friedman, Office of the National Coordinator for Health IT*

Consumer Empowerment Workgroup Recommendations
– *Nancy Davenport-Ennis, National Patient Advocate Foundation, Co-Chair*

Confidentiality, Privacy & Security Workgroup Recommendations
– *Kirk Nahra, Wiley Rein, Co-Chair*

11:30 a.m. **BREAK**

11:45 a.m. **State-Level Health Information Exchanges - Update**
– *Lynn Dierker, Colorado Health Institute*
– *Rachel Block, New York eHealth Collaborative*

12:15 p.m. **Public Comment**

12:30 p.m. **ADJOURN**

Meeting Report

American Health Information Community
February 26, 2008

The American Health Information Community (AHIC), a federally chartered commission formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within ten years, held its 20th meeting on February 26, 2008, at the Rosen Centre Hotel, 9840 International Drive, Orlando, FL, 32819, in conjunction with the Healthcare Information and Management Systems Society (HIMSS) annual conference.

The purpose of the meeting was to bring together Community members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to the Department of Health and Human Services (HHS) on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting focused on: (1) an update on the progress made towards convening AHIC 2.0; (2) updates on chartered value exchanges (CVEs) and the Nationwide Health Information Network (NHIN); (3) an overview of a 2007 health information exchange (HIE) survey; (4) recommendations from the Personalized Healthcare and Confidentiality, Privacy, and Security Workgroups; (5) recommendations from the Office of the National Coordinator for Health Information Technology (ONC) regarding enhancing data quality; and (6) a discussion of AHIC priorities for 2009 .

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

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

Call to Order

Joining Secretary Leavitt around the table were:

Robert Kolodner, MD, National Coordinator for Health Information Technology

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

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

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

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

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

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

Kevin Hutchinson, At-Large AHIC member; former CEO of Surescripts

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

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

Karen Patti, Benefits Manager, Wal-Mart (Ms. Patti represented John Menzer, Vice Chairman, Wal-Mart)

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

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

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

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

Approval of January 22, 2008, Meeting Minutes

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

Introductory Comments

Secretary Leavitt began by recommending that participants view the displays at the Healthcare Information and Management Systems Society (HIMSS) meeting that were being held concurrent to this AHIC meeting. He mentioned in particular a display that demonstrated how a patient's health data flowed and could be tracked through a particular medical incident. Technologically, it is possible for a patient to deploy the information in his or her personal health record (PHR) to a different physician for a new assessment. There are, however, policy questions about who owns that data, and whether a patient has the right to take the data and deploy them.

The Secretary reminded the Community that he has 329 days left in his term, and that AHIC 1.0 will transition to AHIC 2.0 before his term expires. To that end, LMI Government Consulting and The Brookings Institution have begun to work on this transition. Secretary Leavitt reminded the group that this transition must take place as quickly and as seamlessly as possible by late fall.

AHIC Vice Chair Kerry Weems noted that the day before this meeting, the third in a series of warnings about the cost of health care in America was received (the first warning was that Medicare was going to exceed 45 percent of general revenues; the second was that the Part A trust fund will not have sufficient

funding 11 years from now). Now, it has been announced that by 2017, national health expenditures will reach $4 trillion. National health expenditures are growing at 6.7 percent—three times the rate of inflation—and are very close to doubling every 10 years. Mr. Weems noted that EHRs can help control these costs.

Mr. Weems noted that the Centers for Medicare and Medicaid Services (CMS) is recruiting communities for a demonstration project involving EHRs in which physicians will be paid bonuses over a period of five years for performance with an EHR. CMS anticipates awarding this benefit to 12 communities. Mr. Weems explained that the definition of a "community" for the purposes of this project has been intentionally vague—it could represent a metropolitan area or an entire state, for example.

National Coordinator for Health Information Technology Dr. Robert Kolodner reported that the strategic plan currently is in the clearance process. The plan is a cooperative, collaborative effort across the federal government that outlines how the different activities across those federal entities that are involved in health care are working together to move forward the nationwide health information infrastructure. Also, work is progressing to collaborate with other federal agencies and private payers at two sites to evaluate both the cost and quality outcomes associated with the use of secure messaging between patients and providers, and particularly patients with chronic diseases. This work is in response to an initial set of recommendations proposed by the Chronic Care Workgroup that the Community sent to the Secretary. Dr. Kolodner also reported that a small grant award opportunity has been posted, inviting networks that exchange health information to implement the exchange of proposed standards currently under development.

Community member Kevin Hutchinson asked about Drug Enforcement Agency (DEA) issues related to controlled substances and electronic prescribing, and whether HHS could provide an update on activities in this area. Mr. Weems indicated that although he could not provide specific details, the DEA regulations are a priority within the Department. Secretary Leavitt indicated that these issues are being worked on, and expressed optimism that they would be resolved during the current administration.

Chartered Value Exchanges – Improving Quality and Value: Measure Nationally, Act Locally

Dr. Carolyn Clancy, Director of the Agency for Healthcare Research and Quality (AHRQ), echoed a comment made previously by Secretary Leavitt, that trust is necessary in order for health IT to transform health care, and that trust must be established locally. To that end, the Secretary has posed a challenge throughout with a vision of the future that gives consumers good information to make informed choices. Dr. Clancy presented a mock-up of a Web site that would demonstrate how far each institution is from a patient's home; how many patients have had a procedure done; and indicate the quality rating, the cost estimate, the patient's out-of-pocket cost verses what the insurer pays, and the patient assessment of care. Although most quality Web sites are not yet this sophisticated, there are insurers now who have this information in selected markets and it is clear that there is increasing demand. Dr. Clancy emphasized that public reporting is associated with significant improvements in care. However, there are multiple disparate monitoring initiatives, which can be problematic. There are also private—and now, publicly funded—initiatives that link payment with performance.

Dr. Clancy reported that over the past few years she is seeing an emerging recognition among multiple stakeholders, consumers, providers, insurers, physicians, and hospitals that there needs to be one set of measures. Quality alliances have emerged, including the Hospital Quality Alliance, the AQA Alliance, the Quality Alliance Steering Committee, and others. The Quality Alliance Steering Committee is co-

chaired by Dr. Mark McClellan of Brookings and Dr. Clancy, representing important opportunities for connectivity as the AHIC successor develops.

Dr. Clancy discussed the four cornerstones of value-driven health care:

- **Quality Standards:** Design systems to collect quality of care information and define what constitutes quality health care.

- **Price Standards:** Aggregate claims information to enable cost comparisons between specific doctors and hospitals.

- **Interoperability Standards:** Set common technical standards for quick and secure communication and data exchange.

- **Incentives:** Reward those who provide and purchase high-quality and competitively priced health care.

Dr. Clancy then presented a national framework for quality and cost transparency for high-value care, noting that for most clinicians, doctors, nurses, and pharmacists, at best the quality enterprise is not painful—but it is rarely, if ever, value-added. Yet when the power of health information technology is connected to efforts to improve value, there is obvious potential. The following are needed to advance the goals associated with the framework for quality and cost transparency for high-value care: (1) good measures and data (local data, but national benchmarks); (2) strong local coalitions; (3) evidence-based reporting and payment strategies; (4) evidence, tools, and strategies for improvement; and (5) collaboration across sites.

Efforts have been underway for the past year on working towards a "value exchange." Dr. Clancy noted that the first class of value exchanges would be charted the week of this AHIC meeting. She explained that a value exchange is a local organization of health care stakeholders recognized for meeting the following criteria: (1) engagement with payers, plans, providers, and consumers; (2) a non-profit entity; and (3) a focus on improving value through the four cornerstones of value-driven health care. These value exchanges will serve as hubs for stakeholder engagement and information sharing. They will use standardized performance information to partner with providers in care improvement, facilitate consumer decision making through public reporting, and promote effective payment policies that create more value for patients. They will also participate in a value exchange network to further promising practices or lessons learned, and continually refine their efforts.

Value exchanges will have access to information derived from pooling Medicare data with private sector data across multiple payers at the physician group level. CMS will "crunch the numbers," and the value exchanges will disseminate the results, with the objective of providing a comprehensive picture of physician quality in each community. Dr. Clancy presented a map showing the location of 14 chartered value exchanges across the United States

The AHRQ has established a Learning Network for Value Initiative, with the goal of having all community leaders become or join charted value exchanges. The Network will:

- Encourage sharing of experiences and lessons learned.

- Identify and share promising practices that improve health care value.

- Identify gaps where innovation is needed.
- Provide face-to-face and virtual opportunities for peer-to-peer sharing of experience.
- Identify interventions or tactics that yield the best outcomes.
- Translate interventions into adaptable change strategies.
- Create a user-friendly, Web-based knowledge repository.

Overarching issues and challenges facing these efforts include questions such as whether consumers have the information they need to make choices, and whether providers are given the tools they need to improve. An additional challenge is defining what "value" is. Dr. Clancy noted that this work relates to AHIC activities in recent years. She described the role of the AHIC/health IT enterprise, noting that "information governance" is essential to value-driven health care. The relationship between the chartered value exchanges and HIEs is very much a work in progress; better outcomes for consumers is the most important goal associated with the quality enterprise.

Discussion Highlights

"I believe the granting of a charter is essentially the granting of a local control franchise, if you will. Franchise is the wrong term, but it will give you a sense that we want to brand these organizations so as to connect their use of standards." – Secretary Leavitt

"I'm concerned about what appears to be outstanding work that's being done at random, as opposed to following a roadmap that says 'this is how we're going to get to our end result.' And it seems to take me back to a lot of how our health care policy has been made over time, and that's by anecdotes. There is a mistake that occurs, a bad outcome occurs, and all of a sudden we have a law that's addressing some little tiny piece of the health care sector, which has untold, unintended consequences. But because we didn't follow a plan and we didn't lay out a map that said 'these are the highest priority things we need to get done first,' we tend to kind of cut all over the place." – Mr. Serota

"It's easy enough to say that costs are going up, up, up, and much, much faster than quality is improving. Quality is improving, but the gap is fairly striking, something like seven percent versus two to three percent, cost versus quality." – Dr. Clancy

"There are huge differences in the distribution of providers, facilities, capacity in the community and so forth; so, a solution that's going to be very effective in Minnesota may not have any meaning in Florida, and vice versa. So I think the real challenge you're going to have, as you work through this transition…is figuring out how detailed to make that map and how general. That said, I think it would give lots of people a sense of confidence to have the beginnings of a map moving forward so that they can begin to imagine what this trajectory looks like." – Dr. Clancy

"It is not a mistake that we don't have price transparency. You can't have price transparency and cost shifting. They are mutually exclusive. And so we have to address that. I'm not for universal entitlement, necessarily, but universal enfranchisement I am for. But we have to figure out a way to get there, to get to price transparency." – Mr. Roob

"Two questions. One is, I'm confused about the financial model for this. How does the money work to support the entity and its sustenance? And the second question is, is it conceivable that a local health department could serve as the locus for a value exchange?" – Dr. Geberding

"If a local health department in reverse order could actually engage stakeholders, payers, consumers, providers and so forth, there is no particular reason why they couldn't. We have asked that they are a nonprofit entity, but beyond that, it feels like health departments are probably a not profitable entity. So that makes sense to me." – Dr. Clancy

"They are not actually getting grants here or contracts. What they are getting are investments solely in this learning network. So to some extent, we're taking advantage of both the fact that there were collaborations that were nascent or already established in some communities, and in some cases we're building on investments made by the Robert Wood Johnson Foundation and others. To that end, we have made every effort possible to make sure that our efforts are aligned, that we're not telling them one thing and other funders are telling them something else." – Dr. Clancy

AHIC 2.0 Successor Update – LMI-Brookings Approach To Convening the AHIC Successor

Mr. Arthur Hamerschlag, Senior Fellow at LMI, explained that the LMI-Brookings team is excited to have received the grant and is ready to accept the challenge of transitioning to AHIC 2.0 within the timeframe stipulated by HHS. Dr. Mark McClellan, Director of the Engelberg Center for Health Care Reform at The Brookings Institution, participated in the meeting via conference call and emphasized that all of the Community's ongoing activities will continue to be important to the successor group. The goal is not to resolve every obstacle now facing AHIC, but to make identifiable progress and work quickly in a limited timeframe to create a sustainable framework for future progress.

Dr. McClellan discussed the process by which LMI-Brookings will seek input and recommendations from a range of public and private stakeholders on the formation of the AHIC successor in the areas of management, strategic direction, key activities, and business modeling. It is planned that the LMI-Brookings team and their collaborators will engage a broad range of national experts, policymakers, organizations, and individuals, to gather the insights needed to build a balanced, inclusive, transparent, and results-oriented AHIC successor. This successor will be an independent and sustainable public/private partnership that brings together the best of public and private sector efforts, significantly contributes to the creation and use of an interoperable nationwide health information system that is effective in improving quality of care and lowering costs, and eventually realizes interoperability in the health care system.

Dr. McClellan then outlined the following six principles that will guide the design of the organization: (1) the entity should exist for the benefit of the individual/consumer; (2) the entity should establish and enhance trust among stakeholders; (3) the entity should have broad participation across health care industry stakeholders; (4) the governing bodies of the entity should have necessary authority to make decisions, but only the authority that is necessary to do this; (5) the entity should be feasible to establish and operate, and sustainable into the future; and (6) the entity should be adaptable over time and across future circumstances. In the coming weeks, the team's main goal is to identify the keys to an effective AHIC successor. This includes identifying and clarifying the focus and scope for the successor organization, and then implementing the effective structures and processes for achieving sustainable progress. In order to do this, the team must understand the main attributes of the successor organization's membership, its governance, and its model for financial sustainability.

Mr. Hamerschlag identified members of the multidisciplinary team that will be needed to address all aspects of establishing the AHIC Successor. These include:

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

In addition to staff from Brookings and LMI, the AHIC successor effort will rely on communications expertise from Edelman and Nahigian Strategies; legal counsel from Sonnenschein, Nath, and Rosenthal; and management consulting from Booz Allen Hamilton.

Mr. Hamerschlag explained that the successor organization will be established within four months and transitioned to full operation after 11 months. Stage one—the first four months—will involve planning and establishing the AHIC successor. Stage one activities will focus on designing the governance structure, addressing incorporation and legal considerations, designing membership processes, addressing financial sustainability, and developing transition processes. After that four-month period, the new successor organization will be established, at least on paper. Stage two (months 5 through 10) will involve establishing the Board of Directors, hiring the Chief Executive Officer, transitioning activities from the current AHIC and its Workgroups to this new organization, expanding the membership, and developing strategic plans for sustainability. By the eleventh month of this transition process, it is planned for the successor entity to be fully functional.

Mr. Hamerschlag explained that planning groups will be established during stage on and will focus on four areas: (1) governance, (2) membership, (3) sustainability, and (4) transition planning. Each group will address issues central to AHIC 2.0 and will work towards specific deliverables that the grant award specified. Public meetings have been planned for March 10, April 8, and May 30. The intent is to ensure that there is a formal mechanism for public input, and that the process adheres to the values of transparency and openness. To have credibility with the many stakeholders that will be invested in AHIC 2.0, they must be a part of the process. There also will be several planned "listening opportunities," which will involve discussions about the plans for AHIC 2.0.

Mr. Hamerschlag then provided more detail on the planning groups, explaining that these groups will be led by co-chairs identified by LMI-Brookings with input from stakeholders. Depending on its respective charge, each planning group will have the support of legal, marketing, or accounting expertise. Each planning group's target size is 20 members; planning group members will be selected from across the stakeholder community and will include federal stakeholders. The Organization and Governance Planning Group will focus on identifying the organizational mode for AHIC 2.0 and defining the roles and responsibilities of the Board of Directors. The Membership Planning Group will address how the many interested communities are represented to the AHIC successor, whether membership is paid or unpaid, and other issues. The Business Sustainability Planning Group will define how to create a sound

basis for financial sustainability. The Transition Planning Group will steer activities relating to the handoff from the current AHIC, its Workgroups, and its associated organizations to the new AHIC 2.0.

Discussion Highlights

"To me, the most critical group here is the business sustainability group. Are there any models that you see out there that are interesting or instructive for the successor to consider?"
– Mr. Isenstein

"All of these have to succeed if any are going to succeed…The intent is to make sure that there are folks on the group who have actual experience in setting up organizations. Membership types, not for profits, trade associations, whatever, who have got experience, recent experience and expertise in doing that, so they can bring their experience and knowledge to the group as they think about that sustainability."
– Mr. Hamerschlag

"Any merger acquisition transaction involving a successor needs to have a continuity of one to the other, and I'm hoping that somewhere, certain of the non-public members who have so graciously served on this one would be considered for some kind of bridging activity to the next one. I don't say that to in any way alarm those who think they're going to go home when this is done, but there will be a need for the kind of continuity that is required in order to make this transition good." – Secretary Leavitt

"One of the things we have taken very seriously, given the amount of activity that has to take place in a very short period of time, and the interconnected nature of those activities, is the requirement to have a very sound project plan, milestones, deliverables…and if you're behind schedule, how do you get back on schedule? So a lot of the work behind the scenes has been focused on those sorts of activities."
– Mr. Hamerschlag

"The Web site is ahicsuccessor.org. There is a "Contact Us" button, and I think under that, there is a nomination form…our hope is we get a lot of nominations from a lot of very interested people, and then the group chairs have a real challenge on paring those nominations down to a tight and functioning group." – Mr. Hamerschlag

"We look forward to working with you and moving forward. And also for the federal members of the AHIC, just to let you know, my staff will be contacting you to find out who from your organization you'd like to have involved. We'll also be going to the non-AHIC federal entities that are involved in health and getting nominations for them, and working together to identify individuals to work on the planning groups as the federal representatives, and also making sure that we have good communication."
– Dr. Kolodner

An Overview of Results of 2007 Survey on Health Information Exchange

Janet Marchibroda, Chief Executive Officer of the eHealth Initiative and Foundation, explained that the eHealth Initiative is a nonprofit, multi-stakeholder organization that engages leaders at the national and local level within every sector of health care. Beginning four years ago, the group has taken an annual survey of improvements at the local level of health care using information technology.

On December 19, the results of the 2007 Fourth Annual Survey of Health Information Exchange at the State, Regional, and Community Levels were released, showing continuing maturation of HIE efforts across the country. Ms. Marchibroda indicated that 130 initiatives responded to the survey. Of these, 20 are just getting started, 68 are in the process of implementation, 32 are operational, five are no longer

moving forward, and five did not respond to the "stage of development question in the survey. Thirty of the 2006 respondents showed an advancement in their stage of development. Ms. Marchibroda reported that the most important factors driving advancement were: (1) improving quality (94%), (2) improving patient safety (80%), (3) addressing inefficiencies experienced by providers (61%), and addressing rising health care costs (59%). The majority of survey respondents are non-profit organizations.

In terms of where HIEs receive funding, Ms. Marchibroda indicated that there has been an increase in upfront funding from hospitals (increasing from 24 percent in 2006 to 53 percent in 2007). Funding from the federal government increased from 42 percent to 44 percent; funding from state or local grants and contracts increased from 29 percent to 43 percent; funding from payers increased from 12 percent to 32 percent; and philanthropies increased their giving from 23 percent to 31 percent.

The survey took a close look at the 32 operational initiatives. Ms. Marchibroda reminded Community members that the definition of an operational initiative is one that is a fully operational health information organization, transmitting data that is used by health care stakeholders. Three quarters of the operational initiatives responding to the survey are no longer dependent on "non-operating revenues" (e.g., grants). All operational initiatives reporting in 2006 are still operational. The 32 operational initiatives are exchanging data such as outpatient episodes, laboratory data, inpatient episodes, radiology results, etc.

With regard to the services (with a focus on improving care delivery) offered by these 32 operational initiatives, three-quarters are engaged in delivering laboratory test results. Additional services include clinical documentation (63 percent), consultation/referral (54 percent), enrollment or eligibility checking (54 percent), etc. Ms. Marchibroda cited the Indiana HIE as a pioneer in terms of providing these types of services. She noted that there is an increasing number of groups focusing on improving population health. Between one quarter and one third of these organizations are examining activities such as public health surveillance, quality improvement, performance reporting, chronic care management, and others—areas relating to improving not only care delivery within the physician's office, but also improving population health.

Of the 32 operational initiatives, one-half of them obtained startup funding from grants and contracts from the federal government. However, these dollars couldn't be relied on in terms of the initiatives moving forward. More and more of these groups are receiving upfront funding from hospitals and/or health plans. Hospitals also are the top funding source for ongoing operations. Private payers, physician practices, laboratories, and others are providing financial support for ongoing operations as well.

Ms. Marchibroda reported that the most difficult challenge facing these groups has been related to the development of sustainable business models. A number of advanced-stage initiatives are able to generate revenue to support their ongoing operations, however. She noted that analysis of the data being exchanged by these operational initiatives and the services that are being provided indicates that there are a number of near-term opportunities for leveraging these local initiatives for national and local efforts. These efforts could be centered on quality improvement and performance reporting, chronic care and disease management, drug safety, assessing both the risks and benefits of medications, public health needs, comparative effectiveness, and consumer access to clinical information.

Discussion Highlights

"We're connecting the clinicians, and the hospitals, and in some cases the health plans, particularly in Indiana, and increasingly, we're very excited about the work of the value exchanges, they tell us there are…two big reasons. The lack of a business case for consumer access to the electronic information, number one. And so as these initiatives are trying to deliver value to a customer within their markets, and who's willing to pay for that value, we haven't quite tackled that. But then the second issue, I think that

there is some nervousness around the liability and the policies for information sharing that make folks nervous about this. I know some new models are emerging now to address that, as well as policies. And I think in tackling those two things, we're hopeful that these numbers will go up." – Ms. Marchibroda

"I'm really fascinated to see what happens with [the Cleveland Clinic arrangement with Google], because we don't have a patient portal. I've not seen a patient portal into one of these systems." – Mr. Roob

"Our perspective is, the outcome of the data, the analysis of the data belongs to us, because we did it. You can get all the way back to ingredient cost and say, 'but ultimately you did it, based on my data.' We scrambled the data. We de-identified the data, so from our perspective, it isn't any one individual's, it's really a community asset, a community being all of our members, and then we put it out there." – Mr. Serota

"I think if you assume that my data is my data, and we can stipulate that's the case, is there anything particularly in these environments that are federally supported, at least in part, that would prohibit a private sector enterprise like a Quicken to come in and to innovate around the system? Is it allowable to have private sector innovators come in and try to create consumer portals and create an independent business case for that?" – Dr. Geberding

"They are doing it now." – Dr. Kolodner

"So that's not being captured in this assessment, but it is going on." – Dr. Geberding

"There actually are different models for exchanging health information. The ones that we've been talking about the longest are the ones that are kind of geographically based, area-based, but these others, whether they be integrated delivery networks, integrated delivery systems, some of which, like Cleveland Clinic are providing portals, or whether they are pure portal model kinds of entities, or specialty networks or other things, I think we're seeing an enrichment and a broadening of the kinds of entities that we're looking at in the space." – Dr. Kolodner

"We want to make sure that we're doing with the infrastructure that we put in place, and the approach, is to not predetermine which models are best, other than to make sure that certain fundamental principals are honored in terms of protecting the individual and the privacy of having a secure system." – Dr. Kolodner

"When we're talking about the sharing of information and the rights to the sharing of the information, we talk a lot about consumers controlling their information, and their access to that information. But we have to remember that there is another layer of depth of information that really only clinicians and providers of care have an understanding of how to use, and how to share for the purpose of treatment of care that consumers in the average consumer won't have that depth of knowledge of understanding of that information…the depth of the information for consumers versus clinicians is very, very different." – Mr. Hutchinson

"Ten or 20 years from now that may not be the case. And if data is standardized, then there certainly are opportunities for innovators to be able to take these complex concepts and have different ways of providing those." – Dr. Kolodner

"I would think ten years ago, UPS and airlines probably never figured that the average consumer would care about load limits, seat assignments…now as we have become more accustomed to engaging those entities, we drive more of the process. They've had to take that layer of expertise and, you know, not dumb it down for us, but provide an interpretation for us, which has really empowered us as flyers and

package shippers. I want to know where my book is at all times along the process. So I think the market can do the same thing, once you begin to get the consumer involved in the process." – Mr. Devore

"My fear is that we keep layering barriers in the way of progress, because if we start talking about EHR data, you better deal with the tort system before you start talking about allowing patients to see every note and every comment that a physician makes, lest they won't make them." – Mr. Serota

"And I think what we've done to speak to the health literacy issue is, when a lab is presented to them, we provide them links to user friendly things written in more lay terms to explain the lab, for example. And I think that's the direction that most of the portals that have been successful have done to really make that a tool for the patient to find more information." – Ms. Graham

"I think these exchanges or these entities will have to find a business case very quickly…because patients are going to be demanding this interoperability and this exchange of information…and the quicker they demand it, the faster it's going to happen." – Dr. Henley

"People are hungry for this information, and will empower themselves to participate in their medical decisions. And I think those of us who are of the old school haven't quite caught on to the fact that is a tsunami of empowerment that is on our doorstep now. And we can't hold it back. We just have to figure out how to enable it in a way that's as constructive as possible. It's so exciting." – Dr. Geberding

"Every single insurer has their own internal coding schemes, and there is no reason they would have any consistency with other insurers, so the literal aggregation just of claims is going to be very messy." – Dr. Clancy

"I think the other issue that is going to be very unique in the quality world and has relevance here are the series of agreements recently signed in New York State between health insurers and the Attorney General. The original issue was the attorney general saying, 'we don't want you to provide information to consumers because you're really just going to be encouraging them to go to low-cost doctors and calling that quality. And so we're going to protect them from that misinformation.' And a number of consumers and employers worked with the HA staff to say that's not exactly how we would like to be protected." – Dr. Clancy

Nationwide Health Information Network: Data Use and Reciprocal Support

Dr. John Loonsk, Director of the Office of Interoperability and Standards, ONC, described some of the agreements that need to be in place to develop the types of trust arrangements necessary for an NHIN. He explained that the NHIN is a shared set of standards and agreements that allow for HIE among multiple participants. Oftentimes today, information is shared in a point-to-point fashion, with a data originator and a data recipient. Sometimes there is an intermediary, but frequently not. What is envisioned in the NHIN is a network of trust that is built from a series of other networks. In that regard, the technical standards as well as the agreements need to be in place to allow for that trust to be perpetuated in that more complicated array of participants. These activities need to take place in concert with state laws and regulations, with federal laws and regulations, and a series of other considerations. Dr. Loonsk then discussed the NHIN Cooperative's efforts to develop such an agreement that would allow for the different participants to work together in this network of networks.

