The Community

American Health Information Community

MEETING MATERIALS

January 23, 2007 8:30 a.m. - 4:45 p.m.



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

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AGENDA

11th Meeting of the American Health Information Community

January 23, 2007

8:30 a.m. - 4:45 p.m. (EST)

U.S. Department of Veterans Affairs The G.V. "Sonny" Montgomery Veterans Conference Center 810 Vermont Avenue, NW, Washington, DC

8:30 a.m.	CALL TO ORDER – Secretary Leavitt		
8:35 a.m.	Introductory Comments – Secretary Leavitt		
8:45 a.m.	Comments – David Brailer and Rob Kolodner		
9:00 a.m.	State-Level Health Information Exchange (HIE) Recommendations • Linda Kloss – American Health Information Management Association		
9:45 a.m.	 Health Information Exchange Business Models Kelly Cronin, Office of the National Coordinator John Glaser, Partners HealthCare Systems Stephen Parente, HSI Network LLC Victoria Prescott, Regenstrief Institute 		
10:45 a.m.	 AHIC Priorities and 2007 Use Cases Overview of Process – John Loonsk, Office of the National Coordinator Consumer Perspective – Rose Marie Robertson, American Heart Association Provider Perspective – Blackford Middleton, Partners HealthCare Systems Population Perspective – John Lumpkin, The Robert Wood Johnson Foundation and Carolyn Clancy, Agency for Healthcare Research and Quality 		
11:45 a.m.	Comments – Secretary Nicholson, U.S. Department of Veterans Affairs		
12:00 p.m.	LUNCH		

1:15 p.m. Workgroup Recommendations and Updates

Confidentiality, Privacy & Security Workgroup Recommendations

- Jodi Daniel, Office of the National Coordinator
- Paul Feldman, The Health Privacy Project

Consumer Empowerment Workgroup Recommendations

- Nancy Davenport-Ennis, National Patient Advocate Foundation
- Rose Marie Robertson, American Heart Association

Quality Workgroup Update

- Carolyn Clancy, Agency for Healthcare Research and Quality
- Richard Stephens, The Boeing Company (unable to attend)

Biosurveillance Workgroup Update

- Charles Kahn, Federation of American Hospitals
- John Lumpkin, Robert Wood Johnson Foundation

2:30 p.m. **Nationwide Health Information Network (NHIN) Prototype Architecture Demonstrations**

- *John Loonsk, Office of the National Coordinator*
- Ginny Wagner, IBM
- Robert Cothren, Northrop Grumman
- J. Marc Overhage, representing Computer Sciences Corporation
- Brian Kelly, Accenture

4:30 p.m. **Public Input**

4:45 p.m. Adjourn

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.



American Health Information Community

State-level Health Information Exchange Steering Committee

Recommendations

Linda L. Kloss American Health Information Management Association & The FORE Foundation

January 23, 2007

State-	level	HIF	Project	Overview
State-	ICACI		FIUICCE	OACI AICM

1

"State Level Health Information Exchange Initiative Development Workbook: A Guide to Key Issues, Options and Strategies"

AHIC: 9/12/06

2

State-Level Health Information Exchange and Major Federal Initiatives	Health Information Exchange and Quality and Transparency Initiatives
AHIC: 12/12/06	AHIC: 12/12/06
Medicaid and Health Information Exchange Initiatives	Financially Sustainable Health Information Exchange Services

(Reports available at www.staterhio.org)

HIE 01/23/07

AHIC: 12/12/06

1

AHIC: 1/23/07

State-level HIE Steering Committee

- Molly J. Coye, MD, MPH, Founder and CEO, Health Technology Center, San Francisco, CA, chair
- Laura L. Adams, President and CEO, Rhode Island Quality Institute, Providence, RI
- · Antoine Agassi, Director and Chair of the Tennessee eHealth Council, Nashville, TN
- Ray Campbell, Esq., MPA, CEO, Massachusetts Health Data Consortium, Waltham, MA
- Devore Culver, Executive Director, HealthInfoNet, Manchester, ME
- Lynn Dierker, RN, Director for Community Initiatives, Colorado Regional Health Information Organization, Denver, CO
- Lori Hack, Interim CEO, CalRHIO, San Francisco, CA
- W. Michael Heekin, JD, Chair of the Florida Governor's Health Information Infrastructure Advisory Board, Atlanta, GA
- Kala Ladenheim, Program Director, Forum for State Health Policy Leadership, National Conference of State Legislatures
- Marc Overhage, MD, PhD, CEO, Indiana Health Information Exchange, Inc; Indianapolis, IN
- Jan Root, PhD, Assistant Executive Director, Utah Health Information Network, Murray, UT

HIE 01/23/07

2

Part 1: Recommendations

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

HIE 01/23/07

3

Part 2: Strategy Recommendations

- 1. HIE and quality/transparency practices and direction
- 2. AHIC Successor
- 3. State coordination
- 4. Enabling success by states

HIE 01/23/07

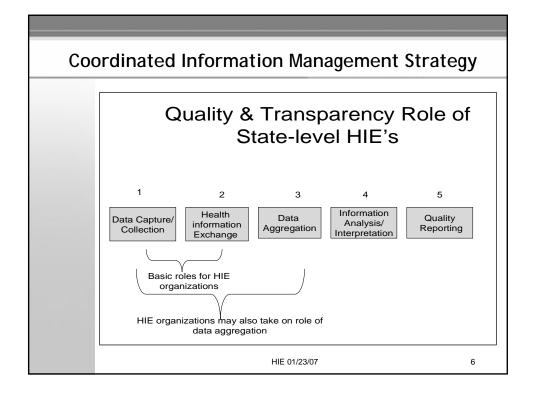
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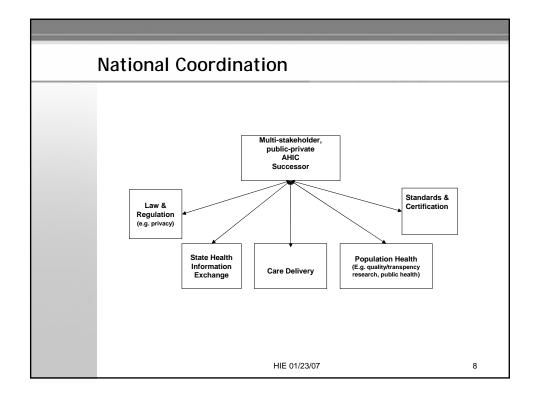
Recommendation #1

- Recommendation 1: The federal government should consolidate oversight of health IT and quality/transparency initiatives under the American Health Information Community.
 - 1.1: Create incentives for innovation and cost effective coordination.
 - 1.2: Fund research on models for data capture, aggregation, privacy.
 - 1.3: Appoint representative of HIEs to quality workgroups and projects.
 - 1.4: Study sustainable business models for HIEs that supply aggregate data for quality measurement and reporting.

Accept	Table	Reject



Recommendation #2 • Recommendation 2: The Secretary should design the successor to AHIC and transition it to a public-private organization by 2008. - 2.1 Charge a design group working in 2007 for implementation in 2008. - 2.2 Reintroduce the revised 2004 Framework for Strategic Action that accounts for AHIC, state and local HIEs, and the NHIN. Accept Table Reject



Recommendation #3 Recommendation 3: Each state should establish or designate a consolidated, public-private health transformation governance mechanism that includes at least HIE and quality/transparency. - 3.1: Build on work in state-level HIE Workbook to describe models, authority and core roles. - 3.2: Appoint new state workgroup for formal liaison to AHIC. - 3.3: Support a state-level learning community. - 3.4: Insert state perspective into work of all AHIC Workgroups. Accept Table Reject HIE 01/23/07 9

Recommendation #4

- Recommendation 4: The federal government, to the degree possible under statute, should fund transformation and provide strong leadership through CMS policy.
 - 4.1 State workgroup to develop criteria and recommend mechanisms for funding.
 - 4.2 Leadership regarding Medicaid and Medicare support for state level HIE and quality/transparency.
 - 4.3 Identify funding mechanisms.
 - 4.4 Process for advancing the criteria.

Accept	Table	Reject
	HIE 01/23/07	

To State-Level HIE Project

- Accelerate progress
- Align the parts
- Look ahead
- System learning

HIE 01/23/07

11



January 12, 2007

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

Dear Secretary Leavitt:

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

- Coordination between state and federal health IT and related initiatives.
- Health information exchange (HIE) services that have achieved financial sustainability, and
- The role of public payers and state-level HIE.

Following the September 12, 2006 AHIC discussion on state-level HIE, the Steering Committee also examined the relationship of State-level HIE and quality/transparency initiatives. Specific recommendations on each of these four topics are detailed in the attached report.

This letter outlines several important cross-cutting recommendations to ensure effective partnerships between state and federal efforts in the years ahead to transform health care through your "four cornerstones" of a value-driven health care system.

1. The federal government should consolidate oversight of health IT and quality/transparency initiatives under the American Health Information Community (AHIC).

Health information exchange initiatives all have a mission of improving quality through sound information practices; quality/transparency initiatives require accurate information. These two cornerstones of a value-based health care system must be coordinated at federal, state and local levels and across the public and private sectors.

This is not the case today. Today there is a cacophony of quality measures, "silos" of data, and proprietary "black box" analytics that add cost and complexity. This is a very critical moment in time to achieve a coordinated strategy that will use information to improve care and help people make informed choices.

Coordination does not mean a singular approach. AHIC should:

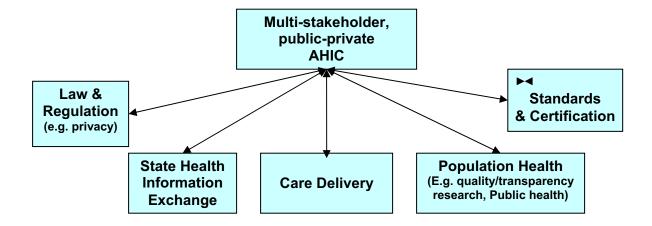
- 1.1 Create incentives for innovative and cost effective coordination between state-level HIE and quality and transparency initiatives at the state and local levels in areas of governance, data capture and aggregation, and use of information and across states. The quality community and the HIE community must work together to make decisions about data capture, exchange, and aggregation of data for quality.
- 1.2 Fund research on models for clinical data capture and aggregation to reduce data silos while guarding confidentiality and security of primary and secondary data. While states must determine their preferred models for data capture and aggregation, research is needed to standardize valid data sets and reduce data acquisition costs.
- 1.3 Appoint representatives of HIEs to existing national work groups on quality measurement to design integrative strategies.
- 1.4 Continue to study sustainable business models for HIEs that supply aggregate data for quality measurement and reporting. Our research shows that this is likely a critical long-term business funding strategy for HIE entities and unless a critical mass of useful data is achieved and participants are on board, the HIE business model may not be viable.

2. The Secretary should design the successor to AHIC and transition it to a public-private organization by 2008.

AHIC has been an effective vehicle for spotlighting needs and opportunities and tasking work. It has served as a single point of focus for federal efforts, shaping policy and securing agreement to move a common agenda for health care transformation through information. Because multistakeholder coordination will be required for years to come and to ensure there is no leadership gap at this critical time, plans for an AHIC successor must be prepared in 2007 and in place before the end of this Administration.

The project Steering Committee strongly recommends that the AHIC successor be a public-private sector multi-stakeholder entity. It will function as the approval and coordinating body, and maintain the vision and directional strategies. Its charge must be non-duplicative and it must have authority to take action consistent with its mission. There must be a clear relationship to the Office of the National Coordinator and other federal agencies.

As shown in the diagram, standing committees of experts and consumers will advise AHIC on direction, policies, and best practices. To illustrate, the Steering Committee suggests standing committees such as: *legal and regulatory* to advise on critical matters such as privacy; *care delivery* to track improvements and best practices in safety and quality; *state health information exchange* to advance best practices and the impact of state-led efforts; *population health* to oversee practices in secondary uses of data for quality improvement, clinical research, and public health; and *standards and certification* to coordinate and accelerate progress.



Models for private sector governance of critical public interest agendas exist in other industries. Examples include the Financial Accounting Standards Board (FASB) independent of the government and all other business and professional organizations; Canada's Health Infoway, an independent not-for-profit organization charged with advancing Canada's health information transformation; and SEMATECH with its 20 year history of industry-government cooperation to strengthen the U.S. semiconductor industry.

The Secretary should:

- 2.1 Charge a design group with recommending a structure and operational plan for the successor AHIC including:
 - o Mission
 - o Type of legal entity
 - o Source of authority and participation by federal agencies
 - o Business plan and funding
 - o Composition and selection for the AHIC Board
 - o Committee or council structure, charges and composition
 - Transition of work groups
 - Stakeholder input and transparency
 - o Formal links to state-level governance entities
 - Methods for assessing effectiveness

This design work should be vetted and refined in 2007 so implementation can be accomplished in 2008.

2.2 Reintroduce an updated version of the 2004 *Framework for Strategic Action*. This unifying strategic Health IT vision and plan should be refreshed to account for the role of state and local public-private HIE initiatives, the American Health Information Community (AHIC) and its planned successor, and new strategies to advance the Nationwide Health Information Network (NHIN). The Framework continues to be a very useful way to bolt together strategies for change, but its dynamic vision has blurred with the scope and pace of change.

3. Each state should establish or designate a consolidated, public-private health transformation governance mechanism that includes at least health information exchange and quality/transparency; a formal liaison to AHIC should be established through a new workgroup of states.

States are critical to the health transformation agenda and they are stepping up. Over 30 states have Executive Orders or legislative action on health IT. Our research revealed multiple quality improvement and reporting programs with minimal or no formal coordination with one another or with state-level HIEs. If the problems facing healthcare were not so urgent, it may be desirable to let this marketplace of ideas play out. However, as noted above, the HIE and quality/transparency goals are inextricably linked and just as coordinated oversight is needed on a nationwide level, designated oversight is needed in each state.

A public-private governance mechanism is needed to bring together governmental, healthcare, employer, and consumer stakeholders to set direction and align actions. There are some strong models emerging in a number of states, but there is also fragmentation and duplication of effort that should be harnessed now by encouraging alignment instead of competition. A state-level entity should have authority at minimum to:

- Develop consensus on the statewide roadmap for HIE, quality and other initiatives to advance value-based health care
- Foster collaboration of local HIE and quality efforts to reduce duplication, share best practices, and help align efforts throughout the state.
- Set or advise on statewide policy and remove policy barriers
- Align and leverage state government health programs, including Medicaid, public health and other programs and departments
- Encourage adoption of national standards
- Serve as a bridge to AHIC and to other states
- Ensure benefits for underserved populations
- Make available technical assistance resources
- Ensure stringent safeguards for confidentiality and security of information
- Engage and educate consumers
- Support the requisite informatics/information management/IT workforce

The Secretary should:

3.1 Call on the State-level HIE Steering Committee to function as a work group of AHIC to define and describe the composition, criteria and characteristics for a state-level health transformation governance mechanism that includes at least the health IT and quality initiatives. It should be noted that this work can build on the work presented in the *State Level Health Information Exchange Initiative Development Workbook* which described stakeholders, governance, roles and other requirements for effective public-private collaborative entities. The Steering Committee should be expanded to include other states with promising models. It should also work with the State Alliance for e-Health project to achieve consensus on direction.

- 3.2 Continue the State-level HIE work group of AHIC until there is a standing committee of the AHIC successor. Charge it with establishing channels for effective bi-directional communication to keep state and regional initiatives better informed about federal programs and projects.
- 3.3 Support the formation of a state-level learning community to support communication and coordination across states to accelerate the development of effective state level governance and programs.
- 3.4 Ensure that the state perspective is represented in the work of all AHIC workgroups so issues are also being viewed from the state HIE perspective.
- 4. The federal government, to the degree possible under statute, should fund transformation efforts through or under the guidance of formally recognized health transformation entities in each state and provide strong leadership through CMS policy.

