Meeting Report

American Health Information Community
January 17, 2006

The American Health Information Community (AHIC), a federally-chartered commission formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within 10 years, held its third meeting on January 17, 2006, at the Department of Health and Human Services (DHHS), 200 Independence Avenue, SW, Washington, DC, 20201.

The purpose of the meeting was to bring together the Community's 17 members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to the DHHS 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 included a detailed discussion of the focus areas identified during the October 7 meeting.

DHHS 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 will serve 2-year terms.

The meeting was chaired by Secretary Leavitt and David Brailer, MD, PhD, National Coordinator for Health Information Technology.

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

Call to Order

Secretary Leavitt called the meeting to order by noting that the more than 200 individuals who attended the last AHIC meeting in person and the additional 500 who viewed the proceedings via Webcast are evidence that the group's deliberations are important to the broader community. Since the last AHIC meeting, the DHHS has made significant progress. For example, the Department is funding four projects to test the standards of e-prescribing that will be conducted jointly by the Centers for Medicare and Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ). The programs will evaluate how the standards work together to enable e-prescribing and improve the safety and quality of care. Many federal agencies beyond those represented in AHIC are significantly involved in health information technology (HIT). Dr. Brailer has been asked to convene a task force whose members will be representative of those other federal agencies. The task force will respond to Community decisions and coordinate these decisions across the agencies so that the government acts in concert to accelerate the progress of HIT. Secretary Leavitt emphasized his commitment to ensuring that the recommendations of the Community are implemented as a matter of policy across the federal government.

The purpose of the November 29, 2005, AHIC meeting was to discuss forming workgroups to create deliverables this year so that consumers will begin to see direct impacts of the Community's work. AHIC's general strategy to date has been to find the immediately available progress, consolidate it, and work toward the pure vision. The potential to produce early breakthroughs was identified in four areas:

(1) biosurveillance, (2) consumer empowerment, (3) chronic care, and (4) electronic records. The purpose of this meeting was to set these workgroups in motion in such a way that they can begin to fulfill their charges and meet quarterly goals that will enable them to produce real outcomes this year.

Joining Secretary Leavitt counterclockwise around the table were:

David Brailer, MD, PhD, National Coordinator for Health Information Technology

Mark Warshawsky, PhD, Assistant Secretary for Economic Policy, U.S. Department of the Treasury

William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs

Rob Kolodner, MD, Chief Health Informatics Officer, Veterans Health Administration, representing Jonathan Perlin, MD, Under Secretary for Health, Department of Veterans Affairs and Veterans Health Administration

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

Dan Green, Deputy Associate Director, Center for Employee and Family Support Policy, Office of Personnel Management (representing Linda Springer, Director of the Office of Personnel Management, who was unable to attend)

Mark McClellan, MD, PhD, Administrator of the Centers for Medicare and Medicaid Services (Dr. McClellan was able to attend the afternoon portion of the meeting and was represented by Barry Straube, MD, Acting Director of the Office of Clinical Standards and Quality and Acting Chief Medical Officer at CMS)

Ed Sondik, MD, Director of the National Center for Health Statistics (Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services was unable to attend)

Michelle O'Neill, Acting Under Secretary for Technology, U.S Department of Commerce

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

Steven Reinemund, CEO and Chairman of Pepsico

Kevin Hutchinson, CEO of SureScripts

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

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

Craig Barrett, PhD, Chairman of the Board, Intel

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

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

Naming of Directors in the Office of the National Coordinator for Health Information Technology

Dr. Brailer announced the following appointments within the Office of the National Coordinator:

- Karen M. Bell, MD, MMS, Director, Office of Health IT Adoption
- Kelly Cronin, Director, Office of Programs and Coordination
- Jodi G. Daniel, JD, MPH, Director, Office of Policy and Research
- John W. Loonsk, MD, Director, Office of Interoperability and Standards

In addition, Robert Wah will continue to support the activities of the Office of the National Coordinator as Acting Deputy National Coordinator, and Dana Haza will continue serving as AHIC's Acting Executive Director. Maya Bernstein, the Department's Senior Privacy Officer, will continue to serve as the lead on privacy policy issues.

Health Information Technology Deployment Coordination

Dr. Brailer presented a detailed diagram depicting the conceptualization of health information technology deployment coordination. As shown in the diagram, spouting from components of the technology industry are a variety of infrastructure components, such as standards harmonization, compliance certification, a nationwide health information network, privacy/security, and HIT adoption. The Office of the National Coordinator has engaged in contracts with partners, each of which have a substantial public-private process underway to develop their own respective components (i.e., biosurveillance, consumer empowerment, chronic care, and electronic health records). These will create the enablers of substantial change in how health care is delivered, how the work of physicians and nurses is done, and how hospitals operate."

The community has divided the health care industry into four breakthroughs (biosurveillance, consumer empowerment, chronic care, and electronic health records). Dr. Brailer noted that "they result in value that is realized by the consumer and that delivers immediate change. The breakthroughs…are very focused on something that American consumers could benefit from in a year, something that would touch lives in a near-term way."

There are many intersection points between the technology industry infrastructure components and the four health care industry breakthrough areas. This is where the Office of the National Coordinator and AHIC come together to coordinate the policies, resources, and priorities that allow the interplay between these groups. Dr. Brailer explained that "this conceptualization is about how we view the work of our office and the work of the Community going forward. Today will represent a key turning point. Besides locking down these breakthroughs, we will also begin the process of learning about the infrastructures being laid out and over time, this group and the workgroups will begin examining how this can play."

Discussion

"How does the agenda of the American Health Information Community relate to this? That is the overarching question. These four breakthroughs that we are talking about today are starting points and over time, I would expect the Community to continue to evolve…and then determine to some degree

what its own course of inquiry is going to be. We have identified the breakthroughs as a particular element of that." – Dr. Brailer

My request would be…that we might have explicit boxes [on the diagram Dr. Brailer presented]. The reason I am hung up on them being explicit is because it is going to be easy as people are really pushing forward on the top four to get output and for these [other categories] to be forgotten. From my standpoint and the standpoint of hospitals…how is this going to relate back to measurements we are going to be expected to make? How is this going to relate back to the potential for medical research to collect information? – Mr. Kahn

"We have a variety of other processes underway that are not depicted on this chart, some involving research and looking at the question of quality." – Dr. Brailer

Overview of the Office of the National Coordinator's Process for the Workgroups

AHIC members were provided with handouts containing information on the background, broad (2-3 years) and specific (1 year) workgroup charges, workgroup members, support, and quarterly milestones for each of the four workgroups. In general, support for each of the four workgroups will be provided in the following manner:

- The Office of the National Coordinator's Office of Health Information Technology Adoption will provide analytical support.

- The Health Information Technology Standards Panel and the Certification Commission for Health Information Technology (both contractors to the Office of the National Coordinator) will designate a Workgroup Liaison.

- A Federal Health IT Policy Council will be formed to consider federal policy issues that are raised across all breakthroughs as recommended by the Community. Liaisons from the Council will interact with the workgroups who also can identify issues that the Council should consider.

Because of the urgency of these efforts and the short timeframe for implementation, the Office of the National Coordinator will manage accountability of each of the four workgroups on a quarterly basis. The following quarterly milestones represent the key metrics for each workgroup in making recommendations to the AHIC (content for each milestone will be specific to each workgroup):

- First Quarter 2006: (1) identify existing tools and solutions that could be rapidly deployed and present recommendations to the Community; (2) identify local, state, federal, non-governmental organizations (NGOs), and private entities that are needed to support the tools and solutions; and (3) present a detailed timeline for realization of the specific charge to the Community.

- Second Quarter 2006: (1) identify public and business policies that need to be changed or that are needed to meet the specific charge, and make recommendations to the Community; (2) consider privacy issues that may arise from this effort, and report discussions to the Community; and (3) review standards architecture and certification criteria relevant to the realization to the goal and make recommendations to the Community.

- Third Quarter 2006: (1) make recommendations to the Community to identify deployment targets and models for deployment; (2) make recommendations to the Community to develop an education and awareness plan; and (3) make recommendations to the Community to develop a timetable to transition from the specific charge to the broad charge.

- Fourth Quarter 2006: (1) make recommendations to the Community to implement a pilot effort and a rollout plan that will realize the specific charge; and (2) evaluate the year and progress toward achieving the broad charge.

Dr. Brailer provided the Community with the broad and specific charges of each workgroup—after reading the charges, he opened the floor to Community members to comment on each of the workgroups.

Biosurveillance Workgroup

AHIC Co-Chairs: Dr. Julie Gerberding and Mr. Mitch Roob.