Dr. Loonsk presented a slide illustrating some of the different types of HIEs that will participate in the NHIN, including geographic national health information exchanges (NHIEs), specialty network NHIEs, personally controlled health record network NHIEs, etc. As a part of the grant process that Dr. Kolodner

alluded to earlier, the ONC has made available grant funds to support integrated delivery system participation and foster participation by personally controlled health record networks or support services.

Dr. Loonsk explained that in this "network of networks" environment, one provider may share and have an agreement with a geographic HIE through which they are working. In the context of a network of networks, however, this refers to a relationship that may extend out to another HIE, and to another provider who is positioned off of that one. This manner of trust network needs to be implemented to have assurances that these data will be securely exchanged, and that patient confidentiality will be maintained. Dr. Loonsk reviewed several possible tools for ensuring policies and standards, in terms of state and federal laws and regulations, certification, accreditation, governance, and data use and reciprocal support agreements (DURSAs). He explained that DURSAs are not just about how data are shared, but about how one HIE supports another HIE. If one is making a request of another, how do they respond? What are their responsibilities in that response? DURSAs are broader than typical data sharing agreements, because they also need to consider some of the behaviors of the participants.

Dr. Loonsk noted that the trial implementations that will be demonstrated this fall for the NHIN involve test data; there will be a DURSA for the test activities to be effective March 2008. In November 2008, there should be a DURSA for live, production data with all of the federal agencies that are participating in the trial implementations of the NHIN.

Mr. Steve Gravely, Counsel from MedVirginia, represents one of the HIEs participating in the NIHN and co-chairs a DURSA workgroup. He added that DURSAs:

- Are multi-party agreements among participating HIEs that define how the HIEs relate to each other.
- Creates the legal framework within which HIEs can exchange data.
- Assume that each HIE has trust relationships in place with its participants.
- Include participants that expect the HIE to protect their interests when exchanging data with other HIEs.
- Are being designed to accommodate many kinds of HIE organizations.

Mr. Gravely explained that the purpose of the document is to define how independent legal entities relate to each other in the context of the NHIN and to create the legal framework for such activity. There is no legal framework now for how an HIE in Virginia, an HIE in New York, an HIE in California, and an HIE in Indianapolis all relate to each other. So, the DURSA is the vehicle to create that framework through contract law, understanding that at the state and federal levels, there will continue to be a body of law that evolves to address this.

There are a number of assumptions that underlie the DURSA. Most important is the assumption that each of the HIEs, in their own right, has a complete and robust infrastructure that they bring to the table when they participate, with fully developed trust relationships within their own organization. That would include data use and support agreements with their data suppliers, with their data users, privacy and security policies and procedures, audit protocols, and breach protocols. All of the HIEs that will be signatories to the DURSA have those infrastructures in place. Each of the participants in the HIE will have expectations of the other HIEs, revolving around what they bring to the table and the way they conduct themselves within the context of the HIE.

There are community standards for conduct, and the DURSA attempts to reflect this. The DURSA is not necessarily being prescriptive about what those standards are, but it attempts to reflect that such standards are important. Other Workgroups are working to develop those standards. Mr. Gravely indicated that he believes they have succeeded in creating a document that is flexible, scalable, and that can accommodate not only test data but live data. The DURSA can serve the private sector and the federal partners with a broad sharing arrangement. Key components of the DURSA are as follows:

- **Privacy Protection:** HIEs will be exchanging personal health information, so compliance with the Health Information Portability and Accountability Act (HIPAA) is essential.

- **Reciprocal Duties:** Including the duty to only forward data in response to an authenticated request for data, and the duty to respond to a valid request.

- **Performance Specifications:** The DURSA incorporates the interoperability performance specifications being developed by the NHIN. HIEs must comply with these specifications.

- **Warranty:** Comprehensive representations and warranties are included, and the HIE warrants that it is sending a complete and accurate copy of the information that it has.

- **Dispute Resolution:** The current draft calls for binding arbitration; government participants may not be able to agree to this.

- **Entity Protection:** The goal is that each HIE is financially and legally protected from damages caused by another HIE's breach of the DURSA. There is a challenge due to restriction on government participants' ability to indemnify private parties.

Several challenges remain to be solved in terms of using live data in a DURSA. The Workgroup is trying to create a framework that will resolve these issues so that they do not become barriers to participation. These issues include: (1) the exchange of live data exposes all participants to significantly greater risks; and (2) specific issues that currently are being worked on, such as governing law, necessary patient consent or authorization for exchange of live data under some laws and regulations, reporting of suspected or actual breaches within each HIE that are unrelated to data exchange, how to contain liability to party that caused the breach, the exchange of "high risk" data, and evaluation of the impact of federal laws.

Discussion Highlights

"Having the patient play a more prominent role addresses some of the issues. It introduces others, as the discussion pointed to this morning. So that is an integral consideration of what's being looked at in the context of the DURSA...That is how we are thinking of this moving forward. And it helps with some issues, and it obviously complicates others." – Dr. Loonsk

"One of the core services of the NHIN is to support lookup services, so data can be identified where they exist, so that the patient can retrieve them, but also where a provider is trying to find the data that is relevant to a patient for which they're providing care." – Dr. Loonsk

"What we need to do is to put in place something that allows competition to occur while also making sure that we have a secure exchange of information, knowing that some people will choose not to have a personal health record on the Web, but still want to get the care as they move around the community." –Dr. Kolodner

"So what the NHIN is about, from a technical standpoint, is establishing those standards so those all can work together, and what we're talking about here is an agreement that is an analog to how those different trust relationships exist to make that happen." – Dr. Loonsk

"The point is to make sure we don't get caught in something that other industries sometimes get caught [in], where you get large players who have incompatible solutions, and you get into VHS/Beta wars, or HD-DVD/BlueRay wars that slow things down. So I think part of what we're doing is just having enough to not to decide the solution, but to preclude the things that can get in the way and slow us down from getting there." – Dr. Kolodner

"Around the world, I know there are certainly other countries that have much higher adoption rates of EHRs, and some with higher rates of PHRs. There are a few that are just now starting to connect and move data. But they're early. I think…we're right up there near the edge, as far as this goes. We're very much lower, as far as adoption, but in terms of beginning to set up a connectivity, I think there isn't a standard out there yet that's dominant in the national, international community." – Dr. Kolodner

"Today, providers receive requests—physicians, in particular, receive requests all the time, from patients that want their records moved to another physician…There are specific state laws that spell out what that physician's obligations are, both in terms of responding to the request and in terms of retaining records, either copies or originals of those records. Most state law says that the record, itself, actually belongs to the physician, although it's the patient's data. And that's an issue that is at the center of what we're talking about right now. However, there is a current world infrastructure for that, and while those state laws don't contemplate HIEs, we are extrapolating that to the HIEs. And the state law is really trying to play catch-up with the evolving technological frontier." – Mr. Gravely

"Well, most of the HIEs that I'm familiar with have terms of use that are exactly what you just described. They're pop-ups on their screens and usually they're for first time logins by physicians. And then there is the "I agree" button at the bottom…Whoever has access to that system agrees to the terms of use, and what that really describes is, how is that user going to interact with that organization? And [stipulates] they're not going to try to copy the architecture. They're not going to put in malicious viruses, et cetera." – Mr. Gravely

"The DURSA really is a different relationship. It is attempting to govern the host, the organization that you're logging into, in this case an HIE. It's trying to govern how that HIE interacts with a dozen other HIEs around the country. So it's distinct from the terms of use." – Mr. Gravely

"So I'm subscribing to a treaty as opposed to agreeing to a set of terms." – Secretary Leavitt

"Yes, sir. That's a good analogy, and it's not that far off, because each of the HIEs are legally independent organizations that are participating voluntarily in this community." – Mr. Gravely

Personalized Health Care Workgroup Recommendations

Community member and Personalized Health Care Workgroup Co-Chair, Dr. Douglas Henley, reminded the Community of the definition of personalized health care that was adopted several months ago: a consumer-centric system in which clinicians customize diagnostic, treatment, and management plans. The Workgroup has identified four perspectives as being important to the vision of personalized health care: (1) consumer, (2) clinician, (3) researcher, and (4) health plan/payer. In addition, the Workgroup identified four priorities across each perspective (genetic/genomic tests; family health history;

confidentiality, privacy, and security; and clinical decision support). Dr. Henley explained that the Personalized Health Care Workgroup has developed a series of recommendations that relate to newborn screening. He reported that there are more than 4 million births in this country per year; it is important to ensure that newborn screening information can be electronically captured and transmitted to the places that it needs to be in order to help in the early diagnosis and intervention and treatment of children who have a positive test result. Newborn screening illustrates the need to standardize the key data elements and terminologies.

1. The Workgroup's other Co-Chair, Dr. John Glaser of Partners HealthCare, noted that as the science of medicine evolves, it is likely that the number of tests carried out early in a child's life will increase, as better understanding is gained of the types of diseases, and how best to treat them. Dr. Glaser explained that there are three overarching goals for newborn screening. The first is to identify, develop, and encourage adoption of appropriate standards by instrument manufacturers, public health laboratories, and EHR vendors, to facilitate interoperable exchange of newborn screening test results (including genetic, metabolic, and hearing tests). The second goal is to ensure timely communication among state public health laboratories and newborn nurseries conducting screening and immediate follow-up, and the primary care professionals and specialists who are involved in the diagnosis, treatment, and management of the affected infants. The third goal is promoting the potential to support newborn screening program evaluations and quality improvement efforts.

Dr. Glaser then presented the Workgroup's recommendations as follows:

Newborn Screening Information Exchange

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

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

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

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

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

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

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

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

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

Confidentiality, Privacy, and Security Issues Specific to Newborn Screening

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

Reporting of Newborn Screening Results To Improve Population Health

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

For the remainder of this year, the Workgroup will be focusing on a high-level use case related to newborn screening. Later this year, the Workgroup hopes to bring some additional recommendations about clinical decision support and the area of pharmacogenomics.

Discussion Highlights

"This last recommendation makes references to an advisory committee, and it might be hard for the department to back off of that internally. But for people who are familiar with federal advisory committees, that terminology takes on a very special meaning, and I think the spirit here is to get advice from external stakeholders, and there are a lot of different ways to do that." – Dr. Gerberding

"Over time, if you ask us to collect the data, and use it in an MMIS system, it will be relatively inexpensive, over time, for us to collect that data and effectively transmit it and create a kind of national platform for at least half the births in the country. So I thank the task force for the use of the very precise language that you put in here." – Dr. Henley

"We will undoubtedly have an opportunity to talk about some of the priority items in the next meeting. And we'll now go back to HHS and look at which of those can be ordered up in a relatively near term and long term." – Secretary Leavitt

"There is one that we might want to separate out that we don't need to advance, and that is [Recommendation] 1.0.1, which basically is a recommendation of the Workgroup to itself, which we can proceed on and we don't need to move forward."
– Dr. Kolodner

Following this discussion, The Community accepted these recommendations by consensus and advanced them to the Secretary for consideration (with the exception of Recommendation 1.0.1, as noted above).

Confidentiality, Privacy, and Security Workgroup Recommendations

Confidentiality, Privacy, and Security Workgroup Co-Chair Ms. Deven McGraw reminded the Community that in June 2008, the Workgroup recommended that all persons or entities that participate directly in or comprise an electronic HIE network through which individually identifiable health information is stored, compiled, transmitted, modified or accessed should be required to meet enforceable privacy and security criteria at least equivalent to any relevant HIPAA requirements. The Workgroup further recommended that persons or entities that currently function as business associates, but are essentially carrying out that direct participation in an HIE network with identifiable data, should be required to meet HIPAA requirements directly, and independent of those that might be established in their contractual arrangement as a business associate.

Ms. McGraw summarized that the recommendations being presented to the Community at this meeting would: (1) exempt HIEs from certain HIPAA notification and individual right requirements only when they do not have independent relationships with consumers or patients (otherwise, all HIPAA requirements apply to all direct participants); and (2) ensure that all rights will continue to apply in full through the entity with whom the consumer or patient has an independent relationship. She emphasized the nature of HIEs' unique interface with HIPAA Privacy Rules by noting that current HIPAA Privacy Rule requirements are dependent on a consumer or patient's relationship with a health care provider or health plan. Currently, few HIEs have independent relationships with patients or consumers. An HIE that uses or discloses health information directly to, or on behalf of, a patient or consumer rather than via

other HIE participants (e.g., providers) has an independent relationship with that patient or consumer. Also, HIEs that do have independent relationships with patients or consumers should be required to follow all HIPAA Privacy Rule requirements.

Ms. McGraw then presented the following recommendations:

Notice of Privacy Practices

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

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

Individual Rights

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

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

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

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

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

Discussion Highlights

"To clarify, because these entities aren't covered by HIPAA…you're not suggesting that HIPAA be changed, but that the entities, themselves, either voluntarily abide by these or if government has contractual or other non-regulatory means to encourage, incentivize this movement, that it should do so. Is that correct?" – Dr. Kolodner

"We expressly did not say that HHS would have to change HIPAA rules, but it's definitely our recommendation, consistent with the one that we made back in June, that these new entities that are directly handling the data be covered under HIPAA…And then leaving to ONC and HHS to make the determination about how that would take place." – Ms. McGraw

"Notice of privacy practice to consumers is not relevant to HIEs…there's got to be other ways of wording that so I think the average layperson person, who doesn't track privacy and security at the depth that you do, can understand what we're actually recommending." – Mr. Devore

"The first statement, if we can go back to [Recommendation] 1.0, is basically setting the stage for the recommendation, which basically would say we recommend that HIEs that do not have an independent relationship should be exempt from the HIPAA privacy rule." – Dr. Kolodner

"If I'm a covered entity, I have an obligation and a responsibility. I can't delegate that obligation and responsibility. However, I can contract with somebody…but it doesn't mean because I've contracted with them that I have in any way foregone or stepped aside from my obligation and responsibility. So we're simply acknowledging that an HIE is an administrative function for covered entities, and that the responsibility stays with them, and that the consumer is in no way compromised by having an HIE." – Secretary Leavitt

"You're not suggesting that the obligations under HIPAA are going to change for HIEs, you're just giving clarification to what those obligations should be for HIEs. I would suggest that we address somewhere, either in these recommendations or as a following work—because there is a lot of what we're not going to require them to do—of what we are going to require them to do." – Mr. Hutchinson

"Are you going to come back and address the business associate contracts as it relates to HIPAA?" – Mr. Hutchinson

"The initial recommendation that we put forth again back in June was that these entities should be ideally covered by HIPAA as direct participants, and not just through business associate arrangements. So this is really following up on that recommendation" – Ms. McGraw

"And that's why it's sort of put in terms of exemptions, because quite frankly, we think that other than these exemptions, they should have to comply with all of it. So, consistent with our earlier recommendation, we think that it should be directly, and not just through business associate agreements." – Ms. McGraw

"We're looking at sort of a future construct where these entities that are holding and touching the data in ways that was not in people's minds when HIPAA was first passed by Congress, and then the rules promulgated by the administration." – Ms. McGraw

"Can I suggest, given the importance and the sensitivity we all have to privacy on this, I think we're kind of bracketing with language, and I don't think it will slow us down in responding to them if we were to go back and sort of simplify this in its expression…and bring it back not necessarily for agenda next time, but for members to review and we can, with a quick action next time, ratify the more simplified language." – Secretary Leavitt

Enhancing Data Quality Recommendations

Jodi Daniel, ONC, reminded the Community that in late 2006, ONC contracted with RTI International for a project involving three tasks: (1) develop recommendations for requirements for EHRs to enhance data quality by reducing incidences of improper payment, (2) validate those recommendations through public comment, and (3) work with appropriate organizations to encourage adoption of those recommendations where appropriate. RTI formed the Model Requirements Executive Team (MRET), which consisted of a group of industry experts both from public and private sectors to develop recommendations. In

September 2007, those recommendations were presented to the AHIC, and the Community had asked that the CPS and EHR Workgroups review those recommendations.

In January 2008, the two Workgroups reported on their review of those recommendations. The CPS Workgroup examined Recommendation 8, which addressed auditor access. Ms. Daniel reminded Community members that there was some concern as to whether or not this provided any additional rights to auditors than they would have currently under existing law. The CPS Workgroup reported back that the recommendation was consistent with HIPAA, and did not seem to grant any new rights, but did suggest that the recommendation would benefit from greater specificity of the type of auditors, and that certain auditors may need more restricted access than others.

The EHR Workgroup examined two recommendations: (1) Recommendation 5, which was about evaluation and management coding; and (2) Recommendation 6, which was proxy authorship. The Workgroup suggested no modifications from those recommendations. However, there was a lively discussion among the AHIC about requirement 5.2 in the MRET report, and there was some discussion about some modified language to that recommendation.

Ms. Daniel then presented the following recommendation:

- **Recommendation 1.0:** With the exceptions listed below, the recommended requirements for enhancing data quality in EHRs set forth in the RTI Report dated May 2007 should be used to inform the Certification Commission for Healthcare Information Technology (CCHIT) as it establishes plans for new certification criteria development and HHS should request CCHIT to identify how these issues fit in their roadmap. Exceptions:
    - Criteria for more specificity to the auditor role described in Recommendation #8 (e.g., government auditor vs. commercial auditor, vs. internal auditor); and
    - MRET's Recommendation 5.2 should be considered with the following amendments (AHIC additions in **bold**):
        - Prompts that are driven by E&M administrative processes shall not explicitly or implicitly direct a user to add documentation **for the purpose of achieving higher level code**. This does not apply to prompts for additional documentation for E&M levels already achieved, for medical necessity, for quality guidelines/clinical decision support, **or for previously documented clinical information**.

The Community voted by consensus to approve this recommendation and move it forward to the Secretary for his consideration.

AHIC 2009 Priorities and Use Cases

Dr. Loonsk presented a roadmap graphic showing the priorities that the Community put forward that have culminated in standards recognized in January of this year. It also showed the priorities that the AHIC advanced that were accepted in January of this year, with the intent of being recognized in January of next year. These first priorities, he said, are also being tested and demonstrated in the NHIN trial implementation. The graphic also showed the use cases that have just come out of public comment, will be advanced in March, and will go onto the agenda as next steps in the coming year.

The ONC asked the AHIC Workgroups, as well as others who have participated in prioritization in the past rounds, to review those very detailed priorities to question whether they are still valid, and to determine whether other priorities should be added to the list. Some items were added and some were removed. Also added were several new areas that represent full use cases unto themselves, which are

substantial projects that would need to be considered in terms of moving them forward. After analyzing all of the input and considering available resources, ONC recommends that the AHIC prioritize three new use cases for 2009 and help prioritize a list of smaller "gaps and extensions" that will also be put forward in detailed form for the next round of work. Because many of these priorities represent a balancing between workgroups, ONC will follow-up after this meeting with a process for the AHIC to determine final prioritization.

Dr. Loonsk presented a list of very large use cases that will require much more work. These include newborn screening; maternal and child health; eligibility, prior authorization and scheduling; disability and other qualifications; authorization and release of information; medical home and care coordination; clinical research and clinical trials; long-term care and assessment; and sore and forward telemedicine. Dr. Loonsk indicated that the ONC will be sending an e-mail to the Community and will ask that every member rank these potential use cases according to the priority that they would see fit to advance them. It likely will be possible to carry out three of these larger use cases over the coming year. The ONC also will send Community members a list of much more granular priorities for gap-filling as well.

Dr. Loonsk then shared a list of criteria that the Community previously used to rank priorities, which included:

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

Discussion Highlights

"I was going to encourage us not to re-plow fertile ground…the Continua Health Alliance…this year in Q3 will have labeled products in the market for interoperable connected health devices in the home. I think it might be beneficial…for them to come and let this group know what they've done. I'm concerned by the time we actually define use case—I mean, these guys have already got the use cases vetted and the connectivity is going to be there." – Mr. Devore

"My concern is that…AHIC 2.0 will be taking over those priorities, and they could easily decide, since we're giving them the flexibility to set their own direction and agendas, that these are not the priorities that they would prefer to work on in 2009." – Mr. Hutchinson

"I just have a fundamental problem with having people start working on things that we don't know if we're going to see [them] finished, because there is a good chance, if, in fact, we are true to our statement, that we're going to allow AHIC 2.0 to set its own course, their course may not agree with these priorities." – Mr. Hutchinson

"I think the Secretary's clear statement is he wants to not have any loss of momentum. The danger of not doing this is there will definitely be a loss of momentum." – Dr. Kolodner

"Most of the work in the next several months with this is really around work that ONC contracts for and then a common period, rather than work that goes to the Workgroups. The recommendations that came forward were the work from the Workgroups. This is now where it comes from AHIC and would go on to the next stage." – Dr. Kolodner

"It takes a while to get it going. And I think we would be a disservice not to at least provide AHIC 2.0 with that option of something that they're ready to build." – Mr. Roob

"Will there also be some rationale for why ONC picked these particular [potential use cases] rather than others that they might have picked? The case for these cases, in other words." – Mr. Green

"There will be a description that will emanate from those who recommended them. We did not pick them." – Dr. Loonsk

"It would be important…to make sure we have information on how they're going to fill in and build upon existing use cases and the necessity. But on the larger use cases as well, will there be some information…about how these build upon existing…use cases that get us to the vision, not only the gaps but the larger use cases?" – Ms. Handelman

"Any discussion about how the existing standards that have been recognized will be implemented, so that we can look at what will be implemented and be required on stakeholders to make a determination of what makes sense in the next session to put forward, just some bigger picture information of how this all builds upon each other, to make the best determinations in moving forward." – Ms. Handelman

"That's a helpful suggestion…If you would like us to add, in addition to that, some comments on how those relate to activities that have already occurred in the use cases and how that would match, I think we could easily accommodate that." – Dr. Loonsk

"Just to be clear, the list that we showed you was a limited list of priorities that were advanced that were large enough to be a use case unto themselves. There is a much longer list of priorities that we have determined to be smaller in terms of how much effort or how big they are, how much time they'll take to work through. That longer list is the second thing we'll be sharing with you. If, at that time, a priority that was recommended doesn't show up there, please do tell us. We want to make sure that they're all there. But we think we have them all." – Dr. Loonsk

"It sounds like what you would like is for us to bring back the prioritized list, and there would be an opportunity for discussion of that prioritized list, to see whether the group, on discussing it, then determines that that's how to go forward." – Dr. Loonsk

"May I suggest one modification?…What we could do is to move forward on the top two use cases, to begin the work on those, because that will allow us to move forward in some, and then you can bring back the rest of the discussion, you know, to finalize that here." – Dr. Kolodner

"So that's all I'm asking for, is that we come back and have a chance to converse about if something is low on the list, and we think there is the need, a passionate need to move it up, then let everybody show their passion and have another vote." – Dr. Henley

"I'm hearing [a ranking process] being laid out here…We will return the materials. We'll put them in the context of the other use cases that have been done. We'll return the materials to you that indicate the ranking. We will also, when the ranking occurs, ask for comments from those, and we will pull those

together, share those with you, and then lead to another discussion at the AHIC to finalize those prioritizations." – Dr. Loonsk

Closing Remarks

There being no public comments, Dr. Kolodner thanked all participants and declared the 20th meeting of the AHIC adjourned.

American Health Information Community

Moving to the Successor

Mark B. McClellan, M.D., Ph.D.