While grants have been helpful in getting state and local RHIOs established, our research confirms that grants are unlikely to build sustainable organizations. Further, uncoordinated funding to disparate entities within a state is not likely to produce systemic change. Thus, federal funding, as permitted by law, must be available to or through formally recognized state level health transformation governance entities. Funding would serve as an incentive for states to organize effective governance. Coordination between the nationwide and state initiatives and across states will be improved if funding is predictable and recurring,

In addition to direct funding, CMS should demonstrate strong national leadership by defining a clear position on HIE in and across state Medicaid programs and address restrictions to Medicare participation in state level HIE.

As a prerequisite to funding, some form of recognition for qualified state health transformation governance entities group would be needed.

The Secretary should:

- 4.1 Task the State level HIE work group of AHIC with developing criteria for recognizing a state health transformation entity. These criteria should evolve over time so that formative process targets are replaced by results targets as soon as feasible. It should also define the process for conveying recognition. It should seek input from all interested stakeholders, including Centers for Medicare and Medicaid Services (CMS) as meaningful engagement by state Medicaid programs may be an important criteria.
- 4.2 Call upon the Centers for Medicare and Medicaid Services (CMS) to formulate a clear position in support of HIE in and across state Medicaid programs, while also serving as a clearinghouse for program guidance and innovations regarding the collaboration process.
- 4.3 Identify funding mechanisms and eligible activities. Again, attention should be paid to the role that CMS can play in demonstrating strong national leadership and financial support for health transformation by states.

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4.4 Continue to document successful HIE, quality/transparency and other transformative best practices so there is reliable public domain information to support the advancement of criteria, the recognition process, and the work of recognized entities.

There is urgency to all of these recommendations because states are full participants in health transformation. It has been a privilege to contribute to advancing health care through information in the State Level HIE Best Practices project. We look forward to discussing the enclosed report and these cross-cutting recommendations for improved coordination with you and the AHIC.

Sincerely,

Linda L. Kloss

Chief Executive Officer

Linea L. Klass

cc: Dr. David Brailer, Vice Chair, AHIC

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Development of State Level Health Information Exchange Initiatives

FINAL REPORT: Extension Tasks

Contract Number: HHSP23320064105EC

January 23, 2007

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Development of State Level HIE Initiatives: Extension Tasks

AHIMA/FORE

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Revised: 1/15/2007

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Report Sections

- > Project Overview
- > Task #1—Relationship of State-Level Health Information Exchange to Federal and Other Major Health Information Technologies Activities
- > Task #2—Report and Recommendations on Health Information Exchange Services
 That Are Financially Sustainable
- > Task #3—The Role of State Medicaid Programs and Their Involvement with Health Information Exchange Initiatives
- > Task #4—Health Information Exchange and Quality and Transparency Initiatives: Toward Strategic and Operational Coordination

Development of State Level HIE Initiatives: Extension Tasks

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1 Project Scope and Genesis

This is the report of research performed under an extension to the contract from the Health and Human Services/Office of the National Coordinator (HHS/ONC) "Development of Consensus Best Practices for State-Level Regional Health Information Organizations." Three specific aspects of the operation of state-level Regional Health Information Organizations (RHIOs) were studied in this extension:

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

Under the original contract, carried out between March and September 2006, a sample of state-level RHIOs was studied to determine successful governance, legal, financial, and operational characteristics and provide guidance for developing state-level HIE initiatives. A Steering Committee of state-level HIE leaders, with guidance from technical advisors and the National Conference of State Legislatures (NCSL) guided the study and shaped its key work product, the *State-Level Health Information Exchange Initiative Development Workbook*, now publicly available at www.staterhio.org.

In addition, a final report was issued with recommendations to advance state-level RHIOs. It addresses factors that both advance and impede the development of state-level RHIOs and calls for state, federal, and private sector action to strengthen the effect of state-level HIE activities. *The Final Report: Development of State-Level Health Information Exchange Initiatives* is also publicly available at www.staterhio.org. The three topics studied in this contract extension were recommended in the final report. Thus, this report is a continuation of the earlier research, drilling down in three areas that offer short-term insight policies and practices to advance and strengthen state-level HIE initiatives.

On September 12, 2006, the findings and recommendations of the original research were reported to the American Health Information Community (AHIC). During discussion, the role of HIEs in quality and transparency measurement and reporting was identified as another issue to be explored by the Steering Committee. Specifically, the Steering Committee was asked to offer recommendations regarding opportunities for coordination of HIE and quality reporting initiatives. These recommendations are also covered in this report as a fourth targeted study: *The Role of State-Level Health Information Exchange Initiatives in Quality Improvement and Reporting*.

2 Research Design and Organization of This Report

The four studies were conducted concurrently between September 15 and November 15, 2006, by four teams. The survey methods, findings, and recommendations are detailed in the project reports provided in the appendices.

The Project Steering Committee and investigators met October 23-24, 2006, to review the findings and draft recommendations for each study, including the roles of HIE organizations in quality improvement. Specific recommendations based on task research and analysis are presented in each of the task reports. Readers are encouraged to consider the breadth of recommendations that are offered in the task reports, and in the final report of the original study.

TASK #1

Relationship of
State-Level Health Information Exchange
to Federal and Other Major Health
Information Technologies Activities

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Revised: 12/13/2006

1 Overview of Task #1 Scope

1.1 How This Project Originated

A previous project funded by the Office of the National Coordinator for Health Information Technology (ONC), Health and Human Services (HHS), and American Health Information Management Association (AHIMA) and its Foundation of Research and Education (FORE) studied the successful governance, legal, financial, and operational practices of state-level health information exchange (HIE) initiatives. That initial project produced a final report, *Development of State-Level Health Information Exchange Initiative Development Workbook*. The workbook provided guidance for developing state-level HIE initiatives. The final report contained a number of recommendations for further action or research needed to increase the likelihood of success for state-level HIE initiatives.

One of the recommendations was to study the interactions between state-level HIE initiatives and other health information technology (HIT) activities (e.g., those surrounding the electronic health record [EHR] and local Regional Health Information Organizations [RHIOs]) as well as the major federal HIT initiatives, including the Healthcare Information Technology Standards Panel (HITSP),³ the Certification Commission for Healthcare Information Technology (CCHIT),⁴ the Health Information Security and Privacy Collaborative (HISPC),⁵ and the Nationwide Health Information Network (NHIN).⁶

The current project follows up on that recommendation. It is one of four recommendations stemming from the initial research funded for further study and is thus termed Task #1. (Note: The other three recommendations funded for further study revolve around state-level HIE financial sustainability, the role of Medicaid in state-level HIE activities, and quality reporting. Because Task #1 addresses barriers in coordinating HIT activities, many of the issues addressed here will touch on those other three tasks. When such issues arise, this report will focus on the aspects that affect the roles and interactions between state-level HIE and other HIT activities and refer the reader to those other task reports for more detail on the substantive issues.)

1.2 Task Description

The charge for Task 1 was to explore the potential roles of, and interactions between, state-level HIE initiatives and:

• Other HIT activities, including the major federal initiatives

Relationship of State-level HIE to Federal/Other HIT Activities AHIMA/FORE

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¹ AHIMA/FORE (September 1, 2006). Development of State -Level Health Information Exchange Initiatives. HHS Contract HHSP2332006410SEC.

² AHIMA/FORE (September 1, 2006). State-Level Health Information Exchange Initiative Development Workbook: A Guide to Key Issues, Options, and Strategies. Contract HHSP2332006410SEC.

³ Healthcare Information Technology Standards Panel (HITSP).

 $[\]underline{www.ansi.org/standards_activities/standards_boards_panels/hisb/hitsp.aspx?menuid=3.}$

⁴ Certification Commission for Healthcare Information Technology (CCHIT). <u>www.cchit.org</u>.

⁵ Health Information Technology Security and Privacy Collaboration (HISPC). <u>www.rti.org/hispc</u>.

⁶ Nationwide Health Information Network (NHIN). www.hhs.gov/healthit/nhin.html.

• Other healthcare initiatives, not necessarily confined to HIT

1.3 Task Deliverables

- Recommendations for establishing formal communications among states and federal agencies, including a plan for informing state-level HIE entities of relevant federal initiatives
- Documentation of the barriers and concerns expressed by state-level HIE that HHS/ONC and other federal agencies can constructively address and alleviate

2 Methodology

2.1 Project Team

Principal Investigator. Donald T. Mon, PhD, vice president, Practice Leadership, AHIMA **Project Manager**. Harry Rhodes, MBA, RHIA, director, Practice Leadership, AHIMA

2.2 Process

To accomplish the task, the project team:

- Reviewed existing materials generated from current federal initiatives—including the NHIN functional requirements, the HITSP use cases, and CCHIT certification criteria—and identified potential: (a) roles and interactions between state-level HIE initiatives and federal HIT activities, and (b) disconnects between them. These materials helped the project team identify the areas to probe during the interviews described below.
- Developed a set of basic interview questions designed to:
 - Identify state-level HIE barriers, concerns, and issues that should be addressed by HHS/ONC and other federal agencies.
 - Explore the potential roles and interactions and communications options between state-level HIE and federal HIT initiatives.
- Developed a representative list of individuals to interview. A maximum of 12 interviews were required under the contract.
- Interviewed the Project Steering Committee and individuals from the major federal HIT initiatives and other local RHIO projects.
- Reviewed and validated the findings and developed recommendations with the Project Steering Committee and technical advisors at a day and a half meeting held October 23-24, 2006. (See Appendix A.)

A total of 30 individuals were interviewed over 12 ninety-minute sessions. The following were interviewed:

- Members of the Project Steering Committee
- The four NHIN contractors and/or individuals from participating local RHIOs
- The CCHIT principal investigator, executive director, work group co-chairs, and staff
- The HITSP principal investigator and co-chairs of two technical committees
- Individuals from two state HISPC subcontractor organizations
- Individuals from other local RHIO projects

See Appendix B for the list of interviewees according to HIT initiative.

2.3 Interview Questions

Interviews with the identified subjects were conducted by phone. The project team began the interviews by asking the general questions attached in Table 1.

Table 1. Sample Interview Questions

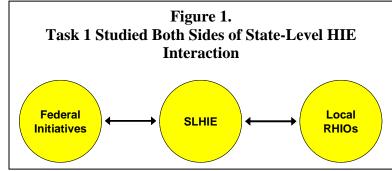
- 1. What formal mechanisms of communication exist between state and federal activities? How can communication be improved?
- 2. What do you see as the roles of the state-level HIEs?
- 3. Do American Health Information Community (AHIC) use cases help align federal and state activities?
- 4. Standards and certification
 - A. What standards should be developed, harmonized, or certified to support state-level HIEs and their interaction with other HIT initiatives?
 - B. How does the timing of standards harmonization and certification compliance affect state-level HIE progress and interaction with other HIT initiatives?
 - C. How does the existence of standards and certification help the state-level HIEs immediately and in the long term?
- 5. For specific examples of privacy, security, and confidentiality barriers
 - A. Which ones affect state-level HIEs?
 - B. Which ones can state-level HIEs affect?

These interview questions served as a guide, and specific areas were explored in varying degrees depending upon the interviewees' areas of expertise or concern.

The individuals interviewed represented the full range of federal, state-level HIE, and local- or regional-level HIE interaction (Figure 1). On one side, the state-level HIE needs to engage with the federal HIT contractors. On the other side, the state-level HIE must interact with local RHIOs.

Individuals from each of the federal HIT initiatives were interviewed, providing strong

representation from that side of the spectrum. Among those individuals were participants from three RHIOs involved in NHIN contracts—the Santa Cruz RHIO, the North Carolina Healthcare Information and Communications Alliance, Inc. (NCHICA), and the Mendocino Health Record Exchange (Mendocino HRE). The Health Information Exchange of Montana (HIEM) and



the Michiana Health Information Network (MHIN) represented the local RHIO perspective.

The Research Triangle Institute, contractor for the HISPC project, identified Minnesota and Oregon as two subcontracted states that could articulate well the security and privacy practices, laws, and

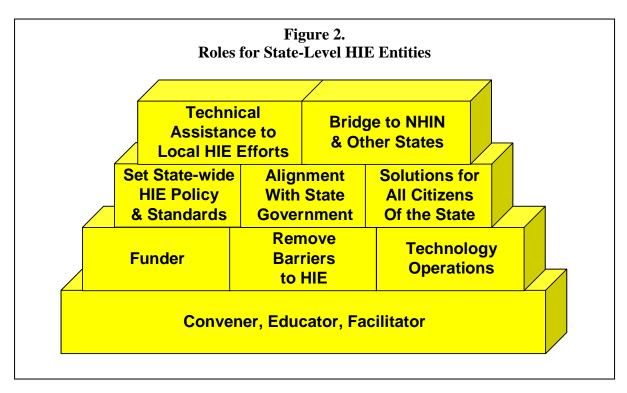
regulations that could hinder HIE within their respective states and how that might affect the role of the state-level HIE.

3 Findings: Documenting Problems and Barriers

By themselves, the individual findings from the interviews are not groundbreaking. It is when the findings are combined with deeper analysis and the insights of those interviewed that the recommendations become bold. Interview findings are described below.

3.1 Validation of the Roles of the State-Level HIE

The initial project's final report⁷ identified the various roles of the state-level HIE in detail and will not be repeated here. These roles are depicted at a high level in the categories shown in Figure 2. Because this study included a broader range of stakeholders than the initial report did, each of these roles were reviewed and discussed during the interviews.



By and large, the participants validated every described role of the state-level HIE. Some participants had slight concerns regarding a few of the roles, while voicing strong support for other roles. The salient findings are highlighted below:

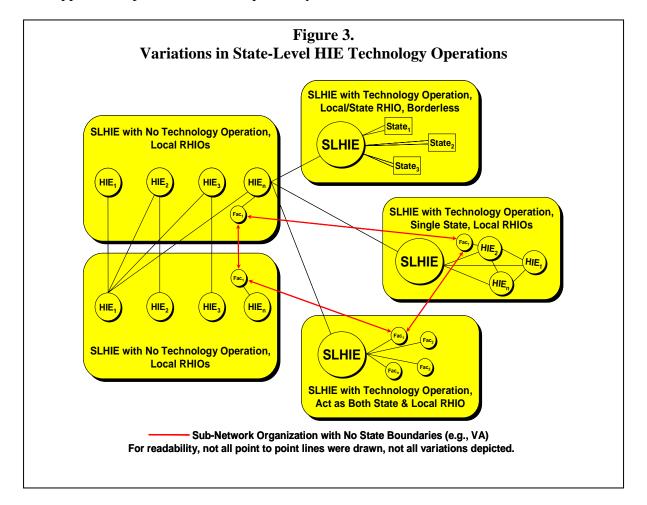
⁷ AHIMA/FORE (September 1, 2006). Development of State -Level Health Information Exchange Initiatives. HHS Contract HHSP2332006410SEC.