Broad charge: Make recommendations to the Community to implement the informational tools and business operation to support real-time nationwide public health event monitoring and rapid response management across public health and care delivery communities and other authorized government agencies.

Specific charge: Make recommendations to the Community so that within 1 year, essential ambulatory care and emergency department visit, utilization, and laboratory result data from electronically enabled health care delivery and public health systems can be transmitted in standardized and anonymized format to authorized public health agencies within 24 hours.

Following Dr. Brailer's description of the workgroup charges, a discussion on the activities and role of the Biosurveillance Workgroup followed. The following are highlights from that discussion.

"It is my intention to have this implemented at whatever level possible within the year…AHIC inherently does not have the legal authority to implement; AHIC advises the Secretary and the Secretaries of the other federal agencies…Many of the things that will need to be implemented to make this work will have to happen in various federal agencies. While AHIC's operational wording may not denote action, I can assure you that what is going to happen underneath it is action oriented." – Secretary Leavitt

"The overall goal in fact is to have a system implemented in a year that is working. That is quite different than making recommendations. I am just not quite of the structure from a hierarchical sense of where we intend to take the system." – Dr. Barrett

"Is a year soon enough? We are on the sharp edge of the health care delivery system…I was aware of what you were able to do with Katrina health.org in a week, so I just wanted to ask is a year enough?" – Ms. Gelinas

"There are two components to this, the technology and the sociology. I've never found technology to be the right limiter, it has always been sociology. I would also want to stress that we are not talking about the pure vision here. We're talking about finding a way to take what is readily available and begin to connect it together faster…I will be delighted if at the end of the year we've accomplished what this task represents." – Secretary Leavitt

"In the charge statement it refers to presenting this information transmission to authorized public health agencies within 24 hours. That is very broad and understandably so, but it might be worth working

towards at least the Centers for Disease Control or HHS, something of a national nature. We [the Department of Defense] would be interested in participating and being a designated user."
– Dr. Winkenwerder

"I believe we will end up at the end of the year not so much measuring success or at least the pattern of our data collection by states as much as we do systems…It appears to me the fastest progress we'll make here is to be able to go to the existing systems that have the capacity and link that data together, and it will overlap a lot of states and it will begin to work…on a state-by-state basis." – Secretary Leavitt

"The lab industry has spent the last several decades automating its processes including systems in place, returning laboratory results electronically, and enabling them to be delivered electronically. I don't know if the members [of the Biosurveillance Workgroup] are locked in, but because lab results are so prevalent with respect to biosurveillance, it might behoove us to add a representative from the lab industry."
– Mr. Hutchinson

Following the discussion, Secretary Leavitt declared consensus on this issue.

Consumer Empowerment Workgroup

AHIC Co-Chairs: Ms. Nancy Davenport-Ennis and Ms. Linda Springer

Broad Charge: Make recommendations to the Community to gain widespread 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 1 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 1 year, a widely available pre-populated medication history linked to the registration summary is deployed.

Following Dr. Brailer's description of the workgroup charges, a discussion on the activities and role of the Consumer Empowerment Workgroup followed. The following are highlights from that discussion.

"This is as close to Katrina Health on a long-term basis as we get…This is an area where the technology barrier is probably quite narrow. So the question becomes which populations can be targeted and accessed and what are the education and awareness processes that can support them…it should be a population in the hundreds of thousands or low millions to be able to accomplish a meaningful test of this." – Dr. Brailer

"In my judgment, this is going to be answered by how well it is embraced by some number of private-sector vendors…there could be any number of people who view this as an appealing thing to offer their members or subscribers." – Secretary Leavitt

"If the answer to that is 100,000 to 1 million, then I would say this is relatively incidental to what is going on in the marketplace already. It would have to engage a number substantially larger than that to achieve some degree of success here." – Dr. Barrett

"We already know that there are lots of insurers who view this as an appealing opportunity to offer their policyholders…I think our purpose here is to create a sense of commonality and harmonization to allow that information to be used on a more broadly focused basis. I would harbor both the aspiration and suspicion that it would be a substantially larger number." – Secretary Leavitt

"If we only got 100,000 to 1 million inclusive, then we would consider it a failure, so I think we need to look at numbers significantly larger as we move into medication records. I think the numbers are going to be very big." – Mr. Serota

"One of the reasons I felt so strongly about having this as part of our early breakthroughs is because one of the things that we've lacked is a consumer driver, something that consumers demanded that can move the market in a viral way. I believe this is the item that will ultimately drive a viral market."
– Secretary Leavitt

"We have the opportunity through this breakthrough to engage the employment community and to launch a national education process for consumers so that they understand the benefit of having this tool in the marketplace…I think the major hurdle that we are going to have in making this a successful breakthrough is in direct proportion to the time we spend reaching out to consumers to engage them on this issue."
– Ms. Davenport-Ennis

"Is this group focused on a personal health record, or as we've alluded to in the last two meetings, focusing on a medication history or registration history? I would propose that we should be focusing on the personal health record, I hope that is the direction we are going, because in my view at least, representing the provider community, that there needs to be a technology that provides all of that data at the time that patient or consumer interacts with any part of the healthcare system." – Dr. Henley

"The idea is to have a growing and expansive record that begins with some component parts and grows as we have the capacity to do it, but we ought not to wait until we have it all until we begin to build it."
– Secretary Leavitt

"One of the ways that diffusion might be undertaken other than through the insurance sector would be through hospitalizations…It seems to me that at each hospitalization, there is a lot of information collected, and there is some kind of electronic notation made…and that could possibly be one of the crossover points…You could create at least a record for those people who are hospitalized…and ask hospitals to do it…If you want to go down that path, I would suggest considering adding a hospital to the membership, it is one area that is missing." – Mr. Kahn

"The rate limiter here isn't the technology, it is working though the privacy issues and all the things we need to be very careful in pushing through. I also want to emphasize that I am resolved to using the authority provided me as Secretary of Health and Human Services to use the government paid health care mechanisms as a means of driving this." – Secretary Leavitt

A glaring on omission [in the workgroup membership] is the office managers, who actually deal a lot with the process of registration in the physician's office and they understand the level of data…Security and authentication is going to be a major issue in this particular process. I think there are organizations out there that spend a great deal of time focused on security in this particular space and it might be helpful to have them at the table…Lastly, individuals that have some working experience with the deployment of personal health records [should be included]." – Mr. Hutchinson

"As a member of the first workgroup, I know these quarterly milestones are going to be important to the groups, and I wonder if it makes sense to give them what we'd like to achieve at the end of the year…I'm a little concerned that it is too late in this for us to achieve the charge in the first year [unless the pilot is moved up]." – Dr. Sondik

"The ideal would be if we could move the demo to the third quarter, then we could get the evaluation process done in time for the fourth quarter, and obviously if we are really going to have something to

evaluate, we would try to move it early into the third quarter rather than later in the third quarter." – Ms. Davenport-Ennis

"In the Medicare program, we have set up a Medicare beneficiary portal that now focuses on allowing the individual beneficiary access to all of their Medicare-related information. That includes a lot of administrative data that is probably used by individual consumers in its raw form, but it could be a link to a consumer personal health record product. We are looking at a pilot program to expand this, and it might be a way to build on [these efforts]." – Dr. McClellan

Following the discussion, Secretary Leavitt declared consensus on this issue.

Chronic Care Workgroup

AHIC Co-Chairs: Drs. Craig Barrett and Mark McClellan

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

Specific Charge: Make recommendations to the Community so that within 1 year, widespread use of secure messaging, as appropriate, is fostered as a means of communication between clinicians and patients about care delivery.

Following Dr. Brailer's description of the workgroup charges, a discussion on the activities and role of the Chronic Care Workgroup followed. The following are highlights from that discussion.