April 22, 2008

Where We've Been

- Goal: All Americans to have access to secure electronic health records by 2014
- AHIC – established in 2005 to push this goal forward
- Focus on interoperability, security, and market adoption

Taking AHIC to the Next Stage

- The LMI-Brookings project, with a grant from HHS, will help take AHIC to its next stage
  - An independent public-private partnership
  - Focused, results-oriented, and inclusive
- Build on AHIC's achievements to
  - Accelerate implementation of a unified approach to nationwide health information exchange
- Convene stakeholders to collaboratively design and establish the AHIC Successor
  - We are the conveners for the transition process

The Transition Phases

Month 1 – Month 4 Planning & Establishing	Month 5 – Month 10 Transition & Initial Operations	Month 11 and Beyond Fully Operational
Leadership • Mark McClellan/ Larry Kocot, Senior Investigators & Policy Leaders (Brookings) • Arthur Hamerschlag, Project Director (LMI) • Support from LMI-Brookings • Planning Group Co-Chairs	**Leadership** • Board of Directors (Operational) • Officers and staff • Project support from LMI-Brookings	**Leadership** • Board of Directors (Final) • Permanent CEO • Permanent staff
Strategic Input • AHIC and ONC • Early supporters • Multiple stakeholders • Four planning groups	**Strategic Input** • Board of Directors • AHIC • Multiple stakeholders • Four planning groups	**Strategic Input** • Board of Directors • Multiple stakeholders • Four planning groups
Key Activities • Design the governance structure • Address incorporation & legal considerations • Design membership process • Address financial sustainability • Develop transition process	**Key Activities** • Establish the Board of Directors • Hire the CEO • Transition AHIC activity to AHIC Successor • Expand membership • Develop strategic plans	**Key Activities** • To be determined based on findings and recommendations from key activities in the first 12 months
LMI-Brookings Institution		**AHIC Successor**

Existing AHIC

Government: Privacy & Security

Planning Groups Represent a Broad Range of Stakeholders

Planning Groups Will Make Recommendations On:

Organization Governance
John Tooker, MD, MBA
Lori M. Evans

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

Membership
Jon Perlin, MD
[2nd co-chair TBD]

A draft outreach plan to ensure recruitment of broad-based membership across sectors as well as possible segmentations of the stakeholder community

Business Sustainability
John Glaser, PhD
[2nd co-chair TBD]

Options for obtaining financial sustainability in alignment with the organizational development plan

Transition
Lillee Smith Gelinas, RN, MSN
[2nd co-chair TBD]

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

Governance Planning Group: Members

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

* Co-chairs

Planning Groups Represent a Broad Range of Stakeholders

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

Membership Planning Group: Members

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

* Co-chair

Planning Groups Represent a Broad Range of Stakeholders

Planning Groups Will Make Recommendations On:

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[2nd co-chair TBD]

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

Sustainability Planning Group: Members

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

* Co-chair

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Lillee Smith Gelinas, RN, MSN
[2nd co-chair TBD]

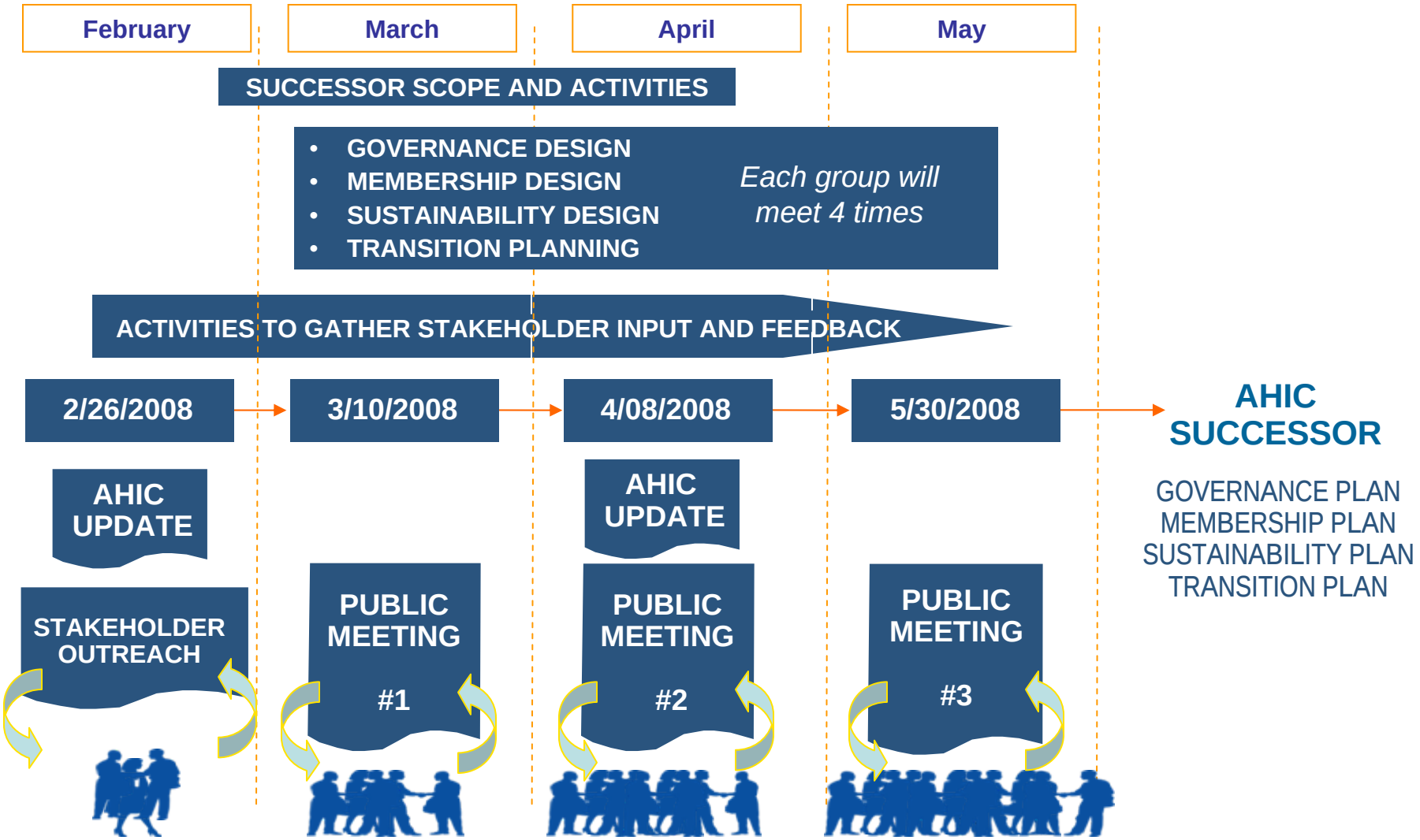
Plan for identifying actions and initiatives to be transferred from AHIC to the new organization and a plan for the transition of these activities by Fall 2008

Transition Planning Group: Members

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

* Co-chair

The First Four Months Of Activity Are Focused On Building Commitment And Defining Governance



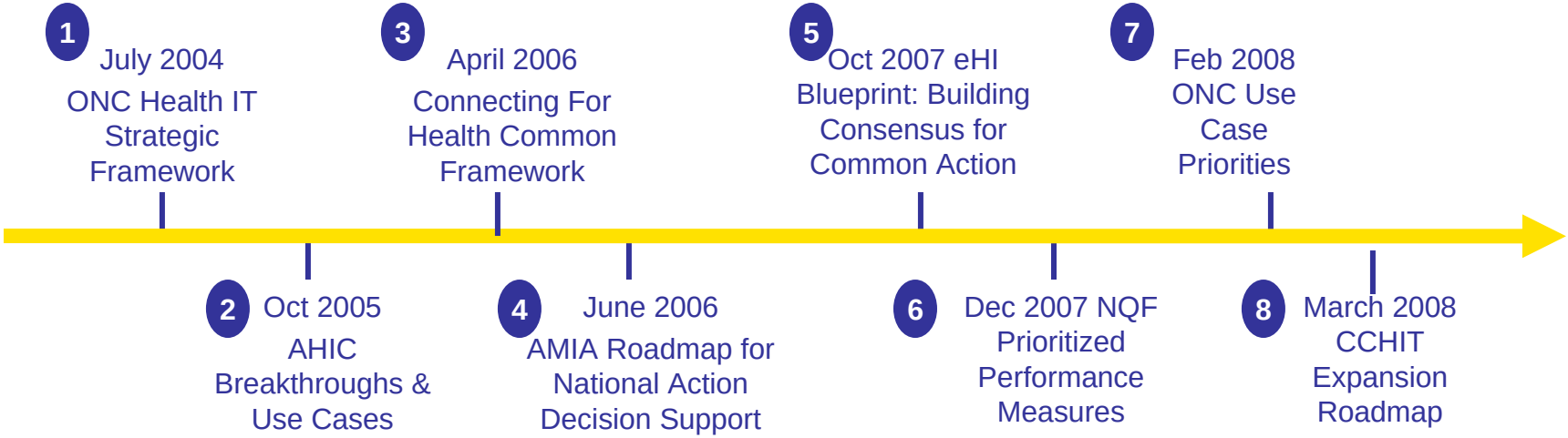
Four important focus areas emerged for the AHIC Successor to consider as part of its scope

- Accelerating and coordinating the movement towards increased health IT interoperability, while avoiding duplication of efforts and keeping the focus on what the Successor can feasibly accomplish
- Prioritizing and accelerating the development of health IT interoperability requirements
- Harmonizing technical standards and implementing policies to support them
- Streamlining the health IT certification process with a goal of helping drive health IT adoption in the near-term

Considerable work lies ahead to create a new enterprise with functioning and sustainable core operations. These efforts will be driven, in large part, by the scope of the AHIC Successor. As such, developing clear recommendations of scope are an essential part of the Successor process .

We will not be starting from scratch, but we must harmonize and build upon the work that has been done:

An overview of current roadmaps



1	Goals for the rapid adoption of EHRs to improve workflow efficiencies in clinicians' offices and deliver higher quality care for patients. Inform and interconnect physicians, personalize care, improve population health
2	Places where using health IT produces a tangible and specific value to the health care consumer and that can be realized within a 2-3 years. Consumer Empowerment, Chronic Care, Bio-surveillance, and EHR
3	Includes 16 policy and technical guides for implementing private and secure information exchanges
4	Recommends a series of activities to improve Clinical Decision Support development, implementation and use to help enable improvements in health, and the quality, safety and efficiency of healthcare delivery
5	A shared vision and actions for improving health and healthcare through information technology
6	An overarching quality measure development framework to facilitate developing, using, and reporting on quality measures from EHR systems
7	Presents the use case scenario priorities for 2008 – 2009 that will inform standards harmonization
8	Presents the sequence with which certification criteria for product capabilities will be developed

Health IT is One Element

- AHIC and HIT are One Piece of the Strategy

- We Need:
  - Better Measures of Quality and Cost
  - Changes in Payment To Support Better Value
  - Changes in Coverage To Support Better Value
  - Better Evidence on What Works

The Goal is Connecting People to Better Health

- Quality
  - Interoperable health IT should improve quality and safety for every patient
- Cost
  - Avoiding unnecessary and preventable expenses, duplication

Building on these themes, we will host a series of listening events that highlight concrete examples of health IT adoption

- Real progress will be driven by the lessons learned from prior and ongoing efforts to use health IT to make clear improvements in health care

- We are organizing a series of events on a "listening tour" designed to:
  - Bring together stakeholders to highlight opportunities for effective health IT adoption,
  - Identify specific short-term roadblocks to broader adoption, and
  - identify strategies for collaborative action to get widespread implementation.

- Examples of specific issues to be addressed in such meetings include, but are not limited to:
  - chronic care improvement,
  - e-prescribing,
  - quality measurement,
  - drug safety, and
  - administrative simplification.

- Please share your suggestions (via www.ahicsuccessor.org) on topics for future events and/or how we can maximize their contributions to the AHIC Successor and the health-care system at large.

Stay involved and send us your thoughts and suggestions

- Sign up for notices on www.ahicsuccessor.org
- Read "*The Better Health Connector*" newsletter
- Submit comments via www.ahicsuccessor.org
- Attend meetings
  - Public Meetings
  - Planning Group Meetings
  - Listening Events

American Health Information Community

AHIC 2009 Priorities and Use Cases

John W. Loonsk
Office of the National Coordinator for Health IT

April 22, 2008

AHIC Priorities and Use Case Roadmap (Updated)

AHIC Priorities and Use Case Roadmap

2006

Consumer Empowerment Use Case
- Registration
- Medication History

EHR Use Case
- Laboratory Result Reporting

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

2007 Use Cases

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

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

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

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

2008 Use Cases

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

Patient – Provider Secure Messaging
- Structured email
- Reminders

Consultations and Transfers of Care
- Referrals
- Problem Lists
- Transfer of Care

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

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

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

→ CANDIDATE 2009 ←

"New" Use Cases and …

Medical Home and Care Coordination
- PCP as Care Coordinator
- EHR as Med Hm

Prior Authorization and Scheduling in support of TPO
- Prior Auth and Scheduling
- Admin Data

Authorization for Release of Information for Third Parties
- Patient/ Consumer ROI Communication

Maternal and Child Health
- Antenatal, Prenatal, and Labor & Deliv

Newborn Screening
- Screening and Transition to Pediatric Care

Long-Term Care and Assessment
- LTC Needs
- Assessment Tools and Data

Clinical Research – Clinical Trials Data and EHRs
- Research Protocols
- Qualifying Ptnts

Store and Forward Telemedicine
- Teleconsults
- Health Data in Native Forms

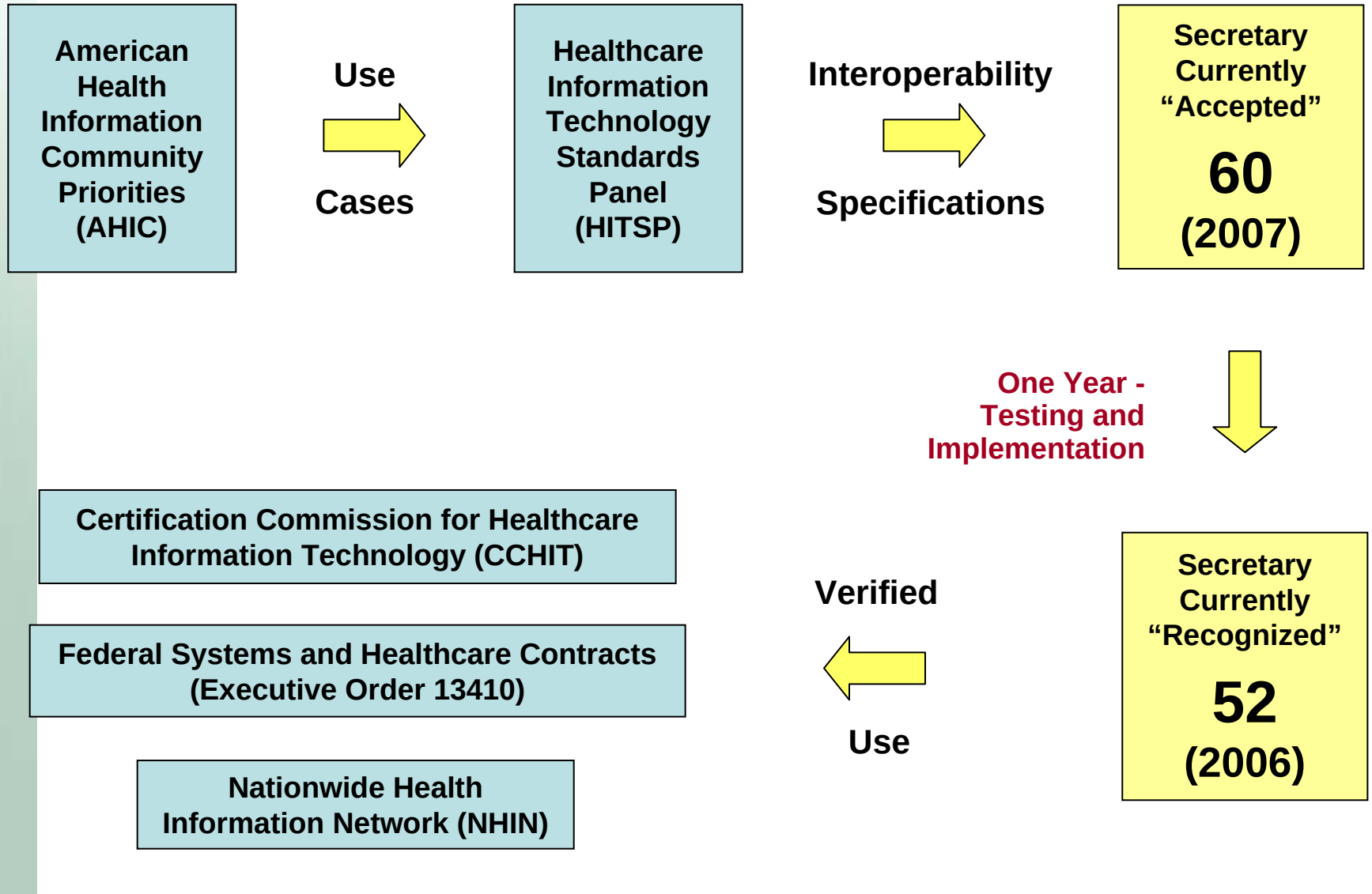
Extensions and Gaps

- General Laboratory Orders
- Medication Gaps
- Common Device Connectivity
- Clin Encounter Note Details
- Order Sets
- Consumer Preferences
- Common Data Transport
- AP Laboratory Results
- Ptnt/Consumer Adv Event Rptg
- Ptnt-reptd Probs and Outcomes
- Health Surveys
- Distributed Query
- Death Reptg and Surveillance
- Cancer and Tumor Registries
- Occ Health & Injury Registries
- Other Adverse Events
- Blood Banks
- Organ Donor Registries

Status of AHIC Prioritized Needs and Issues

- 230 AHIC “needs & issues” were addressed in the 2006, 2007, and 2008 use cases
- 9 needs & issues were leftover
- During the 2009 refresh process, an additional 149 needs & issues were advanced – in the candidate 2009 use cases & extensions / gaps

Standards in the National HIT Agenda



Candidate 2009 “New” Use Cases

- Results of AHIC member feedback:

Proposed Use Case	Tally
Medical Home and Care Coordination	5
Prior-Authorization and Scheduling in support of Treatment, Payment, & Healthcare Operations	5
Authorization for Release of Information for Third Parties	4
Maternal & Child Health	4
Newborn Screening	3
Long Term Care and Assessment	3
Clinical Research – Clinical Trials Data and EHRs	3
Store and Forward Telemedicine	2

Candidate 2009 Use Case Extensions/Gaps

Proposed Extensions/Gaps	Tally
General Laboratory Orders (Extension to 2006 EHR - Lab Result Reporting)	10
Medication Gaps	9
Common Device Connectivity in Care Settings (Relates to 2008 Remote Monitoring)	9
Clinical Encounter Note Details (Extension for 2008 Consultations and Transfers of Care)	8
Order Sets	5
Consumer Preferences	5
Common Data Transport	5
Anatomical Path Lab Results (Extension for 2006 EHR - Lab Result Reporting)	4
Patient/Consumer Adverse Event Reporting	4
Patient Reported Problems and Outcomes	2
Health Surveys	2
Distributed Query	2
Death Reporting and Surveillance	1
Cancer and Tumor Registries	1
Occupational Health and Injury Registries	1
Other Adverse Events	1
Blood Banks	1
Organ Donor Registries	1

Dear American Health Information Community Member,

Thank you for your feedback regarding the Candidate 2009 New Use Cases and Extensions/Gaps. Per the email sent on Wednesday, April 2nd 2008 entitled "AHIC April 22 materials for Use Case Priority Discussion," ONC collected input from 12 AHIC members and have now collated this input. With this document, the collated materials are now being re-distributed to AHIC members in anticipation of the discussion at the April 2008 AHIC meeting.

Included herein are tallies of the priorities expressed by the responding AHIC members for both the 2009 Candidate New Use Cases and Extensions/Gaps. Also included are the comments that were given by AHIC members relative to their rationale for their priorities. ONC has simply taken all of the AHIC input we received and organized it by the Candidate 2009 New Use Cases or Extensions/Gaps instead of the submitter.

At the AHIC meeting ONC will present materials about work that has already been done as background for your discussion and decision-making.

Thank you for your ongoing work to establish these important priorities. The work that you have done to date has been critically important for a number of national HIT agenda activities.

We look forward to the discussion at the April AHIC meeting.

Sincerely,

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

Executive Summary: AHIC FEEDBACK ON CANDIDATE 2009 NEW USE CASES

Proposed Use Case	Total
Medical Home and Care Coordination	5
Prior-Authorization and Scheduling in support of Treatment, Payment, & Healthcare Operations	5
Authorization for Release of Information for Third Parties	4
Maternal & Child Health	4
Newborn Screening	3
Long Term Care and Assessment	3
Clinical Research – Clinical Trials Data and EHRs	3
Store and Forward Telemedicine	2

SUMMARY OF AHIC FEEDBACK ON 2009 NEW USE CASES

Medical Home and Care Coordination **Total: 5**

For purposes of 2009 use case prioritization, the Medical Home and Care Coordination use case focuses on the activities and information needs of a primary care physician operating as the manager of all of a patient's medical information and health needs across multiple providers and care settings. The use case includes the processes by which information flows to the primary care physician as well as capabilities to manage co-morbidities.

- *"Essential to a better functioning health care system with improved quality and cost efficiency"*
- *"Supports numerous private and public efforts"*
- *"The Medical Home demonstrates to providers and to patients the real value of care coordination and IT in its ability to store a complete record for a patient. This is where many elements converge in the minds of the provider and patient to bring clarity to how patient information sharing will be done. Establishing the standards to do this as well as providing the incentives to primary care providers to move in this direction could move the market to the adoption of health IT and the overhaul of a reimbursement structure that is broken and does not support our goal of measuring quality and coordinating care across a patient's healthcare team."*
- *"Numerous efforts are underway in the private sector and government health programs to support the medical home and care coordination. More than 20 BCBS Plans are participating in current or future PCMH demonstrations. Health IT is an essential component to its success."*
- *"Primary care coordination is essential to quality health care delivery by health plan providers especially for patients with co-morbid conditions."*

Prior-Authorization and Scheduling in support of Treatment, Payment, & Healthcare Operations **Total: 5**

For the purposes of 2009 use case prioritization, the Prior-Authorization and Scheduling in support of Treatment, Payment and Healthcare Operations use case focuses on the information needs of patients, consumers, payors, and providers during prior-authorization and scheduling activities. For prior-authorization activities the use case includes delivery of relevant clinical information in conjunction with administrative data.

- *"This is an important day to day issue in health care and solving this would be a huge effort towards administrative simplification"*
- *"Large impact; easily built on current foundation"*
- *"This is a major issue that the industry has been struggling with for years."*
- *"These areas of health plan and provider interaction are in need of streamlining through automation"*

Authorization for Release of Information for Third Parties **Total: 4**

For the purposes of 2009 use case prioritization, the Authorization for Release of Information for Third Parties use case focuses on the information needs associated with the processes by which patients/consumers communicates their authorization to release applicable health information to third parties and the processes by which that authorization is acted upon by the third parties and clinicians who hold the data.

- *"Critical to the balance of healthcare information security/privacy and accessibility as PHRs and EHRs become part of the every-day-life of every consumer and healthcare worker"*
- *This is essential for building patient trust in the health information technology infrastructure."*

Maternal & Child Health **Total: 4**

For the purposes of 2009 use case prioritization, the Maternal and Child Health use case focuses on the information needs associated with antenatal, prenatal and labor & delivery patient care activities with emphasis on the exchange of that information among the involved providers and care settings. Although closely related, the information needs specifically associated with newborn screening are the focus of a separate 2009 candidate use case due to the complexity of the workflows and information exchange requirements for newborn screening. The completion of labor & delivery is the end-point for this use case.

- *"PHCCC priority"*

Newborn Screening **Total: 3**

For the purposes of 2009 use case prioritization, the Newborn Screening use case focuses on the information needs associated with newborn screening activities with emphasis on the exchange of that information among the involved providers, parents and care settings as well as the delivery of related EHR information to appropriate registries. The transition in care from labor & delivery to pediatric care serves as the endpoint for this use case. While closely related, this use case has been separated from the proposed Maternal and Child Health use case due to the complexity of the workflow and information exchange requirements for newborn screening.

- *Frequent occurrence and important"*
- *"It begins here and can in fact drive more compliance with known best practices for screening newborns avoiding some complications or healthcare issues down the road."*

Long Term Care and Assessment **Total: 3**

For the purposes of 2009 use case prioritization, the Long Term Care and Assessment use case focuses on the information needs in long term care settings associated with specific issues of medications management and patient assessments as well as other long term care needs. The use case builds on the 2007 Medication Management Use Case as well as the 2008 Consultations and Transfers in Care Use Case to incorporate the unique needs of the long term care settings.

- *"Extends current use case to additional care venue"*
- *"Assessment technologies may improve population health measures for chronic conditions"*
- *"Critical to meeting the health care demands of the aging population for the next few decades"*

Clinical Research – Clinical Trials Data and EHRs **Total: 3**

For the purposes of 2009 use case prioritization, the Clinical Research – Clinical Trials Data and EHRs use case focuses on the information needs associated with provision of EHR data to support clinical trials and other clinical research activities. Potential aspects of this use case for further consideration include methods to incorporate research protocols into EHRs, methods to gather patient-specific research data not normally collected within an EHR, and the information needs associated with qualifying and re-qualifying patients for clinical trial research.

- *"Supports surveillance tasks for public health and other hypothesis based enquiry"*

Store and Forward Telemedicine **Total: 2**

For the purposes of 2009 use case prioritization, the Store and Forward Telemedicine use case focuses on the information needs associated with communicating a request for clinical consultation to a remotely located clinician who does not directly interact with the patient in real time. The use case includes the processes associated with recording relevant patient data, images, waveforms, visual observations, etc. which are forwarded to the remotely located consulting clinician. This use case builds on the 2008 Consultations and Transfers in Care use case and may incorporate some additional types of information, but definitely focus on recording information for consultations performed without direct patient interaction.

- *"Existence of mature standards; impact on accessible healthcare"*
- *"Critical to the continuation of advancing telemedicine globally"*

Other Comments:

'All in all I firmly believe AHIC 1.0 should not be establishing any new use cases for AHIC 2.0. We made a firm commitment to the establishment of AHIC 2.0 to allow them to be independent in their decision making and establishing their own priorities. We are giving them plenty to consider with all the work done to date and work that is still outstanding on the use cases we already have in place today. The focus of AHIC 1.0 should be on what we can do over the next several months to have the most impact in driving adoption of health IT for providers. We should focus on 1 or 2 things we can really make an impact on like incentives to drive the adoption of electronic prescribing. In the MMA of 2003 it establishes that PDP's must "support" electronic prescribing. But there is no clarity as to what "support" means. Let's spend time giving clarity to things like that to drive the adoption and use of electronic prescribing. Let's make sure the DEA changes their policy on not allowing controlled substances to go electronically. Let's complete something that we can look back and state during our tenure as AHIC 1.0 we eliminated waste, improved quality for patients, drove the adoption of health IT by "completing" X, Y, and Z. We have started a lot of things…good things…but let's use our remaining time to see a couple of things through completion.'

'the 2009 focus should be on "extensions and gaps" that build upon the work of previous use cases, touch the largest number of clinicians and is an important component of their day-to-day work. Priority must be placed on those items that can best support widespread adoption of EHRs. It is for this reason we recommend a strong emphasis on "extensions and gaps" and limiting the broader use case to one: medical home and care coordination. This broader use case builds upon the work already done and underway, supports primary care and care coordination, and it relies on health IT to be done well. In addition, there are numerous efforts underway in the private sector and government to advance the medical home and care coordination and this work will help support those efforts.'