- There was universal agreement that the state-level HIE plays a vital role as convener, educator, and facilitator. As shown in the recommendations later in this report, convening and educating will continue to be critical roles for state-level HIE when participating in federal initiatives in the immediate future.
- There was consensus that the state-level HIE could and should work with local RHIOs within the state to develop standard operational policies, business agreements, and the like. However, concerns were raised when "setting standards" was initially interpreted by some participants as technical or interoperability standards currently under the purview of standards development organizations (SDOs) or HITSP. These concerns diminished when the state-level HIE role was described as using existing standards, encouraging the rapid development and harmonization of standards from SDOs and HITSP, and facilitating the implementation of harmonized standards across the state as they are released. An important point arose from these discussions: there is a major disconnect between the standards being harmonized at the moment and those most urgently needed by state-level HIEs. Further action is required to increase the level of collaboration between standards harmonization and the state-level HIE business case.
- There was universal agreement that state government plays a significant role in HIE in setting policy, purchasing healthcare services, and monitoring public health and quality of care. There was strong consensus that state governments need to be much more involved in HIE initiatives than they are now, and they need to become involved immediately. State government involvement can greatly facilitate HIE and will be further discussed in the analysis and recommendations. See also Task #3's final report for more discussion on the role of state Medicaid agencies in state-level HIE initiatives.
- Participants generally agreed with the role state-level HIEs may play in providing HIE infrastructure and services (Technology Operations in Figure 2). Some of the more specific findings from this discussion are:
 - State-level HIE financial sustainability continues to be among the top concerns among the participants. It was pointed out that the services state-level HIE might like to offer first may not be those that are financially sustainable. Although this was also observed by the state-level HIEs themselves in the initial project's final report⁸ and workbook⁹, the important point to note is that other stakeholders have also expressed the same concerns, indicating that financial sustainability is everyone's top issue and should be among the first issues to be addressed. Moreover, there is a strong connection between financial sustainability and lack of alignment of both incentives and the sequence of industry actions in moving HIT forward.
 - There is strong agreement across all stakeholders that the NHIN will be composed of different HIE implementations at the state and local levels (see Figure 3) and that the NHIN can accommodate these variations only if the implementations are based on the same set of HIE standards. The message is that the notion of a single NHIN

⁸ AHIMA/FORE (September 1, 2006). Development of State -Level Health Information Exchange Initiatives. HHS Contract HHSP2332006410SEC.

⁹ AHIMA/FORE (September 1, 2006). State-Level Health Information Exchange Initiative Development Workbook: A Guide to Key Issues, Options, and Strategies. Contract HHSP2332006410SEC.

infrastructure is not paramount and that more energy and resources should be committed for accelerating standards-based HIE development and deployment to support multiple levels of interoperability.



- There continues to be some disagreement about how thick or thin the NHIN should be. Part of the issue stems from the definitions of the words "thick" and "thin." However, the deeper issue is defining and testing the variations in network services between a thick and a thin architecture and how the current state-level HIE technology operations will coexist in the eventual NHIN. It is not desirable for state-level HIEs to replace existing technology and infrastructure to accommodate eventual nationwide standards.
- There was wide agreement that healthcare enterprises that crossed state boundaries (e.g., Veteran's Administration hospitals, proprietary health systems) could form their own RHIOs (the set of red arrows in Figure 3) and exchange health information internal to their enterprises within these, provided that such an arrangement is (as depicted in Figure 3) in addition to, rather than to the exclusion of, participation in the HIEs operating in the various local markets in which the healthcare enterprise resides. The need for HIE standards is underscored because enterprises participating in more than one RHIO will benefit from not having to work with different standards from one RHIO to another.

- The notion that a state-level HIE could provide services and technology operations to other states or regions bordering their state met no resistance. This finding supports the emerging concept of HIE service providers and supports the possibility that state-level HIEs can fill this connecting or coordinating role.
- Activities such as biosurveillance, public health reporting, population health status monitoring, and quality and performance measurement and reporting call for the aggregation of secondary data at the state level. At present, 38 states require healthcare entities to report or submit data for quality measurement or accountability purposes. A number of those interviewed saw potential for the state-level HIE as an ideal entity to aggregate the data on behalf of the state and disseminate it to the various public health, quality reporting, and other entities as appropriate. The need for coordination between HIE and quality and transparency initiatives is discussed more fully in the Task 4 report.
- The aggregation of secondary data also illustrated the difference between possible ideal roles for state-level HIE versus local RHIOs. Some participants advocated that, unless the state-level HIE operated as both a local RHIO and a state-level HIE, local RHIOs should handle HIE transactions and state-level HIEs should manage data aggregation for the state. However, it was emphasized that these decisions about roles and functions are a local matter and more than one model will be needed.
- Variations in business practices, as well as in security and privacy laws and regulations, reveal a potential role for state-level HIEs. Once iterative solutions are found through the current and post-HISPC process, state-level HIEs can then facilitate the actual implementation of HIE by developing model data-sharing agreements that can be used within the state. They may also be in the best position to negotiate data-sharing agreements with other state-level HIEs. Although there was some consensus around the feasibility of this role, the possible next step of actually playing a role in the physical sharing of the data across borders was considered much more difficult because of the challenges inherent in writing software logic that mirrors privacy and security laws. HIEs may also be in a position to advocate for changes to state law and regulation that impede or impair the efficiency of HIE.

3.2 HIT Projects Need Better Alignment and Coordination

All the participants acknowledged that there is more activity to advance HIT now than ever before in the industry. However, there was a universal feeling that the various HIT projects are still disconnected and need better alignment and coordination. Some examples that highlight these concerns are as follows.

- The use cases developed by the American Health Information Community (AHIC)¹⁰ workgroups, although useful for the public good and important for advancing key areas of HIT, do not support the state-level HIE business cases and are therefore not a high priority for state-level HIEs. The emergency first response use case, for example, will certainly be needed to improve care during common emergency situations and natural disasters, but there is currently no business case to support implementation by state-level HIEs. The identification of use cases that create simultaneous value (i.e., both public good and a revenue stream for state-level HIEs) will accelerate their adoption.
- Currently, there is little sharing of lessons learned, products (e.g., business agreements, policies, service contracts), and services between the NHIN contractors and the state-level HIEs beyond those states directly involved in the NHIN contract projects.
- It is not clear whether the NHIN contractors will be funded for a second year, and, if so, what the next set of objectives will be. It is also unclear whether those objectives will leverage statelevel HIE services and operations.
- There was major concern among the Steering Committee members that the State Alliance for e-Health project could disrupt the efforts of, and possibly drain resources away from, state-level HIEs. One of the primary concerns was duplication of efforts already under way between state-level HIEs and their state governments and the need to ensure that the State Alliance for e-Health project is fully informed of work in progress to avoid rehashing issues the state-level HIEs have already addressed. The Steering Committee applauded efforts to coordinate both their individual work and the work of this project with State Alliance for e-Health but strongly encouraged that the continued sharing of information be mandated by ONC to ensure coordination.
- It is unclear to participants whether the legislative branch is fully aware and supportive of the role of HIT in increasing patient safety and quality of care and if there is a congressional agenda to fund projects that will increase incentives for adopting HIT. This situation indicates that Congress may need further education of the issues surrounding HIT adoption.
- There is no central authority that: (1) is accountable for ensuring that HIT is directed toward transforming healthcare, or measuring progress against that goal; or (2) makes key HIT adoption-related decisions, such as resolving disputes among collaborating entities.

In summary, there is an understanding of how standards harmonization, certification compliance, security and privacy collaboration, and NHIN prototyping all relate strategically to the acceleration of HIT adoption. However, the disconnects among these tactical projects create the perception of multiple efforts directed at individual issues with no overarching strategic plan connecting them. It is unclear if funding and other resources are being allocated appropriately to ensure planned movement toward a common objective. There was also concern that current funding mechanisms

¹⁰ Office of the National Coordinator, American Health Information Community (AHIC). www.hhs.gov/healthit/ahic.html.

foster and encourage multiple start-up efforts but are not then sequenced to support next-stage growth and continued sustainability of projects.

3.3 Better Communication Needed

Better communication will obviously help achieve buy-in and move the HIT agenda forward. Examples of where communications can improve:

- The two-way communication paths between the various federal initiatives and the state-level HIEs are not clear. There are no current mechanisms for formalizing such communication. Specifying the communication paths and developing mechanisms for communication will increase collaboration among federal and state-level HIE projects.
- Given the proliferation of new HIT projects, and the confusion stemming from the problems and barriers documented in this report, it is easy to lose sight of how the current HIT activities map back to a guiding vision. The industry has seen various vision and milestone measurement documents, including the 2004 strategic framework¹¹ from ONC; the Secretary's 500 Day Plans; and, more recently, the guidance from AHIC. The participants would benefit from an update of the HIT vision that includes information on how current HIT projects map to, and are performing against, the current overall strategic objectives and which changes in the strategic vision may be indicated given two years of experience implementing the various HIT projects.
- The objectives of the NHIN contracts are not entirely clear. There is an understanding of the
 exploratory nature of these efforts, but less understood is how the NHIN projects and state-level
 HIE projects jointly study the issues. Disseminating more widely and more frequently the
 findings generated from the NHIN projects will help clarify and maintain the focus on the
 project's objectives.

4 Analysis and Recommendations

On the basis of the findings of this study, ONC and HHS should implement a series of strategic and tactical actions that:

- Refresh the HIT vision and reenergize the industry by creating clarity around the activities that will truly transform healthcare
- Clarify objectives, roles, and responsibilities among current HIT project activities
- Facilitate communication among the federal HIT project contractors and the state-level HIEs
- Align incentives and sequence funded HIT activities so that projects can build on each other
- Leverage the resources and knowledge of the state-level HIEs

Relationship of State-level HIE to Federal/Other HIT Activities

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¹¹ Office of the National Coordinator for Health Information Technology (ONC). 2004. Framework for Strategic Action—The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care. Washington, DC: Department of Health and Human Services. www.hhs.gov/healthit/strategicfrmwk.html.

• Communicate these actions clearly to the larger industry, as well as to those working on federal and state-level HIE initiatives

4.1 Transforming Healthcare: Refreshing the HIT Vision and Reenergizing the Industry

Recommendation #1

Begin the transition to a public-private health information community successor to AHIC.

Coordination of federal HIT and state-level HIE activities must be treated as both long-term and short-term issues. In the long term, coordination would be greatly aided by a transformational agenda, as well as a single authoritative body accountable for implementing the transformation.

Currently, AHIC is the entity responsible for providing "long-term governance for healthcare transformation." AHIC "is chartered for two years, with an option to renew for a duration of no more than five years…to be succeeded within five years by a private-sector health information community initiative."¹²

Although the initial directive was to follow AHIC with a private-sector health information community, it is recommended that a public-private collaborative succeed AHIC instead. Moreover, it is not too early to begin considering how the transition to a new public-private health information community will take place. Given that AHIC has begun its second chartered year, it may take a full year to work out the details of the new community, as well as the logistics of the transition. This timing may obviate the federal government's need to renew the current AHIC for an option year.

Recommendation #2

The public-private health information community should develop a transformational agenda by the end of its first year of existence.

The new public-private AHIC should be an organization composed of multiple stakeholders, with a commitment to quality, cost, and access improvement. It should be a learning community, using its authority and resources to educate providers, employers, and consumers; create innovative solutions; and disseminate information. Most importantly, it must be a body with sanctioned authority.

The new public-private AHIC should be the single body that:

- Is charged with developing and implementing a transformational agenda
- Has the sanctioned authority to set priorities and modify structures to support them

Relationship of State-level HIE to Federal/Other HIT Activities

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¹² Office of the National Coordinator, American Health Information Community (AHIC). www.hhs.gov/healthit/ahic.html.

- Is advised by various sanctioned entities, including the federal contractors, the state-level HIEs, State Alliance for e-Health, SDOs, quality organizations representing the broad spectrum of care delivery, and consumers
- Is accountable for maintaining collaboration across the sanctioned entities
- Has the authority to resolve disputes among sanctioned entities
- Develops performance criteria to measure the progress of transformation through HIT
- Creates an inclusive process, encouraging engagement in the transformation by conducting open and transparent deliberations and consensus-driven processes
- Stays intact for three or four years, with staggered terms in office for its officials
- Has the necessary resources to carry out its activities

4.2 Align Incentives and Sequence of HIT Projects

Recommendation #3

Select, develop, and fund demonstrations of use cases that align more clearly with state-level HIE or RHIO business cases.

Although the transformational agenda is necessary for the long term, the disconnections among the various HIT projects need to be rectified now. The industry cannot wait until the transformational agenda is published two years from now. As outlined in the Findings (Section 3), the multiple barriers between the federal HIT and state-level HIE initiatives interact with each other causing a diffusion of focus and resources. The solution is to create a value proposition that advances the public good and aligns incentives for multiple stakeholders to contribute equitably to the building of HIE infrastructure or the delivery of state-level HIE services. In this manner, no one stakeholder bears the burden of funding state-level HIE infrastructure, but their collective contributions allow state-level HIEs to obtain a pool of funds to help build infrastructure or sustain services.

Although they are just one aspect in harmonizing project efforts, use cases are a concrete mechanism, one through which those involved in the various federal HIT and state-level HIE initiatives are well accustomed to creating and maintaining focus. Having use cases that promote integration will increase the level of coordination among initiatives.

Recommendation #4

Select, develop, and fund demonstrations of new use cases that require the actual exchange of health information at the state level.

The current set of AHIC use cases were initially selected because they offered great potential to effect short-term benefits for the consumer. Requiring actual exchange of health information at the

state level (e.g., between local RHIOs within the state or exchange of health information across state boundaries) as the next step of the use case compels HITSP to test its interoperability and CCHIT to certify both the EHR and the core network components. This requirement also compels state-level HIEs to be engaged in the development of certification criteria.

As mentioned in the Findings (Section 3), some use cases may not provide state-level HIEs with a viable business case. The intention of this recommendation is to engage state-level HIEs and other key stakeholders in identifying new use cases that will create value for the stakeholder and revenue streams for state-level HIEs. One stakeholder that should be engaged in this recommendation is state government. In the ensuing project, state government's needs (e.g., data aggregation for quality reporting, Medicaid reimbursement, public health, or population health monitoring) can be aligned with the state-level HIE business case. Educating the various state government agencies and offices will be a major effort required here. However, the state-level HIEs have a wealth of knowledge on the HIE issues plus existing work products to assist in the education process (e.g., policies, business agreements).

Recommendation #5

Align incentives and engage the state-level HIEs in the NHIN process.

Currently, the NHIN process and the state-level HIE initiative are two independent projects when, in fact, if incentives were aligned correctly, the state-level HIEs can serve as existing sites for testing and implementation sites for rollout. Engaging the state-level HIEs in the NHIN process may help contain project costs because some or most of the organizational and infrastructure start-up cost has already been incurred. The state-level HIEs can help build consensus and serve as a conduit to the local RHIOs for rolling out harmonized standards.

ONC and HHS should fund the NHIN projects for a second year, requiring that actual data exchange occur with at least one state-level HIE. The alignment of incentives and engagement in the NHIN process positions state-level HIEs to be NHIN service providers.

4.3 Communication

Recommendation #6

Implement a formal communication process between federal HIT projects and state-level HIE initiatives.

Better communication will obviously help increase awareness of what is happening in other projects that may affect state-level HIE projects and vice versa. Informal communication is not adequate to foster awareness and coordination. ONC and HHS should implement the following formal communication processes:

- Hold meetings with the state-level HIEs for ONC to discuss what it is planning and for the state-level HIEs to impart what they can do to support ONC activities. This can also serve as the mechanism by which ONC can communicate how current HIT activities map back to the strategic framework and overall HIT vision, gather information, and share eventual recommendations about updates to the vision on the basis of the experiences of the last two years.
- Require regular formal communication between stakeholders from the federal HIT projects and state-level HIE initiatives. These meetings should be used to discuss the priorities and business case options of the state-level HIEs and coordinate activities moving forward. The recommendation is that some of these meetings should be held regionally.
- Publish a monthly electronic newsletter highlighting the progress of the various HIT projects and how such progress has advanced the HIT vision.
- Host webinars when key information from other HIT projects should be imparted on a more timely ad hoc basis.

The above formal process can also be used to communicate project status to the larger industry, as well as to those working on federal and state-level HIE initiatives.

Appendix A—Agenda and Participants at the State-Level HIE Project Steering Committee Meeting to Review Initial Findings and Recommendations

Development of Consensus Best Practices for State-Level Regional HIEs HHS Contract Extension Steering Committee Attendees, October 23-24, 2006.