"Most patients who have a chronic disease have more than one chronic disease…it is about a process of care over a continuum of time. In terms of looking at additional members of the workgroup…you might want to get someone from the home health care community…Also, this may be an area where you may want to expand and have more than one physician group represented or perhaps other health care representatives as well…this is a team approach and a multiplicity of providers needs to be represented." – Dr. Henley

"One of the groups missing [from the workgroup] is nursing representation, there are so many nurses that provide long-term chronic care as well as monitoring at home." – Ms. Gelinas

"Those suffering with developmental delays and disabilities and the mentally ill, which are very expensive subsets of this population [need to be considered]. If you do chose to include them, having people from AHRQ involved in this would be appropriate…this deserves an overt decision, otherwise they will be out there in the gray, one of the worst places to be." – Mr. Roob

"We have not expressly excluded any population segments from this, so it is really a question to the Community, do you want to task further instructions to the workgroup before they come back here in March, because they will come back and start targeting populations and potential 'low-hanging fruit' where we can get significant progress." – Dr. Brailer

"We have a whole disease management industry that has developed…obviously they are deeply into this and I wonder if someone from that sector…ought to be on here." – Mr. Kahn

"We [should] have representatives from specific chronic disease organizations that could serve on this working group because we are dealing with such specific needs in chronic care. [We also should]

consider having representatives from the social worker community that serves both the pediatric and adult populations in the area of chronic care." – Ms. Davenport-Ennis

"Many of these [working groups] have unlimited categories [of members] that could in fact be included properly, it will be impossible for us to include everyone, but it is not impossible for us to hear from everyone. One of the characteristics of these groups is that they have to be a small enough subset that they are able to manage, but large enough that they have a broad representation and are able to reach out to a broad community." – Secretary Leavitt

"We chose expressly to not limit populations in these charges…Because these are public workgroups, they are extensions of the federal advisory committee rules, they will have open meetings…so membership is not the only vehicle for getting the input that is necessary here. But early on we do expect all of [the workgroups] to start focusing on which populations would accelerate the realization of this goal." – Dr. Brailer

"There is an exact parallel in industry, the financial industry today, which is involved with the secure transmission of information and confidentiality…hopefully we can draw heavily on the experience in that field and not reinvent the wheel as we go forward. I suspect that the bulk of the framework for the communications and secure transmission capability are already heavily in use today." – Dr. Barrett

"What we have on the table then is this document, modified to provide the suggestion to accelerate the pilots by the third or fourth quarter and recommendations on expanded level of participation in a couple of categories…Would there be any objection on the need to deploy immediately and get started? Hearing none then, I would declare a consensus and empower the group, move them forward subject to additions that will be made along the way." – Secretary Leavitt

Electronic Health Record Workgroup

AHIC Co-Chairs: Ms. Lillee Gelinas and Dr. Jonathan Perlin

Broad Charge: Make recommendations to the Community on ways to achieve widespread adoption of certified electronic health records, minimizing gaps in adoption among providers.

Specific Charge: Make recommendations to the Community so that within 1 year, standardized, widely available and secure solutions for accessing current and historical laboratory results and interpretations is deployed for clinical care by authorized parties.

Following Dr. Brailer's description of the workgroup charges, a discussion on the activities and role of the Electronic Health Record Workgroup followed. The following are highlights from that discussion.

"At the end of the day, whether it is chronic disease monitoring or biosurveillance, et cetera, the meat and guts of all that will be the electronic health record implemented throughout the health care system. This is extremely important. There is a significant movement, certainly in the physician community and elsewhere to move strongly in this direction." – Dr. Henley

The specific charge talks about historical lab results. I was curious why, because of all the work going on with medication history, we wouldn't also include medication history, especially in the electronic health record with its specific charge to get integrated." – Mr. Hutchinson

"We tried to stay very narrowly focused, and to recognize that to some degree under the guise of electronic health records, we are doing work that is complimentary to medication history, and under medication history there is a lot of that can be leveraged." – Dr. Brailer

It is worth realizing what a powerful combination we will have created…if at the end of the year we have created a vehicle for [these efforts] to move forward on a broad and ubiquitous basis, we've changed the world in a fairly significant way. So while this may seem in component pieces to be narrowly focused, the aggregate of those narrow pieces begins to move this whole thing forward rapidly and in a bold way." – Secretary Leavitt

"With regard to electronic health records, we have islands of excellence breaking out all over the place, but islands of excellence are also silos, and so the silo issue is one that this workgroup is going to have to be dealing with very early. There are outstanding, freestanding, piecemeal components of the electronic health record that are already in the public sector." – Ms. Gelinas

Following the discussion, Secretary Leavitt declared consensus on this issue.

Secretary Leavitt noted that the Community, as a result of these discussions, empowered four the four workgroups at this meeting. Each has been given a schedule on which they will report, milestones for which they will be responsible, and a plan of integration. Secretary Leavitt stated that "this is an important step forward in the development of our long-term vision."

Quality Monitoring Discussion

Dr. Karen Bell, Director of the Office of Health Information Technology Adoption in the Office of the National Coordinator, explained that quality of care issues continue to be heavily publicized. Quality management requires commitment at all levels of an organization to follow the data management, prioritization principles, and action steps necessary to improve outcomes. Quality improvement is dependant on information, tools, and processes that can support safer, more effective care. Dr. Bell noted that quality monitoring involves tracking and reporting outcome measures of the quality management/quality improvement program.

Dr. Bell reviewed some real-world examples of quality monitoring, including the Maine Health Management Coalition; Bridges to Excellence; multiple quality coalitions among payers, providers, and employers; Northern New England Cardiovascular Collaborative; and Institute for Healthcare Improvement Collaboratives. Efforts also are underway in the government sector (e.g., at the AHRQ/CMS, CMS/quality improvement organizations, Health Resources Services Administration/Bureau of Primary Care, VA, DoD, and Indian Health Service). In the private sector, quality monitoring activities are ongoing in: (1) multiple HMO plans; (2) coordination in the Ambulatory Quality Alliance (AQA) among payers, physicians, plans, and employers; (3) integrated delivery systems; (4) the Leapfrog Group; and (5) national specialty societies.

The primary barriers to quality monitoring include:

- A lack of harmony among measures (variability in measurement methodology).
- Evidence-based measures are limited to a small subset of physician specialties.
- A lack of patient-focused measures (patients with special needs or multiple comorbidities).

- An inability to identify appropriate accountable clinicians in a fee-for-service system with patients who have multiple problems.

- The infrastructure for collecting and reporting quality measures is fragmented or not yet established.

There are key accelerators in the government and private sectors, such as: (1) the widespread adoption of interoperable, certified EHRs; (2) national consensus on a set of evidence-based quality measures applicable to all types of providers; (3) standardized measurement methodologies; and (4) a secure infrastructure for collecting, processing, and reporting quality metrics that is acceptable to the public.

Dr. Carolyn Clancy, AHRQ Director, is currently focusing the rollout of the AQA pilots, which are testing the ability of physicians to report out of a starter set of metrics. She will be available to brief the Community on a regular basis on progress that will be made in this area and others. Once there are consistent standards and methods, the broader health IT community can move forward to facilitate electronic reporting.

Discussion Highlights

"The Hospital Quality Alliance was missing from the presentation…The question over time is how will the process that AQA has…and the process that HQA has…going to be squeezed together? The HQA and AQA have met together for some preliminary discussions…The question for this group is what is the interaction between development of the record and that process of putting all of the reporting on a single platform so that it will be meaningful and common across providers." – Mr. Kahn

"HQA and AQA are making a lot of rapid progress, but without those kinds of electronic standards in place, much of it is happening in the ambulatory setting off of existing data systems and in some cases working off administrative claims record reporting. From the CMS standpoint, we'd very much like to support the efforts of the AQA and HQA to get a more integrated reporting structure that relies on electronic records." – Dr. McClellan

"Just last week, the AQA agreed to broaden its scope to include the entire physician community, not just those related to primary care. This will bring a degree of uniformity to the whole process…in a very important way." – Dr. Henley

"What we hear from the marketplace…is a need for transparency. As we develop these systems, we can't develop them so…that they are not of any utility to those outside the system. Our customers, consumers, and others are demanding information about quality. If we are going to invest the energy in developing good, solid accurate measures of quality…we have to develop them in such a fashion that the average consumer can use them. Transparency is a critical issue." – Mr. Serota

"In looking at the list of efforts underway in the government sector and the private sector, I don't see the FEHVP listed, and I am curious as to whether there are any barriers to that significant federal entity in participating in these efforts." – Dr. Warshawsky

"Next week [the Office of Personnel Management] is meeting with some key stakeholders. We already require reporting NCQA results for all HMOs that participate in the FEVHP. We are focused at this point on the insurance company level...75% of our enrollees are in PPOs. So we are working with CMS and following their lead, and will be meeting to discuss ways of rolling out a set of measures for the PPO plans that are in the program. That will be our primary focus on quality in the next year." – Mr. Green

"The number one issue that keeps coming up when you talk about quality is reimbursement. There are many pilot programs going on in different specialties around pay-for-performance…and there is a lot of confusion out there about ultimately how are physicians and hospitals and other entities going to be reimbursed based on quality measures." – Mr. Hutchinson

"Many of [CMS'] current activities are focused on how we can support better quality reporting and payment systems. We are working to support quality measures and use of electronic health records systems, [to provide] better quality at lower cost." – Dr. McClellan