Executive Summary: AHIC FEEDBACK ON CANDIDATE 2009 USE CASE EXTENSIONS/GAPS

Proposed Extensions/Gaps	Total
General Laboratory Orders (Extension for 2006 EHR (Laboratory Result Reporting) Use Case)	10
Medication Gaps	9
Common Device Connectivity in Care Settings (Relates to 2008 Remote Monitoring Use Case)	9
Clinical Encounter Note Details (Extension for 2008 Consultations and Transfers of Care Use Case)	8
Order Sets	5
Consumer Preferences	5
Common Data Transport	5
Anatomical Pathology Laboratory Results (Extension for 2006 EHR (Laboratory Result Reporting) Use Case)	4
Patient/Consumer Adverse Event Reporting	4
Patient Reported Problems and Outcomes	2
Health Surveys	2
Distributed Query	2
Death Reporting and Surveillance	1
Cancer and Tumor Registries	1
Occupational Health and Injury Registries	1
Other Adverse Events	1
Blood Banks	1
Organ Donor Registries	1

SUMMARY OF AHIC FEEDBACK ON CANDIDATE 2009 USE CASE EXTENSIONS/GAPS

General Laboratory Orders **Total: 10**

(Extension for 2006 EHR (Laboratory Result Reporting) Use Case)

- *"Completes cycle"*
- *"gap remaining from the 2006 EHR Use case"*
- *"Facilitates integration of ELR data in public health surveillance"*
- *"high priority for providers and info. is highly valued by consumers"*
- *"Labs and meds continue to be the highest ranking items in the minds of the providers to have electronic access. Ensuring a result is matched appropriately to the original order is critical to workflow as well as acceptance by users. This may require work on a standardized lab set from a terminology standpoint."*
- *"Touches most clinicians, builds upon important work of sharing lab results and can help spur EHR adoption."*
- *"Promotes interoperability"*

Medication Gaps **Total: 9**

- *"Potential to facilitate adoption of e-prescribing"*
- *"Supports e-rx"*
- *"Could help with final pieces of eRx"*
- *"We still have a need for things like a standardized SIG, consistency in required regulations across the states, ability to route prescriptions for controlled substances, variations of requirements as it relates to a "wet signature" on a prescription, over burdensome reporting requirements where each day physicians are required to "print" all prescriptions sent electronically and sign with a "wet signature" the document to be filed away, etc. These present administrative overhead and confusion which impact technology development as well as provider adoption and utilization issues."*
- *"E-Rx is the low-hanging fruit. It is readily available, with a proven track record in improving quality, safety and creating efficiencies."*
- *"Essential in preventing adverse events"*

Common Device Connectivity in Care Settings **Total: 9**

(Relates to 2008 Remote Monitoring Use Case)

- *"Extends remote monitoring; provides additional clinical data"*
- *"Supports common reporting standards across care settings"*
- *"There is a rising of home devices in use and if monitored appropriately could tremendously help patients manage their disease conditions at a lower cost with higher quality results. This would require remote monitoring as well as storage of this data in a patient's EHR."*
- *"In particular, it is important to create uniform terminology and standards to report information. Currently, different terminology and gradient scales exist (e.g. high blood pressure vs. hypertension; grams vs. milliliters). These must be addressed to support interoperability."*

Clinical Encounter Note Details **Total: 8**

(Extension for 2008 Consultations and Transfers of Care Use Case)

- *"gap remaining from the 2006 EHR Use case"*
- *"addresses 70% of push mechanisms in healthcare"*

- *"This would be a great benefit both to patients and to physicians. Too many times patients are left to explaining their condition and their visits with previous providers which certainly is not the most efficient or accurate way of describing past medical history or actions taken to treat a condition. The ability to share clinical notes and encounters between providers would prove real value to providers to adopt technology and lower patient's frustration with describing past events."*
- *"Touches most physicians and will allow the sharing of pertinent clinical information."*
- *"Greater granularity of health data is required for quality care, reporting and clinical research."*

Order Sets **Total: 5**

- *"Extends lab orders/results to additional clinical data; economy of scale"*
- *"gap remaining from the 2006 EHR Use case"*
- *"This area of information sharing continues to be the highest value item in a healthcare providers mind and if widely implemented could very well be the catalyst for demonstrating the value of IT in healthcare for providers and patients."*
- *"Touches most clinicians and can help spur EHR adoption."*

Consumer Preferences **Total: 5**

- *"Enhances consumer confidence; facilitates health IT adoption"*
- *"Promotes consumer centric care and trust"*

Common Data Transport **Total: 5**

- *"Focuses on transport security technology"*
- *"Promotes interoperability"*

Anatomical Pathology Laboratory Results **Total: 4**

(Extension for 2006 EHR (Laboratory Result Reporting) Use Case)

- *"gap remaining from the 2006 EHR Use case"*
- *"While this element is probably lower in priority than labs and meds it is still quite important from a data collection standpoint so long as the information can be searchable like lab results and meds to trend patient population issues and measuring conformance to quality performance in treating conditions that meet certain parameters from pathology results. Like other lab tests it can be a basis for measuring progress/improvement or the lack there of…without it the task is difficult to see, in an automated way, patient improvement."*
- *"Touches most clinicians, builds upon important work of sharing lab results and can help spur EHR adoption."*
- *"Promotes interoperability"*

Patient/Consumer Adverse Event Reporting **Total: 4**

- *"Promotes consumer centric care"*

Patient Reported Problems and Outcomes **Total: 2**

- *"Promotes consumer centric care"*

Health Surveys **Total: 2**

- *"Electronic data capture for surveillance activities from identified populations"*

Distributed Query **Total: 2**

- *"Complex extension that is similar to federated/grid technologies being explored by NCPHI. Potential high impact on real time surveillance capabilities"*

Death Reporting and Surveillance **Total: 1**

- *"Critical to monitoring of outbreaks, no standards for data capture from EHRs"*

Cancer and Tumor Registries **Total: 1**

- *"Supports traditional public health activities"*
-

Occupational Health and Injury Registries **Total: 1**

- *"Supports traditional public health activities"*

Other Adverse Events **Total: 1**

Blood Banks **Total: 1**

Organ Donor Registries **Total: 1**

2009 AHIC Candidate Use Case Extensions & Gaps April 2, 2008

2009 Candidate Use Case Extensions and Gaps

1. *General Laboratory Orders (Extension for 2006 EHR (Laboratory Result Reporting) Use Case)*
    a. The ability to support interoperable laboratory orders between EHRs, Laboratory Information Systems (LISs), and other related systems and the ability to link laboratory orders with laboratory results.

2. *Order Sets*
    a. The ability for pre-determined order sets to be communicated between EHRs and other systems. Order sets may include examples such as medications, laboratories, and radiology orders.

3. *Anatomical Pathology Laboratory Results (Extension for 2006 EHR (Laboratory Result Reporting) Use Case)*
    a. The ability to retrieve and send anatomical pathology results including interpretation and critical values associated with the results.

4. *Clinical Encounter Note Details (Extension for 2008 Consultations and Transfers of Care Use Case)*
    a. This extension includes additional details for the development, completion, and exchange of interoperable clinical encounter notes and reports. This can be structured and unstructured information exchanged between EHRs and other systems.

5. *Common Device Connectivity in Care Settings (Relates to 2008 Remote Monitoring Use Case)*
    a. Integration of data from diagnostic/therapeutic medical devices (e.g., physiological monitors, infusion pumps, ventilators, glucometers, blood pressure cuffs, etc.) into EHRs and other systems. This may also enable next generation clinical decision support systems and enhances patient safety and therapeutic efficacy.

6. *Medication Gaps*
    a. Between the ePrescribing regulations and the 2007 Medication Management Use Case, many of the medication interoperability needs have been addressed. This “gap filler” would seek to address remaining unmet needs in this important area.

7. *Distributed Query*
    a. The ability to complete a query or search that can be executed across multiple provider and health exchange settings. An advantage of such a standardized approach to a distributed query is that it offers the potential of providing population data for clinical outcomes, surveillance, adverse events, etc. without having to further aggregate data.

8. *Consumer Preferences*
    a. The ability to identify choices and consents a consumer may want to grant for their personal health data. A standard for exchanging consumer preferences may allow consumers to choose whether or not to participate in health information exchange activities and whether to authorize the release of their data for different purposes. Different preferences may be applicable in different jurisdictions and settings.

9. *Common Data Transport*
    a. Exchanging health information requires data and security standards as well as standards for information systems to transport data from one place to another. Historically, a number of different approaches to "transport" have existed, which has limited acceptance and implementation of more advanced approaches to transport security.

10. *Death Reporting and Surveillance*
    a. While not always integrated with EHRs, the reporting of death information has implications for information exchange with clinical systems as well as public health and administrative transactions.

11. *Cancer and Tumor Registries*
    a. Like other registries, cancer and tumor registries could benefit from the availability of EHR information and integration of reporting and management functions. There is a significant overlap of EHR data and data needed for these functions.

12. *Occupational Health and Injury Registries*
    a. Like other registries, occupational health and injury registries could benefit from the availability of EHR information and integration of reporting and management functions.

13. *Blood Banks*
    a. Blood supply and blood supply management have implications for EHRs functions and data. Integration of blood related data is relevant to transfusions, supply management, and public health.

14. *Organ Donor Registries*
    a. The ability to have organ donation and transplant information exchangeable among EHRs and other related systems.

15. *Other Adverse Events*
    a. The ability to electronically approve and submit adverse events specific to medical devices, blood products, biologics, special nutritionals, and cosmetics.

16. Patient/Consumer Adverse Event Reporting

a. The ability for a patient or consumer to report adverse events related to a condition, medication, or other treatment.

17. Patient Reported Problems and Outcomes

a. The ability for a patient to report problems and health outcomes related to treatments that might not normally be captured as part of a clinician's problem list or summary of encounters.

18. Health Surveys

a. The ability to implement on-line surveys with the ability to extract available health information from EHRs and other systems. This capability is intended to speed the collection of data for health survey activities.

2009 AHIC Candidate Use Cases

April 2, 2008

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Maternal & Child Health

ONC Description

For the purposes of 2009 use case prioritization, the Maternal and Child Health use case focuses on the information needs associated with antenatal, prenatal and labor & delivery patient care activities with emphasis on the exchange of that information among the involved providers and care settings. Although closely related, the information needs specifically associated with newborn screening are the focus of a separate 2009 candidate use case due to the complexity of the workflows and information exchange requirements for newborn screening. The completion of labor & delivery is the end-point for this use case.

Defining Quotes from AHIC Working Groups and Others

The focus of this use case is derived from needs and issues expressed by the AHIC community including AHIC PHC, AHIC PHCCC, HITSP, and CCHIT**.** Representative quotations from these contributors are included below:

"AHIC should focus one of its use cases on prenatal care, labor and delivery. Practitioners who would use the aggregated record include: obstetricians, perinatologists, certified nurse midwives, family practice physicians, pediatricians, labor and delivery staff, anesthesiologists, hospitalists, social workers, and other medical specialists. Communication among these caregivers is important to patient care and safety. A study by White et al noted that communication failures among obstetric providers occurred in up to one-third of adverse outcomes. A standardized integration profile does not currently exist to allow for the exchange of the antepartum record information among all healthcare professionals who care for pregnant women. Obstetric patients must have a complete summary of antepartum care available for all care providers and for labor and delivery staff. Incomplete information can be a danger to the mother and child and result in injury, inadequate treatment or undesirable outcomes. The aggregated information contained in a patient's antenatal record should be available across multiple care settings. The goal of this use case would be to improve prenatal care and reduce costs by improving communication between ambulatory practices and Labor and Delivery centers."

Information Needs Addressed by Existing Use Cases

Many of the information needs for a possible Maternal & Child Health use case have been previously addressed and are published in the following use cases:

- Delivery of a core set of patient data between EHRs - 2008 Consultations and Transfers of Care Use Case
- Delivery of laboratory results to authorized providers – 2006 EHR – Laboratory Results Use Case
- Ability to automatically route information to appropriately authorized entities - 2008 Consumer Access to Clinical Information Use Case and 2007 Quality Use Case
- Ability to perform and communicate specific test results and clinical assessments - 2008 Personalized Healthcare Use Case
- Validated family and personal health history - 2008 Personalized Healthcare Use Case
- Utilization and reporting into registries - 2008 Immunizations and Response Management Use Case

New Information Needs Arising in this Use Case

An initial analysis of needs suggested by a possible Maternal & Child Health use case includes some new, unmet information needs in the following areas.

- Integrated documentation and reporting of all antenatal, prenatal, labor & delivery care needs within and between providers and care settings.
- The inclusion of routine medical prenatal and prenatal testing information in the EHR.
- Documentation of demographics, financial data, guardianship and custodial information.

- Specific aspects of decision support.
- Development of a uniform child health record for consumer-provided family medical history into a PHR or an EHR. (This follows on the work from the 2008 Personalized Healthcare Use Case.)
- Standardized data sets for antenatal, prenatal, labor & delivery care needs.

Policy Considerations

Development of this Use Case may require exploration and resolution of issues that are fundamentally issues of policy. Potential policy issues relevant to this use case include:

- Is the time of birth the appropriate point to initiate a lifelong "problem list" for patients?

Newborn Screening

ONC Description

For the purposes of 2009 use case prioritization, the Newborn Screening use case focuses on the information needs associated with newborn screening activities with emphasis on the exchange of that information among the involved providers, parents and care settings as well as the delivery of related EHR information to appropriate registries. The transition in care from labor & delivery to pediatric care serves as the endpoint for this use case. While closely related, this use case has been separated from the proposed Maternal and Child Health use case due to the complexity of the workflow and information exchange requirements for newborn screening.

Defining Quotes from AHIC Working Groups and Others

The focus of this use case is derived from needs and issues expressed by the AHIC community including AHIC PHC, AHIC PHCCC, HITSP, and CCHIT**.** Representative quotations from these contributors are included below:

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

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

Information Needs Addressed by Existing Use Cases

Many of the information needs for a possible Newborn Screening use case have been previously addressed and are published in the following use cases:

- Delivery and reporting of genetic/genomic test results - 2008 Personalized Healthcare Use Case
- Ability to automatically route information to appropriately authorized entities - 2008 Consumer Access to Clinical Information Use Case and 2007 Quality Use Case
- Ability to incorporate and populate electronic forms for the purposes of reporting and information exchange – 2008 Public Health Case Reporting Use Case
- Utilization of and reporting information to registries - 2008 Immunizations and Response Management Use Case

New Information Needs Arising in this Use Case

An initial analysis of needs suggested by a possible Newborn Screening use case includes some new, unmet information needs in the following areas.

- Incorporation of state requirements and guidelines for Newborn Screening into the EHR
- An interoperable nomenclature for all Newborn Screening results and interpretations.
- A harmonized data set for Newborn Screening result information.
- The inclusion of specific medical genetic testing information into the EHR.

Policy Considerations

Development of this Use Case may require exploration and resolution of issues that are fundamentally issues of policy. Potential policy issues relevant to this use case include:

- Variations in state-mandated newborn screening tests may create challenges to the effective exchange of information.

Medical Home and Care Coordination

ONC Description

For purposes of 2009 use case prioritization, the Medical Home and Care Coordination use case focuses on the activities and information needs of a primary care physician operating as the manager of all of a patient's medical information and health needs across multiple providers and care settings. The use case includes the processes by which information flows to the primary care physician as well as capabilities to manage co-morbidities.

Defining Quotes from AHIC Working Groups and Others

The focus of this use case is derived from needs and issues expressed by the AHIC CC workgroup, CE workgroup, and HITSP. Representative quotations from these contributors are included below:

"*The Advanced Medical Home is a concept whereby a patient's primary care physician office would operate as the care coordinator for all the patient's medical conditions and needs. This would include coordinating test results and feedback from the patient's multiple providers and ensuring that the patient's care addressed all co-morbid conditions.*

In order to advance the advanced medical home (AMH), three components are necessary:

1) The AMH requires specific interoperable data elements which can be included in the CCHIT certification process. A physician must be able to receive and incorporate lab and test results and treatment histories from all of the patient's myriad providers as well as various equipment such as remote monitoring tools. All this information must be available to the physician in a reliable, secure, timely, and efficient manner.

2) In order for a physician to operate as the patient's advanced medical home, the primary care physician must have access to an EHR that addresses all the needed functionalities to manage multiple conditions. This includes, among other things, registry functions, the ability to track aspects of specific conditions, and a way to receive data from monitoring systems which evaluate the patient's ongoing condition(s) outside of the office setting.

3) The final component is a model for reimbursement of the AMH that is not dependent on only FFS. Development of appropriate models will require participation by private and federal payers, and will be more likely to occur once the technical infrastructure necessary to support the AMH has been developed"

Information Needs Addressed by Existing Use Cases

Many of the information needs for a possible Medical Home and Care Coordination use case have been previously addressed and are published in the following use cases:

- Delivery of laboratory results to an EHR - 2006 EHR- Laboratory Results Use Case
- Delivery of a summary care record to an EHR - 2007 Emergency Responder EHR Use Case
- Delivery of prescriptions, current medications, and allergies to an EHR - 2007 Medication Management Use Case
- Delivery of a core set of patient data between EHRs - 2008 Consultations and Transfers of Care Use Case
- Delivery of remote monitoring information to an EHR - 2008 Remote Monitoring Use Case
- Delivery of immunization information to an EHR – 2008 Immunizations and Response Management Use Case
- Communications between patients and providers including health reminders for patients - 2008 Patient-Provider Secure Messaging Use Case

- Ability to automatically route information to the appropriate provider - 2008 Consumer Access to Clinical Information Use Case and 2007 Quality Use Case

New Information Needs Arising in this Use Case

An initial analysis of needs suggested by a possible Medical Home and Care Coordination use case include some new, unmet information needs in the following areas.

- Functionality to support management of co-morbidities and related problem lists, specific clinical decision support, quality indicators, and health reminders.

Policy Considerations

Development of this Use Case may require exploration and resolution of issues that are fundamentally issues of policy. Potential policy issues relevant to this use case include:

- Reimbursement models may impact willingness to assume responsibility for managing all of a patient's medical information and health needs across multiple providers and care settings.
- Is the primary care provider the appropriate home for all of a patient's medication information?

Store and Forward Telemedicine

ONC Description

For the purposes of 2009 use case prioritization, the Store and Forward Telemedicine use case focuses on the information needs associated with communicating a request for clinical consultation to a remotely located clinician who does not directly interact with the patient in real time. The use case includes the processes associated with recording relevant patient data, images, waveforms, visual observations, etc. which are forwarded to the remotely located consulting clinician. This use case also builds on some exchanges addressed in the 2008 Consultations and Transfers in Care use case and would include some greater specificity regarding images, waveforms, and visual observations.

Defining Quotes from AHIC Working Groups and Others

The focus of this use case is derived from needs and issues expressed by the AHIC community including the CC and EHR Workgroups and HITSP. Representative quotations from these contributors are included below:

"Store-and-forward is a type of telehealth encounter or consult that involves the use of digital images (still and/or motion) and/or audio recordings of a patient for the purpose of rendering a medical opinion or diagnosis. While already in use extensively for healthcare services requiring a simple reading and interpretation of images such as radiology, the use of store-and-forward for physician-to-physician clinical consultations that include both a diagnosis and treatment plan is in use in various geographies and sectors of the US healthcare system.

"Technology advancements and results from years of evaluative research have made the use of store-and-forward technology an important and viable option in the delivery of care. The evaluative research has documented: (i) important savings in time and money, (ii) improved clinically efficacious outcomes and (iii) in several specialty areas, no difference in diagnosis and treatment plans between face-to- face consultations and store-and-forward telemedicine. Over the past few years, there have also been significant advances in telemedicine to include development of standards. These developments have come at a critical time. There are well-documented shortages of medical specialists and mal-distribution of said specialists, and this trend is not expected to change. At the same time, there is a growing population of aging Americans who are hitting the healthcare system en-mass and will need care that our present system will be unable to meet. Thus, this store-and-forward telemedicine provider-to-provider tele-consultation use case represents a critical capacity builder to enable efficacious, high quality rapid care in the years ahead."

"Expanding Results/Image Exchange **–** Waveforms**:** *Ability to exchange medical images between health systems in their native waveform format, rather than snapshots or summary data. This is particularly important for the standard 12-lead ECG.* Radiographs/studies: *Includes still images and studies: MRI; CT; Echo; etc."*

"Radiology images – …*greater emphasis regarding the sharing of radiology images and associated reports. These data types are certainly pertinent to some of the early use cases, particularly the EHR, Biosurveillance and Emergency responder cases. This said the sharing of images and reports obtained at various sites remains a major bottleneck for patients and providers in the delivery of care which is often provided across various enterprises. Lastly there is potentially a high level of return given the high level of information content available in images and reports."*

Information Needs Addressed by Existing Use Cases

Many of the information needs for a possible the Store and Forward Telemedicine use case have been previously addressed and are published in the following use cases:

- Format and communication of a consultation request and consult report – 2008 Consultations and Transfers of Care Use Case.
- Delivery of a summary care record to an EHR - 2007 Emergency Responder EHR Use Case.
- Capture of appropriate history and images based on standard protocol – 2008 Consultations and Transfers of Care Use Case.
- Support for store and forward communications – 2008 Patient – Provider Secure Messaging Use Case.
- Support for healthcare in the event of national emergency – 2007 Emergency Responder EHR Use Case.

New Information Needs Arising in this Use Case

An initial analysis of needs suggested by a possible Store and Forward Telemedicine use case include some new, unmet information needs in the following areas.

- Capture, store, and communicate images (still and/or motion), audio recordings and other information for subsequent evaluation. Capture of data in native form for images, EKGs, assessments, and history and physical would be covered in this use case if not addressed in Consults and Transfers of Care, but in addition, the needs associated with the storage of these data would be addressed.

Policy Considerations

Development of this Use Case may require exploration and resolution of issues that are fundamentally issues of policy. Potential policy issues relevant to this use case include:

- Current reimbursement models may not fully support store and forward telemedicine.

Long Term Care and Assessment

ONC Description

For the purposes of 2009 use case prioritization**,** the Long Term Care and Assessment use case focuses on the information needs in long term care settings associated with specific issues of medications management and patient assessments as well as other long term care needs. The use case builds on the 2007 Medication Management Use Case as well as the 2008 Consultations and Transfers in Care Use Case to incorporate the unique needs of the long term care settings.

Defining Quotes from AHIC Working Groups and Others

The focus of this use case is derived from needs and issues expressed by the AHIC CC Workgroup, the Joint LTC Group, and federal agencies. Representative quotations from these contributors are included below:

"Persons with chronic conditions require assessments across a variety of domains, often including assessments of physical and cognitive functioning. Such assessments are essential for identifying appropriate and effective clinical interventions, supporting continuity care, monitoring the effectiveness of clinical interventions, and sometimes for paying for needed services. Applying recognized HIT standards to the content of assessment instruments and for the exchange of complete assessment instruments and/or specific assessment results is essential for real-time exchange and re-use of assessment information. The application of content and messaging standards to assessment instruments and results will enable improvements in quality, enhance continuity of care, and allow efficiency gains in care delivery and payers/regulators/researchers to maximally re-use assessment information (assuming appropriate protections are in place).

"…Several types of assessment instruments are used in caring for persons with chronic conditions, many of which include assessments of the individual's physical and cognitive functioning. Identifying the HIT content and messaging standards needed for assessment instruments and/or specific assessment results is critically important for persons with chronic conditions."

"The numerous medications that LTC patients receive demands health information exchange between care settings and providers of care as well as the collection of accurate medication information. This is critical to the reduction of medication errors in the transfer of patients between care settings as well as ongoing patient safety while in the LTC facility. There are numerous communication transactions between the nursing facility and the dispensing pharmacy related to each patient and each medication order - creating significant opportunities to improve efficiency and effectiveness through the electronic exchange of information"

- *"Pharmacy dispenses re-supply of medication per a pre-determined schedule ("cycle fills"), and transmits dispensed medication fill status information to the facility"*
- *"Facility accepts pharmacy delivery (reconciliation between ordered and dispensed medications)"*
- *"Facility transmits return authorization request to the pharmacy"*
- *"Facility dispenses medications from facility stock (over-the-counter products) and/or pharmacy-maintained emergency supply residing at the facility (emergency first dosing)"*
- *"Facility and pharmacy communication disposition of discontinued medications"*

Information Needs Addressed by Existing Use Cases

Many of the information needs for a possible the Long Term Care and Assessment use case have been previously addressed and are published in the following use cases:

- Delivery of a summary care record to an EHR - 2007 Emergency Responder EHR Use Case.
- Delivery of prescriptions, current medications, and allergies to an EHR - 2007 Medication Management Use Case.
- Delivery of discharge documentation to next provider of care - 2007 Medication Management Use Case and 2008 Consultations and Transfers of Care.
- Delivery of a core set of patient data between EHRs - 2008 Consultations and Transfers of Care Use Case.
- Delivery of remote monitoring information to an EHR - 2008 Remote Monitoring Use Case.
- Delivery of immunization information to an EHR – 2008 Immunization and Response Management Use Case.
- Communications between patients and providers including health reminders for patients -2008 Patient-Provider Secure Messaging Use Case.
- Ability to automatically route information to the appropriate provider - 2008 Consumer Access to Clinical Information Use Case and 2007 Quality Use Case.

New Information Needs Arising in this Use Case

An initial analysis of needs suggested by a possible Long Term Care and Assessment case include some new, unmet information needs in the following areas.

- Assessment of cognitive functioning: tools and their content, data sets, results communication.
- Assessment of physical functioning may include Activities of Daily Living (ADL): tools and their content, data sets, results communication.
- Integrated, collective, collaborative assessment and care planning.
- Chronic disease management functionality including management of co-morbidities, problem lists, clinical decision support, quality indicators, and health reminders.
- Inclusion of assessment data within EHRs.
- Information needs and processes related to medication administration for long term care.
- Information needs related to eligibility, qualifications for programs/services, and disability would be addressed in the 2009 Prior-Authorization and Scheduling and Release of Information Candidate Use Cases.

Prior-Authorization and Scheduling in support of Treatment, Payment, & Healthcare Operations

ONC Description

For the purposes of 2009 use case prioritization, the Prior-Authorization and Scheduling in support of Treatment, Payment and Healthcare Operations use case focuses on the information needs of patients, consumers, payors, and providers during prior-authorization and scheduling activities. For prior-authorization activities the use case includes delivery of relevant clinical information in conjunction with administrative data.

Defining Quotes from AHIC Working Groups and Others

The focus of this use case is derived from needs and issues expressed by the AHIC community including the CE and EHR WGs, HITSP, CCHIT, and federal agencies. Representative quotations from these contributors are included below:

"Upon this framework, however, the extended eligibility use case has a subset of clinical information most commonly needed by practitioners at the point of care. This may employ the continuity of care record, clinical document standard from HL7, or other emerging standard representations of core clinical data. At a minimum, this must be inclusive of patient demographics, problems and conditions, medications, allergies, advanced directives, and ideally the data associated with United States Preventive Services Task Force Guidelines for healthcare maintenance and preventive care services."

This may also include*: "The ability to access to certain laboratory data or certain patient attributes and characteristics which may be utilized for eligibility determination/verification. This may include a subset of clinical information most commonly needed by practitioners at the point of care…The ability to access various form of information to assist in eligibility determination, pre-certification, etc."*

"…In addition to the ability for a consumer to monitor and manage financial information related to an individual account such as premiums, claims, payments, co-payments, reimbursements etc.

"Ability to determine and communicate preventative appointments and/or schedule and communicate preventative, routine care, requested appointments, etc. Furthermore, the ability for a consumer to request, schedule, confirm, change, or cancel appointments with one or more providers."

"Ability for a consumer to indicate demographic information, health insurance, coverage information and gather information on the status of eligibility and claims."

Information Needs Addressed by Existing Use Cases

Many of the information needs for a possible the Prior-Authorization and Scheduling in support of Treatment, Payment and Healthcare Operations use case have been previously addressed and are published in the following use cases:

- Delivery of laboratory results to an EHR - 2006 EHR- Laboratory Results Use Case
- Delivery of a summary care record to an EHR - 2007 Emergency Responder EHR Use Case
- Communications between patients and providers including health reminders for patients -2008 Patient-Provider Secure Messaging Use Case
- Access to a web portal for the purposes of communication (e.g. scheduling information) - 2008 Patient-Provider Secure Messaging Use Case
- Delivery of a core set of patient data - 2008 Consultations and Transfers of Care Use Case

- Ability to communicate eligibility information - 2008 Consultations and Transfers of Care Use Case
- Ability to automatically route information to those appropriately authorized - 2008 Consumer Access to Clinical Information Use Case 2007 Quality Use Case
- Ability to incorporate and populate electronic forms for the purposes of reporting information such as assessment information – 2008 Public Health Case Reporting Use Case
- Delivery of patient specific communications – 2008 Public Health Case Reporting Use Case
- Ability to incorporate consumer access permissions – 2007 Consumer Access to Clinical Information Use Case
- Identification of providers who have a relationship with the patient/consumer – 2008 Consumer Access to Clinical Information Use Case

New Information Needs Arising in this Use Case

An initial analysis of needs suggested by a possible Prior-Authorization and Scheduling in support of Treatment, Payment and Healthcare Operations use case include some new, unmet information needs in the following areas.

