Meeting Report

American Health Information Community
December 12, 2006

The American Health Information Community (the Community), 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 tenth meeting via conference call on December 12, 2006.

The purpose of the call was to bring together Community members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to the Department of Health and Human Services (HHS) on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting's discussions focused on: (1) an update on the Personalized Healthcare Workgroup, (2) State Health Information Exchange Steering Committee Recommendations, (3) an update on the Nationwide Health Information Network (NHIN), (4) and an update on Healthcare Information Technology Standards Panel (HITSP) activities.

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

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

Call to Order

Joining Secretary Leavitt on the teleconference were:

David Brailer, MD, PhD, Vice Chairman, AHIC

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

Alex Azar II, JD, Deputy Secretary, DHHS

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

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

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

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

Ed Goodman, VHA, Inc. (Mr. Goodman represented Lillee Gelinas, RN, MSN, Vice President of VHA, Inc.)

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

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

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

Kevin Hutchinson, CEO of SureScripts

Stephen Jones, DHA, Principal Deputy Assistant Secretary of Defense for Health Affairs (Mr. Jones represented Dr. William Winkenwerder, Jr., Assistant Secretary of Defense for Health Affairs)

John Menzer, Vice Chairman, Wal-Mart

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

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

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

Ed Sondik, MD, Director of the National Center for Health Statistics, Centers for Disease Control and Prevention (CDC) (Dr. Sondik represented Dr. Julie Gerberding, Director, CDC)

Introductory Comments

Before introducing Secretary Leavitt, Dr. Brailer welcomed participants to the call, noting that comments would be sought following the meeting to evaluate the effectiveness of holding AHIC meetings via teleconference. Secretary Leavitt, who joined the call from Beijing, noted that he met with the Chinese Minister of Science and Technology; part of their discussion focused on standards for health information technology (HIT). Secretary Leavitt also welcomed John Menzer to the Community.

Approval of October 31, 2006, Meeting Minutes

Minutes from the October 31, 2006, AHIC meeting were distributed and reviewed by Community members. A motion to accept the minutes with no changes was made, seconded, and approved unanimously.

Update on Personalized Healthcare Workgroup

Dr. Brailer reviewed the members and advisors of AHIC's newly formed Personalized Healthcare Workgroup, comprised of representatives from federal agencies, major universities and health plans, pharmaceutical companies, and providers. The Personalized Healthcare Workgroup is Co-Chaired by Drs. John Glaser and Douglas Henley and has the following proposed broad and specific charges:

- *Broad charge:* Make recommendations to the Community for a process to foster a broad, community-based approach to establish a common pathway based on common data standards that encourages the incorporation of interoperable, clinically useful genetic laboratory test data and analytical tools into electronic health records to support clinical decisionmaking for the health care provider and patient.

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

Initial Workgroup activities include the following: (1) survey existing standards efforts for genomic test data and interpretation in electronic health records and evaluate their maturity, (2) develop recommendations to further standards development and implementation, (3) assess needs for analytical support tools to support genetic testing-based clinical decision support and identify associated EHR functional and technical requirements, (4) evaluate privacy and security issues that are unique to genomic test results, and (5) develop use case scenarios to guide this work.

Dr. Gregory Downing, Director of the Office of Technology and Industrial Relations, National Institutes of Health, commented that the Workgroup has been focused primarily on patient-health care provider interactions. He explained that the broad charge essentially is facilitating information exchange that can support a broad array of applications in the future, for example on clinical decision support activities as well as efficacy decisions and safety aspects. The specific charge primarily focuses on establishing standards for reporting and incorporation of common medical genomic test data into electronic health records.

Workgroup Co-Chair and AHIC member Dr. Doug Henley noted that it is important that the group initially focus on the relative standards that will allow laboratory tests and their results to be incorporated and transmitted seamlessly into EHRs. A longer term goal, as indicated in the Workgroup's broad charge, is to embed clinical decisionmaking support tools within EHRs and other electronic tools to assist clinicians and patients in making important health care decisions.

Dr. Brailer concluded this portion of the meeting by indicating that the proposed broad and specific charges for the Personalized Healthcare Workgroup have now been formalized and accepted by the Community.

State Health Information Exchange Steering Committee Recommendations

Linda Kloss, Chief Executive Officer of the American Health Information Management Association (AHIMA), described the critical roles that state-level initiatives play, noting that at the September 12, 2006, AHIC meeting, she and her colleagues presented information on the roles and emerging best practices for state-level regional health information organizations (RHIOs). At that meeting, she also presented a workbook for use by developing state-level health information exchange (HIE) initiatives. State-level HIE initiatives generally are public-private entities that can serve the roles of convener, educator, and facilitator with a commitment to advancing quality and transparency in health care.

At that September 12 meeting, the following series of recommendations were made to the Community: (1) examine mechanisms to promote strategic synergies among states and between state and federal efforts, (2) increase efforts to develop salient financial models, (3) engage and leverage public and private payers, (4) advance understanding of how state policymakers and governmental agencies should be involved, and (5) identify vehicles for support and knowledge sharing among state-level HIE initiatives.

Since the September 12 AHIC meeting, those recommendations have been carried through in four targeted studies. Two of the studies relate to organization and communication between the state-level efforts and federal efforts, and how to leverage and enable those. These two studies focus on: (1) state-level HIE and major federal initiatives, and (2) HIE and quality and transparency initiatives. The remaining two studies are more programmatic in nature and involve: (1) Medicaid and HIE initiatives, and (2) financially sustainable HIE services.

Results and findings of these studies were discussed in the following presentations, with the exception of the study on financially sustainable HIE services, which will be discussed at a future AHIC meeting. In concluding her opening remarks, Ms. Kloss recognized and thanked the Steering Committee that has been supporting these efforts. She also recognized the Task Leaders and Technical Advisors lending their expertise to each of the four studies.