"This is the right thing to be doing and it needs to be accelerated. The thing that limits us is the ability to have electronically compatible data that is rolled up into one place at one time…I think the purpose of this briefing today was to say 'what is the best role for us to play, what can we reasonably take on in the next period of time that will advance that process.'" – Secretary Leavitt

"Maybe AHIC could formally ask [AQA and HQA] what do you think AHIC ought to do to support your agenda, and what do you think you ought to do to support our agenda. List some things in a very precise way that might press them to accelerate their work." – Dr. Winkenwerder

"Physicians and hospitals and other providers are going to be judged on certain measures, and someone is going to have to go mine those measures records whether at the physician office level or some other level…a lot of what goes on in hospitals that is going to be judged is ordered by doctors." – Mr. Kahn

"A logical next step would be to invite those that are broadly involved in this…to meet with ONC with the idea that we would invite them to our next meeting to come and talk about the ways we can use this process of driving the standards process faster and in a more coordinated way." – Secretary Leavitt

"On behalf of the AQA…we would welcome the challenge to answer that question about what the Community can do from a technology perspective to push forward the whole issue of performance measures and how they relate to the ambulatory environment. Last week we decided to create a subcommittee in our workgroup on data sharing and aggregation that specifically deals with the issue of health information technology and its role in this reporting environment." – Dr. Henley

"It has been my aspiration as Secretary to create a community—this one—to become the process by which improvements could be arrived at and moved forward...Until we get that part of the Community involved here where we are able to coordinate…we will continue to see progress, but in a separate way than we are and we will ultimately end up with a giant reconciliation that will have to be made later that is unnecessary if we start now." – Secretary Leavitt

"This is the only industry in the world that needs more IT infrastructure and capability to report on its own quality. Wouldn't it be cheaper to hire JD Power and Associates to come in? Ultimately what you are really interested in is providing the consumers with information. Most of what I've heard today is providing the system with capability and it leaves the consumer totally out of the loop." – Dr. Barrett

"I understand the extremely complex nature of the transaction we are talking about, there is an immense amount of data. But there seems to be two ways to look at it. You can hide behind the complexity and say that I can't do anything until I get more and more information analysis capability to smooth out the complexities, or you could just say I am going to report the data." – Dr. Barrett

"Patient characteristics as well as the characteristics of the provider and the actions of the provider influence patient outcomes, and it is exactly those sorts of issues that are best worked out through the collaborative public process that the AQA and HQA have underway." – Dr. McClellan

"We are still developing unfortunately the metrics to measure how good a job a hospital does. This is partly insider, but it is very public too, because Hospital Compare is a Web site that is up there right now…I wish we were at a point at which I could say that I trust JD Powers…but I don't think we're there yet. At the end of the day, consumers need to know more…but also, hospitals need to know where to improve, so that they can meet the expectations from consumers." – Mr. Kahn

"In terms of what are the barriers, there is always the sociology of the issue that has to be addressed. Consumers need to know more, patients desperately need to know more, but there needs to be a universal standard of what it is that we are measuring…We have a lack of harmony among the measurement tools that are being used…There has to be an answer to defining who the primary care physician is for the chronically ill patient receiving multiple services in a fee-for-service system. If we know who that physician is, then we can capture the data from there." – Ms. Davenport-Ennis

"We have a lot of data in health care in the United States, we just don't have information. We don't have a failure of medical evidence, we have a failure of execution. It is not about creating more systems and more processes, it is about getting on with it. There is one key thing that we haven't mentioned in all of this, and I would add it to the barriers—analysis and benchmarking." – Ms. Gelinas

"As a statement of consensus, we need to bring the larger quality movements into this discussion with the idea of engaging the Community to reach conclusions about both priorities, standards, and agendas to move it forward on a more rapid basis." – Secretary Leavitt

At the conclusion of this discussion session, Secretary Leavitt directed the ONC to make contact with organizations involved in quality monitoring efforts and to indicate to them AHIC's desire to engage their efforts into the Community's conclusion process, with the belief that AHIC can accelerate their movement forward by reaching conclusions that would be broadly and widely deployed. Secretary Leavitt declared consensus on this point and directed the ONC to prepare for a discussion at a future meeting that involves these organizations and specific ideas on how they can be integrated into AHIC's conclusion process.

E-Prescribing Discussion

Ms. Jodi Daniel, newly appointed Director of the ONC Office of Policy and Research, explained that as CMS expands coverage of drugs, e-prescribing is a critical tool to improve safety, quality, and efficiency of medication use. Widespread adoption of e-prescribing with clinical decision support could: (1) eliminate 2.1 million adverse drug events per year (136,000 of which are life threatening), (2) enable appropriate use of medications, and (3) reduce overall drug expenditures by $29 billion. Ms. Daniel described e-prescribing efforts underway in the government sector, including:

- **E-Prescribing and Medicare Part D.** These activities include regulation of e-prescribing standards included in the Medicare Modernization Act to achieve interoperability and encourage adoption.

- **E-Prescribing Pilots.** Five programs involving seven states will test standards, evaluate work flow, and determine impact on patient safety.

- **Prescription Bar Coding.** This effort will set standards and requirements for unique product identifier for prescription drugs and biologics.

- **Structured Product Labeling.** This initiative requires that labeling content be submitted to FDA electronically and will speed the approval of labeling changes.

- **Stark and Anti-Kickback Exceptions.** A proposed exception to the Stark law and safe harbor to anti-kickback statutes to allow certain entities to donate e-prescribing and electronic health record technology to physicians. Broader exception/safe harbor measures are proposed for certified electronic health records, as well.

- **Grant Funds.** HHS is authorized to make grants to physicians for e-prescribing in 2007-2009.

Efforts underway in the private sector include e-prescribing programs in 20 states/regions. For example, some plans and physician organizations are giving providing free e-prescribing software and services to physicians. In addition, under current law, prepaid health plans and medical societies can give free technology to physicians (i.e., Nevada and California). Finally, more than 50 organizations have been offered a reward or incentive programs for quality in 2004—many of these include incentives for e-prescribing.

Ms. Kelly Cronin, newly appointed Director of the Office of Programs and Coordination within the ONC, provided a timeline of key initiatives and described the following barriers to implementation of e-prescribing:

- Health IT products lack uniform standards and functions for e-prescribing. Approximately 80,000 physicians have electronic health records software from more than 20 vendors with the capability to e-prescribe, but still have versions that transmit via fax.

- Clinical decision support is needed to realize that the full value of e-prescribing is insufficient in most software packages.

- There is a negative business case for many physicians because the costs can be prohibitive and work flow challenges reduce productivity.

- States have different requirements for e-prescribing that hamper electronic transmission of prescriptions or prescription-related information.

There are a number of potential accelerators. For example, in the federal government, actions could be taken to: (1) evaluate additional standards to fully enable e-prescribing and coordinate with the CCHIT, (2) consider guidance regarding additional state preemption based on evidence of State laws that are barriers to e-prescribing, and (3) continue to develop EHR adoption strategies through Community workgroups. In the health IT industry, accelerators include adopting NCPDP SCRIPT and installing versions of software in the existing install base/physician offices, as well as getting EHRs certified to meet key interoperability and functionality requirements. Physician organizations can communicate the benefits of e-prescribing to members, including the need for software upgrades that will enable true connectivity to pharmacies and PBMs. Health plans can continue to offer incentives for improved quality through use if health IT and ensure compliance with regulated standards for e-prescribing under Medicare Part D. Finally, small and independent pharmacies without the capability to receive an electronic prescription should work with vendors and wholesalers to enhance existing software capabilities.