- Prior-Authorization/Eligibility information capture
- Prior-Authorization/Eligibility tracking and management
- Scheduling management

Authorization for Release of Information for Third Parties

ONC Description

For the purposes of 2009 use case prioritization, the Authorization for Release of Information for Third Parties use case focuses on the information needs associated with the processes by which patients/consumers communicates their authorization to release applicable health information to third parties and the processes by which that authorization is acted upon by the third parties and clinicians who hold the data.

Defining Quotes from AHIC Working Groups and Others

The focus of this use case is derived from needs and issues expressed by AHIC through the PHC Workgroup, HITSP, CCHIT, and federal agencies. Representative quotations from these contributors are included below:

"*Claimants contact third-parties to apply for disability benefits. With the application, the claimants sign as Authorization to disclose information to the third-parties. After determining a claimant's eligibility for disability benefits, third-parties send a request to all of the patient's providers for medical records of the patient and includes the patient's authorization for release of information to the provider… Once the provider receives this request, the authorization is verified and medical records are sent back to third-parties."*

"The authorization for release of information is used for disclosures for purposes other than treatment, payment, and operations. Claimants sign an authorization to release information as part of their claims application. They authorize third-parties to obtain medical records from any sources holding this information."

" Capabilities will be needed to transmit the patient's authorization for release of information and patient identification information to the provider. The provider must have the have the capability to electronically assess the content of the authorization and the request to release the appropriate information to SSA."

"Electronically handling the patient authorization 'form' to allow for true interoperability without manual intervention. Handling of authorizations for releasing medical records is critical because it is not the same as consent, which has been addressed. Authorized release of information is useful to many scenarios in addition to disability benefit processing."

"Functioning and disability data are relevant to…eligibility determination and general health status and would benefit from greater standardization."

Patient authorization capabilities as expressed by HITSP and CCHIT:

"…Patients/Consumers need be able to participate in authorizing how data can be used and shared. Capabilities should exist which allow for communication and implementation of patient/consumer authorization."

Information Needs Addressed by Existing Use Cases

Many of the information needs for a possible Authorization for Release of Information for Third Parties use case have been previously addressed and are published in the following use cases:

- Ability to incorporate consumer access permissions – 2007 Consumer Access to Clinical Information Use Case
- Delivery of a core set of patient data - 2008 Consultations and Transfers of Care Use Case
- Ability to automatically route information to those appropriately authorized entities - 2008 Consumer Access to Clinical Information Use Case 2007 Quality Use Case
- Ability to incorporate and populate electronic forms for the purposes of reporting and information exchange – 2008 Public Health Case Reporting Use Case
- Delivery of patient specific communications – 2008 Public Health Case Reporting Use Case
- Identification of providers who have a relationship with the patient/applicant – 2008 Consumer Access to Clinical Information Use Case
    - Although many of the information exchanges which support this use case have been addressed, additional information may need to be present in these information exchanges, including: patient/claimant identification and authorization information, authorization communications to providers, etc.

New Information Needs Arising in this Use Case

An initial analysis of needs suggested by a possible Authorization and Release of Information use case include some new, unmet information needs in the following areas.

- Consumer release of information request
- Transmission of release of information and reconciliation with other information controls
- Tracking and managing release of information requests

Policy Considerations

Development of this Use Case may require exploration and resolution of issues that are fundamentally issues of policy. Potential policy issues relevant to this use case include:

- What constitutes a "trusted" third party presenting an authorization for release?
- Consumers may want to have choices relative to what information is shared.

Clinical Research – Clinical Trials Data and EHRs

ONC Description

For the purposes of 2009 use case prioritization, the Clinical Research – Clinical Trials Data and EHRs use case focuses on the information needs associated with provision of EHR data to support clinical trials and other clinical research activities. Potential aspects of this use case for further consideration include methods to incorporate research protocols into EHRs, methods to gather patient-specific research data not normally collected within an EHR, and the information needs associated with qualifying and re-qualifying patients for clinical trial research.

Defining Quotes from AHIC Working Groups and Others

The focus of this use case is derived from an amalgamation of needs and issues expressed by the AHIC community, HITSP, and PHCCC**.** Representative quotations from these contributors are included below:

"Clinical Research: *Clinical/Medical Research provides a significant opportunity for HIT/EHR for the following reasons: 1) the opportunity to employ electronic health records (EHR) for secondary use case purposes including clinical/medical research, biosurveillance, disease registry, imaging and lab data exchange; 2) Medical/Clinical research conducted for regulatory purposes must incorporate informed consent, patient privacy and confidentiality, and a complete audit trail to ensure traceability and integrity of the data; 3) Clinical/Medical Research informs healthcare, which in turn informs medical/clinical research. Evidence-based healthcare relies on research for the information upon which to base decision support; and 4) improving patient safety"*

"Clinical Trials: *The enterprise EHR systems are the outreach for the clinical trials in the US. Therefore, getting the standards established and uses cases assured facilitate the national movement of translational research – accelerating from bench to bedside in a quicker timeframe*"

The AHIC - Population Health and Clinical Care Connections (PHCCC) Workgroup has also prioritized population-based research

"*Providing data from clinical care for use in conducting population-based research"*

Information Needs Addressed by Existing Use Cases

Many of the information needs for a possible Clinical Research – Clinical Trials Data and EHRs use case have been previously addressed and are published in the following use cases:

- Extraction of relevant clinical information from EHRs - 2008 Consultations and Transfers of Care Use Case.
- Ability to automatically route de-identified information to the appropriate provider - 2008 Consumer Access to Clinical Information Use Case and 2007 Quality Use Case.
- Use of Genomic Standards – 2008 Personalized Healthcare Use Case.
- Adverse Event Reporting Standards - 2008 Public Health Case Reporting Use Case.
- Delivery of a summary care record to an EHR - 2007 Emergency Responder EHR Use Case.
- Delivery of prescriptions, current medications, and allergies to an EHR - 2007 Medication Management Use Case.
- Delivery of discharge documentation to next provider of care - 2007 Medication Management Use Case and 2008 Consultations and Transfers of Care.
- Delivery of a core set of patient data between EHRs - 2008 Consultations and Transfers of Care Use Case.
- Delivery of remote monitoring information to an EHR - 2008 Remote Monitoring Use Case.

- Delivery of immunization information to an EHR – 2008 Immunizations and Response Management Use Case.
- Communications between patients and providers including health reminders for patients - 2008 Patient-Provider Secure Messaging Use Case.

New Information Needs Arising in this Use Case

An initial analysis of needs suggested by a possible Clinical Research – Clinical Trials Data and EHRs use case include some new, unmet information needs in the following areas.

- The ability to incorporate clinical trial "eligibility" criteria into EHRs.
- Analyze the Integration Profile and Clinical Research Profile developed by the members of the research community for potential inclusion in this use case.
- Analyze components of the research lifecycle.
- Evaluate existing clinical care information for its ability to support research lifecycle, including use of EHR information and incorporation of research findings into clinical care.
- Incorporation of research protocols into EHRs.
- Standardized data within an EHR to support clinical research and clinical trials.

Policy Considerations

Development of this Use Case may require exploration and resolution of issues that are fundamentally issues of policy. Potential policy issues relevant to this use case include:

- Additional specificity about sharing of clinical information for research purposes and associated state and federal regulations may be necessary.

American Health Information Community

Quality Workgroup Vision Roadmap and Recommendations

Carolyn Clancy
HHS/Agency for Healthcare Research and Quality

Richard Stephens
The Boeing Company

April 22, 2008

Quality Workgroup Members

Co-Chairs:

– Carolyn Clancy	HHS/Agency for Healthcare Research and Quality
– Richard Stephens	The Boeing Company

Members:

– Abby Block	HHS/Centers for Medicare and Medicaid Services
– Janet Corrigan	National Quality Forum
– Helen Darling	National Business Group on Health
– Anne Easton	U.S. Office of Personnel Management
– Nancy Foster	American Hospital Association
– George Isham	HealthPartners and AQA alliance
– Jane Metzger	First Consulting Group
– Susan Postal	Hospital Corporation of America
– Gerald Shea	AFL-CIO
– Barry Straube	HHS/Centers for Medicare and Medicaid Services
– Jonathan Teich	Brigham & Women's Hospital
– William M. Tierney	Regenstrief Institute, Inc.
– Phyllis Torda	National Committee for Quality Assurance
– Reed V. Tuckson	United Health Group
– Charlene Underwood	Siemens Medical Solutions & HIMSS EHR Vendor Association
– Margaret VanAmringe	The Joint Commission
– Josie Williams	Quality and Patient Safety Initiatives

Office of the National Coordinator for Health IT:

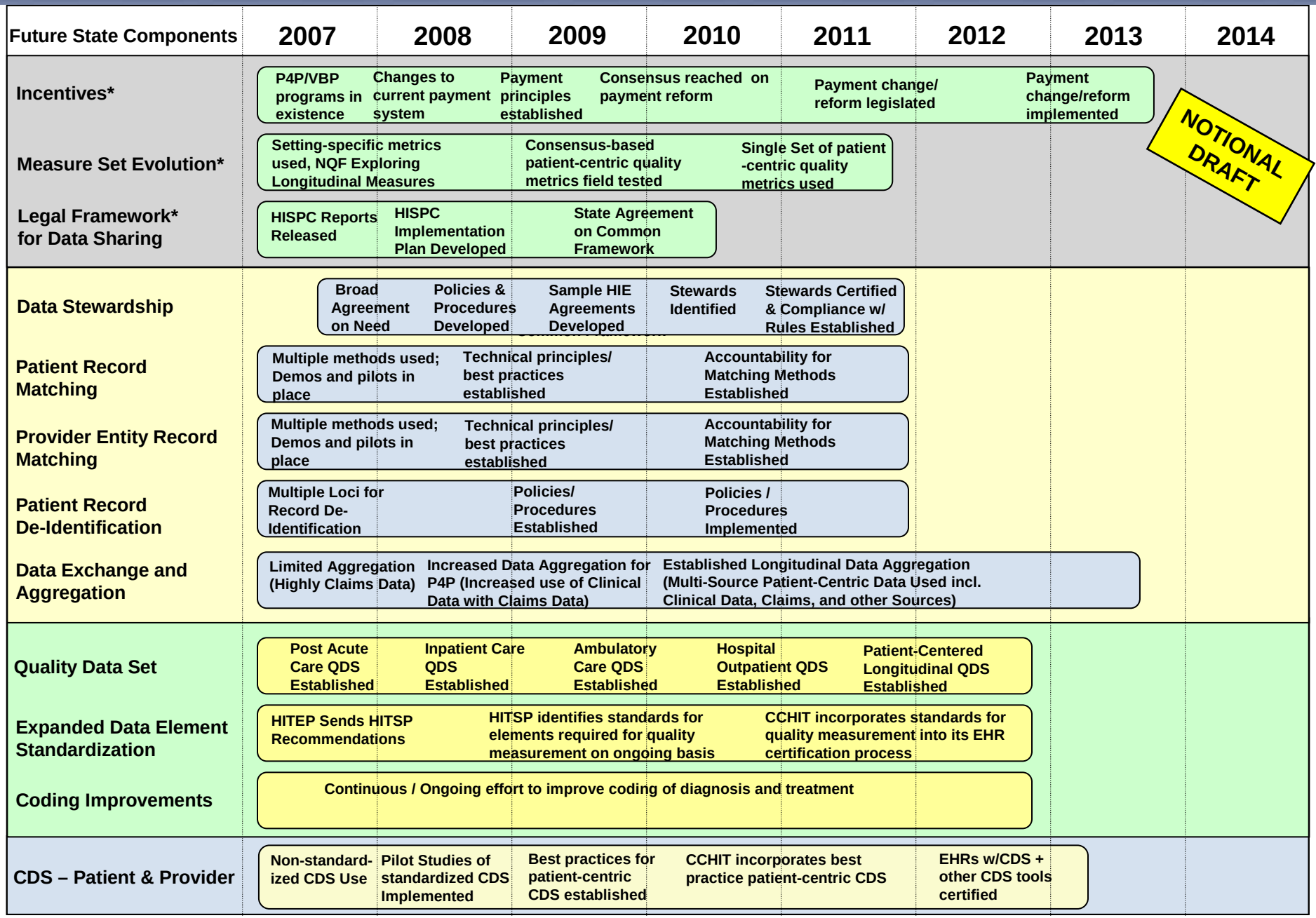
– Kelly Cronin

Broad charge: What are we trying to accomplish?

Make recommendations to the American Health Information Community so that health IT 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. Also, make recommendations for how performance measures should align with the capabilities and limitations of health IT.

Quality Workgroup
Vision Roadmap

Roadmap for Developing the HIT Capabilities to Achieve Quality Workgroup Vision+



KEY: Activity

+ The vision is continuously evolving as we move closer to it becoming a reality. Accordingly the representations in the diagram, while shown as linear, are also evolving and will require cycles to remain current.

* Potential Accelerant

Key themes from the Vision Roadmap

Patient-centric quality measurement

The patient-centric emphasis in the broad charge indicates a need for longitudinal quality measurement and improvement, where data is collected and used to inform quality improvement across care settings and over time, thereby putting the patient at the focal point of any improvement efforts.

Payment reform as an accelerator

Payment reform is required to create incentives for both better-coordinated, high-quality health care and the development of a health IT infrastructure to enable the exchange of health information across care settings.

Importance of data exchange and aggregation

Patient-centered care requires data exchange between providers and across care settings. Data aggregation is needed to create population-level metrics for the purpose of longitudinal quality measurement and improvement. Policy decisions and industry consensus must be established in order to further develop existing strategies and technological solutions, which include, but are not limited to: interoperable IT systems; protocols for physician and provider matching; and rules related to privacy and security.

Key themes from the Vision Roadmap (cont.)

Alignment around national priorities

A national priority setting process will focus the development of measures, the needed enhancements to medical coding, and the development of IT specifications and standards related to interoperability, data export and storage that are necessary to allow efficient assessment of the nation's progress towards quality goals.

Proactive consideration of health IT needs to support quality

The links between quality measurement and improvement and health IT need to be addressed proactively to achieve the future state of the vision. A common set of data elements, i.e., a quality data set, can be used across quality measure development, health IT standards development and harmonization, guideline development, and clinical decision support to facilitate better coordination.

Support for a hybrid data strategy

Much of the work toward the future state vision can begin now; there is no need to wait for full electronic health record (EHR) adoption. A hybrid data strategy can make use of existing sources of data (paper-based and electronic, administrative and clinical) for quality measurement while also integrating increasing amounts of clinical data from EHRs as it becomes available.

Quality Workgroup Recommendations

Translating the Vision Roadmap into actionable recommendations

- All of the components of the roadmap are critical and will need to be addressed in order to achieve the vision.
- While the scope of the vision roadmap is quite broad, the Quality Workgroup chose to focus on a few areas where substantive progress could be made within the next year and which have the potential to create a cycle of progress towards the eventual realization of the future state vision.
- Many of the activities described in the recommendations should continue beyond the initial funding cycle. Therefore, funding models are needed to help sustain these efforts into the future, including the possibility of transition to the AHIC successor.

Quality Workgroup recommendations

- The recommendations are focused on improving the quality of data used for quality measurement and reporting through:
  - Facilitating the alignment of initiatives to develop and implement quality measures.
  - Developing and implementing a quality data set to support quality measurement and reporting.
  - Prioritizing the creation of standards for structuring selected clinical data.

Facilitating the alignment of initiatives to develop and implement measures for quality improvement

- Recommendation 1.1: HHS, including the Office of the National Coordinator for Health IT and the Agency for Healthcare Research and Quality, in coordination with the Quality Alliance Steering Committee and the AHIC successor, should convene forums at regular intervals through December 2008 in order to facilitate the alignment of quality improvement and health information technology initiatives; in particular, those initiatives supporting quality measure development and implementation. Representatives of specific organizations should be included in the forums, such as the Centers for Medicare and Medicaid Services, the Federal Health Architecture, NIH/National Library of Medicine, the National Quality Forum, HITSP, CCHIT, Integrating the Healthcare Enterprise (IHE), and the AMA-NCQA Collaborative. Additionally, representatives of organizations such as guideline developers, AQA, HQA, the Joint Commission, and standards development organizations (SDOs) may be invited. As an outcome of the forums, HHS, in collaboration with the represented organizations, should develop a plan by October 28, 2008, for continued public-private cooperation to align the initiatives.

☐ **Accept** ☐ **Table** ☐ **Reject**

Developing and implementing a quality data set to support quality measurement and reporting

- Recommendation 2.1: HHS, including the Agency for Healthcare Research and Quality and the Centers for Medicare and Medicaid Services, should collaborate with key private sector stakeholders, including measure developers, health IT vendors, clinicians, providers, and quality organizations, to define a quality data set that would support quality measurement that is automated, patient-centric, and longitudinal with the goal of improving care delivery and outcomes. The quality data set should include, at a minimum, relevant data captured during inpatient and physician office visits, and data required to support transitions of care among other provider settings.

Developing and implementing a quality data set to support quality measurement and reporting

- Recommendation 2.1.1: By December 31, 2008, the collaborative effort named in recommendation 2.1 should review existing data sets used for quality measurement, including those developed by the Centers for Medicare and Medicaid Services for its CARE tool, by the HITEP in its initial work, by the Joint Commission for transfers of care, and by others as appropriate, as the basis of a harmonized minimum set of data types or elements that can be used for automating quality measures. The effort should also incorporate into the harmonized quality data set those data types or elements needed to support measure sets and national priority areas. The effort should assign a priority level to each data type or element within the quality data set as an aid to implementation.

Developing and implementing a quality data set to support quality measurement and reporting

- Recommendation 2.1.2: The Centers for Medicare and Medicaid Services, in expanding its set of quality measures, should work with the Indian Health Service to test the effectiveness of the harmonized minimum set of data types or elements, as developed in Recommendation 2.1.1, to capture and aggregate data from electronic health records.

- Recommendation 2.1.3: HHS, in coordination with the Quality Alliance Steering Committee and the AHIC successor, should maintain the minimum quality data set over time, modifying the quality data set as needed to address new measures and national priorities for quality measurement, and obtaining feedback on the quality data set from measure developers, health IT vendors, clinicians, providers, and quality organizations.

☐ **Accept** ☐ **Table** ☐ **Reject**

Developing and implementing a quality data set to support quality measurement and reporting

- Recommendation 2.2: Within three years following the identification of a quality data set, the Centers for Medicare and Medicaid Services should promote the use of the quality data set in its requirements for quality measurement and reporting across care settings.

☐ **Accept** ☐ **Table** ☐ **Reject**

Developing and implementing a quality data set to support quality measurement and reporting

- Recommendation 2.3: To accomplish some quality objectives, electronic health records must not only exchange data but also use and store certain data types or elements within electronic health records. Therefore, the Healthcare Information Technology Standards Panel (HITSP) should identify the data standards needed to fill identified gaps for inclusion of the identified quality data set for use in both ambulatory and inpatient electronic health records.

☐ **Accept** ☐ **Table** ☐ **Reject**

Developing and implementing a quality data set to support quality measurement and reporting

- Recommendation 2.4: The Certification Commission for Healthcare Information Technology (CCHIT) should consider developing the appropriate criteria necessary to support the inclusion of the identified quality data set in both ambulatory and inpatient electronic health records. This requirement should be submitted for inclusion on the CCHIT Roadmap in sufficient time for implementation in 2010.

☐ **Accept** ☐ **Table** ☐ **Reject**

Prioritizing the creation of standards for structuring selected clinical data

- Recommendation 3.1: The Agency for Healthcare Research and Quality, in collaboration with the Office of the National Coordinator for Health IT and in consultation with NIH/National Library of Medicine, should conduct an environmental scan of current initiatives where electronic clinical data is being used to inform quality improvement initiatives in order to identify areas where data standards for structured clinical data are needed. Initiatives for review include, but are not limited to, the Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) pilots and the Nationwide Health Information Network (NHIN) Trial Implementation sites. In preparing the environmental scan, which should be completed by November 30, 2008, experts could be convened from the BQI and NHIN sites that have experience in combining clinical and administrative data from multiple sources.

☐ **Accept** ☐ **Table** ☐ **Reject**

Prioritizing the creation of standards for structuring selected clinical data

- Recommendation 3.2: The Agency for Healthcare Research and Quality, in collaboration with the Office of the National Coordinator for Health IT and in consultation with NIH/National Library of Medicine, should use the results of the environmental scan from Recommendation 3.1 as well as the work of the National Quality Forum's Health Information Technology Expert Panel (HITEP) to develop recommendations to the Healthcare Information Technology Standards Panel (HITSP) for the identification of standards for structuring clinical data. These recommendations should be submitted to HITSP by January 31, 2009.

☐ **Accept** ☐ **Table** ☐ **Reject**

Prioritizing the creation of standards for structuring selected clinical data

- Recommendation 3.3: Through its convening function, the Agency for Healthcare Research and Quality, in collaboration with the Office of the National Coordinator for Health IT and in consultation with NIH/National Library of Medicine, should produce an action agenda by March 31, 2009. The action agenda should prioritize areas for structuring selected clinical data used across care settings, and identify opportunities to align efforts that are already underway to create standards related to clinical data. This work should be guided by an expert panel comprised of members of the EHR vendor community, clinicians, providers, specialty societies, standard development organizations, the National Quality Forum, guideline developers, measure developers, health plans, the Quality Alliance Steering Committee, the AHIC successor and others as appropriate, to ensure that standardization of documentation is aligned with care delivery and the development of executable guidelines and automatable quality measures.

☐ **Accept** ☐ **Table** ☐ **Reject**

April 22, 2008

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

Dear Mr. Chairman:

The American Health Information Community Quality Workgroup (QWG) was formed in 2006 and given the following broad and specific charges:

> **Broad Charge for the Workgroup:** Make recommendations to the American Health Information Community so that breakthroughs in health information technology (health IT) 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. Also, make recommendations for how performance measures should align with the capabilities and limitations of health IT.
>
> **Specific Charge for the Workgroup:** Make recommendations to the American Health Information Community that specify how certified health information technology should support the capture, aggregation, and reporting of data for a core set of ambulatory and inpatient quality measures.

This letter puts forth recommendations that advance the broad charge of the workgroup; a recommendations letter presented to the Community in March 2007 addressed the specific charge. In addition to the recommendations for the broad charge, this letter describes the QWG's approach to developing the recommendations, key themes that shaped the recommendations, and important activities occurring today that impact the recommendations. Appendix A contains a glossary of terms used in this recommendations letter and Appendix B contains a diagram that gives an overview of the roadmap of the QWG's vision for the future.

The Quality Workgroup's Approach to Date for the Broad Charge

In January 2007, the Quality Workgroup presented a vision for an ideal future state for quality measurement and improvement to the American Health Information Community (AHIC). The Quality Workgroup envisioned a future where transparent reporting of quality performance and quality improvement is used to inform decisions about patient care in a system that is both information-driven and patient-focused. Thus, the vision incorporates an expectation that quality measurement and improvement activities will evolve from a site-centric focus to a patient-centric focus. This evolution will require new policies and technical advancements to collect, aggregate and analyze longitudinal data to evaluate and improve the quality of patient care over defined time periods and across care settings, at both the individual and population levels. Moreover, the

future state is strongly informed by the perspective that the use of health IT can improve quality by both reducing reporting burden and driving improvements in care at the point of delivery.

After gathering testimony and conducting research, the Quality Workgroup undertook a requirements analysis in August 2007 to define the capabilities and policies needed to achieve the vision. The requirements analysis identifies enablers and barriers in today's environment and summarizes the policy, technical, and business requirements throughout the health IT and quality communities needed for successful operation in the future environment.

Based on the requirements analysis, the Quality Workgroup developed a vision roadmap during Fall 2007 that articulates a path forward for developing the health IT capabilities needed to achieve the future state by 2014. The vision roadmap is predicated on several themes from the vision and articulates key changes that must occur over the next six years. However, these key changes will require the identification of sources of funding and business models over this period of time to support the creation of the infrastructure that will enable data sharing and aggregation.

Key Themes from the Vision Roadmap

The roadmap is made up of twelve components that can be further divided into policy-related components and technical data-oriented components as shown in the exhibit below. Please see Appendix B for the detailed vision roadmap.

Vision Roadmap Policy Components	Vision Roadmap Technical Data-Oriented Components
• Business Case / Incentives • Measure Set Evolution • Legal Framework for Data Sharing • Data Stewardship • Patient and Provider Record Matching • Patient Record De-Identification • Data Exchange and Aggregation	• Quality Data Set • Expanded Data Element Standardization • Coding Improvements • Patient and Provider-Oriented Clinical Decision Support

The following key themes emerged from the vision and inform the vision roadmap:

- **Patient-centric quality measurement:** The patient-centric emphasis in the broad charge indicates a need for longitudinal quality measurement and improvement, where data is collected and used to inform quality improvement across care settings and over time, thereby putting the patient at the focal point of any improvement efforts.

- **Payment reform as an accelerator:** Payment reform is required to create incentives for both better-coordinated, high-quality health care and the development of a health IT infrastructure to enable the exchange of health information across care settings.

- **Importance of data exchange and aggregation:** Patient-centric care requires data exchange between providers and across care settings. Data aggregation is needed to create population-level metrics for the purpose of longitudinal quality measurement and improvement. Policy decisions and industry consensus must be established in order to further develop existing strategies and technological solutions, which include, but are not limited to:

interoperable IT systems; protocols for physician and provider matching; and rules related to privacy and security.

- **Alignment around national priorities for quality measurement:** A national priority setting process will focus the development of measures, the needed enhancements to medical coding, and the development of IT specifications and standards related to interoperability, data export and storage that are necessary to allow efficient assessment of the nation's progress towards quality goals.

- **Proactive consideration of health IT needs to support quality:** The links between quality measurement and improvement and health IT need to be addressed proactively to achieve the future state of the vision. In the current system, quality measures are developed in silos within care settings, necessitating measure data harmonization in the testing and maintenance phases of measure development across care settings and across measure sets, and expending significant resources. A common set of data types or elements, i.e., a quality data set (QDS), can be used across quality measure development, health IT standards development and harmonization, guideline development, and clinical decision support during the design of measure sets to increase efficiency, lower net costs, and ultimately facilitate better care coordination.

- **Support for a multi-source data strategy:** Much of the work toward the future state vision can begin now; there is no need to wait for full electronic health record (EHR) adoption. A multi-source data strategy can make use of existing sources of data (paper-based and electronic, administrative and clinical) for quality measurement while also integrating increasing amounts of clinical data from EHRs as it becomes available. An advantage of a multi-source data strategy would be the availability of cost of care data at the point of care so that providers are better able to make cost-effective decisions as appropriate.