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

Dr. Donald Mon, Vice President, Practice Leadership, AHIMA, explained that the purpose of this study is to explore the potential roles/interactions between state-level HIE initiatives and major federal health care and HIT activities. Two specific deliverables include: (1) recommendations for establishing formal communications among states and federal agencies, and (2) identification and documentation of barriers and concerns expressed by state-level HIEs that HHS/Office of the National Coordinator for Health Information Technology (ONCHIT) and other federal agencies can constructively address and alleviate.

Dr. Mon noted that the project has identified barriers between state-level HIE and major federal initiatives in terms of validation of roles. These include: (1) the standards harmonized today are not always the ones most urgently needed by state-level HIEs; (2) state governments need to be much more involved in state-level HIE initiatives; (3) financial sustainability is still a top issue—there is a strong relationship between financial sustainability and the lack of alignment between incentives and the sequence of activities moving HIT forward; (4) there is no consensus on how thick or thin the NHIN should be; and (5) state-level HIEs may be ideal entities to aggregate secondary data for the state, but there currently is no business case to support this activity.

Dr. Mon described additional barriers related to HIT alignment/communication that have been identified. For example, there is little sharing of lessons learned between state-level HIE and federal HIT initiatives. State governments, through the State Alliance for e-Health, should leverage but not disrupt progress on a state level. Dr. Mon added that it is unclear whether the legislative branch is fully supportive of the role of HIT in improving quality of care, and there is no central authority accountable for HIT's role in transforming health care or for making key HIT adoption-related decisions.

This effort led to the development of the following recommendations:

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

Discussion Highlights

"CMS today has enormous control in terms of data, and the development of data architecture around MMIS systems…as CMS rolls out its new architecture, this needs to be a part of it…I'm in the process of procuring a new MMIS system, and I don't see all those dots being quite connected the way they could be, to leverage the federal and state investment at this point." – Mr. Roob

"I think that is a good lead-in to our task two report on specific Medicaid and Health Information Exchange Initiatives." – Ms. Kloss

"To what extent have the states been funded by the legislature and set up these administrative and MMIS architectures to develop health information exchange and HIT?" – Mr. Eisenstein

"We are going to touch on both MMIS and CMS's role in assisting the states, and particularly the Medicaid programs, in advancing or engaging in health information exchange at the state level." – Ms. Kloss

"How many state-level HIEs…did we find in the study? And is that related to the term 'RHIOs?' Are they one and the same, or are they different?" – Mr. Hutchinson

"The project initially was called 'State-Level RHIOs,' and the Steering Committee just felt there was some confusion…and chose to retitle this, at least for purposes of this study, 'State-Level Health Information Exchange Initiatives.' But understand that the purpose and scope does vary from state to state. So what we call it perhaps is less important than really getting into what the role and purpose is. But we did that to differentiate and to suggest that there may be a state-level health information exchange initiative, and still within the state, throughout the state, various regional and local initiatives, and that would be the way the group envisioned this as developing." – Ms. Kloss

"Are you proposing criteria by which one can distinguish a state HIE or RHIO, or whatever it would be called, from one that meets certain criteria, from one that does not?" – Dr. Brailer

"We described certain roles, but we did not, in our study, describe criteria." – Ms. Kloss

"There were about 28 states that we looked at. And from those 28, we selected 9 projects to study in more depth. But we know that this is expanding, and it's highly likely there will be some public-private entity in each state as we continue to move forward." – Ms. Kloss

"On the fourth [recommendation], which has to do with the use case for the actual transfer of information, it sounds in a way like there's an option to not do that, to have that use case. And I would think that would be very important to this. Because if we don't do that, then what are we really going to know about this?" – Dr. Sondik

"If you look at the current use cases, they are scoped in a way that is achievable for the first year. So for example, if you were to take a look at the registration summary and medical history, the first year was to just identify what is contained in a registration summary and what is contained in a medication history…scoping did not involve the state-level HIEs. A next step could possibly involve health information exchange, once that information has been identified then the next step is to go ahead and exchange it. But that use case for that current period of time did not address something that the HIEs felt that they could be actively engaged in, even at that first stage. And so the challenge is to then to be able to construct a use case where the HIEs can feel engaged at that point in time." – Dr. Mon

"A second example is the emergency responder use case. There now obviously will be some health information exchange again once the information about what should be transmitted in an emergency first response, but again, that was a situation where the state level HIEs just didn't feel that it was an immediate use case for them to work on." – Dr. Mon

"The existing use cases were functionally defined, they are about information exchange, but more about a particular function. I think one of the things we're seeing with the emergency responder EHR use cases is that it definitely seems to point to a transfer of care, or summary record need that would probably be actually very helpful at the state level for state exchange, as well." – Dr. Loonsk

"Recall the underlying motivation in part for this analysis, and certainly for the state alliance that's been recently formed, is to have a more formal mechanism by which more formalizing entities in the states can have a dialogue with a national structure like the community. So that needs at that level have been taken into account, and implementation coordination can occur…in a way this recommendation speaks to that need to begin having attention to issues that are seen as relevant at the state level." – Dr. Brailer

"Procedurally, there is a draft letter of recommendation that contains these recommendations…and we'll be asking AHIMA to take that letter, based on this discussion, and transmit a final letter of recommendation that the AHIC will take up at its next meeting to approve or disapprove. And I think this discussion certainly will get us most of the way towards having that as a decision point." – Dr. Brailer

"In the barriers we had identified, there's no central authority accountable for HIT's role in transforming health care, or making key HIT adoption-related decisions. Perhaps we're going to hear more about that in the next presentation around the state issues. But if not, that is certainly an area that we would want to have addressed." – Ms. Davenport-Ennis

"The draft letter itself calls for an updating of the strategic framework to be able to continue to guide ONC's role in doing that central leadership, even though it is not a central authority." – Dr. Brailer

"Is there a strategy and timeline for the transition of AHIC, the Community officially disbanding and this public-private community continuing in its place?" – Dr. Henley

"I certainly have an ambition to have it complete before the President's term is up. So that's not too far out in the future. Which means we would need to begin thinking very seriously about this soon." – Secretary Leavitt

Medicaid and Health Information Exchange Initiatives

Shannah Koss, Vice President of Avalere Health, LLC, explained that the purpose of this project is to explore the role of state Medicaid programs in HIE initiatives, with consideration given to barriers and drivers to engagement and opportunities for and value of Medicaid's participation. As part of the project, interviews were conducted with nine HIE initiatives represented on the AHIMA Steering Committee, five additional HIE initiatives, two state Medicaid officials, four representatives from a regional CMS office, and one representative from the Center for Medicaid and State Operations.