Discussion Highlights

"If the country had a breakthrough project in the way in the way that we have established breakthroughs, this would be it…We certainly play a role in being able to inspire a greater adoption of electronic health records. I have chosen not to bring larger portions of this to the Community, simply because there is already so much momentum…I want to make sure that the Community knows about that momentum and can play into it and accelerate it…It seems most productive for us to know where that is so we can play into it but not necessarily be part of the direct process." – Secretary Leavitt

"I'd like to encourage in the area of potential accelerators, that we add the category of consumers…If consumers can be educated to begin to ask for this service from treating physicians in an effort to minimize potential medical errors in their treatment, it certainly could be a tool that could advance this initiative forward." – Ms. Davenport-Ennis

"[There are] 150,000 to 160,000 physicians out there today using some device to help them electronically prescribe, but the prescriptions are being printed out or faxed. I would say that 90% of those physicians are using an electronic health record versus a stand-alone prescribing system. Those electronic health systems do in fact have the capability to do the lookup as long as it is in the database. Those EHRs are not connected to the PBMs or to the payers or to the pharmacies in any type of electronic fashion. There is a large install base that over the last 10 years has been starting to use electronic health records." – Mr. Hutchinson

"We are moving this vision forward in a deliberate way but in a fast-paced way by comparison to lots of other things that happen in the world. Hopefully, the timeline can be accelerated." – Secretary Leavitt

"Where we are today with the rollout of electronic prescribing is because of the Medicare Modernization Act and all the work that the government has done to make this a focus…I would ask that we think about the audiences that could participate in deployment of technologies to physicians be included. Consider labs as well who have relationships with physicians who have been deploying technologies to physicians for the purposes of delivering lab results to those physicians either in paper form or electronically. They would be a very good source of ability to rapidly deploy technology." – Mr. Hutchinson

"We need to be very careful in ensuring that the stand-alone e-prescribing applications have the ability then from a certification standpoint interoperate with the electronic health records and move the data from one application from the next." – Mr. Hutchinson

"The DoD is willing to help support this effort…this is an area that we have a lot of experience in and our pharmacy data transaction system…connects our roughly 12,000 physicians who e-prescribe and roughly 55 hospitals and several hundred clinics in the United States with 55,000 pharmacies across the United States…We connect with every pharmacy in the U.S…and we believe we have eliminated well in excess of 100,000 adverse drug-drug interactions." – Dr. Winkenwerder

Briefing by the Privacy and Security Solution for Interoperable Health Information Exchange

Dr. Chuck Thompson of Research Triangle Institute noted that the existing paradigm for security and privacy does not fully accommodate active consumer participation in health information exchange. Consumers, organizations, and state and federal entities share concerns related to maintaining the privacy and security of health information. Organizations within states have varying privacy and security

business policies and practices that affect electronic clinical health information exchange. In addition to the Health Insurance Portability and Accountability Act, many state-based health information privacy rules protect Americans. Stakeholders, especially patients and consumers, at the state and community levels must be involved in developing solutions. States are interested in supporting electronic health information exchange to improve public health and health care quality, but want to preserve essential privacy and security protections.

Dr. Thompson described the purposes of this project, which are to:

- Identify variations in organization-level business privacy and security policies and practices that affect electronic clinical health information exchange. For those that are "best practices," document and incorporate into proposed solutions. For those with a negative impact, identify the source of the policy or practice and propose alternatives.

- Preserve privacy and security protections as much as possible in a manner consistent with interoperable electronic health information exchange.

- Incorporate state and community interests, and promote stakeholder identification of practical solutions and implementation strategies through an open and transparent consensus-building process.

- Leave behind in states and communities a knowledge base about privacy and security issues in electronic health information exchange that endures to inform future health information exchange activities.

The project's overall contract is managed by RTI International in partnership with National Governor's Association (NGA). The contract spans an 18-month period at a cost of $11.5 million. RTI will subcontract with up to 40 states to: (1) identify business practices that affect electronic health information exchange, (2) propose solutions and implementation plans, and (3) collaborate on regional and national meetings to develop solutions with broader application. A final report on overall project outcomes and recommendations will be provided to the Community.

Dr. Scott Young, who directs the health IT portfolio at AHRQ, explained that the Health Information Security and Privacy Collaboration (HISPC) will support collaboration within and among states to foster the participation of stakeholders. RTI and the NGA will support the HISPC, which will include membership from state governments, the federal government, and leaders from key non-governmental organizations. The purpose of HISPC will be to maximize knowledge exchange and identify common solutions. HISPC will seek consensus-based solutions and implementation plans through a public, community-based model.

Dr. Thompson stated that RTI's mission is to improve the human condition by turning knowledge into practice. The company provides objective, multidisciplinary research and policy analysis to a wide variety of federal agencies in the fields of health, education, governance, environment, and advanced technology. RTI has relevant expertise in the fields of health economics, technology assessments, health communications, and managing large complex federal projects with multiple stakeholders.

The following project outcomes are expected:

- Stakeholders, including state entities, will have a full understanding of variations in business privacy and security policies and practices in their states and communities.

- States, through the use of stakeholder groups, will design practical solutions and implementation plans for preserving privacy and security protections while implementing electronic health information systems

- Through the HISPC, long-lasting collaborative networks will be established for states and communities to support future work.

- Stakeholders will have increased knowledge of best practices and how to implement them within their organizations and their state.

- Project output will be available to optimize construction of the NHIN prototypes, and inform the architecture and standardization projects.

- States will have access to state, regional, and national best practices and solutions to optimize health information exchange.

Dr. Thompson briefly reviewed the project's timeline. The project was awarded on September 30, 2005, and a kick-off meeting was held on November 7, 2005. The RFP was released to Governors' Office on January 4, 2006, and proposals are due March 1. Interim implementation plans are scheduled to be completed by November 30. In 2007, a national meeting is planned for February, with a final assessment of variation, analysis of solutions, implementation plans, and nationwide summary due by March 30, 2007.

Discussion Highlights

"The approach you are taking has very much to do with the states…is there a need for any federal involvement, and are there any other controlling authorities, perhaps through professional associations, that are relevant as controlling authorities here?" – Dr. Warshawsky

"When we look at the stakeholders, we see them as full stakeholders with full representation. We also see the interaction with…many organizations that will have an impact on this. The focus is at the state and local level, so we know what those issues are." – Dr. Thompson

"We are quite aware of the interplay between federal rules under HIPAA and other things that drive privacy at the national level and then the state activities. We chose this vehicle to focus on the states for two reasons. One, the majority of Americans have the minimum rules for privacy set by state actions, since many states have superseded HIPAA. Secondly, the particular issue that we are driving into here is the variations in the implementation of privacy rules across states." – Dr. Brailer

"We are trying to think about the interplay between federal and state laws, regulations, and rules right now, it looks like a mountain range, where the federal statutes are the floor of the mountain, and there are lot of different peaks. We are trying to define what that mountain range looks like right now to develop that knowledge base. The next phase is to hand that knowledge off on the state decisionmakers and HISPC and let them find out where it makes sense to change practices and modify practices and create a clear path." – Dr. Young

"The states are directly involved in this up front, so we have looked very closely at things that have been done recently [for example] in adopting uniform e-commerce sales tax structures. We now have 18 states that have uniform and harmonized state policies around uniform e-commerce state taxes. That is an

example of a state-based initiative built around replicating model legislation. That structure could lend itself here because harmonization is one of the key goals that we wanted to have." – Dr. Brailer

"The interplay of this with Congress is an unknown at this point. The goal is not to create a congressional agenda, but to identify what it is going to take and if there is a role for the federal government to set new minimum changes or to guide this process…That has to be led by states beginning to look at their policies. Different private organizations, doctors offices or hospitals, can implement privacy and security rules in different ways and still be within the law…There is also a role for developing more uniform business policies about how this works." – Dr. Brailer

"Because different states are in different stages of implementation of health IT…we are going to have this wide variety we hope to get the full picture and we hope to end up with those futuristic things that will be a part of the recommendations." – Dr. Young

"It was interesting to see the wide spectrum places where states are, all the way from some very forward-thinking policymakers at the state level to ones who are dealing with some fairly basic issues, and everything in between." – Mr. Serota

"It is refreshing to hear the role of the consumer that you have anticipated in the process…It is important to note for the record that there has to be collaboration between what is happening at the state and federal levels, because…states are only going to have regulatory authority for those plans that are not being regulated by ERISA at the federal level. As we are looking at the issue of privacy and security and we are working with states to more clearly define where they are in that process of development, likewise we have to look at the federal [environment] for assuring privacy and security of this medical information that is being transmitted through the ERISA plan." – Ms. Davenport-Ennis

Briefing by the Nationwide Health Information Network

Dr. Wes Rishel of the Gartner Group explained that most practices do not have electronic health records, and where EHRs exist, they usually do not exchange data with each other, with hospitals, laboratories, or pharmacies. Furthermore, most EHR data must be input manually, which impedes adoption by consumers and clinicians. The primary transfer of clinical information is paper mail, phone, and fax. Often, all approaches have to be supported by the physician. There are missed opportunities for taking advantage of the positive impact of technology to reduce errors, improve monitoring, and advance the quality of care. In addition, clinicians lack the systems and the collaborative data to take advantage of these opportunities.

There are many efforts to improve cooperation among regional networks (most have not yet achieved significant data sharing), and there are a handful of successes that have been built on trust and regional business goals. Many areas must build their own regional network because there is no alternative. In these cases, unique regional solutions impede the commercial market for technology and services. Non-regional health care stakeholders must develop individual approaches to work with each region, and there is a limited ability to address interoperation between regional networks.