The vision roadmap provides guidance for the efforts of current and future quality improvement efforts for groups such as the AHIC and its successor. The Quality Workgroup recognizes that the scope of the vision roadmap is quite broad. Therefore, the workgroup has chosen a few components about which to make formal recommendations, areas where substantive progress could be made within the next year and which have the potential to create a cycle of progress towards the eventual realization of the future state vision. The recommendations are focused on improving the quality of data used for quality measurement and reporting through:

1) Facilitating the alignment of initiatives to develop and implement measures for quality improvement.
2) Developing and implementing a quality data set to support quality measurement and reporting.
3) Prioritizing the creation of standards for structuring selected clinical data.

Relevant Organizations and Projects

Several key activities are occurring in parallel with the work of the Quality Workgroup. These activities offer opportunities for alignment with the vision roadmap and within the quality community's measure development process, and offer potential inputs to a quality data set.

The *National Committee on Vital and Health Statistics* (*NCVHS) Quality Workgroup* submitted a report to the Secretary of the Department of Health and Human Services (HHS) on January 28, 2008, titled "Quality Measurement and Public Reporting in the Current Health Care Environment." The report focuses on the emerging use of a multi-source data model to measure and report quality, and offers ten recommendations in the areas of public reporting, data quality, performance measurement reporting infrastructure, and the evolving landscape of performance measures and EHRs.

At the direction of the Agency for Healthcare Research and Quality (AHRQ), and in fulfillment of a prior Quality Workgroup recommendation, the *National Quality Forum's Health Information Technology Expert Panel (HITEP)* has completed an initial effort to prioritize and define types of data elements for inclusion in EHRs to facilitate standardized measurement and reporting for a core set of HQA and AQA measures. Some of the recommendations from the HITEP have gone forth to the Healthcare Information Technology Standards Panel (HITSP) as inputs to the interoperability specifications to support the Quality Use Case. HITSP's harmonized interoperability standards, which have been accepted by the AHIC and will in time be endorsed by the Secretary of the Department of Health and Human Services, will become requirements for EHR certification by the Certification Commission for Healthcare Information Technology (CCHIT). These data types could be considered as foundational inputs to a quality data set.

The *National Quality Forum* has begun working in partnership with other leadership organizations to establish national priorities and goals for performance measurement and public reporting through its *Priorities Partners* committee. The Priorities Partners committee anticipates releasing their first set of national priorities for conditions as well as certain cross-cutting areas in the summer of 2008.

The *Centers for Medicare and Medicaid (CMS)* is currently developing its Continuity Assessment Record and Evaluation (CARE) instrument which will contain key data items to support care transitions. In the Deficit Reduction Act of 2005, Congress required CMS to develop a uniform assessment instrument to measure and compare Medicare beneficiaries' health and functional status across provider settings, at intervals, and over time, upon hospital discharge. CMS is also required to test the instrument's usefulness in a 3-year demonstration that would start in early 2008. With this instrument, CMS is taking advantage of an opportunity to move from the paper-based tools of the past to an internet-based application for data collection.

The Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) Project is a CMS-funded quality improvement organization (QIO) special project in which the Delmarva Foundation for Medical Care has subcontracted with six communities, or pilot sites. These pilot sites are testing methods to aggregate Medicare claims data with data from commercial health plans and, in some cases, Medicaid, in order to calculate and report quality measures for physician groups and, in some cases, individual physicians. The results from this project will be used to guide future efforts for aggregating Medicare claims data with data from other payers to produce quality measure results that provide a more comprehensive picture of the quality of services being provided by physicians to Medicare beneficiaries.

The *Joint Commission* has developed a proposed list of data items that should be transferred with a patient from a hospital to another provider setting, whether by a paper or electronic system. The items were chosen because they represent areas that have high impacts on safety and quality of care but were not being addressed by other health IT organizations. This data set was originally intended for use within the Joint Commission's activities yet could become part of a data set across organizations.

The *Quality Alliance Steering Committee (QASC)* is a collaborative effort among existing quality alliances, government, physicians, nurses, hospitals, health insurers, consumers, accrediting agencies and foundations to dramatically improve the quality of health care across the U.S. The vision of QASC is to advance high-quality, cost-effective, patient-centered health care through the coordination of the various groups that are working to promote public reporting of health care provider information. QASC is currently testing approaches to combining summary provider information from Medicare and private health plan data at the national level, as well as developing a roadmap for integration of administrative data and other data streams (e.g., clinical registries, laboratory and imaging results reporting) to support quality measurement and reporting.

AHRQ recently convened a meeting of medical specialty societies and other selected experts to discuss strategies to obtain and use data needed for quality improvement and to move measurement from an environment of "data convenience" to an environment where clinical guidelines drive development of clinical decision support and quality measures. During this meeting, participants discussed the need for a data strategy that would involve the coordination and alignment of standards for structured clinical data to support effective use of clinical guidelines, clinical decision support and quality measurement. The outcomes of this meeting, and any follow-up meetings, will be useful input for the activities recommended below.

The *Nationwide Health Information Network (NHIN)* is intended to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and healthcare. Often referred to as a "network of networks," the NHIN will enable health information to follow the consumer, be available for clinical decision making, and support appropriate use of healthcare information beyond direct patient care to improve health. Now in its second year of development, the NHIN has awarded several grants for trial implementations through state and regional health information exchanges. Participants will implement and test the NHIN specifications, including the 2007 Quality Use Case, and demonstrate their connectivity to other networks.

Plans are now underway to establish a successor to the AHIC as a public-private partnership based in the private sector by fall 2008. The *AHIC successor* will be independent and sustainable and will bring together the best attributes and resources of public and private entities. This new public-private partnership will develop a unified approach to realize an effective, interoperable nationwide health information system that supports the health and well-being of the people of this country.

Recommendations

The Workgroup has identified the following actionable recommendations to meet the broad charge.

1. Facilitate the alignment of initiatives to develop and implement measures for quality improvement.

In its vision, the QWG states, "To realize the future vision, a unified national agenda for quality measurement must be developed and must be aligned with the common framework for measurement and use standard definitions of terms to the extent possible. Measure developers will have to collaborate to facilitate measure harmonization and vendors will have to collaborate with the National Quality Forum (NQF) and quality measurement organizations to encourage development and implementation of common conventions and guidelines for measure development."

The QWG believes that quality improvement efforts and health IT efforts could become better aligned to achieve this vision, creating synergies among currently siloed efforts in order to streamline and automate the quality measurement that would lead to improvement in the quality of care. More specifically, HHS and the Quality Workgroup have recognized an ongoing need to help coordinate the alignment of initiatives to develop and implement measures for quality improvement across multiple public and private organizations. In response to that need, staff from the Office of the National Coordinator for Health IT (ONC) and members of the Quality Workgroup organized two meetings of representatives of relevant organizations in Fall 2007, resulting in the documentation of the existing and future measure development process with a set of diagrams. The organizations represented at these meetings included ONC, AHRQ, CMS, National Quality Forum, HITSP, CCHIT, Integrating the Healthcare Enterprise (IHE), and the AMA-NCQA Collaborative. The participants at these meetings have expressed a common desire to continue meeting regularly and more formally to further align the various initiatives. The intent would be to identify areas of overlap or areas where gaps exist with the goal of enhancing efficiency in the measure development process, while avoiding the creation of extra burden for participating organizations.

> **Recommendation 1.1: HHS, including the Office of the National Coordinator for Health IT and the Agency for Healthcare Research and Quality, in coordination with the Quality Alliance Steering Committee and the AHIC successor, should convene forums at regular intervals through December 2008 in order to facilitate the alignment of quality improvement and health information technology initiatives; in particular, those initiatives supporting quality measure development and implementation. Representatives of specific organizations should be included in the forums, such as the Centers for Medicare and Medicaid Services, the Federal Health Architecture, NIH/National Library of Medicine, the National Quality Forum, HITSP, CCHIT, Integrating the Healthcare Enterprise (IHE) and the AMA-NCQA Collaborative. Additionally, representatives of organizations such as guideline developers, AQA, HQA, the Joint Commission, and standards development organizations (SDOs) may be invited. As an outcome of the forums, HHS, in collaboration with the represented organizations, should develop a plan by October 28, 2008, for continued public-private cooperation to align the initiatives.**

2. Develop and implement a quality data set to support quality measurement and reporting.

The Quality Workgroup recognizes opportunities to advance standardization of the data elements that are inputs into quality measures and care coordination efforts by supporting the development and implementation of a quality data set. The QDS refers to a minimum set of data elements or types of data elements that can be used as the basis for developing harmonized and machine-computable quality measures. More specifically, the QDS will serve as the basis for prioritizing data elements for inclusion in EHRs and other health IT systems and for prioritizing the development of standards for interoperability, data export, and data storage and for prioritizing related certification criteria.

It is anticipated that the development of the QDS will be dynamic and iterative. The efforts to define the QDS will need to be anchored in the clinician's view of data that is important for exchange across caregivers and sites of care to support high quality, coordinated care. At the same time, the QDS must enable evaluation of that care and support the evolving quality measurement landscape, which is being articulated, in part, by the National Quality Forum's Priorities Partners initiative. The QDS will facilitate the exchange of information across providers, institutions, and care settings to support care coordination and transitions across care settings, thereby promoting a more patient-centric approach to care delivery and a longitudinal approach to quality improvement. The QDS will also serve as a means to communicate clearly to providers and EHR vendors about which data elements need to be reliably and accurately captured. The improved availability of certain data elements will support the implementation of clinical decision support systems that enhance patient care.

The value proposition for the establishment of the QDS is the savings for several stakeholder groups that could be realized by increasing the efficiency of the measure design and data definition process. Currently, significant resources are expended by measure endorsers to reconcile measure definitions across settings and to reconcile data definitions across measure sets. IT vendors often must respond to these multiple data definitions, hampering efforts to streamline product implementation and provider workflow. If measure sets and data definitions were harmonized during the design of measure sets, rather than downstream during the testing and maintenance phases of measure development, much of this retro-fitting work could be avoided and efficiencies could be realized.

Recommendation 2.1: HHS, including the Agency for Healthcare Research and Quality and the Centers for Medicare and Medicaid Services, should collaborate with key private sector stakeholders, including measure developers, health IT vendors, clinicians, providers, and quality organizations, to define a quality data set that would support quality measurement that is automated, patient-centric, and longitudinal with the goal of improving care delivery and outcomes. The quality data set should include, at a minimum, relevant data captured during inpatient and physician office visits, and data required to support transitions of care among other provider settings.

Recommendation 2.1.1: By December 31, 2008, the collaborative effort named in recommendation 2.1 should review existing data sets used for quality measurement,

including those developed by the Centers for Medicare and Medicaid Services for its CARE tool, by the HITEP in its initial work, by the Joint Commission for transfers of care, and by others as appropriate, as the basis of a harmonized minimum set of data types or elements that can be used for automating quality measures. The effort should also incorporate into the harmonized quality data set those data types or elements needed to support measure sets and national priority areas. The effort should assign a priority level to each data type or element within the quality data set as an aid to implementation.

Recommendation 2.1.2: The Centers for Medicare and Medicaid Services, in expanding its set of quality measures, should work with the Indian Health Service to test the effectiveness of the harmonized minimum set of data types or elements, as developed in Recommendation 2.1.1, to capture and aggregate data from electronic health records.

Recommendation 2.1.3: HHS, in coordination with the Quality Alliance Steering Committee and the AHIC successor, should maintain the minimum quality data set over time, modifying the quality data set as needed to address new measures and national priorities for quality measurement, and obtaining feedback on the quality data set from measure developers, health IT vendors, clinicians, providers, and quality organizations.

Recommendation 2.2: Within three years following the identification of a quality data set, the Centers for Medicare and Medicaid Services should promote the use of the quality data set in its requirements for quality measurement and reporting across care settings.

Recommendation 2.3: To accomplish some quality objectives, electronic health records must not only exchange data but also use and store certain data types or elements within electronic health records. Therefore, the Healthcare Information Technology Standards Panel (HITSP) should identify the data standards needed to fill identified gaps for inclusion of the identified quality data set for use in both ambulatory and inpatient electronic health records.

Recommendation 2.4: The Certification Commission for Healthcare Information Technology (CCHIT) should consider developing the appropriate criteria necessary to support the inclusion of the identified quality data set in both ambulatory and inpatient electronic health records. This requirement should be submitted for inclusion on the CCHIT Roadmap in sufficient time for implementation in 2010.

3. Prioritize the creation of standards for structuring selected clinical data.

Currently, most quality measures are based on data abstracted from paper records or from administrative data. Administrative data is easily accessible, structured, and standardized, but lacks clinically rich information. Clinical data, on the other hand, is not easily accessible or useable. However, the common consensus among the quality improvement and health information technology communities is that structured clinical data could help drive significant improvements in the quality of health care delivery. Progress to create this structure has been

slow and could benefit from increased coordination across standards development organizations (SDOs).

Greater standardization of clinical data would facilitate consistent and complete capture of clinical information in EHRs and support the use of clinical decision support tools. Additionally, clinical data could be used to help providers and quality improvement professionals better understand outcomes and other aspects of patient care. Greater standardization of clinical data would also support near-term efforts to develop "clinically-enriched" data sources to support quality measurement and reporting. The QASC is currently developing a roadmap for aggregating administrative data and clinical data (e.g., registries, laboratory results reporting, medications) to produce clinically-enriched data sources capable of supporting a broader range of quality measurement and reporting requirements.

Recommendation 3.1: The Agency for Healthcare Research and Quality, in collaboration with the Office of the National Coordinator for Health IT and in consultation with NIH/National Library of Medicine, should conduct an environmental scan of current initiatives where electronic clinical data is being used to inform quality improvement initiatives in order to identify areas where data standards for structured clinical data are needed. Initiatives for review include, but are not limited to, the Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) pilots and the Nationwide Health Information Network (NHIN) Trial Implementation sites. In preparing the environmental scan, which should be completed by November 30, 2008, experts could be convened from the BQI and NHIN sites that have experience in combining clinical and administrative data from multiple sources.

Recommendation 3.2: The Agency for Healthcare Research and Quality, in collaboration with Office of the National Coordinator for Health IT and in consultation with NIH/National Library of Medicine, should use the results of the environmental scan from Recommendation 3.1 as well as the work of the National Quality Forum's Health Information Technology Expert Panel (HITEP) to develop recommendations to the Healthcare Information Technology Standards Panel (HITSP) for the identification of standards for structuring clinical data. These recommendations should be submitted to HITSP by January 31, 2009.

Recommendation 3.3: Through its convening function, the Agency for Healthcare Research and Quality, in collaboration with the Office of the National Coordinator for Health IT and in consultation with NIH/National Library of Medicine, should produce an action agenda by March 31, 2009. The action agenda should prioritize areas for structuring selected clinical data used across care settings, and identify opportunities to align efforts that are already underway to create standards related to clinical data. This work should be guided by an expert panel comprised of members of the EHR vendor community, clinicians, providers, specialty societies, standard development organizations, the National Quality Forum, guideline developers, measure developers, health plans, the Quality Alliance Steering Committee, the AHIC successor and others as appropriate, to ensure that standardization of documentation is aligned with care delivery and the development of executable guidelines and automatable quality measures.

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

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

Sincerely yours,

/Carolyn Clancy/
Carolyn Clancy
Co-chair, Quality Workgroup

/Richard Stephens/
Richard Stephens
Co-chair, Quality Workgroup

Appendix A: Glossary of Terms Relevant to the Quality Data Set

Data Element: A discrete unit of data (such as patient birth date or principal diagnosis) of interest to an organization. It is a unit of data for which the definition, identification, representation, and permissible values are specified by means of a set of attributes.

Data Format: A description of the allowed format for the values of a data element.

Data Standard: A standard that will enable information systems to exchange clinical systems in a private and secure manner both within and between institutions.

Data Strategy: A well-defined approach to collecting and using data to support a business process that:

- has been agreed upon by a group of experts
- has been publicly vetted
- provides rules, guidelines, or characteristics
- helps to ensure that materials, products, processes, and services satisfy the needs that result from the intended use of the data
- is available in an accessible format
- is subject to an ongoing review and revision process

Data Type: A group or category of data elements.

Data Value: One of the allowable values of a data element.

Measure Specification: Detailed instructions necessary to convert health care data into a quality measure

Quality Data Set: A minimum set of data types or elements that can be used as the basis for developing harmonized and machine-computable quality measures. The QDS will serve as the basis for prioritizing data elements for inclusion in EHRs and other health IT systems and for prioritizing the development of standards for interoperability, data export, and data storage and for prioritizing related certification criteria.

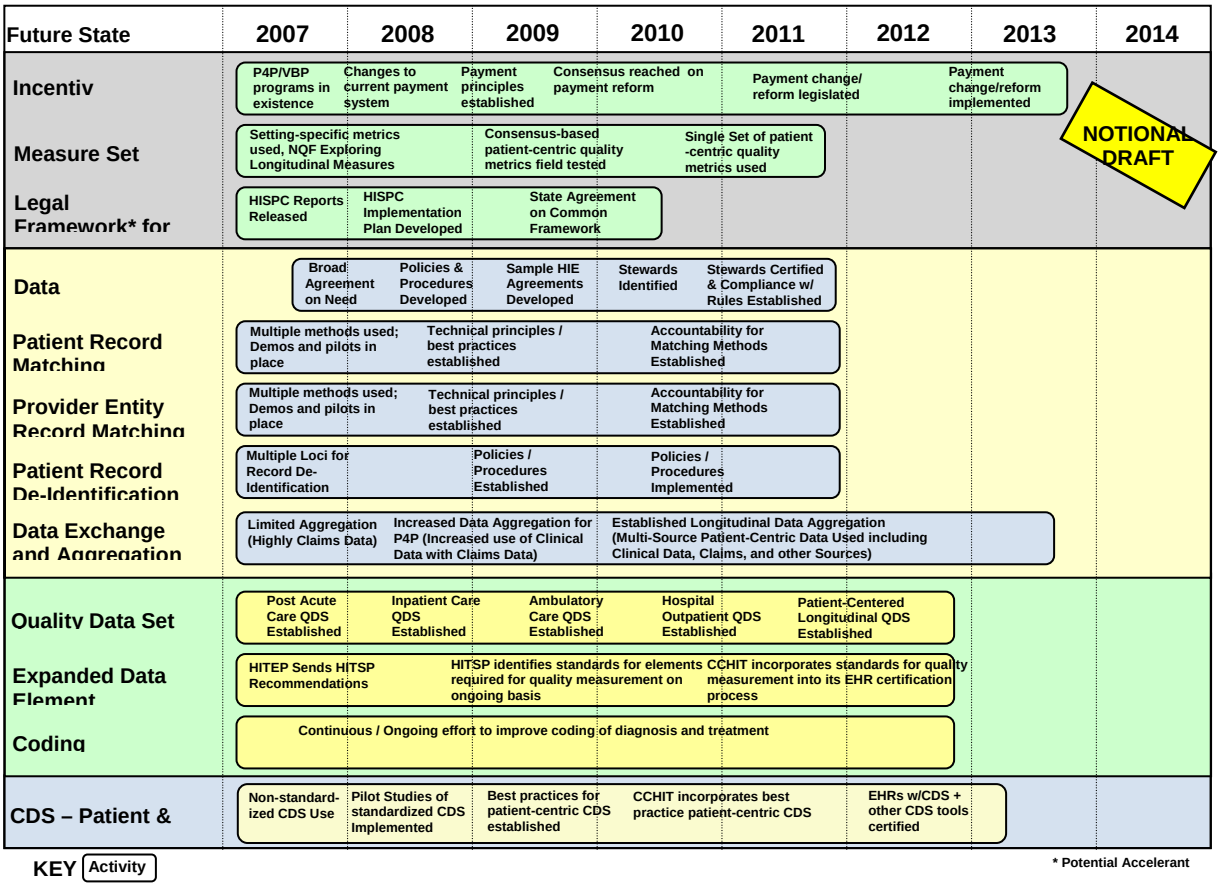
Sources: HITSP Glossary v.1.0; Quality Use Case; The Joint Commission Specifications Manual for National Hospital Quality Measures, Version 2.3b; Connecting for Health; wikipedia.org; National Quality Forum's Health Information Technology Expert Panel report

Example:

Data Type: Diagnosis
Data Elements: Principal Diagnosis, Secondary Diagnoses
Data Value: Principal Diagnosis = 428 Heart Failure
Data Standard: ICD9-CM
Data Format: alphanumeric

In this example, the data element is included in both the numerator and denominator statements of many measure specifications. To produce a measure, data elements are connected through algorithms which specify sequences of retrieval, aggregation and required values for data elements.

Appendix B: A Roadmap for Developing Health IT Capabilities to Achieve the Quality Workgroup Vision



American Health Information Community

Clinical Decision Support Recommendations

John Glaser
Partners HealthCare

Charles Friedman
Office of the National Coordinator for Health IT

April 22, 2008

Overview of Clinical Decision Support

- The use of Clinical Decision Support (CDS) capabilities within electronic health records and related electronic clinical systems holds great potential to improve health care outcomes in the U.S.

- CDS provides clinicians, staff, patients and other individuals with knowledge and person-specific information, intelligently filtered at appropriate times, to enhance health and health care.

- CDS is inherently cross-cutting and engages several AHIC Workgroups.

Objectives of the CDS Initiative

1. Advance patient-centric care and improve health care outcomes through effective use of CDS.

2. Accelerate the successful adoption of CDS in a wide variety of health settings.

3. Enhance patient participation in care through thoughtful applications of CDS.

CDS Ad Hoc Planning Group Formation

- The CDS initiative builds upon the CDS Roadmap, published in June 2006
- An “Ad Hoc CDS Planning Group” was formed in May 2007, comprised of individuals from the public and private sectors
- Ad Hoc CDS Planning Group membership included representatives from five AHIC Workgroups:
  - **Consumer Empowerment Workgroup**
  - **Electronic Health Records Workgroup**
  - **Personalized Healthcare Workgroup**
  - **Population Health and Clinical Care Connections Workgroup**
  - **Quality Workgroup**

CDS Ad Hoc Planning Group Members

- **Chair:**
  - John Glaser — Partners HealthCare
- **Government Lead Staff:**
  - Charles Friedman — Deputy National Coordinator
- **Public Participants:**
  - Don Detmer — American Medical Informatics Association
  - Norman Kahn — Council of Medical Specialty Societies
  - Blackford Middleton — Partners HealthCare
  - Jerry Osheroff — Thomson Healthcare
  - Paul Tang — Palo Alto Medical Foundation
  - Jonathan Teich — Elsevier / Harvard
  - Steve Teutsch — Merck
  - Marc Williams — Intermountain Healthcare

CDS Ad Hoc Planning Group Members (cont.)

- **Government Participants:**
  - Greg Downing — HHS/OS
  - Jon White — HHS/AHRQ
  - Kelly Cronin — HHS/ONC
  - Karen Bell — HHS/ONC
  - John Loonsk — HHS/ONC
  - Les Lenert — HHS/CDC
  - Elizabeth Mansfield — HHS/FDA
  - Miles Rudd — Indian Health Service
  - Kristin Brinner — HHS/OS
  - Chitra Mohla — HHS/ONC
  - Michelle Murray — HHS/ONC

Administrative/Support:

- Dana Womack — ONC Contractor
- Kristine Martin Anderson — ONC Contractor
- Lauren Kim — ONC Contractor
- Yasmeen Ansari — ONC Contractor

Concurrent CDS Effort: Federal CDS Collaboratory

- CDS efforts internal to the government to be coordinated through a Federal CDS Collaboratory
  - Co-sponsored by ONC, AHRQ, and HHS Personalized Healthcare Initiative
  - Builds on a government agency scan
  - 28 representatives of nine federal agencies participated in an organizational meeting on March 20, 2008
  - Will meet quarterly beginning in June, 2008 and will focus on coordination of government activities related to CDS
  - Can be an “effector” arm for several AHIC CDS Recommendations

CDS Recommendations Development

- CDS update provided to AHIC in September 2007

- Ad Hoc CDS Planning Group efforts:
  - December 2007: Worked in teams to develop draft proto-recommendations
  - January 2008: Finalized proto-recommendations
  - February 2008: Coordinated deliberations of the proto-recommendations across five AHIC Workgroups; incorporated feedback into draft CDS Recommendations
  - March 2008: Draft recommendations were again reviewed by AHIC Workgroups; additional feedback was incorporated into final CDS Recommendations
  - April 2008: Letter signed by Co-Chairs of all five Workgroups

Drive Measurable Progress Toward Priority Performance Goals for Health Care Quality Improvement Through Effective Use of CDS

Recommendation 1.1: Guided by the efforts of multiple national priority setting efforts (e.g., National Quality Forum's National Priority Partners Committee), representatives of federal agencies, including "the CDS Collaboratory", should identify priorities for federally funded CDS efforts by December 30, 2008. These priorities should consider existing government funded programs such as pay for performance, research and development grants, public health, and personalized health care. The CDS Collaboratory should develop an evaluation plan to monitor the impact of federally funded CDS programs on high priority areas. The CDS Collaboratory should widely disseminate its list of top priorities for CDS efforts, and how the government's CDS activities are helping to address those priorities.

☐ **Accept** ☐ **Table** ☐ **Reject**

Drive Measurable Progress Toward Priority Performance Goals for Health Care Quality Improvement Through Effective Use of CDS (cont.)

Recommendation 1.1.1: HHS should collaborate with AHIC, the AHIC successor, the Healthcare Information Technology Standards Panel (HITSP) and other organizations to identify and harmonize data types needed to support CDS tools, with particular attention to tools and use cases that address the high priority conditions determined by national priority setting efforts such as the National Quality Forum's National Priority Partners Committee.

☐ **Accept** ☐ **Table** ☐ **Reject**

Drive Measurable Progress Toward Priority Performance Goals for Health Care Quality Improvement Through Effective Use of CDS (cont.)

Recommendation 1.2: Once the priorities and evaluation plan from Recommendation 1.1 have been completed, the CDS Federal Collaboratory should facilitate alignment of CDS efforts, methods and metrics within federal agencies that deploy, support or facilitate CDS. The CDS Collaboratory should establish a mechanism to periodically measure the contribution of CDS efforts to accelerating progress within these agencies towards improving the care delivered for patients with the targeted clinical conditions.

☐ **Accept** ☐ **Table** ☐ **Reject**

Explore Options to Establish or Leverage a Public-Private Entity to Facilitate Collaboration Across Many CDS Development Activities

Recommendation 2.1: By October 31, 2008, HHS and relevant partners should explore options to establish or leverage a public-private entity (e.g., AHIC 2.0 or other) to convene public and private organizations and stakeholders to promote effective CDS development and adoption and address gaps in CDS capabilities through planning, facilitation, and coordination of activities across diverse constituencies. The public-private entity could incorporate the viewpoints of multiple stakeholders by including representation from the CDS Ad Hoc Planning Group, the Certification Commission for Healthcare Information Technology (CCHIT), the Healthcare Information Technology Standards Panel (HITSP), the CDS Government Collaboratory (ex-officio government representatives) and organizations that represent consumers, providers, payers, guidelines developers, medical informatics experts, life sciences, public health, clinical information system and CDS developers, and others.