Key findings include the following: (1) HIE initiatives see value in Medicaid agency participation and expect Medicaid interest, (2) Medicaid has been minimally involved with HIE, (3) Medicaid can play many roles in an HIE initiative, (4) HIE initiatives must address specific Medicaid business problems, (5) vehicles exist to facilitate Medicaid's involvement, and (6) the Medicaid information technology architecture has longer term potential to facilitate HIE for Medicaid.

Ms. Koss explained that perspectives vary on Medicaid's limited involvement in HIE initiatives. According to HIE initiatives, Medicaid does not readily understand or see the value proposition of HIE, functions in an administrative and political environment that limits receptivity, tends to conservatively interpret data-sharing laws, and operates cumbersome legacy claims systems. Conversely, according to Medicaid, there is a lack of a proven HIE value proposition that makes it risky for Medicaid engagement in early stages, priority investments focus on cost-effective program administration, limited state and national leadership constrains Medicaid's support of HIE, and limited staff and financial resources inhibit participation.

Ms. Koss presented recommendations in the following three areas:

- HIE Initiatives:
  - Demonstrate return on investment showing Medicaid cost savings or efficiencies.
  - Seek state political leadership and include Medicaid in HIE governance.
  - Identify and engage in HIE efforts consistent with the needs of Medicaid.

- Medicaid:
  - Work with state agencies and leadership to identify shared HIE needs and value.
  - Leverage contracts and purchasing (e.g., managed care, disease, management, and transparency).
  - Work with Medicare to use HIE to better manage dually eligible beneficiaries.

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

Ms. Koss noted that CMS and other federal stakeholders have an important role to play in these efforts. States generally do not feel that they have the endorsement to engage in HIE in the way they might like to, even when there is a desire to do so. She added that the Community can help CMS by including more Medicaid representation across the AHIC Workgroups, and heightening the importance of including Medicaid's perspective to foster these regional and state-level exchanges.

Discussion Highlights

"I'm wondering at the state level whether it's Medicaid or the public health or some other department on the state level—who is in charge? I know [it] probably must vary state by state, but we're trying to create this structure on a local or state level. Don't you have to have the same kind of very well-developed infrastructure at the Office of the National Coordinator, and are states sort of picking up on this?" – Mr. Eisenstein

"There really is no one flavor of state-level leadership and governance that would work for every state. And how most of these initiatives have emerged is with some key stakeholders that are willing to step up to the leadership position and really encourage the dialogue and invest the resource and time…What we've heard repeatedly is if there is a vocal state champion, regardless of where they sit across those state agencies, that that can make the difference not only for the state, but also for purposes of Medicaid's involvement. But that there needs to be someone there. And it certainly does help if the state or the governor establishes or sets a mission and a goal for the state to do this." – Ms. Koss

"I think there are some specific recommendations that could enable that to occur. And as Shannah reported, we think some demonstration of some specific explicit direction from CMS could help open those doors, and then some further work by the HIEs themselves in building the business case…So we have some specific recommendations on short-term actions." – Ms. Kloss

"Are we in a process to include the State Secretaries of Health, and to determine what their level of support is within their overall program to integrate HIT into that process?" – Ms. Davenport-Ennis

"We had specific recommendations with regard to department of health and other state agencies in collaboration with state level HIEs in our workbook, so I think that has been a common theme that we need. And particularly departments of health to be actively engaged in state-level HIE policy setting and convening." – Ms. Kloss

"There was another context to that under the federal activities project…There are multiple levers that the state government can use. One of them being Medicaid, others being aggregate reporting, public health, and so on. And what came up in the task one report is that all of those various levers should be used. Because if they are used, then what that provides for the state level HIEs is that no specific entity bears the sole burden of trying to fund the [state-level] HIE's efforts, but they contribute to a pool. And therefore, each initiative, like public health reporting for the state, or Medicaid transactions, will have their needs addressed, but their contributions to a common fund will help the sustainability of the state-level HIEs." – Dr. Mon

"Let's remember when you have them about their wallets, their hearts and minds will follow. And what successes we have had here have been based on the use of dollars to help subsidize data movement." – Mr. Roob

"I think it also begs for very deliberate public-private partnership between the state Medicaid programs and other businesses, and their states, that can help fund some of the activity that is required here. And to also provide guidance that may be in the technical area of how they can get their program engaged in this issue." – Ms. Davenport-Ennis

"We do, in the full report, identify some important vehicles, including the Medicaid transformation grants, as opportunities to identify those funds that will encourage the hearts to follow." – Ms. Koss

"I would strongly support Medicaid's involvement in the state-level HIE initiatives. Just to give a real-life example, in the state of Florida where Medicaid was involved in the deployment and rollout of electronic prescribing systems, we saw a rapid acceleration of physicians' use of e-prescribing in those markets when Medicaid became involved in sharing medication history information from their own databases to these devices in the Florida market. The one caution I would give to the group…is that there was a misunderstanding or misperception that this was a Medicaid-only capability…That limited the overall utilization, but we saw very positive results of physicians getting engaged with the adoption of IT when Medicaid became engaged in sharing information with physicians." – Mr. Hutchinson

Health Information Exchange and Quality and Transparency Initiatives

Ms. Kloss discussed the Steering Committee's response to the task that the Community charged this group with during the September meeting, which was to explore the relationship between the quality and transparency initiatives, and state-level HIE. This task was not undertaken as a formal study; rather, data were collected from the nine participating state-level HIEs, and a discussion of these organizations ensued. Ms. Kloss noted that the group's findings in this area represent a consensus based on the discussions of the participating Steering Committee. She further commented that many of the findings support and are consistent with what is being seen in other areas.