Dr. Rishel described the need for a safe market for such a networking environment. In terms of regional risk factors, unique technology approaches bring the risk, cost, and delay of being a pioneer; each network becomes a self-developed or custom-developed project; and the requirement for collaboration beyond the region can force change after initial development. Creating a stable market reduces risk as

networking organizations select products based among competitive offerings and vendor experience in one region transfers to other clients.

"Architecture" is a part of the solution, and involves addressing questions such as: (1) What are the requirements of care provision, privacy, etc.? (2) What are acceptable constraints and costs of operating electronically? (3) What are the requirements for information exchange and interoperability? (4) What are the minimal constraints that can be implemented? and (5) How can standards and requirements support business opportunities?

Dr. John Loonsk, head of the Office of Interoperability and Standards in the Office of the National Coordinator, characterized the Nationwide Health Information Network as a widely available, easy-to-use, and inexpensive service to securely exchange health information. Information exchange and interoperability are necessary to realize the President's vision for health care IT. This effort will involve interconnecting electronic health records and transporting electronic medical information to inform clinicians and follow the consumer. The NHIN also provides a platform for quality initiatives and integrates public health and bioterrorism monitoring with care.

Phase I of the NHIN, currently underway, involves developing potential architectures, prototypes that demonstrate viability, and a business model (future activities include building a shared architecture with best elements, operational implementations, and an environment for sustainability). As part of Phase I, four contracts were awarded by the DHHS and are intended to contribute to the development of an NHIN architecture. Working prototypes are being developed to establish the viability of proposed architectural approaches. Consortia are being led by Accenture, Computer Sciences Corporation (CSC), IBM, and Northrop Grumman. Also included in these consortia are a variety of health information technology organizations, as well as explicitly three health care markets within each consortium. In parallel to this, there will be public convening of the consortia and all other interested parties to ensure public input into the NHIN structure.

Representatives from each of the four companies awarded a prime contract briefly described their respective projects.

Accenture

Brian Kelly of Accenture noted that the company has 13 partners in addition to the provider organizations that will be helping them to build an architecture to facilitate sharing of data and support the interoperability needed to improve health care. Accenture has more than 4,000 professionals serving providers, payers, and pharmaceutical organizations across North America. The company is developing electronic health records across the globe. They will be performing a prototype in Appalachia, lead by the following three groups: (1) CareSpark, (2) the Eastern Kentucky Regional Health Information Organization, and (3) the West Virginia eHealth Initiative.

Computer Sciences Corporation

Jared Adair explained that CSC is working in partnership with the Connecting for Health Collaborative and building on the CFH prototype, which: (1) is agnostic to platform, underlying hardware and software; and (2) adheres to CFH common framework tenets for interoperability. The underlying belief driving the model is that protecting privacy is of paramount importance. In this model, personal health information remains in the hands of those who collect it. The goal of the network is enabling interconnectivity and promoting interoperability. The plan is to leverage the common framework and develop a records architecture at the national level that in its simplicity will allow easy adoption and use.

The health care markets include Mendocino HRE, Indiana Health Information Exchange, and MA-SHARE.

IBM

Ginny Wagner of IBM explained that the company is committed to making health care more effective through its business and clinical innovations, bringing together IBM resources, including information technology, industry insights, and research expertise. IBM helps the health care industry develop and deliver safer, more affordable, and more effective diagnostics, drugs, and medical care. She noted that IBM recently announced and adopted the use of personal health record for all employees. The health care markets for their project are: (1) Taconic Health Information Network and Community, (2) North Carolina Healthcare Information and Communications Alliance (Research Triangle Park), and (3) North Carolina Healthcare Information and Communications Alliance (Rockingham County).

Northrop Grumman

Rim Cothren of Northrop Grumman noted that the company is a large-scale health IT systems integrator; the developer of global enterprise EHRs and nationwide healthcare information exchanges for the DoD and VHA; and experienced in disease surveillance and response solutions supporting the CDC, HHS, and state and local governments. The health care markets in this project are: (1) Santa Cruz RHIO; (2) Greater Cincinnati HealthBridge; and (3) the greater Cleveland, OH, health market, including University Hospitals Health System, Cleveland Clinic Health System, and MetroHealth System.

Dr. Loonsk then described the NHIN timeline. In the short term, breakthrough implementation possibilities will be documented by the consortia. In spring of 2006, detailed technical design and architectures will be developed, and data and technical standards and security policies will be recommended. In the summer of 2006, deployment plans, operational plans, and revenue and cost models for sustaining this activity in subsequent years will be developed. In fall of 2006, NHIN is expected to finish development, evaluate functional prototypes, and conduct live demonstrations.

There are some early opportunities for moving these architecture opportunities forward that include better understanding the requirements, an identification of the architecture and standards to support them, and fostering the critical data exchange for these activities. Common foundational capabilities to support breakthroughs and the NHIN include: (1) patient record locators to help identify all patient data, both paper and electronic; (2) identification and application of appropriate general Internet standards; (3) approaches for user authentication and access controls; and (4) other privacy protections and solutions.

Discussion Highlights

"We have two parallel processes. One is get to four viable prototypes that can be demonstrated through actual operation on clinical data. The other is to throughout the year, be working in a joint consortia activity of teasing out the architectural elements that are common and the needs that are common to feed the standardization needs of the standards harmonization process." – Dr. Loonsk

"We asked each of the contractors to test in three markets…to develop a more robust solution and implement a common, non-customized solution in three different markets…We expect that we will ask for continued funding to support this project in 2007. Over time, we expect industry investment to replace government investment in this area." – Dr. Brailer

"It wasn't clear to me that all of the markets that were spelled out here are regional in the sense of being comprehensive for all of the people in the region. Some of them seemed to be picking a portion of a population within a region." – Dr. Sondik

"I think an interesting part of the evaluation would be to look at it from a geographic point of view…and for some of these see what portion of the population has access to this network and what portion does not have access to it. That would give some very useful insights into how to move forward." – Dr. Sondik

"There is going to be a need for harmonization of these different architectural components and other products from the consortia, and that is one of the things we anticipate coming from these shared public meetings that we are going to have." – Dr. Loonsk

"Each of the contractors is developing an independent technical and business solution to this problem, such that the way they would view the cost or the revenue accrual process tends to be quite different…[The contractors are not competing…they are working independently and quite collaboratively to develop a common language for how to specify the elements of the business case." – Dr. Brailer

"We are going to go for broke here and try to make sure that the capacity to share data is a national asset. But on the other hand, we recognize that it is not a technology solution. The governance of this should not be national, the federal government, the national party should not govern how information is shared across the whole U.S. because of the huge variations in regional attributes of the markets." – Dr. Brailer

"Some highly mature regional projects will build their own infrastructure, they are already far along, and the national effort would be to tie into that. Many rural areas and others won't be able to build a regional network and we can't rely on that happening as a matter of course. In those circumstances, we have to be prepared to tie directly in. It is our hope that at a minimum to make sure that if I am a regional effort and ready to go, that I have a group of willing national suppliers that can bring me a solution that is compatible with federal efforts." – Dr. Brailer

"I think, on behalf of providers and patients, that we will have missed a huge opportunity if at the end of this exercise we don't have a national network for transmitting this information." – Dr. Henley

"We absolutely expect to have a seamless set of information flow around doctors, hospitals, consumers, labs, pharmacies, etc., to be able to achieve the goals that we've laid out." – Dr. Brailer

"We need to have the consumer voice present as an integral part of every step of the process. The consumer is the benefactor of this national asset…As we look at the contracting work that is being done in each of the areas, I would encourage that each subcontractor invite a very deliberate consumer voice to be represented within the working groups." – Ms. Davenport-Ennis

"These contractors and their consortia of other entities and health care markets all with relatively large needs will not only be working together but working in concert with all of the other contractors and doing so in an open forum. We will be inviting anyone from the public and any other technology company, provider, organization, or regional enterprise that wants to come and replicate what they are doing, learn what they are doing, and comment on what they are doing." – Dr. Brailer

"We don't know how much this costs to build. It is our presumption that the key drivers of this over time will be the consumers themselves who want their information and want it to be portable, and we don't know what the economic implications of that are. It is our hope that as we look at the business model we can create the circumstances where private capital is invested in this in a way that achieves these public good aims." – Dr. Barrett

"This really is more of a national health interoperability architecture than it is this health information network, and I think the struggle that we have in looking at this…is that there is going to be some special network that is only going to be used for health care and I think that would be a huge mistake if we are not leveraging existing technologies in place today like the Internet for the exchange of information." – Mr. Hutchinson