☐ **Accept** ☐ **Table** ☐ **Reject**

Explore Options to Establish or Leverage a Public-Private Entity to Facilitate Collaboration Across Many CDS Development Activities (cont.)

Recommendation 2.2: The public-private entity, working with its stakeholders, should plan a CDS infrastructure to serve the nation in the long term, and identify actions that its constituents can take to further the adoption of CDS. Looking across existing efforts within the public and private sectors, the public-private entity should identify approaches where coordination, collaboration and collective action can advance effective use of CDS.

☐ **Accept** ☐ **Table** ☐ **Reject**

Potential Activities to Be Coordinated by the Public-Private Entity

Activities and deliverables may include, but are not limited to:

- Describe a model repository or repositories that will support the aggregation of readily-accessible, reusable, computable knowledge, decrease duplication of knowledge management efforts, and promote broader utilization of CDS.
- Describe mechanisms that can be employed to ensure that consumers and health care professionals can be confident that the knowledge algorithms behind CDS applications provide solid, quality suggestions and advice.
- Develop a framework to optimize the delivery of CDS interventions so that advice is delivered at the right time, place and in a manner that enables consumers and health care professionals to act upon it in a timely manner.

Accelerate CDS Development and Adoption Through Federal Government Programs and Collaborations

Recommendation 3.1: The Agency for Healthcare Quality and Research (AHRQ) and National Institutes of Health (NIH) should support additional research to enhance discovery and application of best practices for utilizing clinician-specific and patient-specific CDS tools supportive of decision-making in EHR and Personal Health Record (PHR) systems by September 30, 2009.

Recommendation 3.2: AHRQ, Centers for Disease Control and Prevention (CDC) and NIH should support additional research to identify CDS approaches and interventions that patients in chronic disease groups such as diabetics, and other special populations, are most likely to use and find helpful when managing their own care by September 30, 2009.

☐ **Accept** ☐ **Table** ☐ **Reject**

Accelerate CDS Development and Adoption Through Federal Government Programs and Collaborations (cont.)

Recommendation 3.3: To facilitate inclusion of consumer preferences in systems that support collaborative patient-provider decision making, HHS, through appropriate funding mechanisms, should support the development of a minimum data set of personal attributes that contribute to individualized care by June 30, 2009, expanding on existing work, such as that of the National Quality Forum's Health Information Technology Expert Panel. (Example attribute categories include: demographics, clinical history, and psychosocial factors.) Once the minimum data set has been created, HITSP should develop interoperability standards for the personal attribute minimum data set so that guideline developers and EHR vendors can produce and work with clinically consistent data. These interoperability standards should be added to the criteria for certification of Electronic Health Records (EHRs), as well as for certification of Personal Health Records (PHRs) at such time as those criteria may be developed.

☐ **Accept** ☐ **Table** ☐ **Reject**

Accelerate CDS Development and Adoption Through Federal Government Programs and Collaborations (cont.)

Recommendation 3.4: The Centers for Medicare and Medicaid Services (CMS) and Agency for Healthcare Research and Quality (AHRQ) should collaborate to ensure that there is a process by which Pay for Performance, and Pay for Reporting initiatives inform the design and content of future model CDS knowledge repositories, so that resulting repositories meet the needs of Medicare Part A and Part B payment updates involving specific quality measures on an ongoing basis. Additionally, a process should be put in place to ensure that future relevant EHR demonstration projects include CDS, and that CDS "lessons learned" are included in demonstration project reports.

☐ **Accept** ☐ **Table** ☐ **Reject**

Next Steps

- Current and future CDS Ad Hoc Planning Group activities:
  - Continue to serve as a planning group for CDS as a timely, cross-cutting area of AHIC concern
- Current and future CDS Federal Collaboratory Activities:
  - Serve as an implementation arm for AHIC recommendations on CDS
  - Share information about current activities in the field of CDS across the government
  - Identify opportunities for cross-agency and cross-department CDS collaboration
  - Host educational events where members can learn more about cutting-edge CDS activities ongoing in the government and elsewhere

April 22, 2008

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

Dear Mr. Chairman:

The use of Clinical Decision Support (CDS) capabilities within electronic health records and related electronic clinical systems holds great potential to improve health care outcomes in the U.S. CDS provides clinicians, staff, patients and other individuals with knowledge and person-specific information, intelligently filtered at appropriate times, to enhance health and health care. CDS encompasses, but is not limited to, computerized alerts and reminders to care providers and patients, methods to bring care into compliance with clinical guidelines; condition-focused order sets, patient data reports and summaries, and documentation templates; advice to promote more accurate and timely diagnoses; and other tools that enhance decision making in clinical workflow. CDS is essential to assuring that the substantial and ongoing investments in biomedical science and innovation are translated as benefits to American taxpayers (in terms of improved health and health care) in a greatly accelerated timeframe.

Over past months, numerous American Health Information Community (AHIC) Workgroups have identified CDS capabilities to improve care as a timely and important area of focus. To address this need, a CDS Ad Hoc Planning Group, comprised of representatives from the Quality, Consumer Empowerment, Electronic Health Records, Personalized Healthcare, and Population Health and Clinical Care Connections Workgroups was created in May 2007 to form a common framework through which a coherent set of priorities for CDS could be generated. A set of "proto-recommendations" was developed and directed to the attention of multiple AHIC Workgroups during the spring of 2008. Workgroup contributions led to the development of formal CDS recommendations to accelerate the implementation of robust and workflow-sensitive CDS interventions that will drive measurable improvement in key health care outcomes.

Objectives of the initiative

- Advance patient-centric care and improve health care outcomes through effective use of CDS.
- Accelerate the successful adoption of CDS in a wide variety of health settings.
- Enhance patient participation in care through thoughtful applications of CDS.

Factors that will improve the ability of CDS to improve health care in the US include:

- Continued implementation of electronic health records with high degrees of interoperability.
- Adoption of national priorities for care improvement with explicit linkage of CDS to drive measurable improvements in these targeted areas.
- Harmonization of CDS tools, quality measures and quality reporting.
- Promotion of provider payment mechanisms that reward safe, high quality, efficient and coordinated patient care based on specific measures of quality and performance.

- Development of organizations, standards, tools and resources to assist small physician practices, hospitals, public health and other health settings to implement CDS efficiently and effectively.

CDS Roadmap – a foundational study

In 2005-06, the Office of the National Coordinator for Health Information Technology (ONC), in partnership with the Agency for Healthcare Research and Quality (AHRQ), supported the development of a CDS Roadmap. The American Medical Informatics Association (AMIA) convened experts in informatics, software engineering, and evidence development from industry, academia, and government to develop a national plan of action for CDS. The CDS Roadmap identified three essential elements for achieving the promise of CDS in health care: 1) access to the best knowledge available; 2) widespread adoption and effective use of CDS tools; and 3) continuous improvement of knowledge and CDS methods. The CDS Roadmap was presented to AHIC in the summer of 2006 and provides a useful background for the development of the recommendations offered in this document. (Journal of the American Medical Informatics Association. 2007;14:141-145)

Federal CDS Collaboratory

To coordinate efforts internal to the government, a multi-stakeholder federal CDS Collaboratory, co-sponsored by Agency for Healthcare Research and Quality (AHRQ), the HHS Personalized Healthcare Initiative, and ONC, has been formed. This group will build upon a scan of CDS-related federal agency activities conducted in 2007, and will work to leverage the efforts and knowledge of multiple agencies to expedite development and widespread adoption of effective CDS capabilities.

CDS Recommendations

The following recommendations will help ensure that clinical decision support is widely available to health care professionals, patients and individuals to enable high quality, cost-effective health care decisions. The recommendations are organized into three areas:

- Driving measurable progress toward priority performance goals for health care quality improvement through effective use of CDS.
- Exploring options to establish or leverage a public-private entity to facilitate collaboration across many CDS development and deployment activities.
- Accelerating CDS development and adoption though federal government programs and collaborations.

1. Drive measurable progress toward priority performance goals for health care quality improvement through effective use of CDS

CDS interventions support clinicians and patients in making decisions and taking specific actions that have been identified as best practices for specific clinical conditions at key decision points in care delivery. In this manner, CDS promotes the delivery of care that is consistent with guidelines designed to improve quality and promote adherence to best practices and guidelines for care.

Priorities for development of CDS tools should be shaped by national priorities for health care quality improvement. Highest priority CDS activities should be directed at health care scenarios

that are targeted for quality improvement. Based on broad stakeholder input, progress toward the identification of national priorities for health care quality improvement has been initiated by the National Quality Forum (NQF) and other priority-setting bodies. In the first half of 2008, NQF's National Priority Partners Committee plans to establish national priorities and performance goals for several common chronic conditions, to identify existing quality improvement measures that can be used to assess progress, and identify areas that need improved measurement of care quality within conditions targeted for quality improvement.

If quality measure development, CDS development, payment policy and evaluation efforts across various stakeholders can be better aligned, system level changes to achieve a high performance health care system will be more likely to succeed. Identification and dissemination of the impact of CDS on the outcomes of clinical conditions targeted for quality improvement will foster information sharing and collaboration helping to accelerate progress toward effective adoption of CDS.

> **Recommendation 1.1: Guided by the efforts of multiple national priority setting efforts (e.g., National Quality Forum's National Priority Partners Committee), representatives of federal agencies, including "the CDS Collaboratory", should identify priorities for federally funded CDS efforts by December 30, 2008. These priorities should consider existing government funded programs such as pay for performance, research and development grants, public health, and personalized health care. The CDS Collaboratory should develop an evaluation plan to monitor the impact of federally funded CDS programs on high priority areas. The CDS Collaboratory should widely disseminate its list of top priorities for CDS efforts, and how the government's CDS activities are helping to address those priorities.**
>
> > **Recommendation 1.1.1: HHS should collaborate with AHIC, the AHIC successor, the Healthcare Information Technology Standards Panel (HITSP) and other organizations to identify and harmonize data types needed to support CDS tools, with particular attention to tools and use cases that address the high priority conditions determined by national priority setting efforts such as the National Quality Forum's National Priority Partners Committee.**
>
> **Recommendation 1.2: Once the priorities and evaluation plan from Recommendation 1.1 have been completed, the CDS Federal Collaboratory should facilitate alignment of CDS efforts, methods and metrics within federal agencies that deploy, support or facilitate CDS. The CDS Collaboratory should establish a mechanism to periodically measure the contribution of CDS efforts to accelerating progress within these agencies towards improving the care delivered for patients with the targeted clinical conditions.**

2. Explore options to establish or leverage a public-private entity to facilitate collaboration across many CDS development and deployment activities

Effective adoption of CDS on a national scale will require the efforts and participation of numerous organizations, many of which sit outside the federal government. A public-private

entity to facilitate information sharing and coordination between relevant entities and activities will play an important role in advancing CDS implementation and improving the quality of health care.

> **Recommendation 2.1: By October 31, 2008, HHS and relevant partners should explore options to establish or leverage a public-private entity (e.g. AHIC 2.0 or other) to convene public and private organizations and stakeholders to promote effective CDS development and adoption and address gaps in CDS capabilities through planning, facilitation, and coordination of activities across diverse constituencies. The public-private entity could incorporate the viewpoints of multiple stakeholders by including representation from the CDS Ad Hoc Planning Group, the Certification Commission for Healthcare Information Technology (CCHIT), the Healthcare Information Technology Standards Panel (HITSP), the CDS Government Collaboratory (ex-officio government representatives) and organizations that represent consumers, providers, payers, guidelines developers, medical informatics experts, life sciences, public health, clinical information system and CDS developers, and others.**
>
> **Recommendation 2.2: The public-private entity, working with its stakeholders, should plan a CDS infrastructure to serve the nation in the long term, and identify actions that its constituents can take to further the adoption of CDS. Looking across existing efforts within the public and private sectors, the public-private entity should identify approaches where coordination, collaboration and collective action can advance effective use of CDS.**

A more detailed description of recommended activities that may be undertaken by the public-private entity is described in Appendix A.

3. Accelerate CDS development and adoption through federal government programs and collaborations

The activities of the public-private entity, the federal CDS Collaboratory, and the collaborative efforts that result should be supplemented by the efforts of specific federal entities. Activities that can be taken by federal entities to advance the charges of multiple Workgroups are outlined below.

> **Recommendation 3.1: AHRQ and NIH should support additional research to enhance discovery and application of best practices for utilizing clinician-specific and patient-specific CDS tools supportive of decision-making in EHR and Personal Health Record (PHR) systems by September 30, 2009.**
>
> **Recommendation 3.2: AHRQ, CDC and NIH should support additional research to identify CDS approaches and interventions that patients in chronic disease groups such as diabetics, and other special populations, are most likely to use and find helpful when managing their own care by September 30, 2009.**

Recommendation 3.3: To facilitate inclusion of consumer preferences in systems that support collaborative patient-provider decision making, HHS, through appropriate funding mechanisms, should support the development of a minimum data set of personal attributes that contribute to individualized care by June 30, 2009, expanding on existing work, such as that of the National Quality Forum's Health Information Technology Expert Panel. (Example attribute categories include: demographics, clinical history, and psychosocial factors.) Once the minimum data set has been created, HITSP should develop interoperability standards for the personal attribute minimum data set so that guideline developers and EHR vendors can produce and work with clinically consistent data. These interoperability standards should be added to the criteria for certification of Electronic Health Records (EHRs), as well as for certification of Personal Health Records (PHRs) at such time as those criteria may be developed.

Recommendation 3.4: CMS and AHRQ should collaborate to ensure that there is a process by which Pay for Performance, and Pay for Reporting initiatives inform the design and content of future model CDS knowledge repositories, so that resulting repositories meet the needs of Medicare Part A and Part B payment updates involving specific quality measures on an ongoing basis. Additionally, a process should be put in place to ensure that future relevant EHR demonstration projects include CDS, and that CDS "lessons learned" are included in demonstration project reports.

Conclusion

We believe that this set of recommendations offers great promise for advancing the goals of higher quality, safer and more efficient patient-centric health care. Thank you for giving us the opportunity to submit these recommendations. We look forward to discussing these recommendations with you and the members of the American Health Information Community.

Sincerely yours,

/John Glaser/
John Glaser
Chair, CDS Ad Hoc Planning Group
Co-Chair, Personalized Healthcare Workgroup

/Nancy Davenport-Ennis/
Nancy Davenport-Ennis
Co-Chair, Consumer Empowerment Workgroup

/Rose Marie Robertson/
Rose Marie Robertson
Co-Chair, Consumer Empowerment Workgroup

/Jonathan Perlin/
Jonathan Perlin
Co-Chair, Electronic Health Records Workgroup

/Lillee Smith-Gelinas/
Lillee Smith-Gelinas
Co-Chair, Electronic Health Records Workgroup

/Doug Henley/
Doug Henley
Co-Chair, Personalized Healthcare Workgroup

/Leslie Lenert/
Leslie Lenert
Co-Chair, Population Health and Clinical Care Connections Workgroup

/John Lumpkin/
John Lumpkin
Co-Chair, Population Health and Clinical Care Connections Workgroup

/Carolyn Clancy/
Carolyn Clancy
Co-Chair, Quality Workgroup

Appendix A

This section augments Recommendations 2.1 and 2.2 by providing additional background information and detail to key activities that may be coordinated by the CDS public-private entity. Potential activities and deliverables may include:

- Describe a model repository or repositories that will support the aggregation of readily-accessible, reusable, computable knowledge, decrease duplication of knowledge management efforts, and promote broader utilization of CDS.
- Articulate public and private contributions and accompanying business models that may be required over time to achieve a broad implementation of a cohesive repository of computable rules/clinical practice guidelines.
- Formulate education efforts and business cases that promote integration of CDS within Electronic Health Records (EHR) systems and create incentives for use of CDS to support improved patient care quality.
- Describe mechanisms that can be employed to ensure that consumers and health care professionals can be confident that the knowledge and algorithms behind CDS applications provide solid, quality suggestions and guidance.
- Develop a framework to optimize the delivery of CDS interventions so that advice is delivered at the right time, place and in a manner that enables consumers and health care professionals to act upon it in a timely manner.
- Articulate strategies to overcome the unique challenges of implementing CDS within Ambulatory Care settings.
- Describe methods by which consumer preferences surrounding care, treatment, and logistical matters can be accounted for, to support truly collaborative decision-making between consumers and care providers.
- Establish a communication forum for CDS stakeholders to promote identification of common interests and execution of mutually beneficial activities that advance widespread and effective utilization of CDS.
- Describe methods to measure CDS contributions to improvements in health care.

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

American Health Information Community

Consumer Empowerment Workgroup Recommendations

Nancy Davenport-Ennis
National Patient Advocate Foundation

April 22, 2008

Consumer Empowerment (CE) Workgroup Members

- **Co-Chairs:**
  - Nancy Davenport-Ennis — National Patient Advocate Foundation
  - Rose Marie Robertson — American Heart Association
- **Staff Co-Chair:**
  - Karen Bell — Office of the Secretary, HHS
- **Members:**
  - Jason Bonander — Centers for Disease Control and Prevention
  - Jodi Daniel — HHS/ONC
  - Lorraine Doo — HHS/Centers for Medicare and Medicaid Services
  - Stephen Downs — The Robert Wood Johnson Foundation
  - Garth Graham — HHS/Office of Minority Health
  - Thomas Horan — Claremont Graduate University
  - Kevin Hutchinson — Surescripts
  - David Lansky — Markle Foundation
  - J.P. Little — RxHub
  - Ross Martin — Pfizer
  - Susan McAndrew — HHS/Office for Civil Rights
  - Davette Murray — Department of Defense
  - Kim Nazi — Veterans Health Administration
  - Nancy Nielsen — American Medical Association
  - Jayne Orthwein — National Institutes of Standards and Technology
  - Charles Safran — American Medical Informatics Association

CE Workgroup Members (cont.)

- **Members:**
  - Justine Handelman — Blue Cross Blue Shield Association
  - Steve Shihadeh — Microsoft
  - Linda Springer — Office of Personnel Management
  - Paul Tang — Palo Alto Medical Foundation
  - Robert Tennant — Medical Group Management Association
  - Sarah Wattenberg — SAMHSA
  - Armin Weinberg — Intercultural Cancer Council/Baylor College of Medicine
  - Myrl Weinberg — National Health Council

CE Workgroup Overview

Broad Charge:

Make recommendations to the Community to gain wide spread adoption of a personal health record that is easy-to-use, portable, longitudinal, affordable, and consumer-centered.

Specific Charge:

Make recommendations to the Community so that within one year, a pre-populated, consumer-directed and secure electronic registration summary is available to targeted populations. Make additional recommendations to the Community so that within one year, a widely available pre-populated medication history linked to the registration summary is deployed.

Persons with Disabilities

Recommendation 1.1: HHS should coordinate activity to ensure that PHRs sponsored by the federal government are consistent with statutes and regulations, including accessibility standards in accordance with Section 503 (29 U.S.C. § 793), 504 (29 U.S.C. §794) and 508 (29 U.S.C. §794d) of the Rehabilitation Act of 1973 (Pub. L. 93-112).

☐ **Accept** ☐ **Table** ☐ **Reject**

Persons with Disabilities (cont.)

- **Recommendation 1.2:** As HHS develops a use case with attendant interoperability standards specific to the needs of persons with disabilities, this use case should include the following:
  - Provision for coordinated care across multiple health care encounters, providers, and caregivers.
  - Access to and assimilation of information currently existing in paper format.
  - The ability of authorized care and service providers, including the Social Security Administration (SSA) and other public and private entities that have purview over disability compensation, to utilize electronic authentication and electronic transmittal to obtain relevant information from the PHR on behalf of the authorizing consumer or surrogate, in accordance with the authorizing parties restrictions on what data can be seen or accessed from the PHR.
  - Functional assessment for use by persons with disabilities in subsequent disability record development.

☐ **Accept** ☐ **Table** ☐ **Reject**

Persons with Disabilities (cont.)

Recommendation 1.3: As PHRs are certified, HHS should coordinate efforts to ensure that relevant electronic health information in these PHRs is interoperable with that in CCHIT certified Electronic Health Records.

☐ **Accept** ☐ **Table** ☐ **Reject**

Persons with Disabilities (cont.)

Recommendation 1.4: Any PHR offered directly or sponsored by HHS should be developed to accommodate technological applications that can be used by persons with disabilities, and can address accessibility issues that include differences in language, the broad range of racial and cultural diversity, and differences in family and community practice.

☐ **Accept** ☐ **Table** ☐ **Reject**

Racial and Ethnic Communities/Underserved

Recommendation 2.1: HHS should increase access for racial and ethnic minorities, persons with disabilities, and the underserved to health care delivery systems which are supported by health IT by specifying language referencing the inclusion of racial and ethic minorities, persons with disabilities, and the underserved in relevant contracts, grants, cooperative agreements, demonstration projects, and pilots which support the adoption of health IT within the delivery system.

☐ **Accept** ☐ **Table** ☐ **Reject**

Racial and Ethnic Communities/Underserved (cont.)

Recommendation 2.2: HHS, through the Office of Minority Health, shall lead the process of conducting an environmental scan on HIT use by medically underserved populations.

☐ **Accept** ☐ **Table** ☐ **Reject**

Racial and Ethnic Communities/Underserved (cont.)

Recommendation 2.3: HHS should pursue partnerships with private sector leadership to foster better communication between patients and providers in underserved areas via secure messaging, tele-health/tele-medicine, and remote monitoring in multiple settings.

☐ **Accept** ☐ **Table** ☐ **Reject**

Racial and Ethnic Communities/Underserved (cont.)

Recommendation 2.4: The Office of Minority Health (OMH) should work with ONC to leverage support for public/private and non-profit partnerships in efforts to market, educate, and increase usage of information technologies by racial and ethnic minorities to reduce health disparities. OMH, working with ONC, should take leadership in communicating about PHRs, their applications, and their benefits to community-based organizations by developing an action plan, timetable and metrics for the implementation of an education outreach plan.

☐ **Accept** ☐ **Table** ☐ **Reject**

April 22, 2008

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

Dear Mr. Chairman:

At its November 29, 2005, meeting, the American Health Information Community (the Community) recommended the formation of a Workgroup on consumer empowerment. The Community charged the Consumer Empowerment Workgroup (CE Workgroup) with the following:

> **Specific Charge for the Workgroup:** Make recommendations to the Community so that within one year, a pre-populated, consumer-directed and secure electronic registration summary is available to targeted populations. Make additional recommendations to the Community so that within one year, a widely available pre-populated medication history linked to the registration summary is deployed.
>
> **Broad Charge for the Workgroup:** To make recommendations to the Community to gain widespread adoption of personal health records (PHRs) that are easy to use, portable, longitudinal, affordable, and consumer centered.

In response to the Broad Charge, the CE Workgroup heard testimony over the past few months from several presenters that helped define the different types of electronic personal health records and the business cases that will support their widespread adoption. A presentation and paper by Joanne Lynn, "*Using Population Segmentation to Provide Better Health Care for All: The Bridges to Health Care Model*," provided a framework for the Workgroup's discussions on opportunities for health information technology to support special populations. Based on the population segments model provided in the paper, it is believed that persons with disabilities and racial/ethnic minorities have specific needs which, if met, would foster adoption of health IT for the benefit of these populations.

Since last October, the CE Workgroup has focused on identifying the specific and unique needs of special and underserved populations that will facilitate widespread adoption of personal health records within a motivated group. The concept of segmenting consumer populations can lead to more creative and effective strategies for safe, efficient, effective, timely, patient centered, and equitable health care, and thus a better understanding of how to achieve better health for both the individual and for all people. Following are the two population segments that the CE Workgroup addressed with respect to defining distinctive and unique features required in a PHR:

1. Persons with Disabilities
2. Racial and Ethnic Communities/Underserved

RECOMMENDATIONS

1. Persons with Disabilities

In October of 2007, the CE Workgroup heard testimony from a panel of presenters that provided a closer look at the use of PHRs among people with disabilities. The presenters represented the diverse needs of this population, including: the Paralyzed Veterans of America; the role of PHRs in facilitating the "disability policy transition" from policies that focus on caretaking to empowerment policies; a business case to promote the ability of PHRs to empower people with disabilities; the role of PHRs to assist in disability determination; and a presentation on the development of a user taxonomy. Regarding the user taxonomy, it was noted that there are differences between the "disabled" and people who are "unwell" regarding privacy needs. Based on the testimony, it was determined that there were several issues that needed to be explored further such as:

- How PHRs might be used to assist with eligibility determination for disability benefits.
- How access needs could be met by the technological design of PHRs.
- How PHRs could facilitate coordinated care among disparate settings.

To further expand on and define the needs of persons with disabilities, the CE Workgroup approved the formation of a Disability Subgroup. The subgroup was convened on December 3, 2007, on a time limited basis (to conclude on or before April 30, 2008). The subgroup held seven meetings and deliberated on recommendations pertinent to the disabled and electronic personal health records. These recommendations were presented to the Consumer Empowerment Workgroup on March 18, 2008, for comment and subsequent presentation to the AHIC.

The recommendations were developed based on the following identified requirements:

- Providing access consistent with 508/504 requirements
- Coordinating disability care and emergency needs
- Addressing authentication challenges
- Coping with multiple PHRs
- Facilitating lifelong portability needs of persons with disabilities
- Recognizing cultural differences among the disability community
- Addressing HIPAA authorization challenges
- Facilitating development of medical evidence for disability benefit determination

Recommendation 1.1: **HHS should coordinate activity to ensure that PHRs sponsored by the federal government are consistent with statutes and regulations, including accessibility standards, in accordance with Section 503 (29 U.S.C. § 793), 504 (29 U.S.C. §794) and 508 (29 U.S.C. §794d) of the Rehabilitation Act of 1973 (Pub. L. 93-112).**

Background: *PHRs sponsored by the federal government refers to PHRs developed, used, and supported by the Federal government through contracts or agreements with health care providers, health plans, or health insurance issuers. These products should meet accessibility standards in accordance with Section 503 (29 U.S.C. § 793), 504 (29 U.S.C. §794) and 508 (29 U.S.C. §794d) of the Rehabilitation Act of 1973 (Pub. L. 93-112).*

Recommendation 1.2: As HHS develops a use case with attendant interoperability standards specific to the needs of persons with disabilities, this use case should include the following:

- **Provision for coordinated care across multiple health care encounters, providers, and caregivers.**
- **Access to and assimilation of information currently existing in paper format.**
- **The ability of authorized care and service providers, including the Social Security Administration (SSA) and other public and private entities that have purview over disability compensation, to utilize electronic authentication and electronic transmittal to obtain relevant information from the PHR on behalf of the authorizing consumer or surrogate, in accordance with the authorizing parties restrictions on what data can be seen or accessed from the PHR.**
- **Functional assessment for use by persons with disabilities and their providers in subsequent disability record development.**

Background: The Consumer Empowerment Workgroup has previously recommended that the AHIC consider a use case for persons with disability in its prioritization processes. With that in mind, this recommendation specifies some of the elements that this use case should consider when it is developed.