Quality improvement is considered "mission critical" for state-level HIEs. Every organization on the Steering Committee includes quality improvement within their respective missions. Of the nine organizations, five currently are or are planning to be suppliers of data for performance reporting. One third of them are or are planning to be suppliers of data for disease or chronic care management, and one-third also are or are planning to actually report performance data to purchasers or payers. Only two of the nine organizations are engaged in public reporting; this is not a function that is foreign to the state-level HIEs, but is being carried out differently depending on their state of involvement. There is a great deal of data reporting already going on in every community and every state; the state-level HIEs conveyed a sense of urgency to the Steering Committee to open a dialog and examine the existing models for ensuring that the practice of data "siloing" does not increase.

Ms. Kloss then presented the Steering Committee's recommendations:

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

- While each state must determine its preferred model for data capture and aggregation, state-level HIEs may be positioned to facilitate cost effective access to statewide data for quality initiatives. At a minimum, they should partner to: (1) assist with data standardization, and (2) work to reduce duplicate data acquisition efforts.

- A more integrated model for the role of state-level HIEs should be further developed and tested.

- A formal and funded role to provide data services to quality measures may be critical to sustaining HIEs.

- HIE representatives must get involved in national committees such as the National Quality Forum, Ambulatory Care Quality Alliance/Hospital Quality Alliance, Agency for Healthcare Research and Quality, and AHIC activities to design integrative data strategies. At the same time, they must strengthen relationships with quality organizations at the state and local levels.

- Broader stakeholder dialog is urgently needed to: (1) conduct an environmental scan of states that have successfully integrated state-level HIEs with quality and transparency initiatives; (2) develop business models that support state-level HIE involvement in quality and transparency initiatives, incorporating the long-term cost savings due to reduced data variations and collection and aggregation burdens; and (3) discuss and clarify the governance structures that are required to support the relationship between state-level HIE organizations and quality initiatives.

Ms. Kloss indicated that in moving forward, multi-stakeholder coordination will continue as a necessity. She reiterated the Steering Committee's concerns about failing to plan what the next-generation coordinating mechanism may be and not risking any slow-down in the initiative. The Steering Committee has envisioned standing working committees reporting to a multi-stakeholder community—one of those standing committees would be state-level HIE, as well as legal, regulatory, population health, care delivery, the impact of technology on improving care, and standards and certification.

Discussion Highlights

"You mentioned on recommendation one, explicit coordination…how come you didn't go that much further or talk about…any kind of operational model which is like pay-to-play, whoever is paying can sit at the table, or [some] kind of construct for how you coordinate?" – Mr. Eisenstein

"We were, first of all, making the point that we can't see these two initiatives as parallel tracks without explicit connects. And that there are ways, through contracting mechanisms, to begin to link our role, let's say, for health information exchange in CMS contracts, and in the work that AHRQ is doing in quality improvement, and looking for those opportunities to create linkage." – Ms. Kloss

"Not only do we need to have the necessary standards so that quality measures and reporting can be embedded in EHRs, and that's a clear role for AHIC…it also addresses the need to have clarity and consensus around a uniform set of quality measures. That all payers, be they public, private, state, federal, whatever, are using the same measures in order to bring some order out of chaos, but also to allow the necessary HIT standards to be developed to allow that embedding to occur." – Dr. Henley

"That's very much the spirit of this, recognizing that right now we have two separate sets of railroads moving. One is the national versus state, and obviously each state is quite different, as you've heard today. And secondly, this health IT movement, and the quality movement. And the AHIC at the national level has begun bridging those by the Quality Workgroup, which as you know doesn't try to take on the

task of defining the standards, but recognizing that the interplay between health IT's capabilities and promise in those standards is critical, so that they move together. We don't have a parallel way to do that at the state level." – Dr. Brailer

"We have two very immature and highly variable sets of structures—i.e., quality and health IT at the state level, that have differing levels of maturity and differing levels of capability, so we don't have a 'one size fits all method.' I think the nuance here is getting a process of bringing them together so they're more coordinated, more closely collaborative, and certainly more able to achieve the goal you laid out, which is being able to implement and move quickly to not have more confusion." – Dr. Brailer

"What the federal government can do…is [to have] everybody adhere to at least the process that the National Quality Forum has in place, to vet and approve measures in a transparent way…There are some measure sets out there that are developed that are not transparent, they are in black boxes, and they are proprietary. And in a spirit of moving forward with quality improvement, that has to be transparent, and the NQF process can allow that to occur." – Dr. Henley

"Maybe the way to raise this then is…to come back with a formal letter of action to the Community in January, to ensure that we think about how to incorporate into the acknowledgment of these state efforts an evaluation of their participation and follow-on with NQF and other projects." – Dr. Brailer

"It's not the Committee's purpose or their recommendation to take a position on how the data is stored. In the industry, there's a controversy between a central data repository, if you will, and community, and then those that are exchanging information from the sources of the data. And I don't believe the Committee is recommending or even taking a position on that, but I just want to get clarity on that." – Mr. Hutchinson