"We believe that this architecture, this network…gives us a linear business and technical process for achieving the goals of making sure that the standards, the certification, economics, and policies relate to each other. We think we have our arms around what it takes to drive this forward and to achieve the goals." – Dr. Brailer

"Where the data actually lives, whether it is in a doctor's office or one national location or some hybrid of those two is an incredibly difficult question and really ought to consume this effort." – Mr. Roob

"I think we've got two viewpoints on whether we should be top down or bottom up in how the system develops…Has there been any instance of competition in the same region between different entities that are trying to establish a regional system? In California there is beginning to be a bit of overlap, and is that something that we anticipate will be a problem down the line?" – Dr. Straube

"There are a number of markets that I would describe it as competition. Often it is an organized effort competing with some large proprietary networks that themselves have been scaled to be regionwide. I'm not that is the same type of competition that you are asking about. In some markets it is playing out that there is partnership developing, and in others I think it is too early to tell." – Dr. Brailer

Briefing by the Health Information Technology Standards Panel

Dr. John Halamka, Chair of the Health Information Technology Standards Panel (HITSP), explained that a standard specifies a well-defined approach that supports a business process and: (1) has been agreed upon by a group of experts; (2) has been publicly vetted; (3) provides rules, guidelines, or characteristics; (4) helps to ensure that materials, products, processes, and services are fit for their intended purpose; (5) is available in an accessible format; and (6) is subject to an ongoing review and revision process. Harmonization is required when a proliferation of standards prevents progress rather than enables it.

The Healthcare Information Technology Standards Panel (HITSP) is a group that was organized to harmonize the standards used to exchange health data in the United States. The Panel brings together experts from across the health care IT community—from consumers to doctors, nurses, and hospitals; from those who develop health care IT products to those who use them; and from the government agencies that monitor the U.S. health care system to those organizations actually writing the standards. The Panel's activities are led by the American National Standards Institute (ANSI), a nonprofit organization that has been coordinating the U.S. voluntary standardization system since 1918. The Panel's members include 150 different organizations, including 12 different standards organizations and a large number of payers, providers, patients, and providers coming together in a community in an open and transparent way.

Panel members and experts have committed themselves to setting and implementing standards that will ensure the integrity and interoperability of health data. In some cases, redundant or duplicative standards will be eliminated. In other cases, new standards may be established to span information gaps. In all cases, the resulting standards serve the consumer and other healthcare stakeholders by addressing issues such as data accessibility, privacy, and security.

Historically, "unique" market needs within the health care community were addressed with customized systems, applications, and standards. More than a dozen standards-setting organizations—from ANSI-accredited bodies to industry consortia and other forums—have developed a plethora of standards to meet the needs of specific sectors within the health care IT market. However, the disparate messaging systems, data elements, and vocabulary now prevent the cross system exchange of health information.

In terms of early HITSP successes, with regard to the U.S. health IT standards community, cooperative partnerships have been and are being developed between and among certain standards developers. Within 1 week of its announcement, HITSP use case committee workgroups were formed and began responding to breakthroughs defined by the Community.

During 2006, HITSP will: (1) implement processes for resolving gaps and overlaps in the health IT standards landscape; (2) develop and implement, as appropriate, harmonized standards that support the Community's breakthroughs; (3) promote public awareness of health IT standards harmonization activities and provide an open, balanced, and transparent review mechanism; and (4) develop a business model that will sustain the HITSP for as long as standards harmonization and coordination is necessary. Beyond these 2006 milestones, the Panel plans to: (1) develop harmonized standards and unambiguous implementation guides that provide precise instructions for data sharing; (2) standardize the interoperability specifications for technology products, while permitting differentiation and competitive advantage in the marketplace; and (3) empower patients and care providers with EHRs that facilitate easy access to critical health data that is accurate, private, and secure.

Discussion Highlights

"The Panel of HITSP, comprised of 150 different member organizations, is really the decisionmaking body. At many companies, the Board provides strategic guidance. In the case of HITSP, the Board is really an administrative entity that ensures that we have good process, appropriate agendas, deal with governance issues, but all votes of substance, how those standards are going to be standardized, and building a consensus in the community is done at the Panel level, with all 150 HITSP members. We very much try to work on consensus and not just a simple majority…All of the stakeholders agree with what we are doing. That Board provides purely administrative work; the panel provides strategic decisionmaking." – Dr. Halamka

"Membership in the panel is open to any organization that represents a standards development organization or stakeholders, such as consumers, doctors, various hospital organizations, payers. Today we have 12 standards development organizations on the Panel, which do represent those major standards producers for health care. Certainly, any new organization would be welcome to join, the criteria are really quite simple." – Dr. Halamka

"When one thinks of standards, they take many forms. Certainly there are standards of content…or of vocabulary, and so although standards comprise content, structure…and transmission standards, we focus on whatever the use cases require us to focus on in the short term. Our charter is to focus on all of those elements—content, structure, and transmission standards as necessary to empower interoperability." – Dr. Halamka

"Can this kind of a system work? The AQA is a very similar organization that has done a remarkable job and has brought together very diverse people, many of whom are in competition with each other in a niche of health care, so I think this is pretty analogous to AQA, and to a lesser extent to the HQA…It is a very workable model, and something that I think you are going to see more and more of." – Dr. Straube

"The standards that AQA and HQA are dealing with are clinical content standards about medical evidence and appropriateness of care. Here, it is the data structures and the standards about how does one actually collect that data, so as we come to how do we have a system of measuring quality of care, standards from both of these groups will come together over time to make that happen." – Dr. Brailer

"Certainly we are leveraging the work of all those individual organizations rather than reinventing something…The notion of building consensus is to take all the good work, expose it to the community, identify those standards that are most appropriate, and then select them by consensus. Does this mean that there may be winners and losers? We believe that there are ways of reaching middle ground, bringing together best practices in ways such that all of the stakeholders feel like they contributed to the consensus." – Dr. Halamka

"HITSPE itself has a use case committee that has been meeting from the very day that HITSPE was formed and has aligned its efforts with the ONC so that it is producing those detailed artifacts that describe what are the actors, actions, and events for biosurveillance, for consumer empowerment, for electronic health record exchange, and they are fairly detailed." – Dr. Halamka

"Laboratories have already done a lot of computerization, so the last decade has prepared us for the exchange of laboratory data." – Dr. Halamka

"The milestones very, very good, and similar to what AQA has…One of the pieces you have here is about communications and getting the message out. Are there any definite plans about that?" – Dr. Straube

"We have to have communication both internal to the process and external to the process. Every week, the HITSP Secretary issues an e-mail to all members saying 'this is what was done this week,' 'these are the challenges this week,' 'these are going to be the work drives that we are going to have in the upcoming weeks,' so across the community of all these stakeholders there is very good understanding of what is going on. Toward the end of May/beginning of June, we hope to have some initial work products, these implementation guides and interoperability frameworks, that we can then begin to circulate in a public fashion for comments." – Dr. Halamka

Briefing by the Certification Commission for Health Information Technology

Dr. Mark Leavitt, Chair of the Certification Commission for Healthcare Information Technology (CCHIT) explained that the Commission's mission is to accelerate the adoption of robust, interoperable health IT throughout the U.S. healthcare system, by creating an efficient, credible, sustainable mechanism for the certification of health IT products. CCHIT's role is to create a mechanism to certify the products, and that mechanism has to be efficient and sustainable, so that value, not cost, is added to the health system. Dr. Leavitt added that the entire success of certification depends on credibility. "Basically, our number one most important product is that this process is credible, and a lot of what we do is focus on making it credible."

In July of 2004, certification of health IT products by three non-profit health IT associations, AHIMA, HIMS and the Alliance, was a key action in the HHS Strategic Framework. In September of 2004, AHIMA, HIMSS, and the Alliance funded and launched the CCHIT. In June 2005, eight additional organizations added $325,000 of funding support. The DHHS July 2005 HHS announced a health IT strategy and released an RFP for compliance certification in July 2005, and in September of last year, the CCHIT was awarded a 3-year, $7.5 million DHHS contract to develop and assess EHR and network certification criteria and inspection processes. The Commission also received additional funding from

eight other organizations. The current round of funding is a 3-year, $7.5 million contract; however, this government contract does not support CCHIT's continuing operations, it is intended to have the Commission develop a certification process. After this contract, the CCHIT will have to become self sustaining.

In terms of organization, the CCHIT has five workgroups, in the areas of functionality, interoperability, security and reliability, certification process, and use case and test plan. The Commission has a fairly small staff but a very large number of volunteers. The workgroups focus on complementary aspects of certification, and the Commission interacts with a diverse group of stakeholders covering both the private and public sectors (e.g., vendors who make the products, providers who purchase the products, and payers).