Entity	Person	Address
CalRHIO www.calrhio.org	Lori L. Hack, MBA Interim CEO	526 Second Street San Francisco, CA 94107
Colorado Health Information Exchange http://www.colorado healthinstitute.org/H ot_Issues/corhio.htm	Lynn Dierker, RN Director for Community Initiatives Colorado Health Institute	Colorado Health Institute 1576 Sherman St., Ste. 300 Denver, CO 80203
Florida Health Information Network http://www.fdhc.stat e.fl.us/dhit/index.sht ml	W. Michael Heekin, Esq. Chair of the Florida Governor's Health Information Infrastructure Advisory Council	930 Grey Field Place Atlanta, GA 30208
Indiana Health Information Exchange, Inc. www.ihie.org	Shaun Grannis, MD, MS Medical Informatics Researcher, Regenstrief Institute, Inc. and Assistant Professor of Family Medicine, Indiana University	351 West 10 th Street Suite 252 Indianapolis, IN 46202
HealthInfoNet (formerly called Maine Health Information Network Technology) www.hinfonet.org	Devore S. Culver Executive Director HealthInfoNet	HealthInfoNet is housed in: Maine Health Information Center 16 Association Drive P. O. Box 360 Manchester Maine 04351-0360
MA-SHARE http://64.78.52.225/ ma-share/index.html Rhode Island	Ray Campbell, Esq., MPA, CEO Massachusetts Health Data Consortium Laura L. Adams	460 Totten Pond Road Waltham, MA 02451 One Union Station
Quality Institute www.riqi.org	Chief Executive Officer	Providence, RI 02903
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Appendix B—Individuals Interviewed

Name	Company	Initiative
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Lori L. Hack, MBA	Interim CEO, CalRHIO	CalRHIO
Lynn Dierker, RN	Director for Community Initiatives Colorado Health Institute	Colorado Health Information Exchange
W. Michael Heekin, Esq.	Chair of the Florida Governor's Health Information Infrastructure Advisory Council	Florida Health Information Network
J. Marc Overhage, MD, PhD, FACP, FACMI	Director, Medical Informatics, Regenstrief Institute, Inc., and CEO, Indiana Health Information Exchange, Inc., and Associate Professor of Medicine, Indiana University School of Medicine	Indiana Health Information Exchange, Inc.
Devore S. Culver	Executive Director, HealthInfoNet	HealthInfoNet (formerly called Maine Health Information Network Technology)
Ray Campbell, Esq., MPA	CEO, Massachusetts Health Data Consortium	MA-SHARE
Laura L. Adams	Chief Executive Officer, Rhode Island Quality Institute	Rhode Island Quality Institute
Antoine Agassi	Director & Chair, State of Tennessee eHealth Council	State of Tennessee eHealth Council
Jan Root, PhD	Assistant Executive Director, UHIN	Utah Health Information Network
CCHIT		
Mark Leavitt, MD	Chairman, CCHIT	Chairman, CCHIT
Alisa Ray	Executive Director, CCHIT	Executive Director, CCHIT
David Tao, DSc	IT Architect, Siemens	Chair, Inpatient Interoperability Work Group, CCHIT
Barry Blumenfeld, MD, MS	Associate Director, Clinical Informatics Research and Development Partners Healthcare System	Chair, Ambulatory Interoperability Work Group, CCHIT

	<u></u>		
Sarah Corley,	Chief Medical Officer,	Chair, Ambulatory	
MD	NextGen Healthcare Systems	Functionality Work	
	·	Group, CCHIT	
Mark Del	Clinical Director, Information Services	Chair, Inpatient	
Beccaro, MD	Associate Chief Emergency Division,	Functionality Work	
Beecaro, MB	Children's Hospital and Regional Medical	Group, CCHIT	
	Center	Group, CCIIII	
G: 1 G		Cl. I	
Cindy Spurr,	Corporate Director, Clinical Systems	Chair, Inpatient	
RN, MBA	Management, Partners Healthcare System	Functionality Work	
		Group, CCHIT	
HITSP			
John Halamka,	CIO, Harvard Medical School	Chair, HITSP	
MD, MS	CIO, Beth Israel Deaconess Medical Center		
,	Chairman, New England Health Electronic		
	Data Interchange Network (NEHEN)		
	CIO, Harvard Clinical Research Institute		
	(HCRI)		
	1 ` ′		
	Associate Professor of Emergency Medicine		
	at Harvard Medical School		
Floyd	Managing Director, Clinical Informatics	Chair, HITSP	
Eisenberg,	Secondary Data Use, Siemens Medical	Biosurveillance	
MD, MPH	Solutions Health Services	Technical Committee	
Jamie Ferguson	Director, Health Information Technology	Chair, HITSP EHR	
	Strategy and Policy, Kaiser Permanente	Technical Committee	
NHIN		<u> </u>	
Greg Debor	Computer Sciences Corporation (CSC)		
Brian Kelly	Clinical Architect and Senior Executive,		
	Accenture		
Greg	PMP Director of IT/Project Manager,		
Wenneson	Alliance for Rural Community Health		
** CHIESOH	•		
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Richard S.	IBM		
Steen	Global Business Services		
	Healthcare-Strategy and Change		
	New York, NY		
Ginny Wagner	Certified Executive Project Manager, IBM		
HISPC			
James Golden,	Project Director,	Project Director,	
MD	Minnesota Privacy and Security Project	Minnesota HISPC	
	,	Subcontractor	
Barbara Wills	Director, Center for Data Initiatives,	Minnesota HISPC	
Daroura Willis	Minnesota Department of Health	Subcontractor	
	winnesota Department of Health	Subcontractor	

Jody Pettit,	Health Information Technology Coordinator,	Project Director,
MD	Office of Oregon Health Policy and	Oregon HISPC
	Research	Subcontractor
Local HIE, Stat	e-Level HIE Not Included in the Contract	
Robert Keet,	President, Western Medical Associates	President, Santa Cruz,
MD	Clinical SME, Northrop Grumman	CA RHIO
Holt Anderson	Executive Director,	Executive Director,
	North Carolina Healthcare Information	North Carolina
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		Alliance (NCHICA)
Alan Snell,	Chief Medical Information Officer,	President, MHIN Board
MD, MM	Saint Joseph Regional Medical Center	
Candy	Director, Kallispell Regional Medical Center	Health Information
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Robert Olsen	Vice President,	Health Information
	Montana Hospital Association	Exchange of Montana
Jeanie Gentry	Vice President, Allied Health, St. John	Health Information
	Lutheran Hospital	Exchange of Montana
Alan Snell,	Chief Medical Information Officer,	Michiana Health
MD, MM	Saint Joseph Regional Medical Center	Information Network
	President, Michiana Health Information	(MHIN)
	Network (MHIN) Board	

TASK #2

Report and Recommendations on Health Information Exchange Services That Are Financially Sustainable

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1 Overview of Task #2 Scope

Task: Identify, examine, and analyze health information exchange (HIE) services that have achieved financial sustainability.

Deliverables:

- 1. Describe the parameters of financial sustainability in a way that serves as a guide to examining successful services and will also be a valuable definition for use by developing state-level HIE initiatives.
- 2. Identify and describe HIE services that meet the parameters of financial sustainability. The Office of the National Coordinator for Health Information Technology (ONC) expects that this will involve no more than six entities and as many as 10 specific revenue-generating HIE services. Study these HIE services and describe their characteristics and reasons for their success.
- 3. Provide recommendations on the listing of services, whether to pursue or defer, and other comments that may be useful to state-level or regional HIE initiatives.

2 Parameters for Defining Financially Sustainable HIE Services for Task #2 Purposes

2.1 HIE—In General

HIE can be viewed as an umbrella term for several different types of specific exchanges of clinical data:

- Patient summary—the ability to retrieve a comprehensive set of clinical data from regional providers (and payers) for a specific patient. For example, this retrieval might involve a request by a physician to pull data for a patient who was just admitted to the emergency room. The information included in the resulting patient summary would depend on the type of data available. For example, it could be simply a medication history for the patient, or it could be a more comprehensive set of data, including laboratory results, transcribed notes, radiology images, and EKG results.
- <u>Clinical messaging</u>—the delivery of clinical results (e.g., discharge summaries, laboratory test results, consult notes) from the organization that generates the data (e.g., laboratory, radiology center) on a push basis to a targeted set of recipients (e.g., the referring physician).
- <u>ePrescribing</u>—involving the movement of prescription-related transactions among providers, pharmacy benefit managers (PBMs), and pharmacies.
- Quality measurement—clinical data can be aggregated and used for reporting on the achievement of quality measures and for decision support (e.g., reminders) to improve clinical care.

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- <u>Biosurveillance or syndromic surveillance</u>—involving monitoring of clinical data (e.g., emergency department chief complaint, positive lab results) for disease outbreak or bioterrorism event.
- <u>Chronic disease management or other population-based services</u>—clinical data can be used to aid in the management of chronic or other diseases that impact populations.

In addition, the exchange of administrative data (data used for processing payment for healthcare services) can also be included under the broader HIE umbrella. These exchanges have certainly proven to be viable business models that HIE initiatives can learn from and that may serve as core, sustainable activities to support the infrastructure on which one could build other services more directly related to the improvement of clinical care.

To determine which services would be potential candidates for inclusion in Task #2, parameters for defining the scope were necessary. The project team developed the following set of parameters:

2.2 Defining an HIE Service

First, there is no generally accepted, clear definition of an HIE service. For the purposes of Task #2 and the general relevance to achieving the vision set out in the *State-Level Health Information Exchange Initiative Development Workbook*, the following parameters were applied:

- Task #2 scope is not limited to state-level HIE services.
- "Service" does not mean the entire HIE organization but rather a specific service.
- The service must exchange health information among multiple parties or stakeholders. A service with only two parties sharing data would not be considered for inclusion.
- A project merely to implement or increase adoption of electronic health records (EHRs) in physician offices would not be considered an HIE service for Task #2.
- A project merely to implement or increase adoption of telemedicine would not be considered an HIE service for Task #2.
- A service to share clinical data, administrative data, or both could be considered an HIE service for Task #2.

2.3 Defining "Financial Sustainability"

Second, as used herein, "financial sustainability" is defined as having sufficient revenue for ongoing operations of the particular service (as opposed to an entire organization). The sustainability assessment did not include the need to recover initial start-up costs because relevant information on initial start-up costs was scarce during the interviews for a number of reasons. For example:

- Part of the infrastructure needed was preexisting.
- Parts of the infrastructure have multiple other uses, and start-up costs cannot be allocated to this one service.
- Many start-up costs were funded through grants from local philanthropic, state, or federal monies.
- Start-up costs slowly accrued over time and were not tracked or allocated to this service.
- Start-up costs were incurred some time ago, and accurate information is not available.
- Start-up costs were incurred some time ago, and the costs today would not be the same because of newer technologies currently available.

Note that, due to the nascence of the HIE industry, some of the services identified and described in this report may have short track records or no track record but enough evidence and financial commitment to argue for financial sustainability. The goal was to include as many different types of HIE services as possible that are financially sustainable or show strong promise and corresponding financial commitments from participants.

3 Findings

The appendices describe the team, list the projects studied, and summarize the findings of the information gathered from the companies interviewed in this Task #2. Specifically, Appendix A lists the project team who worked on Task #2. Appendix B provides a listing of the companies interviewed. Appendix C summarizes the revenue and operations model for the different HIE services studied (to the extent available).

Analysis and Recommendations

This section discusses some of the advantages of specific HIE services and which market conditions would be most favorable. Then, some overall observations regarding sustainable HIE services are made, followed by recommendations on implementation of specific HIE services. Finally, a few suggestions are made as to how a state-level HIE initiative could support and encourage the development and implementation of sustainable HIE services.

4.1 **Analysis of Specific HIE Services**

Several different types of services could be included under the HIE umbrella. The following discusses some of the advantages of each HIE service, as well as offering a summary of which local market characteristics would be conducive to or prohibitive of the successful launching of the specific HIE services.

4.1.1 Clinical Messaging

Brief Description: "Clinical Messaging" is an HIE service that delivers electronic clinical results (such as laboratory test results, radiology reports, or transcribed reports) from the source system (e.g., laboratory, radiology center) to the intended recipients (e.g., ordering physician, primary care physician).

Common Advantages to This HIE Service:

- Physicians like having to go to only one location to retrieve clinical messages from multiple sources (reduces staff time). Plus, if the physician did not receive electronic results before, there is the obvious advantage of having it electronically, rather than receiving and sorting through faxes or having to open mail.
- Physicians generally receive the results faster if they were receiving them via fax or mail
- Hospitals like the reduced cost of not having to maintain their own department to deliver clinical results.

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- This system eliminates the need to manage and store paper results for the physician and for the hospital.
- No master patient index is required to implement clinical messaging; only the physician list must be maintained.
- This system could serve as a platform to enable the push of urgent information to physicians (e.g., public health alerts).

4.1.2 Sharing Clinical Data on a Patient at Time and Point of Care

<u>Brief Description:</u> "Sharing Clinical Data on a Patient at Time and Point of Care" is an HIE service that gathers and provides electronic clinical information (e.g., patient's medical history to the extent available) from multiple sources about a particular patient when the patient presents for care.

Common Advantages to This HIE Service:

- Having the patient data available at the time of care is of tremendous benefit for treating the patient and enhancing the probability of positive outcomes. Ensuring that everyone has a common understanding of the value of HIE to patient care is essential.
- Facilitates more effective management of chronic illnesses.
- Improves patient safety by helping avoid errors.
- Helps reduce duplication of diagnostic tests.
- Improves the continuity of care among multiple physicians treating the patient.
- The ability to aggregate, standardize and analyze clinical data can also benefit public health, scientific researchers, and public policy development.
- The addition of clinical decision support and reminders functionality can further aid providers.
- Of critical importance for national emergencies.

4.1.3 Medication History

<u>Brief Description:</u> "Medication History" is an HIE service that electronically shares a patient's medication history obtained from multiple sources (e.g., PBMs) with the clinician or institution treating the patient. Often, this information is useful to hospitals to aid in their medication reconciliation process (required under hospital accreditation under JCAHO¹).

Common Advantages to This HIE Service:

- The value to clinicians and hospital pharmacists or others involved in the medication reconciliation process of having the patient's medication history available at the time of treatment is of high importance because:
 - o Patients frequently do not know what medications they are using;
 - Other medications could indicate other illnesses that the patient is being treated for, which could affect the immediate treatment regimen; and

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o Interactions with other drugs and adverse drug events could be avoided.

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¹ www.jointcommission.org.

- Some sources of medication history have been pooled (e.g., RxHub) and thus require only one interface to such source. The number of interfaces necessary to set up and maintain a medication history service with enough data to be meaningful² may not be high; however, certification of the software may be necessary.
- Of critical importance for national emergencies.

4.1.4 ePrescribing

<u>Brief Description:</u> "ePrescribing" is an HIE service that automates the process for clinicians to prescribe medications for patients by electronically delivering the prescription information to the retail pharmacy or mail-order service.

Note that medication history could be delivered through an ePrescribing application to the physician placing the order; however, for discussion purposes, medication history as an HIE service was addressed previously in section 4.1.3.

Common Advantages to This HIE Service:

- Physician practices save staff time of having to answer calls from pharmacies to clarify orders and to approve refills; however, work-flow issues must be addressed early to ensure adoption. Can be a valuable benefit to a medical provider previously unfamiliar with HIE services.
- Orders are more accurate, which is expected to reduce the need to resubmit prescription
 requests that did not comply with the formulary and to reduce possible prescription errors
 and adverse drug events.
- Formulary information available to clinicians at time of prescribing would benefit patients, PBMs, and payers by selecting drugs on formulary thus reducing the patient's out-of-pocket costs.
- Pharmacies benefit by reducing the need for faxing.
- Medication management is improved.
- Once the ePrescribing software is certified with the various data providers and delivery network, there would be a higher barrier to entry for others seeking to provide a similar service.