"That's correct, but the Steering Committee is saying that careful thought needs to be given to the role of the aggregators. There will be aggregation of secondary data. And how does that relate to information exchange? There needs to be thought given to how the information that's been handled for exchange purposes can be de-identified and used and aggregated for quality purposes. Otherwise, we have absolutely redundant data collection processes. And as we look at the complexity of the reporting, measurement and reporting activities, we can just well imagine how financially burdensome that will be." – Ms. Kloss

"This discussion has been very helpful, because we will now ask for a final recommendation letter to come from the Steering Committee that will have action points for the AHIC to recommend to the Department of Health and Human Services, as well as to other entities, be they state governments or private sector players." – Dr. Brailer

Nationwide Health Information Network Initiative

NHIN Current Status

Dr. John Loonsk, ONCHIT, provided AHIC members with a brief update on the current status of the NHIN. This year, NHIN activities included the development of four architectures. Four consortia have been working on a number of products throughout the year and have identified the standards they need to move forward with health information exchange. The consortia developed and advanced more than 1,200 functional requirements—declarative statements about what systems need to do to advance this vision of an NHIN. In addition, they have been developing and advancing general and security architectures and putting these architectures into a demonstration in the context of software implementations that will be presented at the next AHIC meeting and at the third NHIN Public Forum. There also will be a discussion of cost revenue models for network service providers and the concept of having a capable, technically savvy network company that can help support information exchange, the potential revenues and cost models for that type of scenario will be another subject for presentation.

The next steps for the NHIN in 2007 include moving from the prototype architectures to "trial implementations." The intent is to establish a new procurement that would directly engage state and regional health information exchange efforts, and bring them together with the technical expertise that was developed through these prototypes and through other technology companies that have been working in this area. An additional next step is to initiate a collaborative environment for the NHIN network-of-networks, and the ways in which these groups can participate in working together to foster interstate and regional health information exchange.

Dr. Loonsk explained that the overall vision is to take a further step toward connecting EHRs as well as connecting personal health records and many other activities that AHIC is involved in. It is anticipated that one component of these activities will include connecting the federal health systems, as well as targeting state governments in terms of connections to help establish the specificity of what needs to be done in the future.

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

Dr. Simon Cohn, Associate Executive Director of The Permanente Foundation at Kaiser Permanente and Chair of the National Committee on Vital and Health Statistics (NCVHS) and the *Ad Hoc* Workgroup on NHIN, discussed the NCVHS and NHIN charge, high-level minimum but inclusive functional requirements for an NHIN, and policy issues and recommended next steps. Before starting his formal presentation, Dr. Cohn introduced Jeffrey Blair, Director of Health Informatics at the Lovelace Clinic Foundation and Vice Chair of the NCVHS *Ad Hoc* Workgroup on NHIN. Dr. Cohn explained that the NCVHS is a statutory public advisory body to the Secretary, HHS, that has a 57-year history of advising HHS in the areas of health data, health statistics, privacy, and national health information policy. The NCVHS includes 18 members (16 appointed by the Secretary, and 2 by Congress) who are leaders and experts in their fields (e.g., HIT, health statistics, clinical, administrative data standards, medical informatics, privacy, population health). The group has a reputation for open, collaborative processes and the ability to deliver timely, thoughtful, and practical recommendations (more information can be found at (www.ncvhs.hhs.gov).

The Committee has an ongoing, congressionally mandated role advising Congress and DHHS regarding the Health Insurance Portability and Accountability Act (HIPAA), including the administrative and financial transactions, code sets and identifiers, privacy and security, and report and recommendations on clinical data standards and interoperability. As part of its HIPAA work, NCVHS was asked to investigate and make recommendations on clinical data standards and interoperability. This work became the core of the consolidated health informatics initiatives and has been an important input to the work of HITSP. The Committee also has advised CMS and HHS on e-prescribing as requested as part of the Medicare Modernization Act.

In addition to its work advising on HIPAA privacy issues, the NCVHS has been asked to provide ongoing advice on privacy and confidentiality. One example of that work is a report released in June relating to privacy, confidentiality, and the NHIN. The Committee also investigated and made recommendations on a number of strategic and forward-looking areas, including population health issues such as shaping a health statistics vision for the 21st century, a report on personal health, and an important report on developing the national health information infrastructure. Dr. Cohn noted that NCVHS liaisons participate on a number of the AHIC Workgroups.

In late spring of 2006, the NCVHS was asked by ONCHIT to review and synthesize the results of the June 28-29 Forum and the functional requirements identified by NHIN prototype consortia contractors that will: (1) define a minimum, but inclusive, set of functional requirements necessary for NHIN activities; (2) be wrapped in a privacy and security structure that warrants the trust of the individual whose information is exchanged; and (3) not include architectural decisions. Given the early state of the consortia prototyping work, NCVHS felt that it was very premature to make any specific architectural

recommendations; the Committee did, however, bring forth some general principles and recommendations related to architectural variation. This work was carried out through an open process, with a significant level of public input.

Dr. Cohn explained that the process used to refine the functional requirements, from 977 in the original materials supplied by ONCHIT, included significant analysis and input from many testifiers. NCVHS initially consolidated the 977 detailed functional requirements into a working set of 154 functional requirements, which were further refined into 11 high-level sets of functional requirements. Dr. Cohn commented that the Committee's report is intended for a broad audience; it is a key educational resource on the NHIN that pulls a complex subject together in lay language, so that a larger audience can be brought to the table to discuss the functionality and purpose of an NHIN. The high-level functional requirements also may serve as a checklist for organizations to assure that they are considering all critical elements for connecting to an NHIN. They also may serve as a description of services to be developed by network service providers and other intermediary entities.