Recommendation 1.3: As PHRs are certified, HHS should coordinate efforts to ensure that relevant electronic health information in these PHRs is interoperable with that in CCHIT certified Electronic Health Records.

Background: The Consumer Empowerment workgroup has previously recommended that PHRs be certified for privacy, security, and interoperability. This recommendation ensures that the interoperability standards necessary for coordinated care are included in both PHRs and EHRs, so that this information can flow directly between provider and patient if requested.

Recommendation 1.4: Any PHR offered directly or sponsored by HHS should be developed to accommodate technological applications that can be used by persons with disabilities, and can address accessibility issues that include differences in language, the broad range of racial and cultural diversity, and differences in family and community practice.

Background: The ultimate goal is to enable all types of electronic health information to flow into the PHR to form a comprehensive portrait of the health and care of the consumer. This comprehensive data base can then be the foundation for a wide variety of market-driven personal health applications that can present the data so consumers or their designees will find value in managing their health.

2. Racial and Ethnic Communities/Underserved

The "Bridges to Health Model" enables rational customization of health care around coherent segments of the population and thus is more useful than the usual focus on diagnoses or provider types. Based on this model, the CE Workgroup heard testimony from a panel of presenters that helped define the needs of racial and ethnic communities. The presentations included: Populomics, which focuses on the potential role of technology to address racial and ethnic disparities; an electronic medical record at a low-income Latino "safety net" health clinic; the use of technology to improve health care among migrant agriculture workers; and possible solutions on how best to implement health information technology (health IT) strategies among racial, ethnic, and underserved populations.

The testimony led to the following key criteria for developing recommendations:

- Proactively work to increase the availability of health IT in the delivery systems that care for persons of racial and ethnic minorities, persons with disabilities, and the underserved.
- Use health IT to foster better communication between providers and patients of racial and ethnic minorities.
- Support public/private partnerships to market and increase education and usage of information technologies by persons of racial and ethnic minorities and the underserved.

Recommendation 2.1: HHS should increase access for racial and ethnic minorities, persons with disabilities, and the underserved to health care delivery systems which are supported by health IT by specifying language referencing the inclusion of racial and ethic minorities, persons with disabilities, and the underserved in relevant contracts, grants, cooperative agreements, demonstration projects, and pilots which support the adoption of health IT within the delivery system.

Recommendation 2.2: HHS, through the Office of Minority Health (OMH), shall lead the process of conducting an environmental scan on health IT use by medically underserved populations.

<u>*Definition for underserved*</u>: *Underserved includes individuals who do not have adequate access to health care services. They share one or more of these characteristics: they may be poor; uninsured; have limited English language proficiency and/or lack familiarity with the health care delivery system; or live in locations where providers are not readily available to meet their needs. Members of ethnic and racial minority groups are not by definition "underserved" but are disproportionately found among their numbers.*

Recommendation 2.3: HHS should pursue partnerships with private sector leadership to foster better communication between patients and providers in underserved areas via secure messaging, telehealth/telemedicine, and remote monitoring in multiple settings.

Recommendation 2.4: The Office of Minority Health (OMH) should work with ONC to leverage support for public/private and non-profit partnerships in efforts to market, educate, and increase usage of information technologies by racial and ethnic minorities to reduce health disparities. OMH, working with ONC, should take leadership in communicating about PHRs, their applications, and their benefits to community-based organizations by developing an action plan, timetable and metrics for the implementation of an education outreach plan.

In proposing the above recommendations, the CE Workgroup would like to ensure that the benefits of new technologies are available to everyone and the potential of health IT is available to help eliminate health disparities.

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

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

Sincerely yours,

/Rose Marie Robertson/
Rose Marie Robertson
Co-chair, Consumer Empowerment Workgroup

/Nancy Davenport-Ennis/
Nancy Davenport-Ennis
Co-chair, Consumer Empowerment Workgroup

American Health Information Community

Confidentiality, Privacy, and Security Workgroup Recommendations

Kirk Nahra
Wiley Rein LLP

April 22, 2008

Confidentiality, Privacy, and Security (CPS) Workgroup Members

- **Co-chairs:**
  - Kirk Nahra — Wiley Rein LLP
  - Deven McGraw — Center for Democracy and Technology

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

CPS Workgroup Overview

Broad Charge:

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

Specific Charge:

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

Recommendations

- **Recommendation 1.0:** The obligation to provide "individual rights" and a notice of privacy practices under the HIPAA Privacy Rule should remain with the health care provider or health plan – who today has an independent relationship with a patient or consumer – and not an HIE. The CPS Workgroup recommends that health information exchanges (HIEs) and regional health information organizations (RHIOs) (collectively referred to in this letter as HIEs) that do not have "independent relationships" with patients or consumers be exempt from meeting the following HIPAA Privacy Rule requirements:
  - §164.520 Notice of privacy practices for protected health information;
  - §164.522 Rights to request privacy protection for protected health information;
  - §164.524 Access of individuals to protected health information;
  - §164.526 Amendment of protected health information; and
  - §164.528 Accounting of disclosures of protected health information.

Recommendations

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

☐ **Accept** ☐ **Table** ☐ **Reject**

April 22, 2008

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

Dear Mr. Chairman:

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

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

Background:

On February 26th, 2008, the AHIC CPS Workgroup presented two sets of recommendations to the AHIC for recommendation to the Secretary of the Department of Health and Human Services. Following the CPS Workgroup's presentation, and subsequent discussion by the AHIC, the CPS Workgroup was asked to reframe its recommendations. In response to AHIC's request, we submit the following reframed recommendations as an addendum to our original letter that contains the context and rationale for our recommendations.

As we noted in our February 26th letter, the recommendations below are neither meant to discount or detract from the privacy rights of patients or consumers, nor reduce the type of protections that should be provided in an electronic health information exchange network. Our recommendations are meant to pragmatically exempt HIEs who are merely acting on behalf of another covered entity from HIPAA Privacy Rule provisions that would otherwise require them to provide certain information directly to patients. All rights will continue to apply in full through the entity with whom the consumer or patient has an independent relationship. Moreover, HIEs will continue – as they do today – to assist these Covered Entities as appropriate in providing individual rights pursuant to existing Business Associate Agreements.

Recommendations:

Recommendation 1.0:
The obligation to provide "individual rights" and a notice of privacy practices under the HIPAA Privacy Rule should remain with the health care provider or health plan – who today has an independent relationship with a patient or consumer – and not an HIE. The CPS Workgroup recommends that health information exchanges (HIEs) and regional health information organizations (RHIOs) (collectively referred to in this letter as HIEs) that do not have "independent relationships" with patients or consumers be exempt from meeting the following HIPAA Privacy Rule requirements:

- §164.520 Notice of privacy practices for protected health information;
- §164.522 Rights to request privacy protection for protected health information;
- §164.524 Access of individuals to protected health information;
- §164.526 Amendment of protected health information; and
- §164.528 Accounting of disclosures of protected health information.

Recommendation 1.1: HIEs should make publicly available on their website (or through other means) a document that reasonably and accurately describes in plain language how they use and disclose health information and their privacy policies and practices, as well as how they safeguard patient or consumer information.

Conclusion:

The exemption of these requirements does not mean that HIEs would now be able to use or disclose health information in ways that Covered Entities or Business Associates could not – all other HIPAA requirements continue to apply. The exemption merely recognizes that it is impractical to impose these particular "individual rights" requirements on HIEs who do not have independent relationships with patients. If, in the future, HIEs were to establish independent relationships with individuals, the CPS Workgroup would expect HIEs to follow all of the rules that are in place today (e.g., all HIPAA privacy and security requirements including an individual's right to access, amendment, request privacy protection, and accounting of disclosures). Moreover, under our current recommendations, HIEs would still have an obligation – consistent with any existing Business Associate Agreements – to assist a Covered Entity in complying with these "individual rights" where appropriate. For example, an HIE could be required to assist a Covered Entity in responding to an individual's request to amend information in the medical record where appropriate (i.e., satisfying the requirement within §164.526(c)(3)).

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

Sincerely yours,

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

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

February 26, 2008

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

Dear Mr. Chairman:

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

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

Background:

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

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

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

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

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

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

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

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

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

Recommendations:

Notice of Privacy Practices

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

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

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

Individual Rights

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

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

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

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

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

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

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

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

Next Steps:

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

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

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

Sincerely yours,

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

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

American Health Information Community

Key Roles for State-Level Health Information Exchange Initiatives

Lynn Dierker

State-Level HIE Consensus Project

FORE-AHIMA

April 22, 2008

Project Overview

- Launched in 2006
- Targeting organized *state-level HIE efforts* (not to be confused with *state government*)
- Field research and analysis (9-15 statewide initiatives)
    - Governance,
    - Financial and operational characteristics,
    - Health information exchange policies and practices, and
    - Short and long-term priorities for implementation and sustainability
- Annual consensus conference to refine guidance
- State-level resources: *State Level Health Information Exchange Initiative Development Workbook,* programs, presentations
- Input to national HIE strategies, projects
- Series of reports, www.Staterhio.org

2007 Project Team and Organization

- Staff
  - Lynn Dierker, RN, Project director, Board of Directors, Colorado Regional Health Information Organization (CORHIO)
  - FORE/AHIMA
- Research Consultants
  - Lammot du Pont, William Bernstein, Manatt Health Solutions
  - Don Mon, VP Practice Leadership, AHIMA
- Steering Committee (and other state-level HIE contacts)
- Project Partners
  - National Council of State Legislators
  - eHealth Initiative
  - HIMSS
- ONC
- Liaisons to other agencies (AHRQ) and projects
  - NGA State eHealth Alliance
  - RTI HISPC

Steering Committee

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
- Rachel Block, Executive Director, **New York eHealth Collaborative**, New York, NY
- **Ray Campbell, Esq., MPA, CEO, **Massachusetts Health Data Consortium**, Waltham, MA
- Devore Culver, Executive Director, **HealthInfoNet**, Manchester, ME
- Lynn Dierker, RN, Senior Advisor, **Colorado Regional Health Information Organization**, Denver, CO
- Don Holmquest, MD, PhD, JD, CEO, **CalRHIO**, San Francisco, CA
- *Beth Nagel, Health Information Manager, Dept of Community Health, **Michigan Health Information Network**, Lansing, MI
- Marc Overhage, MD, PhD, FACP, FACMI, CEO, **Indiana Health Information Exchange, Inc**., Indianapolis, IN
- *Gina Perez, Executive Director, **Delaware Health Information Network**, Lewes, DE
- Jan Root, PhD, Executive Director, **Utah Health Information Network**, Murray, UT
- Christopher Sullivan, PhD, **Florida Office of Health Information Technology, Florida Health Information Network,** Tallahassee, FL
- Roxane Townsend, MD, Asst. VP, LSU Health Systems, Baton Rouge, LA

**Steering Committee Chair

* New in 2008

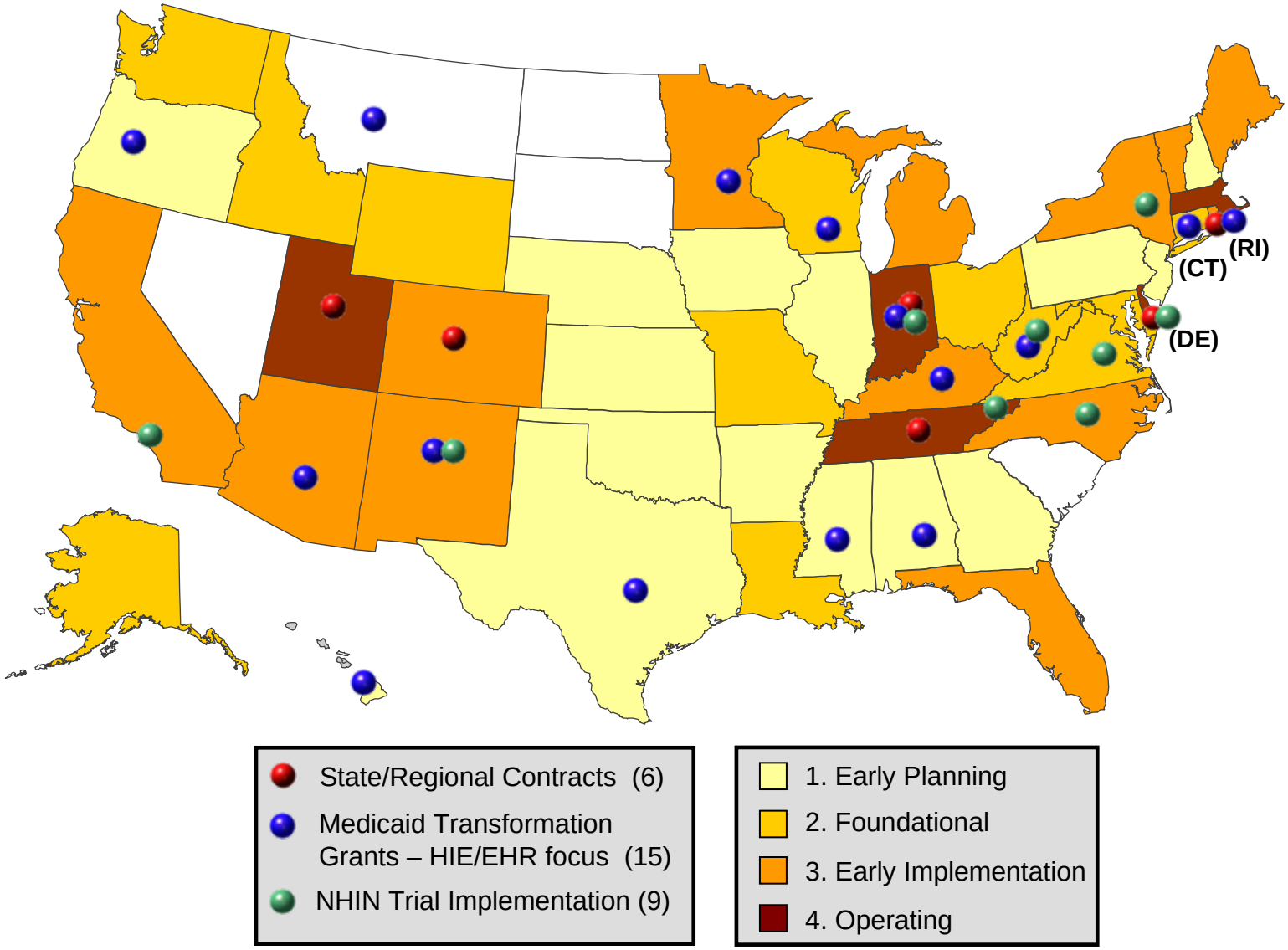
Recap – Major State-Level Issues (as of January 2007)

- Resources
  - Sources of start-up capital
  - Lack of financial models for long term sustainability including support for state-level HIE roles
- Federal/state-level coordination
  - Lack of clear roadmap for how state-level HIE relates to federal programs
  - Coordinating body to lead/structure collaboration
- HIE Roles for state governments
  - Lack of clarity about effective state government HIE roles, organization
- Stakeholder engagement
  - Private payers passive/competitive
  - Medicaid and Medicare not fully leveraging influence
- Accelerating HIE development
  - Collaboration among states
  - Lack of easily replicable early wins
  - Continued public domain technical assistance/guidance

Project Findings – March 2008

- Continued expansion and evolution in state-level HIE efforts
  - 75% of states have established state-level HIE initiatives/governance entities
  - Advanced state-level efforts poised to begin data exchange
  - Health care reform, privacy rights and confidentiality protections are drivers

State Level HIE - An Evolving Landscape



Key Findings March 2008

- Migration to two distinct and key organizational HIE roles *at the state-level*
  - **Governance**:
    - Neutral convening: Structure for engaging stakeholders in statewide mission to build HIE for healthcare quality, cost-effectiveness
    - Coordination: Mechanism to facilitate collaboration across diverse interests
      - Development and implementation of a statewide HIE roadmap
      - Consensus-based HIE data sharing policies and practices to ensure confidentiality protections
      - Facilitate lowest cost HIE development serving statewide stakeholders
  - **Technical operations**:
    - State-level technical functions (owned and/or managed) to facilitate statewide HIE
    - Variable technical models, approaches

Findings - Trends Across States

- State-level HIE governance role is primary
  - Ensure that HIE develops as a public good (beyond silos, corporate interests)
  - Serves all statewide stakeholders and data needs
  - Reduces technology investments and other costs for all participants
- State-level HIE governance entity is a *public-private partnership entity*
  - Sits *between* state government and the health sector and industry
  - Involves state government, but independent of state government
  - Addresses public and private sector interests, blends investments
  - Mechanism for coordination of HIE policies and practices
- State governments play important roles
  - Designating authority to a state-level HIE governance entity
  - Providing resources: start up and ongoing
  - Leveraging public programs, policy levers to create incentives for HIE
- Statewide technical approaches can vary and will likely evolve
  - Size, market characteristics, resources,
  - Stages of development

Organizational Models and Developmental Pathways

State	State Government-Led Collaboration (Focused on *governance* or *technical operations*)	Independent Public-Private Partnership (Focused on *governance*)	Independent Public-Private Partnership (Focused on *governance* and *technical operations*)
Florida	○ →	→	
Kentucky	○		
Louisiana	○ →	→	
Tennessee	●		
Washington	○ →	→	
Massachusetts		●	
Michigan		○	
New York		○	
Arizona			○
California			○
Colorado			○
Indiana			●
Maine			○
Rhode Island			○
Utah			●

Legend ● indicates state-level HIE is currently operating as designed
○ indicates state-level HIE is at a "foundational stage" or in "early implementation"
→ indicates state-level HIE plans to migrate to a different organizational model

Consistent Themes – Building a Network of Networks

- Governance and accountability
  - Policy implications for *public-private* state-level HIE governance entity
  - A common framework needed for HIE roles and accountabilities
- HIE policies and practices
  - Effectiveness of privacy policy linked to *consistent* operational/technical data sharing policies and practices
  - State-level HIE governance entity provides key coordination role
- Value for stakeholders and sustainability
  - Recognize where and how value accrues across levels
  - Recognize realistic phases of development
  - Start-up capital investments to achieve capacity beyond limited provider markets, support multiple HIE services
  - Channel initial and ongoing state and federal funding
  - Structure national incentives (e.g. reimbursement, participation in NHIN, federal programs) to drive stakeholder participation

Implications for AHIC – Priority Recommendations

- Permanent AHIC sufficiently inclusive and empowered
- Agenda to link strategies for HIE development with *health care transformation agenda (secondary use, quality, transparency)*
- Synergy between nationwide and state level HIE governance
    - State-level HIEs key stakeholders in permanent AHIC
    - Design formal mechanism for state-level HIE participation
- Public-private state-level HIE entities engaged in all aspects of AHIC work
    - Reflect HIE readiness across diverse statewide environments
    - Incorporate all state-level perspectives in its mission and activities
    - Serve as vital laboratories for informing, vetting and advancing AHIC priorities.

2008 Project Scope of Work

- Ongoing research
  - Models, guidance for consistent HIE policies and practices
  - State-level value propositions and sustainability models
    - Inventory emerging resources to inform HIE financial sustainability research and development
    - Map and monitor state-level HIE development trajectories
    - Identify state level HIE value models, development and evolution, impact
- Consensus development
  - Potential criteria for credentialing HIE organizations
- State-level HIE Forum
  - Facilitate development of state-level HIE governance, accountability mechanisms
  - Organize state-level interests, prototype for representation as part of permanent AHIC

American Health Information Community

Public-Private Partnership Model to Advance New York's Health Information Strategy

Rachel Block

New York eHealth Collaborative

April 22, 2008

New York as a Case Study

- Independent non-profit state-level HIE governance entity
- Not technical operations (currently)
- Large state population
- Strong state government leadership and collaboration
- Illustrates relevance of findings and recommendations from State-level HIE Consensus Project

Building Blocks for NY Health IT Strategy

- Promote collaboration at state and regional levels
- Support development of RHIOs
- Link to national strategy and standards (focus on interoperability)
- Use infrastructure to expand reach, lift all boats
- Privacy and security are essential to public trust
- Support strategic uses of health IT – high-yield benefits from reducing inappropriate utilization and increasing use of preventive services
- Sustainability hinges on payer involvement

NYeC Goals

- NYeC will galvanize health care systems improvement by promoting broad use of health information technology through a comprehensive and coordinated state policy agenda that:
  - *Stimulates coordinated and collaborative efforts* among health care stakeholders to identify and overcome barriers to widespread HIT adoption and use to *enhance evidence-based practice by clinicians, as well as consumer engagement in health maintenance and management*
  - Advances health care *performance measurement, public reporting and improvement* supported by HIT
  - *Improves public health* through effective prevention and management of chronic disease, as well as stronger public health surveillance and emergency response capabilities
  - *Ensures accountability* by measuring and evaluating HIT impact on health care systems, payers, providers, and consumers

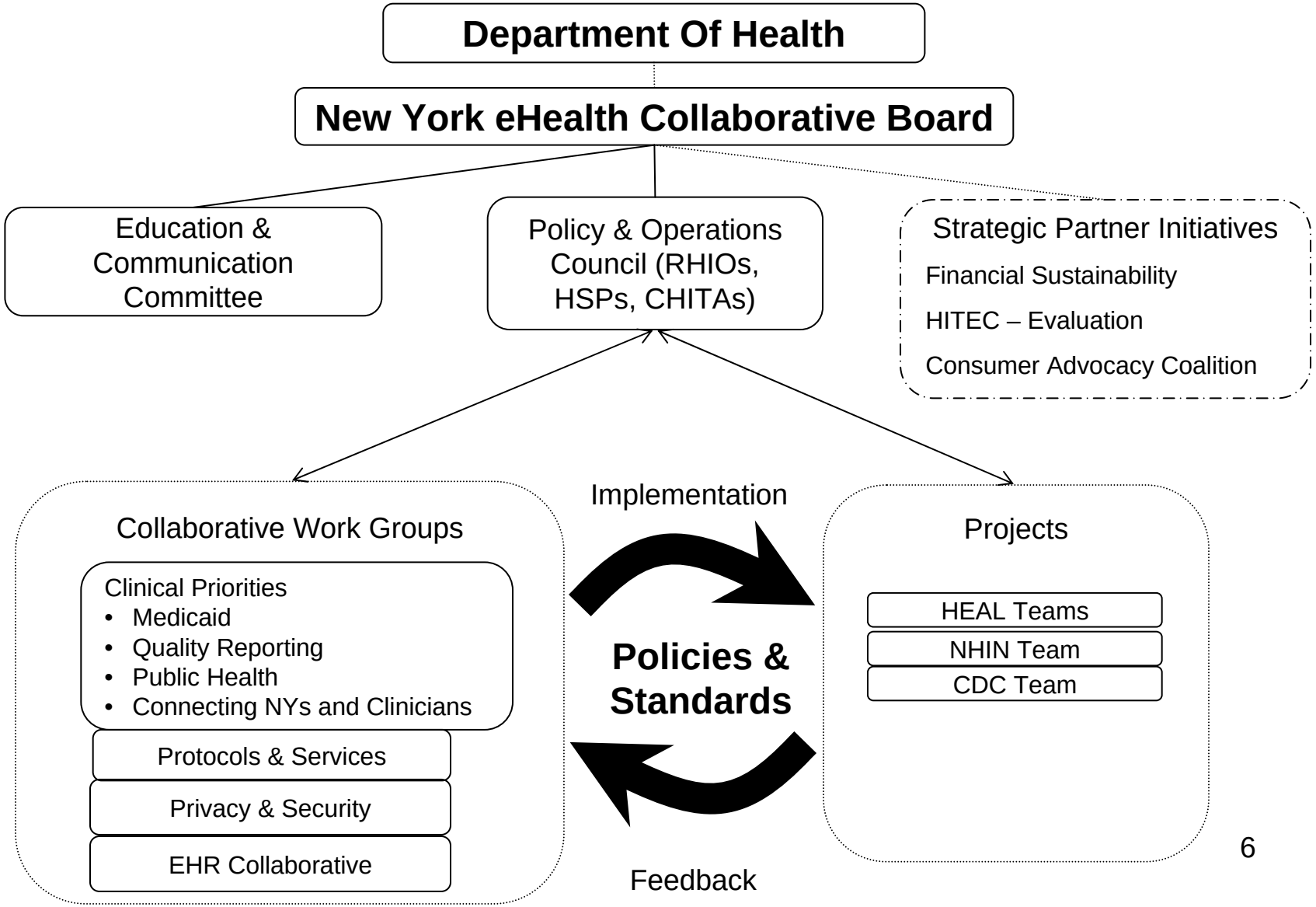
Tools to Implement NY Health IT Strategy

- Coordinated policy leadership at state-level through State Department of Health
- NY eHealth Collaborative established to drive collaborative implementation efforts
- Health Care Efficiency and Affordability Law for New Yorkers (HEAL-NY) grants for state and regional initiatives promoting HIT and HIE
- NY HISPC forging stakeholder consensus on policies and procedures to protect privacy and security, and ensure consumer access and engagement
- Health Information Technology Evaluation Collaborative (HITEC) statewide academic consortia partnering with stakeholders and RHIOs to standardize evaluation measures and methodologies

Statewide Public-Private Partnership & Collaboration Process – Governance & Policy Framework for New York's Health IT Agenda

Governance

Work Structure & Project Management



Collaboration Priorities

- Statewide and Regional Governance
- Technical Requirements for Interoperability
- Components to Sustainability
  - Value Proposition at Clinician and Consumer Levels
  - Cumulative Effect – Can We Bend the Curve
  - Continued Investment in Infrastructure
  - Ensuring Trust through Affirmative Consent and Privacy Protections

Important State-level Challenges and Opportunities

- Relationship of state-level progress to federal strategies, governance and resources
- Sustainable infrastructure – need for government to do what it can, but rely on independent non-profit governance
- Levels of stakeholder engagement to achieve real data sharing
- Perspectives from Steering Committee (and other states)
  - Pivotal time
  - Voice with AHIC, NHIN
- SLHIE Project's role and value
  - Peer learning
  - Real time identification of emerging issues, trends, models
  - Organized perspectives and voice of state-level HIE perspectives

Information and Additional Resources

- State-level HIE Consensus Project

  www.staterhio.org

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