4.1.5 Quality Metrics

<u>Brief Description:</u> "Quality Metrics" is an HIE service that shares healthcare information among multiple data sources for the purpose of quality measurement that can support provider quality initiatives and also serve as a basis for determining incentives (e.g., pay-for-performance or pay-for-quality) to providers from payers.³

² No medication history service would purport to provide a complete medication history on the patient because of the number of different sources and limited availability for that data. There are also over-the-counter (OTC) drugs that are not tracked or available, so the physician must still speak with the patient and use clinical judgment when making treatment decisions. It may be advisable to include disclaimers in this regard.

³ Note that a quality metrics project does not imply that the results of the measurement will automatically be disclosed to the public. Which results are disclosed and who they are disclosed to would be the decision of those involved and Report and Recommendations on HIE Services Financial Stability

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Common Advantages to This HIE Service:

- Payers expect improved quality and anticipate efficiency improvements from high-quality care. By providing a consistent program across payers, they hope to have more influence helping physicians improve the quality of care they provide.
- Providers benefit by having a consistent set of quality measures along with information and incentives that help them and that they can work toward improving.
- If the quality of care is increased, patients will have better outcomes, including fewer exacerbations and/or need for acute care.

Note: This discussion relates to the use of clinical data combined with claims data for quality reporting. Several initiatives are under way in which payer claims data alone are being combined and aggregated by a third party to use as a basis for payment incentives to providers for performance. Task #2 did not pursue data regarding those initiatives, because many are still in their infancy and limited information is available.

4.1.6 Administrative Data Sharing

<u>Brief Description:</u> "Administrative Data Sharing" is an HIE service that shares electronic administrative information related to the payment of a claim for healthcare services (e.g., claims data, eligibility) among multiple parties.

Common Advantages to This HIE Service:

- Reduce the number of days required to pay a claim.
- Payers and providers alike reduce staff time spent inquiring and answering claim status requests.
- Fewer proprietary interfaces to support.
- Increased clean claims, requiring less processing.
- Reduction in write-offs by providers because of eligibility and exceeding the file limit.
- If most payers are local, there will be more of an affect on the participants. If national payers dominate the market, the project may not get the attention of enough key participants to be viable.
- Having the administrative claims data available (e.g., in a data repository) and the content standardized and structured to enable querying for specific events (e.g., quality metrics) could provide an opportunity to link clinical and administrative data for quality-oriented efforts. Neither of the two administrative data-sharing services studied store the claims data centrally, but rather they act as a conduit for delivery.

4.1.7 Credentialing

<u>Brief Description:</u> "Credentialing" is an HIE service that centralizes and shares the information necessary for clinicians to become credentialed at healthcare institutions and/or with payers.

must comply with applicable law. In the instance of Regenstrief/IHIE example, the results are not made available to the public, and the payers and providers must come to mutual agreement on the report formats and type of content, what is measured, and who will be provided which reports.

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Common Advantages to This HIE Service:

- Clinicians benefit from not spending as much time completing the credentialing process at multiple institutions.
- Institutions save time by not having to ask for missing information.
- If there is a lack of collaborative spirit in the region, a straightforward service like this with clear potential return on investment (and no real competitive advantage in the data being exchanged) may be a good way to foster initial collaboration.
- If there are no standards in the community, this service will be valuable. However, some states have adopted laws establishing standards for credentialing, so the benefits of a credentialing service may not be as significant in those states.
- Could use this project to maintain a master physician list, which could benefit other services, such as clinical messaging.

4.2 Common Enablers

There are several sustainability enablers and conditions that were found to enhance the likelihood of project success and were common to many of the HIE services studied:

Planning

- Proper planning and understanding of the complexity of the service are essential to success
 because organizations often underestimate the size and scope of the project. For each of
 these services, there can be very significant (and poorly understood) challenges, some of
 which are mentioned in this report. Failure to estimate the magnitude of these challenges
 appropriately can lead to cost overruns and delay participant willingness to provide
 operating revenues. The sustainability of the service can evaporate.
- A clear understanding of the business case for each participant involved in an HIE service is critical. Tailoring the specifics of the service to address valid concerns of the participants is helpful, as long as one is careful to avoid too much customization, which can affect the costs involved in maintaining the service and the ability to expand to include other participants.
- It is also important to understand the affect on the business models of other entities in the community. The old adage "one man's loss is another man's gain" holds true for HIE services as well. The HIE service may be viewed as a disruptive technology to other vendors or other stakeholders who have an interest in keeping things status quo.
- Although there is no standard financial sustainability template that is either part of
 professional training or used by experts and designers building HIE services, clear financial
 commitments early on from participants expected to pay for the service and solid
 commitments from data sources to provide the needed data are vital to increasing the
 project's chances of success in this uncharted territory.

Participation

• A critical mass of participants is necessary. Failure to address this challenge adequately can lead to services that never deliver enough value to justify participant funding. It may be feasible to start with one participant, if large enough; however, expansion to include

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- multiple participants will reduce the reliance on any one source of revenue and will enhance the likelihood of sustainability over time.
- A history of collaboration among participants is beneficial (e.g., one community's hospitals came together to create a common Web portal, another formed a shared critical air ambulance service, and another collaborated on a research project). Thus, if there is no prior collaboration, it might be good to start with a small project that is less invasive to get the partnering off the ground.
- Strong leadership from the provider community was common for projects involving clinical data. Clinician adoption is key for most HIE services.
- The participants' willingness to make work-flow changes will depend on their perceived value of the service and incentives to adopt the service.
- Early-stage participants who commit to the HIE must perceive a clear return on investment (not necessarily just monetary) from taking a "first cooperative mover" position. Be careful not to set a precedent that cannot be maintained in the long run.

Operations

- A critical mass of data is necessary to make the service valuable to participants. The number of interfaces necessary to be able to assemble enough data to be useful could be high, so the costs to implement would correspondingly be higher.
- The participants' IT staff may have other priorities. Commitment at the highest levels of an organization will help ensure that priorities are set at the lower levels to make the HIE service happen.
- If consensus on standards is required, it is never easy, and adequate time should be allowed.
- Increasing broadband access in rural areas can facilitate the participation by rural physician offices.

Market and Financial Conditions

- Self-interest of a critical mass of key participants must be aligned to enable HIE sustainable cooperation. The participants have to agree not to compete on the subject of the particular HIE service. The concepts of shared services and economies of scale can be emphasized.
- The price to participants must be in line with the perceived value of the service. In addition, the benefit of the HIE entity providing the service must be considered versus a commercial entity or other competitor doing it. Accordingly, the competition landscape should be carefully monitored.
- A market that is sufficiently but not overly fragmented. If there is little fragmentation, a dominant organization may attempt to provide its own proprietary exchange. Too much fragmentation can make the task of collaboration much more difficult and the challenge of attaining a critical mass of data much more expensive and time-consuming.
- The absence of any one dominant participant attempting to grab market share aggressively from the others or attempting to attain a material competitive advantage over others also favors collaboration on HIE projects.
- Payer reimbursement incentives for any of these HIE projects would also help spur participation.

4.3 Recommended Approach Overall

4.3.1 Overall Observations

For the past two years, the industry has focused on HIE architecture, data standards, and privacy models. The importance of the financial sustainability of these undertakings has only recently been elevated in priority. In general, the HIE service should work to reduce the rate of growth of health care costs. Any project that increases the cost of health care is not likely to succeed.

Although there are few sustainable exchanges, the main point is that there *are* some sustainable HIE services. Technology alone is not a panacea, but rather a thoughtful plan for gaining acceptance of the HIE service by a critical mass is needed to enable financial sustainability. The market factors that enable an exchange to be successful and the challenges that confront efforts to become sustainable are not well understood. A solid grasp of the market factors influencing the HIE service and a constant monitoring of the competitive landscape are essential to success. More enablers and/or more barriers may surface at any time, and the ability to react and adjust the HIE service's business model may be necessary to sustain success. The conclusions drawn in the previous section provide some insight into these factors and challenges, but more extensive and in-depth research and experience will be needed.

There is no single approach to achieving sustainability. The projects examined were diverse in scope, activity, and technology. There can be multiple options for any one service type. In addition, there may be other services not yet identified that would be successful and would move the organization closer to achieving the HIE vision. Further innovation in this nascent field is expected.

To date, local community HIE initiatives appear to be more successful than state-level HIE initiatives. This may be due to the fact that the development of state-level initiatives has been more recent, and many are still in the formation stage. However, it may also be due to the fact that it is inherently more difficult and time-consuming to engage and gain consensus from a broader array of stakeholders in order to launch a state-level project or service.

4.3.2 Recommendations on Specific HIE Services

The following recommendations relate to *specific* HIE services. Recommendations regarding the revenue model to support an entire organization, or a state-level HIE initiative that may offer other services, are not addressed in Task #2. As a general principle, an HIE initiative should leverage any infrastructure built and any clinical data collected for developing additional services. It may take a menu of revenue-generating services offered by an HIE initiative to become truly financially sustainable and to support the costs of the infrastructure necessary over time. Other secondary uses of the data that may not generate revenue but would have other benefits for the community could

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⁴ Note that there may be a larger value proposition, separate and apart from revenue generation, that may influence the desirability of pursuing a particular HIE project. Those considerations are outside the scope of Task #2. Some of those issues were more thoroughly addressed in the *State-Level Health Information Exchange Initiative Development Workbook*.

also be explored (e.g., public health, research). The key is not simply to build another "silo" of data but rather to leverage the reuse of the data for purposes that are acceptable to the community. Local circumstances and market conditions will dictate where the HIE initiative should focus its initial efforts. The recommendations that follow are a generalization, and a particular state or region may be more favorable than another for the particular HIE service. In addition, particular laws or regulations may affect the viability of the planned service, which must be carefully reviewed and understood.

4.3.2.1 Recommended Initial Services

On the basis of the information collected, <u>clinical messaging</u> is a good starting project. There is a fairly easy-to-understand return on investment. Clinical messaging would establish the connections needed between the clinical data providers (e.g., hospitals, reference laboratories) and the physician offices. Also, it is not necessary to create a master patient index for patient matching to do clinical messaging (simply knowing the physician is the key). Another major advantage is the clinical relevance of laboratory results, and other data typically included in a clinical messaging service, to the treatment of the patient.

<u>Medication history</u> could also be a good first project. As mentioned earlier, a medication history function may be included in an ePrescribing service, but it can also stand on its own. Hospitals may be willing to pay for medication history by itself because it would be valuable to reduce time spent in the medication reconciliation process required by JCAHO. Others may be willing to pay for this service, but no current examples were found.

4.3.2.2 Recommended Secondary Services

ePrescribing usually will provide eligibility and formulary information, which could help reduce drug costs and increase efficiencies. ePrescribing would also provide other benefits, such as the reduction in administrative expense related to prescription legibility and processing of refills. In addition, ePrescribing has a positive effect on more stakeholders than does medication history alone (e.g., pharmacies, physicians, PBMs, health plans, employers, and patients). However, ePrescribing is more difficult to implement than medication history in a number of ways. First, the software application that the physician would use must be well adopted, that is, used by a critical mass of physicians to make the investment in ePrescribing feasible. Issues involved in incorporating the ePrescribing process into the physician's workflow are not insignificant. Second, the software to interface with the ePrescribing delivery network typically must be certified. The certification process takes time and resources, which must be factored into the business plan if the HIE initiative chooses software that has not already been certified. Third, data format and vocabulary issues must be mapped and addressed, many on an ongoing basis. Fourth, it is important to ensure a critical mass of pharmacies and PBMs are covered to warrant adoption. Momentum seems to be building in the public payer community in support of ePrescribing initiatives, which may warrant embarking on evaluating the feasibility of an ePrescribing service for a particular community or state.

Sharing the full clinical patient summary is a large project to tackle that would require more investment and time to implement. It would also require the creation of a master patient index or some way of matching patients to be able to retrieve the correct data on the patient. Such an HIE Report and Recommendations on HIE Services Financial Stability

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service is highly valuable for treating patients and should ultimately be pursued but perhaps might not be a good choice for a first project. Also, the financial sustainability model is not clearly understood or developed. It is difficult to project the value of this type of exchange across providers, payers, and patients. Hence, there will be hesitancy to invest given the intangible nature of the value and the difficulty of determining who receives the value. A subscription model could be explored and may be feasible, but such a model has not yet been developed.

A <u>quality measurement</u> and/or reporting service is not really feasible until a significant base of clinical data is accumulated to make the quality measurements meaningful. Although such a project would be very relevant to improving clinical care, it would not be a good candidate as a first project. It also would take much more time to implement, because there would need to be consensus on what quality metrics to collect, how to analyze them, and who would have access to the results.

Note on secondary uses: The primary use of clinical data exchange is for improving the treatment of the patient. However, once there is enough of a base of data, a number of different secondary uses of the data could become attractive and would generate interest from the research community, public health, and the pharmaceutical industry, among others. Care should be taken when exploring these secondary uses of data so as not to jeopardize the chance of receiving and utilizing the data for its primary use. In some communities, the issue of secondary uses may be viewed as controversial, and if it comes up too soon in such a community's process, it could result in conflict and loss of momentum, not to mention shaking fragile bonds of trust before anything has gotten off the ground. It is advisable to focus on where stakeholders can agree and to start small to foster trust between the participants. It is too early to assess the potential of these secondary use areas for spawning HIE services that are financially sustainable. As the HIE initiatives grow and mature, there will be more knowledge and experience to gain and share.

4.3.2.3 Services with Limited Applicability

Administrative data exchange would not be a good place to start today because most of the major investments have already been made in response to the passage of HIPAA. Thus, there may be little opportunity to enter this field now. Furthermore, administrative data exchange, although providing administrative benefits and cost reduction, does not move the HIE initiative closer to achieving the vision of providing appropriate access to patient medical history at the point of care. However, if strong market conditions favor an administrative data exchange, it might be useful in establishing the infrastructure on which other services more relevant to clinical care could be built. Another weakness of administrative data exchange may be that national insurers or their agents may build their own systems to use as a utility function. The rationale for such activities is that large ERISA⁵-exempt employers often view health benefits for a national or multistate region.

A <u>credentialing service</u> may be feasible in a given region, but it will likely not help create the broader infrastructure necessary to enable other HIE services. However, it could serve as a starting point for a master physician list that would be useful for clinical messaging or other HIE service for which matching the physician is important. In addition, it could encourage collaboration among stakeholders as they strive to develop a standard. However, similar to administrative data exchange,

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⁵ Employee Retirement Income Security Act of 1974.

credentialing as a service may not move the HIE initiative toward improving patient treatment. Furthermore, credentialing is a service that may be provided by other national payers or their agents. Already, many make such services available. There also may be an issue regarding recreating efforts currently under way by the Council for Affordable Quality Healthcare (CAQH).⁶

4.4 Recommendations for State-Level HIE Initiatives in General

As discussed in the *State-Level Health Information Exchange Initiative Development Workbook*, the state-level HIE initiative could opt to play a number of different roles. If it chooses not to pursue the HIE services described in this report, there are still activities a state-level HIE initiative and/or a state government can do to have a major effect or influence on HIE in the state and to encourage some of the HIE services described in this report. Here are some examples:

- Promote and nurture collaboration among stakeholders.
- Broadly communicate to stakeholders the value of reducing variation and duplication in the
 creation of new databases and services across the state. At a minimum, the state-level HIE
 initiative should stay alert to any plans in the state to create data services that it could
 feasibly provide and at least have a conversation with those involved about the value of
 avoiding duplication. It will not always be possible to integrate, but at least an attempt will
 be made to do so where it makes sense.
- Remove or modify laws that are barriers to the particular HIE service (e.g., a West Virginia state law makes "fully automated" electronic prescriptions illegal⁷).
- Enact laws that encourage HIE or the use of HIT (e.g., a law that limits the ability of a physician to issue handwritten prescriptions).
- Leverage the state's executive office as a vocal and persistent champion of HIE and HIT adoption; the champion messages can be directed to the public, providers, plans, and pharmacies.
- Provide a road map and plan that will lead to using HIE services for state employees.
- Leverage the power of the state as a payer (e.g., state employees and Medicaid) to create incentives for HIT adoption and advance the development of state-level HIE through participation in state-level HIE services.
- Convene stakeholders to guide the state's efforts to implement the HIE service and advise the state and other stakeholders on strategies to overcome barriers to adoption.
- Work with state medical societies to provide education to physicians on the HIE service to help drive adoption.