Dr. Cohn emphasized that the NCVHS report and the high-level functional requirements intentionally do not distinguish what must be done where or by whom. The key question, from NCVHS's perspective, was what needs to be done within this initiative, and within this system of systems. The functional requirements are about the entire initiative, and are not specific to an entity. He noted that as an NHIN is being developed and prototyped in different locations, a number of different ways systems may interact and interconnect with one another are being proposed. The NCVHS recognizes that at times, variations can lead to overhead and complexity that may not be feasible to accommodate. However, where the variations appear to be compatible with one another, and do not impose undue burden, the NCVHS recommends that variations be accommodated and includes them in the functional requirements. Many of these variations relate to where certain services should be performed, but where variations exist and appear to be incompatible with one another or impose an undue burden, the Committee lists the variations and recommends further study to reconcile incompatibilities.

Following these comments, Dr. Cohn described the following 11 high-level functional requirements:

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

Authentication—Enable authentication of an entity's users (systems, software tools, and individuals) as well as independent users whenever location of information and/or data are exchanged within an NHIN.

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

Personal Identification—Utilize a standard person identity/information correlation process to uniquely identify an individual.

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

Transport and Content Standards—Transport types: (1) requests for and their responses to location of information, (2) requests for data, (3) data itself, and (4) other types of messages (such as notifications of the availability of new data). To destinations using general industry-recognized transport types and authorized recipient's specified mode. To and from electronic addresses that are unambiguously identified in a standardized manner.

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

- Automatically sending final lab results for any previously sent preliminary results, sending any changes in medications prescribed, reporting medication errors, notifying public health about the

occurrence of a bio-hazard event, informing individuals about the availability of a clinical trial, and determining hospital census for disaster planning.

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

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

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

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

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

Dr. Cohn also reviewed some of NCVHS's findings regarding policy issues. These issues include:

- Determining where responsibilities for the performance of various functional requirements may exist within an NHIN.

- Assuring ongoing conformance of entities and their systems to the requirements for connectivity and exchange of data.

- Ensuring accurate matching of individuals to their health information, including individual identification and health information location.

- Enabling communication of individual permissions or entity preferences concerning specific data.

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

- Collaborating with other public and private entities to develop a public awareness campaign.

Dr. Cohn presented three recommended next steps for HHS. The first recommendation is to use these high-level functional requirements as a way to communicate the nature of the NHIN initiative. The second is to test the functional requirements against other very common use cases, such as e-prescribing; medication reconciliation; use of clinical decision support; chronic care, long-term care, home health care, behavioral health care, and other settings for care; reimbursement for health care services; clinical research; regulatory reporting; and selected services provided by public health departments. The third recommendation is to continue to refine the functional requirements based on NHIN prototype consortia contractors work and further industry experience.

Dr. Cohn concluded his remarks by stating that the work of the NCVHS as described has helped build a consensus on the base functional requirements for the NHIN initiative, noting that these base functional requirements are a key tool and enabler to support the next steps in the development of the NHIN. Community members were provided with an appendix to Dr. Cohn's presentation that included the membership of the NCVHS *Ad Hoc* Workgroup on NHIN as well as the detailed functional requirements.

Discussion Highlights

"The recommendations that are being made here are not recommendations made to the Community, these recommendations come directly from NCVHS to the Secretary, and the presentation here, as Simon described, is so that the Community is aware of these discussions and can have its own independent work as needed." – Dr. Brailer

"I would just applaud your presentation in the sense that you've taken a very complex topic and very nicely taken it down to the items that are the necessary elements of an infrastructure for the National Health Information Network, and I'm very excited to see that we're finally focused on [the] topic of the need for authentication, both from a policy basis, process basis, and technical basis." – Mr. Hutchinson

"The original HIPAA legislation called for a unique identifier. This was subsequently, after hearings began, pulled back, and I think Congress has appropriately identified that this is not something that HHS should be doing significant work on. The main focus of our hearings in this area was really trying to identify how good the correlation and matching algorithms were, and whether or not they would be equal to the task…We heard that the matching algorithms at least in our testimony were pretty good, but do require manual processes for those areas which are in dispute. Obviously, the more additional identifiers you throw into a matching algorithm, the higher the match is. And the less manual processes will be required." – Dr. Cohn

"Do you feel comfortable, after all the evidence that was submitted, that the technology is out there at a pretty high level? I know there have been experiments and demos, but if HHS adopts your recommendations, you feel they won't be going down the wrong road?" – Mr. Eisenstein

"In many cases [with] the development of the record locater service, the success of the matching is quantified in two ways. Number one, are you able to reduce the number of false positive matches, down to essentially zero. The reason that that becomes almost the critical measure, is that if you falsely match one patient to another, you have a patient safety issue. And that is pretty much something that is unacceptable. The other area is where you have a false negative. The false negative then could have human intervention to try to see if you could do something to match the patient to their record, with a human being involved, that would be a very small percentage of the cases, and it would supplement the initial automated process to match patients to their records. But at least you don't have the risk of inappropriately indicating a medication to a patient that isn't the right patient." –Mr. Blair

"Unique patient identifiers are not perfect, either. In many cases we receive testimony that using algorithms…in many cases are pretty much the same in terms of a success ratio as a unique patient identifier. The reason I say unique patient identifier may not always be perfect is we don't have the ability to rely on government-issued identifiers. The authentication of that person is not perfect, either. So these algorithms, in fact, are proving very successful." – Mr. Blair

"Certainly the work of NCVHS…will inform the next steps of the NHIN activity…We would anticipate that beyond the general guidance, for the fact that there are some architectural commonalities, as well as reasonable architectural variations that can go forward in an ongoing way, those are important advancements for the ways in which the next steps of engaging state and regional health information exchanges will move forward. So we both anticipate that the content and the actual substance of these recommendations will play an important part in the next steps, as well as the work of HITSP, the developing work of CCHIT, and the other products of this year's work on the NHIN." – Dr. Loonsk

"The functional requirements would apply, it seems to me, not only to the NHIN but to the Public Health Information Network as well. And I wonder if any of the speakers or John has a comment about how the two relate." – Dr. Sondik

"Since the NHIN is a network of networks, I tend to think of the PHIN as really part of the overall NHIN, so I think it really should apply." – Dr. Cohn