The CCHIT includes at least two representatives from healthcare providers, health IT vendors, and purchasers/payers and at least one representative from its other stakeholder groups (the Commission also has two federal government representatives). The first pool of applicants for the workgroups was recruited in November of 2004 and included 275 applicants. Each workgroup has two Co-Chairs, each from a different stakeholder group, and consists of approximately 10 members per workgroup

With regard to the role of the CCHIT within the health IT strategic landscape, Dr. Leavitt characterized the Commission as an interface between the strategic initiatives and the private sector health IT marketplace. "We are basically the lever that the strategic initiatives can use to nudge the marketplace."

Dr. Leavitt described the objectives of health IT product certification. They are to: (1) accelerate adoption by reducing the risks of investing in health IT, (2) facilitate interoperability of health IT products within the emerging national health information network, (3) enhance the availability of health IT adoption incentives and relief of regulatory barriers, and (4) ensure that health IT products and networks always protect the privacy of personal health information.

In terms of the CCHIT contractual timetable, in the first year the Commission is tasked to develop criteria for ambulatory care electronic health records. During the second year, the CCHIT will develop criteria and certify inpatient, or hospital-based electronic health records. In the third year, the Commission will start certifying the networks through which they interoperate. Dr. Leavitt noted that work does not stop after the developmental year. Once criteria for ambulatory EHR were developed (the criteria were published in November 2005), they now have to be updated and enhanced.

In addition to periods of formal public comment, the CCHIT holds town hall meetings that involves outreach to specific groups. It is envisioned that the CCHIT eventually will become an organization that is self sustaining, likely paid for by the fees that vendors pay to be certified, and that no longer needs government funding.

Milestones completed or anticipated in 2005 and 2006 include:

- November 2005 – Publish proposed criteria and test process for certifying ambulatory EHR products
- February 2006 – Complete a pilot test of certification
- June 2006 – Have certified ambulatory EHR products in the marketplace

- September 2006 – Begin certifying e-prescribing and laboratory interoperability of EHRs (dependent on standards harmonization)

- October 2006 – Publish proposed criteria and test process for certifying inpatient EHR products.

In addition, the Commission has added special off-year date of September 30, 2006, to start requiring e-prescribing.

Discussion Highlights

"There are plenty of challenges. The first challenge was market rejection…Right now a bigger challenge is the potential complexity of what we're trying to certify, and the risk that we can't find what are the simple five, or ten, or 15 things that we need to focus on, because hospital systems are much more complex. In ambulatory care, there were 250 specific criteria in about 30 major areas…The inpatient systems are much more complicated." – Dr. Leavitt

"We need the providers. We talked about the vendors not coming and signing up, but if the vendors sign up but the providers don't preferentially purchase certified products, then you didn't have an impact. Because of that risk, we actually are funded to do a formal communication effort to the physician community. This is a tough community to reach, because they're busy, they're mostly in smaller offices, it's just expensive to reach them." – Dr. Leavitt

"Just to be clear to the members of the Community, the Certification Commission is responsible under our contract for evaluating its work, and having it evaluated, that in the end the real question with electronic health records being certified or not is do they lead to fewer errors? Do they have more protection of data, and can they share data more easily? And those kinds of end-stage functional outcomes are not the things you're going to evaluate, but we expect the research community to begin looking at those questions over time." – Dr. Brailer

"We can certify that the product in the hands of someone that wants to improve quality will fulfill their needs to measure quality and improve quality…We can't [motivate] the hospital or the doctor…to take the steps to improve the quality." – Dr. Leavitt

"One of the points that I was struck by this morning is we really had a heavy focus on what happens in hospitals. And I think that's appropriate, but I don't want prevention to get lost in all of this."
– Dr. Sondik

"We've had a little bit of experience with getting some vendors on the network to reach pharmacies, and one of the things that we've discovered is when you have vendor A and vendor B working side by side in a closed environment working with a paper process…once you get into interoperability, it actually changes the dynamics of the workflow quite a bit…What are we doing to make sure those certification requirements change?" – Mr. Hutchinson

"In the first year's criteria, we're definitely not at the point to tackle measuring…workflow efficiency or usability. But we structured the testing in such a way that we could measure it in the future."
– Dr. Leavitt

"If medication history is being received from a payer, PBM, or pharmacy, and they see that a patient is actually out of compliance, so they're not being adherent with the physician's orders…Are you highlighting these things, are you alerting? These are things that we've discovered, once you add

interoperability into these applications, the functionality requirements change dramatically of whether you're actually utilizing that to the nth degree." – Mr. Hutchinson

"We should keep in mind, generally the users will drive the marketplace to improve usability. That's not broken; what's broken is that there's no way to plug the systems together without hiring a consultant and paying him $20,000 or $50,000 per site…We're trying to set certification as a basic bar…a capability everyone should have. We're going to let the vendors differentiate themselves over the really fast, slick, extra features…but the basic stuff that protects patients' safety and doesn't lose their information needs to be in all the products." – Dr. Leavitt

"I would anticipate you will find the physician community very receptive to your communication outreach. I think physicians in general are anxious to understand the seal of certification approval in terms of going that next step to purchase electronic health records" – Dr. Henley

"We're not doing the quality assurance function for the vendors. What we're doing is certifying that it has basic functionality needed by this population, and that when you plug it into the network, it's going to be able to send information securely." – Dr. Leavitt

"Everything we do is in the public domain except the actual looking at individual products and looking at their screens and seeing what they do, which is highly confidential between the different vendors. But once you get beyond that, all of our work is public. CCHIT.org has our certification requirements, our test plan, they'll have the pilot test results when the pilot test is over at the end of February." – Dr. Leavitt

Public Input Session

Speaker Number 1 – Kelly Nelson, works for a small encryption software developer in Huntsville, AL, thanked the Community for its efforts on behalf of the U.S. public. Her company is concerned with security, particularly for digital data. For years, developers and programmers have tried to develop systems for digital security that is easy to integrate interoperable with multiple systems, customizable, scalable, and inexpensive. Developers at her company are the first to do so, having created an encryption technology known as Secure Random Key Infrastructure. AHIC members were sent a package before the end of 2005 with information on this infrastructure.

Ms. Nelson indicated that her company could save the Community and the health care industry at least 40 percent on digital security costs. The company will be providing internal and external solutions to SAP in Germany, and is in discussion with the United Kingdom government, and with Hitachi in Japan. The Defense Information Systems Agency has committed to sponsoring this technology for movement into the classified arena. The company can customize encrypt any digital data at rest or in motion for a variety of platforms.

Speaker Number 2 – John Ruiz, National Association of Community Health Centers in Washington, DC, noted that community health centers represent 15 million patients across the country. His organization represents 1,200 grantees, with over 3,000 sites across the country and more than 40,000 FTEs. He thanked AHIC for its efforts and indicated that his intention was to raise the visibility of the community health centers' patients and their safety net providers. He emphasized his organization's desire to collaborate with any of the initiatives and any of the workgroups that are being pulled together, and any of the work that is being carried out by the Community in general.

There is a critical mass of data and patients that are available through the community health centers. There is expertise at the community health centers from the administrators who are familiar with the deployment of information technology at the health centers. Clinicians have the familiarity both with the processes and the needs for managing data at the health centers. Finance directors and information technology staff have long been working at the deployment of information technology at health centers. In addition, many of the health centers participate in networks that have long been funded through the Bureau of Primary Health Care and Health Resources and Service Administration, and therefore bring the knowledge of what it does take to deploy information technology at the health centers and within their communities. Many of them are also in the process of implementing or have implemented electronic medical records.

Many health centers serve migrant populations that travel across the country, where it is challenging to provide continuity of care. As a result of Hurricane Katrina, many health centers around the Gulf Coast area lost medical information because their facilities were devastated. They are familiar with many of the issues that AHIC is tackling.

Mr. Ruiz also discussed the digital divide for both patients who often do not have access to computers or to electronic information as well as the many community health centers in rural communities where connectivity is an issue. Many of these centers are small, nonprofit organizations with little, if any resources for purchasing some of the complex systems discussed at the meeting. He asked how his organization can collaborate with the Community to ensure that the safety net providers of community health centers are at the table.

Closing Remarks

Dr. Brailer thanked those who provided comments during the public input session as well as all Community members, Office of the National Coordinator and Office of the Secretary staff, and all who attended the meeting. Before adjourning, he noted that the next AHIC meeting will be held on March 7, 2006.