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⁶ www.cagh.org.

⁷ Charleston Daily Mail (W.V.)/Associated Press, 10/17/06. See also "Almost heaven: eprescribing in West Virginia," *Today in eHealth Business*, 10/19/06 (http://www.aishealth.com/EHealthBusiness/101906.html).

Appendix A—Project Team

The project team for Task #2 included the following:

Victoria M. Prescott, Esq., Primary Investigator

Stephen Parente, PhD

John Glaser, PhD

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Appendix B—Interviewees

When talking to several HIE leaders and organizations about who would be candidates for Task #2, we found that the same organizations kept being mentioned. After discussion, the project team, American Health Information Management Association (AHIMA) staff, and ONC agreed on the following organizations to interview for Task #2, listed in alphabetical order as follows:⁸

HealthBridge

11300 Cornell Park Dr., #360 Cincinnati, OH 45242

URL: www.healthbridge.org Contact: Keith Hepp Tel: (513) 469-7222 x12

E-mail: khepp@healthbridge.org

Inland Northwest Health Services (INHS)

601 W 1st Ave. Spokane, WA 99201 URL: www.inhs.info Contact: Jac Davies Tel: (509) 232-8120

E-mail: daviesjc@inhs.org

New England Healthcare EDI Network LLC (NEHEN)

266 Second Ave. Waltham, MA 02451 URL: www.nehen.org Contact: Sira Cormier Tel: (781) 290-1300 E-mail: scormier@csc.com

Regenstrief Institute, Inc. (RI) and 1050 Wishard Blvd., RG6 Indianapolis, IN 46202

URL: www.regenstrief.org Contact: Marc Overhage Tel: (317) 630-8586

E-mail: moverhage@regenstrief.org

Utah Health Information Network, Inc. (UHIN)

Washington Building, Suite 320 151 East 5600 South

Murray, UT 84107 URL: www.uhin.com Contact: Jan Root

Tel: (801) 466-7705 x202 E-mail: janroot@uhin.com

⁸ A few other projects were contacted, but some either (1) declined to participate because they thought that they were not at a point to be considered financially sustainable or (2) were not selected for participation because their projects did not fall within the parameters of the scope of Task #2.

351 West 10th St., Suite 252

Indianapolis, IN 46202

Contact: Marc Overhage

URL: www.ihie.com

Indiana Health Information Exchange, Inc. (IHIE)

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Appendix C—Description of Findings from Interviews

The findings from the interviews conducted are summarized and categorized by type of HIE service as follows.

Clinical Messaging

<u>Brief Description:</u> "Clinical Messaging" is an HIE service that delivers electronic clinical results (such as laboratory test results, radiology reports, or transcribed reports) from the source system (e.g., laboratory, radiology center) to the intended recipients (e.g., ordering physician, primary care physician).

HEALTHBRIDGE:

Service Provided:

Data Sources:

- 21 hospitals (includes hospital laboratories, pathology, radiology, transcription, and registration)
- two national reference laboratories

How Delivered: Four ways:

- To the practice's electronic inbox accessed from an HIE's Web portal (which also serves as the community portal for all the hospitals)
- Via fax, if the physician requires it
- Via mail, if the physician requires it
- Directly from data source system to physician's electronic medical system (EMR) through an HL7-formatted⁹ feed

When Delivered:

• Messages are sent in real time to the physicians.

Number of Physicians Using It:

- Type of Physician Using It: Any physicians can use it.
- Total Physicians in the Community: 4,400
- Number of Physicians Using It: All 4,400 are receiving results (2,100 of those use either EMR feed or electronic inbox delivery, and such EMR feed and electronic inbox use makes up 91% of all messages delivered in the region, whereas approximately 9% are delivered via fax or print).

Architecture:

<u>Infrastructure:</u> The HIE leverages Axolotl® software for data sharing. Centralized servers house the data in logically separate "silos" for each data source. Data sources must submit the data in HL7 format to the HIE for incorporation into the system. Fax server is also used for batch faxing for physicians who choose fax delivery.

Standards Used:

• HL7 formatted messages

Health Level Seven is an American National Standards Institute (ANSI) standard. See www.hl7.org for more details.
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- All laboratory results are mapped to LOINC® standard, ¹⁰ but mapping is not necessary for this clinical messaging service.
- EMR feeds are standardized across the region.

Requirements:

Hospital or Other Data Source:

- Required to provide data in a certain standardized HL7 format from its various systems (e.g., laboratory system, pathology system, radiology system, registration system, transcription)
- Required to map laboratory results to LOINC

Physician:

- Internet access or access to one of the member hospital's portals to access his/her inbox is required.
- Physician could also elect to receive results via fax.
- Physician could also elect to receive results via mail.
- If physician elects to receive direct feed into the practice's EMR, then physician would be responsible for developing or purchasing HL7 interface from his/her EMR vendor and then maintaining that connection.

HIE Organization:

- Responsible for training physicians
- Provide 24/7 support of system and help desk

Who Pays?:

- Hospitals and other data sources pay the HIE.
- Physicians pay the HIE a small, onetime fee if electing to receive HL7 inbound feed directly into their EMR.

<u>How Much Do They Pay?</u>: Hospitals and other data sources pay fees to the HIE on a subscription basis. There are levels based on relative size (expenses or number of results delivered). (Note: The exact fees were not disclosed, but HealthBridge stated the hospitals were paying less than 20 cents per message delivered.)

Cost to Deliver the Service?: Undisclosed

Do Costs Exceed Revenue?: No, net income and cash flow are positive.

Market Characteristics That Make the Model Feasible:

- History of collaboration among hospitals
- Physicians practicing at several hospitals and thus receiving results from several systems

REGENSTRIEF INSTITUTE / INDIANA HEALTH INFORMATION EXCHANGE:

Service Provided:

Data Sources:

• 16 hospitals (includes hospital laboratories, pathology, radiology, EKG [text files], transcription, and registration)

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¹⁰ LOINC is a universal standard for identifying laboratory observations developed by Regenstrief Institute and the LOINC Committee. See http://www.regenstrief.org/medinformatics/loinc/ for more details.

- Indiana State Department of Health HIV laboratory
- One regional reference laboratory

How Delivered: Three ways:

- To the practice's electronic inbox accessed from a hospital's Web portal or the HIE's portal
- Via fax, if the physician requires it
- Directly from data source system to physician EMR through an HL7 feed (still in testing phase)

When Delivered:

- Messages are sent in real time to the physicians.
- 11.5 million results are currently stored.

Number of Physicians Using It:

- Type of Physician Using It: Any physicians can use it.
- <u>Total Physicians in the Community</u>: 3,600 physicians in Indianapolis metropolitan area. However, use has now expanded to the eight surrounding counties.
- <u>Number of Physicians Using It</u>: 3,520 physicians (1,200 practices). Approximately 90% of messages are delivered via electronic inbox and approximately 10% by fax.

Architecture:

<u>Infrastructure:</u> The HIE leverages the Regenstrief's DOCS4DOCS® software for data sharing. Data sources must submit the data in HL7 format to the HIE for incorporation into the system. Fax server is also used for batch faxing for physicians who choose fax delivery.

Standards Used:

- HL7 formatted messages
- All laboratory results are mapped to LOINC by Regenstrief, but mapping is not necessary for this clinical messaging service.

Requirements:

Hospital or Other Data Source:

- Required to provide data in HL7 format from its various systems (e.g., laboratory system, pathology system, radiology system, registration system, EKG, transcription)
- Required to provide updated physician lists from each source system periodically
- Provide physicians access to the HIE via the hospital's portal, but physicians can log in to the HIE's own portal if the hospital declines to provide access or if the physician prefers

Physician:

- Internet access or access to one of the member hospital's portals and a common Web browser like Internet Explorer to access his/her inbox is required.
- Physician could also elect to receive results via fax.
- If physician elects to receive direct feed into the practice's EMR, then physician would be responsible for developing or purchasing HL7

interface from his/her EMR vendor and then maintaining that connection. Again, this is still in testing phase.

HIE Organization:

- Responsible for training physicians and configuring their system
- Responsible for keeping physician list file updated daily
- No master patient index necessary
- Provide 24/7 support of system and help desk
- Responsible for continued expansion of HIE by subscribing new data sources

Who Pays?: Hospitals and other data sources pay the HIE for delivery of results.

<u>How Much Do They Pay?</u>: Hospitals and other data sources pay fees to the HIE based on a certain fixed fee per message delivered. This is a tiered scale with volume discounts, that is, lower fee per message delivered for higher volumes. A nominal, onetime start-up fee is also charged. (Note: The exact fees were not disclosed, but IHIE stated the hospitals were paying substantially less than the 81 cents per message that they were incurring prior to the HIE. The 81 cents was an average across all the major hospitals in the community).

Cost to Deliver the Service?: Undisclosed

Do Costs Exceed Revenue?: No, but they are about equal.

Market Characteristics That Make the Model Feasible:

- History of collaboration among hospitals
- Physicians practicing at several hospitals and thus receiving results from several systems

INLAND NORTHWEST HEALTH SERVICES:

Service Provided:

Data Sources:

- 34 hospitals (includes hospital laboratories, nursing notes, medications, images, and other inpatient data, as well as emergency room and outpatient clinic data)
- Two regional reference laboratories
- One regional imaging center

How Delivered: Three ways:

- Directly from data source system to physician EMR
- Through Web portal (physician logs on and views his/her patients' results)
- Wirelessly within hospitals downloaded to physician PDAs

When Delivered:

• Messages are sent periodically (batched) to the physicians' EMRs.

Number of Physicians Using It:

- <u>Type of Physician Using It</u>: Used by primary care providers and specialists, including physicians and clinical staff
- <u>Total Physicians in the Community</u>: 1,100 physicians in Spokane county or 2,000 if you include the surrounding area. Note: about 20% have EMRs, but the percentage is growing rapidly.

• <u>Number of Physicians Using It</u>: 300 physicians (about 20 practices) are using HL7 messaging to receive clinical data directly into their EMR. All physicians in the region have access to the Web portal.

Architecture:

<u>Infrastructure</u>: Hospitals use MeditechTM software that is implemented and maintained centrally by INHS. The HIE leverages the Meditech software and the technology infrastructure for data sharing. Centralized servers house the data in logically separate "silos" for each data source. Data sources that do not use Meditech (e.g., reference laboratory) must submit the data in HL7 format to the HIE for incorporation into the Meditech system. Have mirror site for disaster recovery.

Standards Used:

- HL7 formatted messages
- Laboratory results are not currently mapped to LOINC, but they would like to do that in the future for other projects. The outside reference laboratory data, however, are mapped to LOINC.

Requirements:

<u>Hospital:</u> Required to enter primary care physician for every patient at time of registration

Other Data Source: Required to provide data in HL7 format to be incorporated into the Meditech central system

Physician:

- For EMR feed, physician is required to have an EMR, to pay for the interface to be developed or licensed from the EMR vendor, and to monitor and maintain that feed.
- If physician does not have an EMR and wishes to participate, physician would just need Internet access to log on to portal.

<u>HIE Organization:</u> Responsible for training physicians on portal. Provide 24/7 support of system. Must maintain a master patient index to match patient data from different sources to combine data from outside sources with data in the patient's record in the Meditech system.

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Who Pays?: Hospitals pay the HIE.

<u>How Much Do They Pay?</u>: Not itemized separately from other health information technology (HIT) services offered for a flat fee to each hospital.

<u>Cost to Deliver the Service?</u>: Unknown, because the system and infrastructure are also used for other things. Very minimal effort required to maintain after initial interface setup (approximately 0.25 FTE per year).

Do Costs Exceed Revenue?: No

Market Characteristics That Make the Model Feasible:

- The fact that most of the data sources use the same software platform (Meditech)
- History of collaboration among hospitals
- Willingness by physicians to adopt EMR systems and to pay for HL7 interfaces

Sharing Clinical Data on a Patient at Time and Point of Care

<u>Brief Description:</u> "Sharing Clinical Data on a Patient at Time and Point of Care" is an HIE service that gathers and provides electronic clinical information (e.g., patient's medical history to the extent available) from multiple sources about a particular patient when the patient presents for care.

REGENSTRIEF INSTITUTE:

Service Provided:

<u>Data Sources:</u> The Indiana Network for Patient Care (INPC), Regenstrief's clinical data repository, receives more than 100 data feeds:

- More than 20 hospitals (includes hospital laboratories, pathology, radiology, EKG [text files], transcription, and registration)
- Indiana State Department of Health
- Marion County Health Department
- RxHub (PBM consortium)
- Regional reference laboratories
- Radiology centers
- Multiple physician practices
- Medicaid claims data (new and will go live with first data in about one month)
- Commercial payer claims data (several contracts have been signed and data has been received and is being evaluated for incorporation)
- Medicare (has committed to providing some data for limited purposes under a grant)

How Delivered: Two ways:

- Many hospitals may choose to have a clinical abstract (short) document automatically printed in the emergency department, triggered by the patient registration, so it can be placed in the chart of the patient.
- The full patient record (data from all data sources available) is also available by logging on to the software over a secured connection on the Internet.
- Note that access is severely limited to a specific facility; only to physicians credentialed at that facility; and limited in time to 72 hours after patient discharge or 30 days after admission, whichever comes first.

Number of Physicians Using It:

- <u>Total Physicians in the Community</u>: 3,000 physicians in Indianapolis metropolitan area. However, use has now expanded to the eight surrounding counties.
- <u>Number of Physicians Using It</u>: Physicians credentialed at the member institutions can access the system, so almost all of the 3,000 physicians have access to the system.

Architecture:

<u>Infrastructure:</u> The HIE leverages the Regenstrief software for data sharing. Data sources must submit the data in HL7 format to the HIE for incorporation into the system.

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Standards Used:

- HL7 formatted messages
- All laboratory results are mapped to LOINC by Regenstrief.

Requirements:

Hospital or Other Data Source:

- Required to provide data in HL7 format from its various systems (e.g., laboratory system, pathology system, radiology system, registration system, EKG, transcription)
- Provide listing of authorized clinical users to HIE and for training users on HIPAA privacy and enforcing such policies

HIE Organization:

- Responsible for training physicians on the software
- Responsible for keeping user access updated under the direction of the hospitals
- Master patient index necessary
- Provide 24/7 support of system and help desk
- Set up, monitor, and maintain network connections with all data sources
- Set up, monitor, and maintain network connections with all data recipients

<u>Who Pays?</u>: No money changes hands. However, a philanthropic foundation has committed long-term funding for operations because the HIE is seen as a public good. Grants also help pay for some system support.

Cost to Deliver the Service?: Undisclosed

Do Costs Exceed Revenue?: No

Market Characteristics That Make the Model Feasible:

- History of collaboration among hospitals
- Extremely valuable information in the clinical record provided to the clinician

Medication History

<u>Brief Description:</u> "Medication History" is an HIE service that electronically shares a patient's medication history obtained from multiple sources (e.g., PBMs) with the clinician or institution treating the patient. Often, this information is useful to hospitals to aid in their medication reconciliation process (required under hospital accreditation under the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]¹¹).

REGENSTRIEF INSTITUTE:

<u>Service Provided:</u> Medication history is made available to the appropriate clinicians electronically when a patient is registered at the hospital.

Type of Data: Medication history, formulary

Market Penetration: Live with one hospital. Other hospitals plan to sign up as well.

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¹¹ www.jointcommission.org.