"The coordination of the acronyms is perfect. But beyond that, the Public Health Information Network has developed functional requirements as well, they have been working on implementation-level guidance similar to that which the health information technologies standards panel has been working on relative to the breakthroughs…I see these things going forward in similar paths coming closer and closer together, and the opportunities for harmonizing them are significant." – Dr. Loonsk

"I do hope that we see these not as parallel, but as directly related so that there's communication. I tend to see a network, a system of networks as really what we're after. And I think the public health side will be poorer if it cannot have access to the information that is available through the NHIN. But I'm not sure the situation is vice versa. Because there will be information that is clearly very privileged. But how these two will work together is very important, and should be on our agenda." – Dr. Sondik

"Perhaps this could be part of the internal evaluation of the recommendation letter that came from NCVHS." – Dr. Cohn

"I think they share immediately, you can look at them as sharing functional requirements, sharing standards and implementation-level guidance, and also sharing the importance of certification process to move forward. And what we need to do overall is to make sure that those are all aligned, so that they are indeed cooperating in a network of networks." – Dr. Loonsk

"I would like to commend the work of NCVHS…And particularly, David, to your recommendation that trying bring forward in the letter of recommendation governmentization of NHIN and PHIN will certainly lead to a very broad level of consistent protection for patients who are represented in both of those networks in the country." – Ms. Davenport-Ennis

Standards Update

Dr. John Loonsk, ONCHIT, noted that at the last AHIC meeting, HITSP presented three large packages of standards and implementation-level guidance that trace back to the breakthroughs and the use cases that were developed from those breakthroughs in the last round. He provided the Community with an update on activities related to these and other efforts.

As requested by the AHIC Electronic Health Record Workgroup, there is a new use case for the emergency responder EHR that is now available. The use case has gone through two extensive rounds of public comments, and is anticipated to be a useful tool in guiding HITSP's next steps as well as those of the NHIN and the Certification Commission for Healthcare Information Technology (CCHIT).

AHIC/ONCHIT will be taking the priorities expressed by the different AHIC Workgroups, beyond emergency responder EHR, that were presented at the last meeting in a matrix, and putting those priorities into tangible "prototype use cases." These are anticipated to be high-level articulations of scenarios that can include as many of those priorities as possible. The scenarios will be a topic of discussion at the next AHIC meeting, and Community members will be asked to provide feedback.

Dr. Loonsk also explained that the interoperability specifications that were advanced by HITSP and the Certification Commission have established a joint working group that will work on the timing of implementation and other issues related to the coordination of HITSP and CCHIT. As these interoperability specifications come forward, there will be an increasing need for coordination, including

the timing of the implementation of those interoperability specifications and their components in certification criteria. There are two ongoing processes—one is the timing with the certification criteria; the other is the timing with the expectations for implementation in the Executive Order. Dr. Loonsk noted that the implementation of that timing is trending toward a year of time between implementation-level guidance and implementation.

In terms of HITSP's use of standards development organization (SDO) content versus non-SDO content, it was not made clear at the last AHIC meeting that HITSP, although it does use non-SDO content at times in the implementation guidance, it relies on readiness criteria that have been developed to address many of the same needs that people look to in terms of thinking about SDOs. Dr. Loonsk explained that part of the problem is that the extremely high level of detail of the implementation guides that describe how standards need to be implemented have not always been supported by many of the SDOs. Many of the SDOs have been working at a higher level, the so-called "named standards" level. Although the industry seems to be trending toward the SDOs accepting responsibility for managing that type of very detailed content, not all of those implementation guides are currently managed by SDOs.

Dr. Loonsk further explained that SDOs should be the target for the material wherever possible, and that the acceptance of responsibilities for this level of management of detailed guidance is certainly a goal of the system. For the time being, however, HITSP will have to continue to rely on some non-SDO content.

As part of the review of its first year, HITSP identified a series of steps to make it easier for small organizations to participate and work issues in the HITSP process. One of the issues that has been discussed is whether the process that HITSP uses of in-person participation on technical committees potentially skews the participation to larger organizations that can support that type of ongoing presence. There is great interest in ensuring that the more than 260 different organizations participating in HITSP are involved in the decisionmaking process. One of the recommendations that HITSP has come forward with is to move to virtual meetings, to enable participation by groups that cannot always travel people to participate at meetings. These virtual meetings would facilitate a broader identification of the commitment times and processes in terms of when the decision points are being made in the various HITSP working groups and processes, so that those groups that want to participate can have a certainty that they are aware of when those decisions are being made.

Dr. Loonsk also discussed the issue of volunteer burnout, reminding the Community that more than 12,000 volunteer hours were involved in HITSP work this year. Although volunteer support can be sustained at a certain level, it will be important that as the HITSP process becomes more routine, some practices will have to be adopted to try to minimize the level of volunteer support needed, so that the volunteer times can be focused on the decisionmaking, and making sure that those decisions are as valid and open as possible around the harmonization of the standards, with more of the legwork being done by staff in supporting those processes.

One additional issue is the sentiment held by many who wish that the time for public comments associated in the HITSP process were longer. A commitment has been made to extend the period of public comment, and for the technical committees to address those public comments.

Discussion Highlights

"There was a substantial amount of discussion in and around the time that the HITSP presented its first round of standards. These changes that John has described are part of an evolutionary process that not only make the standards process cohesive, and functioning with the highest level of efficiency possible, but to make sure that all the different constituencies, particularly the user constituencies who ultimately have to deal with the impacts of these standards, are able to participate." – Dr. Brailer

"I too want to thank John for a wonderful presentation and for the update relative to the HIT standards panel on the changes that have been made, I think they will go a long way to facilitating the more open and transparent process, which is clearly important." – Dr. Henley

"It is important…that the standards themselves, while the readiness criteria and implementation guides, might not necessarily at every time currently come from the SDO, the standards themselves, though, I think need to come from SDOs…That's the intent and part of the charter of the HIT standards panel to begin with. So I just make the plea that HITSP deal with, as it relates to electronic standards, and not just the readiness criteria, that those standards be approved by an SDO before they come to HITSP."
– Dr. Henley

"Since HITSP overwhelmingly pointed to standards that originated in standards development organizations in their implementation-level guidance, one of the things that they feel they could perhaps do in the coming year is to point more directly to those standards at times in the existing implementation guides…In the HITSP implementation-level guidance, the so-called interoperability specifications, at times they [HITSP] pointed to implementation-level guidance, which then pointed to the names standards. And that was perhaps more circuitous than needed to be, and added to the level of confusion here."
– Dr. Loonsk

"I think the general trend is, one, to wherever possible, use standards development organization content for the names standards. Two, be more direct in the implementation-level guidance wherever possible to show where those standards, SDO content, are included. And three, to encourage the SDOs to take a larger role in the ongoing management of the implementation-level guidance. Because truly, HITSP doesn't want to be in that business in the long term." – Dr. Loonsk

"I'll call everyone's attention to the original form of contract between ONC and HITSP…which recognized up front the need to take the standards community, the SDOs, and the standards that lay native, in an unchanged way, and to be opportunistic. But more importantly, an expectation…as we move into 2007, that HITSP not passively just allow the standards community to exist as it was a native form, but to take a proactive role in identifying holes, or gaps in standards, so that the standards community can work together to not just stitch things together to respond to a use case, but to anticipate the directional forms of needs of information over time…And secondly, to begin acknowledging that we don't have a streamlined and cohesive set of SDOs. That HITSP is a thin veneer pulling them together, and that deeper collaboration and perhaps even structural alignments with some of the SDOs may be necessary over time to achieve the goals." – Dr. Brailer

"What you're beginning to see now is a push towards saying 'let's move beyond opportunism, and let's begin actually identifying ways to take the 5-7 year perspective, and have this become much more cohesive.' And I think it will invoke the circumstance in the future where there is never a need to call upon a standard that doesn't come from an SDO." – Dr. Brailer

"The initial indications from the SDOs is that they're very receptive to moving in these directions…They are responding very well so far, and we look forward to continuing to move in that direction."
– Dr. Loonsk

"I'm excited to hear that the SDOs are moving in that direction to take a more active role in the maintenance of the implementation guide. But when there's an implementation guide that's recommended by HITSP, that is supported by an SDO standard, if there is a conflict between the implementation guide and the actual SDO standard, what is the process for resolving the conflict between the implementation guide and the standard itself? Is that HITSP's role?" – Mr. Hutchinson

"In general, implementation guidance is a further detailing of names standards and doesn't necessarily represent a conflict…The role that HITSP is playing in regard to the overall work in the standards area is to harmonize and reduce conflicts between standards wherever possible, largely through the identification of appropriate standards to use in appropriate contexts. And that's where the breakthroughs and the use cases are very helpful in specifying the context that they need to do their work." – Dr. Loonsk

"I have seen implementation guides, for example, that try to recommend guidance for implementation of a standard that might take, for example, an optional field and make it required. Or take a field that can be 100 characters in length, and limit it to 50…And those put the guidance in conflict with the actual SDO. That's what I'm trying to make sure that there's clarity on. It may not exist in what's happened today in HITSP, it's a process question that if it were to come up or if it does exist today…the technology vendors are going to be confused by which one to do, the standard itself or the guide." – Mr. Hutchinson

"I think that the broad answer to this is that there are iterations needed between HITSP and the SDOs, and that process has begun. Some of the SDO balloting for example has now started to recognize some of the issues that have come out of the HITSP harmonization process…What we need to see is the further refinement of the SDO-HITSP relationships to work through some of these issues." – Dr. Loonsk

Public Input Session

Speaker Number 1 – Mr. Gary Dickenson, a consultant representing Centrify Health, provided comments explaining why his group cannot support HITSP's interoperability specifications in their current form. He provided a detailed written copy of his comments to AHIC staff. Centrify Health has been a long-term supporter of ANSI standards harmonization and coordination. His group has been engaged in HIT standards development for almost 18 years. Mr. Dickenson noted that at its inception in August 2005, his group joined HITSP technical committee work in anticipation of upcoming use cases, with the belief that this effort would take the broad range of industry requirements and condense them into a small core set of standards, extended only when absolutely necessary to meet the needs of a particular use case. It was hoped, from their perspective, that this highly concentrated focus would converge on a firm foundation, not only for upcoming use cases but for immediate and future industry needs, such as moving from point-to-point transient messaging to end-to-end trusted information flows where health records would be persistent from the point of service, point of care, point of record origination, to each ultimate point of record access and use.

Mr. Dickenson indicated that use case analysis skipped many key steps. User and technical requirements were not made explicit, leaving users and providers to wonder whether their needs had been identified and incorporated, providing no metric to evaluate standards recommendations or the conformance of future implementation.

According to Mr. Dickenson, the goal of breakthroughs "melted into a breakdown." His group attempted to work within HITSP to address and resolve these issues, submitting written comments on four separate occasions. His group identified 19 issues of concern that are detailed in their written comments. These issues of concern are broken down into two categories; one which points to deficiencies in HITSP's consensus process, Mr. Dickenson indicated did not follow the HITSP charter, and did not follow ANSI essential requirements or guidelines for development of open consensus standards. The other category involves identified deficiencies of HITSP's use case analysis, and the interoperability specifications that were produced.

Dr. Brailer thanked Mr. Dickenson for his comments and indicated that due attention will be given to the issues he raised.

Closing Remarks

Dr. Brailer thanked Community members for their efforts and closed the meeting by reminding them that the next AHIC meeting will be an in-person meeting, held on January 23, 2007.