Architecture:

<u>Infrastructure:</u> Uses existing connections to hospitals and Regenstrief's INPC clinical data repository for some medications. Other sources of medication history are also queried, thus requiring network connections and interfaces be set up with those data sources. Requires master patient index to match patient's records from various institutions.

Standards Used:

• HL7 standardized message format

Requirements:

<u>Hospital:</u> Required to provide list of users allowed to access the medication history information. Required to send registration information to HIE to verify patient is under treatment.

HIE Organization:

- Responsible for appropriately maintaining network connections for retrieving the medication history data either from a third-party data source or its own clinical data repository
- Responsible for connectivity to the hospitals for delivery of the medication history at the point of care
- Responsible for training on use of the software and for 24/7 support

Who Pays?: Hospitals. Could expand to physicians later.

<u>How Much Do They Pay?</u>: Undisclosed, but it is based on the number of medication histories pulled, retrieved, and matched.

<u>Cost to Deliver the Service?</u>: Leveraged existing infrastructure, network connections, and clinical data repository. Some medication history data providers charge a fee that the HIE incurs when it queries the data provider's system.

Do Costs Exceed Revenue?: No

Market Characteristics That Make the Model Feasible:

- Nothing specific required
- Applicable to all markets

ePrescribing

<u>Brief Description:</u> "ePrescribing" is an HIE service that automates the process for clinicians to prescribe medications for patients by electronically delivering the prescription information to the retail pharmacy or mail-order service.

REGENSTRIEF INSTITUTE:

<u>Service Provided:</u> ePrescribing is made available to the appropriate clinicians electronically when a patient is registered.

Type of Data: Medication history, formulary

Market Penetration: Live with one large practice

Architecture:

<u>Infrastructure:</u> Uses existing Computerized Physician Order Entry (CPOE) software in use at community health centers.

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Standards Used:

- HL7 standardized message format
- NCPDP message formats¹²
- NDC, ¹³ Medispan GPI, ¹⁴ and RxNORM CUI codes ¹⁵

Requirements:

Clinician: Receives training and uses the ePrescribing system

<u>ePrescribing Delivery Network:</u> Responsible for delivery of ePrescriptions to retail pharmacies

<u>PBM Network:</u> Responsible for providing eligibility data, formulary data, and medication history

Pharmacies: Responsible for providing medication histories

Payers: Responsible for providing medication histories

HIE Organization:

- Responsible for appropriately maintaining network connections between CPOE system and ePrescribing delivery network
- Responsible for getting Regenstrief's CPOE software certified with ePrescribing and PBM networks
- Responsible for aggregating medication history data from multiple sources from NDC code level into clinically meaningful categories
- Responsible for training clinicians on use of the ePrescribing function and for 24/7 support

<u>Who Pays?</u>: ePrescribing delivery network pays Regenstrief a portion of the fees it receives from retail pharmacies.

<u>How Much Do They Pay?</u>: Undisclosed, but it is based on the number of prescriptions processed.

<u>Cost to Deliver the Service?</u>: Leveraged existing infrastructure (CPOE software). Staff costs to get CPOE software certified with ePrescribing delivery network. Staff costs to develop necessary medication history aggregation and message management software.

Do Costs Exceed Revenue?: No

<u>Market Characteristics That Make the Model Feasible:</u> ePrescribing is easier to implement when a high proportion of patients' data is available.

Quality Metrics

<u>Brief Description:</u> "Quality Metrics" is an HIE service that shares healthcare information among multiple data sources for the purpose of quality measurement that can support provider quality initiatives and also serve as a basis for determining incentives (e.g., pay-for-performance or pay-for-quality) to providers from payers.

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¹² National Council for Prescription Drug Programs is a non-profit ANSI-accredited Standards Development Organization. See http://www.ncpdp.org/main frame.htm for more details.

National Drug Code is required by the U.S. government for each medication. See http://www.fda.gov/cder/ndc/database/default.htm for more details.

¹⁴ GPI is the Generic Product Identifier contained in MedispanTM classification system. See http://www.medispan.com/ for details.

¹⁵ RxNorm is a standard nomenclature for clinical drugs. An RxNorm CUI is a concept unique identifier. See http://www.nlm.nih.gov/research/umls/rxnorm/docs/06162005/rxnorm/docs/full061605.html for details.

REGENSTRIEF INSTITUTE / INDIANA HEALTH INFORMATION EXCHANGE:

Service Provided:

"Quality Health 1st" is a central Indiana, community-wide project that supports providers' quality improvement efforts with asynchronous clinical reminders and peer comparisons, derived from administrative and clinical data, along with incentives from payers. The program will begin with primary care physicians and use nationally recognized quality measures. It will later expand to include more measures, specialists, and hospitals. This effort will provide actionable patient-level information that will be of value to physicians, provide summary information on quality performance, and encourage rewards for quality improvement, not just high quality. The HIE will combine payer claims data with its existing clinical data repository to prepare reports for payers and providers to present quality measures that will be used for monetary incentives to providers for improvements in quality.

Data Sources:

- Payers' claims data
- INPC clinical data (which encompasses the data described in Section 5.3) housed at Regenstrief
- Laboratory and other clinical data from physicians' offices

<u>Quality Measures:</u> The initial 36 quality measures will include the AQA¹⁶ starter set and will be mutually agreed to by a formal measures committee consisting of representatives of providers and the health plans.

Reports Provided:

- Payer receives two reports:
 - Physician Level: Aggregate report by physician or practice with the patient deidentified. This report will include the physician's performance on each quality measure computed across all payers' patients.
 - o Patient Level: For the payer's members, patient level outcomes for each approved measure along with supporting data.
- Provider will receive two reports:
 - One aggregated report showing his/her performance compared to that of his/her peers

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One patient-specific report listing the quality measures, along with any relevant reminders for the patient

<u>When Delivered:</u> IHIE will deliver quality reports to providers monthly and payers quarterly.

<u>Number of Payers Participating:</u> Medicaid, Medicare, Anthem, MPlan, MDWise (Medicaid managed care organization). Equates to just over 50% of the lives in the regional market.

<u>Number of Providers Participating:</u> Estimated at 60% of primary care providers in the market (approximately 700)

Architecture:

-

¹⁶ Ambulatory Care Quality Alliance. See http://www.aqaalliance.org/ for details. Report and Recommendations on HIE Services Financial Stability AHIMA/FORE

<u>Infrastructure:</u> The HIE leverages the Regenstrief clinical repository (INPC) for data aggregation.

Standards Used:

- Claims data will be preprocessed and converted into standard HL7 formatted messages for incorporation into the payer's repository record.
- LOINC, ICD-9,¹⁷ CPT®-4,¹⁸ and RxNORM codes are used for data representation and queries.

Requirements:

Payer:

- Make claims data available to the HIE
- Provide HIE with member enrollment files regularly so the HIE knows which members belong to a payer
- Payers will use the quality reports to provide incentives to providers on the basis of their improvements or maintenance of high levels of performance.

Physician:

- Provide laboratory and other clinical data on patients to the HIE on a regular basis
- Review the quality reports for accuracy and to make sure it is the correct patient
- Practice redesign to improve quality and efficiency

HIE Organization:

- Receive claims data from payers and map the data to patients' clinical records for purposes of determining quality measures
- Receive laboratory and other patient-level clinical data from the physician's office and puts the data into a usable electronic format for the purposes of inclusion in the determination of quality measures
- Provide 24/7 support of system and help desk
- Provide quality reports to payers and providers on time
- Correct any misassociations of patients with providers
- Maintain the master patient index to enable the proper matching of patient records

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Maintain provider listing and map primary care providers to individual patients

Who Pays?: Payers subscribe to the quality metric service.

<u>How Much Do They Pay?</u>: Per member per month fee. The fee will be established on the basis of the number of lives covered by participating payers.

Cost to Deliver the Service?: Unknown at this point

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¹⁷ International Statistical Classification of Diseases and Related Health Problems (commonly referred to as ICD) provides codes to classify diseases and a wide variety of symptoms, etc. The ICD was published by the World Health Organization. See http://www.who.int/classifications/icd/en/ for details.

¹⁸ Current Procedural Terminology (CPT) is a list maintained by the American Medical Association to provide unique billing codes. See http://www.ama-assn.org/ama/pub/category/3113.html for details.

<u>Do Costs Exceed Revenue?</u>: This program is still being developed. Funds were supplied by local foundations to pay for the start-up cost.

Market Characteristics That Make the Model Feasible:

- History of collaboration among providers
- Repository of clinical data available
- Critical mass of payers willing to participate
- Critical mass of providers willing to participate
- Quality measures that have been agreed on by the providers and the payers

Other: Note that the agreements with the payers and the providers were negotiated so that their data could be used not only for this quality reporting program but also for clinical treatment of patients and some research purposes. The concept of reusing data is discussed further in Section 3.

<u>Status</u>: This project is under way but is not fully implemented. Not all participants have signed all the necessary contracts, but all have given verbal approval and many are anxious to proceed. Some claims data have been made available and are being reviewed for designing the reports. This service is anticipated to be self-sustaining within two years.

Note: Other quality reporting projects that involve aggregating data across multiple payers are under way; however, this project at Regenstrief/IHIE is the only one we are aware of that combines clinical data with claims data from the payers.

Administrative Data Sharing

<u>Brief Description:</u> "Administrative Data Sharing" is an HIE service that shares electronic administrative information related to the payment of a claim for healthcare services (e.g., claims data, eligibility) among multiple parties.

UHIN:

Service Provided:

<u>Type of Data:</u> Data related to payment of healthcare claims (including eligibility request and response, claim submission, claim acknowledgement, claim status inquiry, claim status response)

Market Penetration:

- Number of Transactions: 60 million per year
- Market Share: UHIN carries about 80% of the administrative claims in Utah.

Architecture:

<u>Infrastructure:</u> No data are stored centrally; UHIN functions more as a central gateway. Have mirrored site for disaster recovery.

Standards Used:

• HIPAA¹⁹ standard transaction X12 format²⁰

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¹⁹ Health Insurance Portability and Accountability Act.

²⁰ ANSI Accredited Standards Committee (ASC) X12 group defines electronic data interchange (EDI) transaction sets for several industries, including health care insurance. Several of the electronic transaction standards mandated under HIPAA are X12. See http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=X&Language=English and http://www.x12.org/ for more details.

• Other standards agreed to by the community and subsequently mandated state uniform claim billing by law

Requirements:

<u>Payer:</u> Required to receive and send data that are in HIPAA standard X12 transaction format and that meet the community standard

<u>Provider:</u> Required to be able to receive and send HIPAA standard X12 transactions in the community standard format

<u>HIE Organization:</u> Responsible for appropriately routing messages, maintaining the system, and enforcing standards

<u>Who Pays?</u>: 70% of revenue comes from payers and 30% comes from providers for administrative exchanges.

How Much Do They Pay?: Fees are publicly available on their Web site.

- Payer pays 17 cents per claim, with a cap of \$450,000 per year. (Note: UHIN processes more transactions than claims; thus, all other transactions are at no charge.)
- Clearinghouse pays 12 cents per non-Medicare claim and/or encounter.
- Hospital providers pay an annual fee on the basis of size: small, \$540; medium, \$2,400; and large, \$6,000.
- Medical provider (physician) pays on the basis of size of practice. Range is from \$120 for a solo practitioner to a \$9,000 annual fee for practice with more than 100 physicians.

<u>Cost to Deliver the Service?</u>: Approximately \$1.6 million per year operating expense Do Costs Exceed Revenue?: No

Market Characteristics That Make the Model Feasible:

- Payers and providers with a strong interest and presence in the state
- Payers and providers have to agree not to compete on HIE
- Determining the standards requires compromise of the stakeholders

NEHEN:

Service Provided:

<u>Type of Data:</u> Data related to payment of healthcare claims (including eligibility request and response, authorization and precertification, claim submission, claim acknowledgement, claim status inquiry, claim status response).

Market Penetration:

- Number of Transactions: 48 million per year
- <u>Market Share</u>: NEHEN has 32 members, which represents 50 hospitals and nine health plans

Architecture:

<u>Infrastructure:</u> Uses a distributed, point-to-point communication rather than a central gateway to exchange standard transactions directly among member organizations. NEHEN software required on each member site, and each member is responsible for its own disaster recovery plan.

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Standards Used:

ANSI format

Requirements:

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<u>Payer:</u> Required to have software installed to receive and send data in ANSI format

<u>Provider:</u> Required to have software installed to receive and send data in ANSI format

<u>HIE Organization:</u> Responsible for coordinating the pilot and production activities among members. Developing and supporting router technology to facilitate transaction exchange such as telecommunication protocols, version control, and so on. Using the ANSI HIPAA standards, NEHEN works with members to build consensus for common implementation.

<u>Who Pays?</u>: All participants: payers, integrated delivery systems, hospitals, medical practices, laboratory/prescription/imaging centers

How Much Do They Pay?: Onetime, start-up costs of approximately \$17,000 to \$63,000, plus a flat monthly membership fee regardless of how many transactions are exchanged.

- Membership fees are tiered according to the size of the organization since April 2007:

 Payers and integrated delivery networks: Range from \$60,000 to \$180,000 annually
 - Hospitals: Range from \$24,000 to \$90,000 annually
 - Medical practices: Range from \$12,000 to \$72,000 annually
 - Laboratory/prescription/imaging centers: Range from \$12,000 to \$36,000 annually

<u>Cost to Deliver the Service?</u>: Undisclosed, but costs are allocated as follows: 27% strategic planning and member services, 33% implementations and technical support, 40% new projects and activities

Do Costs Exceed Revenue?: No

Market Characteristics That Make the Model Feasible:

- Willingness for participants to collaborate for the good of the entire healthcare community
- Large payers and providers who are willing to pay for and install software on their system

Credentialing

<u>Brief Description:</u> "Credentialing" is an HIE service that centralizes and shares the information necessary for clinicians to become credentialed at healthcare institutions and/or with payers.

UHIN:

Service Provided:

UHIN provides a hosted, online credentialing tool for clinicians to have one place to store the data about themselves that are required when applying to be credentialed at healthcare institutions and with payers. The clinician can push the data to a hospital, for example. UHIN has also contracted with a company to verify that all the necessary data are complete before being pushed.

<u>Type of Data:</u> Data about the clinician (e.g., name, address, unique physician identifier number (UPIN), academic degrees, board certifications)

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<u>Market Penetration:</u> UHIN just began marketing this product, so it has limited subscription at this time. However, it is growing rapidly.

Architecture:

<u>Infrastructure:</u> The clinician's data are stored centrally. Have mirrored site for disaster recovery (leveraged from other core service).

<u>Standards Used:</u> The community has created a standard data set and data format (xml).

Requirements:

<u>Payers and Healthcare Institutions:</u> Can receive the credentialing information through the subscription service

<u>Clinician</u>: Required to enter his/her data into the system. Clinician then grants permission for other institutions to receive the data.

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<u>HIE Organization:</u> Responsible for appropriately routing messages and maintaining the system

Who Pays?:

- Clinicians to enter the data and pass it to payers and healthcare institutions
- Payers and healthcare institutions that use the service to receive electronic credentialing applications

How Much Do They Pay?: Fees are publicly available on their Web site.

- Clinician pays on the basis of the size of practice. Range is from \$55 for a solo practitioner to \$7,500 annual fee for practice with more than 100 physicians.
- Payer pays on the basis of the number of covered lives: If fewer than 100,000, the fee is \$4,000 per year. If more than 100,000, the fee is \$7,500 per year.
- Hospital pays an annual fee on the basis of size: small, \$450; medium, \$2,000; and large, \$5,000 annual fee.

Cost to Deliver the Service?: Less than \$50,000 per year

Do Costs Exceed Revenue?: No

<u>Market Characteristics That Make the Model Feasible:</u> The bulk of the healthcare market (both payers and providers) is domiciled in Utah.

TASK #3

The Role of State Medicaid Programs and Their Involvement with Health Information Exchange Initiatives

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1 Overview of Task #3 Scope

Task: Explore the role of state Medicaid programs and their involvement with health information exchange (HIE) initiatives.

The Office of the National Coordinator for Health Information Technology (ONC) contracted with the Foundation of Research and Education (FORE) of the American Health Information Management Association (AHIMA) for a series of follow-on reports to their Development of State-Level Health Information Exchange Initiatives project. Avalere Health (Avalere) was contracted to complete Task 3 of this work, the objective of which is to explore the role of state Medicaid programs and their involvement with HIE initiatives.

Avalere conducted interviews with:

- Nine HIE initiatives represented on the AHIMA Steering Committee;
- Five additional HIE initiatives from the AHIMA candidate list;
- Two state Medicaid officials:
- Four representatives from a regional Centers for Medicare and Medicaid Services (CMS)
- One representative from the Center for Medicaid and State Operations (CMSO).

Appendix A contains the full list of interviewees, their organizations, and relevant contact information.

Appendix B lists the Avalere Health project team.

Appendix C is a copy of the HIE interview guide.

2 Background on Medicaid

Established in 1965 under Title XIX of the Social Security Act, Medicaid finances health and longterm care services for more than 55 million low-income children and adults, including the elderly and individuals with disabilities. Each state operates its own Medicaid program with flexibility in benefit design and payment; as a result, there are substantial differences in how state Medicaid programs are structured and implemented nationwide. The federal government provides states with matching funds and through the CMSO oversees state operations. The federal portion of Medicaid's 2004 operating expenditures totaled just over \$172 billion.¹

Over the years, Medicaid has become one of the states' largest budget items, a trend that has raised much concern and is not expected to wane in the near term. Demographic changes, including growing numbers of uninsured, disabled, and elderly Americans, suggest continued increases in Medicaid enrollment and use. Consequently, Medicaid remains the focus of intense scrutiny from state and federal governments alike.

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¹ Kaiser Commission on Medicaid and the Uninsured, 2004 Medicaid Tables (CMS-64), Table 1, Federal and State Share of Medicaid Expenditures, Task #3 - Page: 3

As states struggle to provide high-quality healthcare services to an expanding population, they use a variety of reform mechanisms to manage costs and improve efficiencies under growing budget constraints. States rely on the overall flexibility of the Medicaid program and use waivers and state plan amendments to revise their program design and alter Medicaid eligibility requirements, reimbursement rates, and benefit offerings.

Federal and congressional leaders have responded to growing concerns to address costs and sustainability issues in Medicaid. The Secretary of Health and Human Services (HHS) established a Medicaid Commission in May 2005 to issue recommendations about how Medicaid could make meaningful and lasting programmatic changes while realizing significant savings. Congress passed the Deficit Reduction Act (DRA), which was signed into law by President Bush on February 8, 2006. Section 6081 of the DRA authorizes new grant funds, known as Medicaid Transformation Grants, for states to adopt innovative methods to improve effectiveness and efficiency in the Medicaid program. Through these grants, CMS will offer \$75 million in fiscal year 2007 and another \$75 million in fiscal year 2008. States may propose grant projects that seek to improve Medicaid's effectiveness in several areas, including improving patient safety and reducing medical errors; advancing adoption of health information technology (HIT), such as electronic health records (EHRs) and electronic prescribing; and reducing fraud, waste, and abuse.

Despite a set of federal initiatives to modernize Medicaid's information technology infrastructure, most states continue to operate a patchwork of dated legacy systems, referred to as the Medicaid Management Information Systems (MMIS). MMIS are used to manage patient information, support the transmission of claims data, and adjudicate claims. The federal government offers states significant matching funds, referred to as Federal Financial Participation (FFP), to modernize and upgrade MMIS. States regularly tap into these funds but rarely make significant changes to their systems. Most MMIS today do not offer functionalities, such as provider-accessible EHRs, that address issues ancillary to Medicaid's core administrative needs (e.g., claims processing). CMSO is working to establish a framework for modernization of MMIS through the Medicaid Information Technology Architecture (MITA) initiative. This initiative is intended to implement IT standards and promote IT interoperability in state Medicaid programs, yet a full rollout of MITA into state Medicaid programs is not expected for at least five years.

Although Medicaid systems house a robust set of administrative data, only recently is a small set of states beginning to consider how HIT could bring enhanced utility to these data and generate increased efficiencies, cost reductions, and greater access to higher quality care for Medicaid beneficiaries. Both the recommendations from the Medicaid Commission and the grants that CMS accepts have the potential to help states reform their Medicaid programs through the use of HIT. The following sections examine Medicaid's role in HIE initiatives nationwide, consider the barriers and drivers to their engagement, identify potential opportunities and value for Medicaid's participation, and present a set of recommendations for key HIE stakeholders to facilitate change and promote Medicaid's participation.

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maintenance. Role of State Medicaid Programs with HIE Initiatives AHIMA/FORE

² The federal government contributes 90% to the cost of MMIS design, development, and implementation and 75% for system operations and Task #3 - Page: 4

3 Medicaid Engagement in HIE Initiatives

The automated exchange of health information across care settings is expected to yield numerous benefits to an array of stakeholders. A mechanism to increase the safety and quality of care, HIE can increase access to information at the point of care, offer greater continuity and care coordination, and reduce medical errors and redundancies in delivered services. The use of HIT and more consistent exchange of health information can also help generate a better understanding of health outcomes for specific populations, and Medicaid beneficiaries are no exception.

However, the research and interviews conducted for this project confirm that state Medicaid agencies currently have limited involvement with HIE initiatives. This section discusses the findings from the HIE initiatives' perspective in more detail, including the ways in which Medicaid is and could be involved, the benefits of HIE, the value of Medicaid's involvement, and factors in the political environment that foster or hinder Medicaid's engagement in HIE.

With an overarching goal of improving quality of care through electronic exchange of health information, hundreds of HIE initiatives have emerged across the country. HIE initiatives possess their own unique goals and priorities but typically engage a broad array of stakeholders including physicians, hospitals, health plans, employers, consumers, laboratories, and state government. Although many initiatives may solicit representation from the state (e.g., governor's office or HHS), few to date have actively engaged Medicaid as a stakeholder. Consequently, almost all HIE initiatives interviewed have sought some type of Medicaid involvement, but few have successfully engaged Medicaid in their HIE initiative beyond an advisory role.

Regardless of low participation rates, many HIE initiatives see value in working with Medicaid and expect its involvement to have a positive effect. Interviewees frequently cited a shared focus on quality promotion and cost reduction and Medicaid's prominence as the largest healthcare purchaser for low-income and vulnerable populations as key factors underlying the desire for Medicaid participation. Interviewees also emphasized the positive effect of Medicaid's involvement through greater access to data, an increased emphasis by the HIE on vulnerable populations, access to new and alternative grant opportunities (e.g., transformation grants), and heightened visibility and credibility for the HIE.

Medicaid's type and intensity of involvement in HIE initiatives today varies significantly. Medicaid can play many roles for an HIE initiative, such as a data source for either or both administrative and clinical data (e.g., claims or laboratory data), and a data recipient. In some current initiatives, the Medicaid agency serves in an advisory capacity through involvement in a governing board, workgroup, or other committees. In this capacity, Medicaid represents a large state payer and can also advocate for the unique needs of its beneficiaries. Some HIE initiatives have only begun their outreach to Medicaid to inform the program of the initiative's activities, whereas others have been attempting to build a relationship with Medicaid for some time. Most, however, have only recently established a connection. For many initiatives, assisting their Medicaid program in preparing Medicaid transformation grant applications was the first targeted encounter with Medicaid. In many cases, interviewees hope these grants will be the tipping point to establish and solidify a formal partnership with Medicaid.

In some states, external state government factors set the stage for Medicaid involvement in HIE,

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often facilitating the process for HIE initiatives to engage Medicaid directly. For example, in similar fashion to the president's Executive Order calling for widespread, interoperable EHRs for all Americans by 2014, a growing number of governors have issued Executive Orders making HIT adoption and HIE a priority in their states. Several state legislators who understand the potential benefits of HIE have appropriated funds to promote HIE and have even encouraged Medicaid to increase its investment in HIE (e.g., in one state, representatives called for continued HIE adoption when it produced cost savings in the previous year). In addition, states with prominent Medicaid directors who are focused on quality improvement initiatives have less difficulty understanding the HIE initiatives' potential benefits and value proposition for Medicaid and are more willing to engage.

These same political forces can also can promote or inhibit Medicaid's participation over time. Several interviewees who were involved with Medicaid through changes in political administrations found that this forced turnover can yield new HIE champions or remove existing proponents. The budget cycle can also alter the relationship between Medicaid and HIE initiatives. For example, if budget constraints increase, and HIE involvement is perceived as requiring additional resources, the partnership may be jeopardized; however, if HIE is seen as a mechanism that generates cost savings, the relationship between Medicaid and HIE initiatives may be improved.

4 Barriers to Medicaid's Engagement

As previously discussed, there are many roles Medicaid can play in HIE initiatives and many ways that Medicaid can bring and receive value by engaging; however, enormous barriers stand in the way. For most Medicaid agencies, their first priority is managing their programs and their evergrowing patient populations in a cost-constrained environment. New investment in technology and initiatives focused on improving care delivery (through external partnerships or other means) that cannot clearly identify a value proposition and clear return on investment for Medicaid are not an immediate priority. This section describes the range of barriers to HIE involvement and the different perceptions of these barriers from both HIE initiatives and Medicaid representatives.

HIE initiatives have a general appreciation for the operational constraints facing Medicaid programs across the country and realize they represent significant challenges that must be overcome to engage Medicaid as a vested stakeholder. Although some of these barriers are hurdles HIE initiatives must manage with any stakeholder, many were perceived as issues unique to Medicaid agencies.

The following list is a synthesis of the key barriers identified through the interviews with HIE initiatives:

- Navigating agency bureaucracy is difficult.
- Medicaid's decision-making processes and contracting mechanisms are confusing and often arcane.
- Medicaid agencies seem fragmented and siloed in their organizational structure.
- Legacy systems are cumbersome and often difficult to manage.
- Political turnover in states directly affects Medicaid agency leadership and often stifles progress in trust building and education.

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 Medicaid agencies are risk averse and extremely protective of their beneficiaries' information.

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 Many Medicaid agencies are very conservative in their interpretation of federal and state privacy and security laws.

Both Medicaid and HIE interviewees agreed, however, that most Medicaid agencies have yet to see a proven value proposition for engaging with HIE initiatives and that Medicaid is heavily focused on its day-to-day operational responsibilities (e.g., paying claims and ensuring access to providers for Medicaid beneficiaries), which limits their ability to focus or commit resources to activities not primary to their mission.

4.1 Medicaid's Leading Priorities

Medicaid interviewees strongly agree that Medicaid has a different set of priorities. As mentioned, their fundamental responsibility is to provide services for a distinct population and to do so under an ever-tightening budget. Although HIE projects have the potential to help support this population, if HIE initiatives are unable to advance the mission and priorities of Medicaid or are viewed as shifting Medicaid's focus away from addressing these issues, interviewees felt that Medicaid should not be involved. However, given that so many initiatives are relatively immature and do not have sustainable revenue models, Medicaid interviewees see involvement with these unproven programs as risky and are hesitant to engage.

4.2 Medicaid's Financial Constraints

Under pressure to contain costs, Medicaid agencies typically have limited staff and financial resources to contribute to what may be perceived as external technology initiatives. In addition, they often must maintain budget neutrality throughout any new investments. Given the financial investment required to receive the FFP match combined with the unknown return on investment (ROI) of participating in an HIE initiative, state Medicaid agencies are challenged to justify the upfront investment of resources, both staff and financial. Interviewees from Medicaid leadership and HIE initiatives alike acknowledged these issues and viewed them as a substantial challenge.

4.3 Lack of HIE Champion

Lack of an HIE champion and insufficient political will to engage in an HIE initiative significantly affect a Medicaid agency's successful participation in more advanced HIE. Several Medicaid interviewees acknowledged that their effective participation in HIE was heavily influenced and dependant on their pro-HIT leadership. However, according to several state Medicaid and HIE initiative interviewees, this lack of political will can often be traced, in part, up to national Medicaid leadership.

4.4 National Medicaid Leadership

Interviewees attribute the absence of individual state Medicaid programs in state-level HIE to the lack of national Medicaid leadership (e.g., CMS, HHS). They stressed that national leadership does not see HIE or HIT adoption as core to Medicaid's mission. Rather, the national office focuses on quarterly spending issues, which sends a message to states that current operations are the priority.

Several interviewees also indicated that federal leadership sends mixed and sometimes conflicting

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messages about what kind of data sharing might be permissible under Medicaid. Some HIE initiatives identified legal barriers to exchanging Medicaid beneficiary information with non-Medicaid providers. Given the frequent turnover among Medicaid beneficiaries, as individuals shift in and out of Medicaid eligibility, this becomes an even more relevant and acute issue.

Despite the perceived lack of HIE focus from national leaders, there are several HIE proponents in CMS, CMSO, CMS regional offices, and local Medicaid programs. Unfortunately, individually, many are not in the position to create sweeping change in Medicaid. In addition, these proponents may cycle in and out of their positions, increasing the challenge to promote change in any one area of Medicaid. To date, there are relatively few regular forums for these individuals to collaborate and communicate consistently with HIE initiatives, yet many of the Medicaid interviewees remain optimistic about the benefits of HIE and the development of a strong value proposition for Medicaid to engage in HIE.

5 Finding a Value Proposition for Medicaid

Almost all interviewees agreed that for Medicaid to see the direct benefit of HIE, these initiatives must address specific business problems that Medicaid faces today. Interviewees from state-level initiatives and state and national Medicaid leadership suggested an initial set of HIE target areas that focus on potential benefits for Medicaid in cost containment and quality improvement through care coordination program integrity and physician participation. A commonly accepted premise in the value proposition for HIE is that financial benefits often do not accrue equally to all stakeholders and often may disproportionately benefit payers more than others. In identifying value propositions for Medicaid, one of the largest healthcare plans in many states, highlighting enhanced benefits to Medicaid as a payer may underscore the value to the agency. This section further discusses specific areas with great potential benefit to Medicaid and those that may most effectively illuminate the value proposition for Medicaid programs.

5.1 Care Coordination

The exchange of electronic patient information and access to patient medication histories can facilitate better information at the point of care for physicians and more comprehensive care coordination and higher quality care for Medicaid beneficiaries. Subgroups of the larger Medicaid population (e.g., dually eligible beneficiaries—those who receive coverage from both Medicaid and Medicare—and the disabled) tend to have multiple comorbidities and are often transient. As a result, they often see multiple providers, including their primary care physician and several specialists. These providers can be geographically dispersed and operate in a paper-based system, yielding inaccurate or partial patient information at the point of care. This information gap can lead to redundancies, inappropriate care, and medical errors that yield poor quality outcomes and more costly care if left unaddressed. HIE could help to narrow this gap.

5.2 Cost Containment

HIE also has the potential to contain costs, a clear priority for most state Medicaid agencies. The use of electronic records as opposed to paper-based records is one cost-saving example. EHRs can minimize the need for physical space to store paper charts, enable more timely submission of

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reports and diagnostic results, reduce the need for follow-up by administrative staff, and reduce duplicative tests. However, some critics would argue that regardless of the potential for long-term cost savings that HIE can bring to Medicaid, the initial cost to invest in HIE would remain prohibitive.

5.3 Fraud and Abuse

Medicaid programs across the country continue to struggle with detecting and managing fraud and abuse, such as inappropriate billing patterns, within their systems. The use of HIE can aid in the detection and prevention of fraud and abuse, particularly if claims and clinical data are accurately linked. For example, participating in an HIE initiative would enable Medicaid agencies to detect and identify "doctor shoppers" and "drug seekers" or individuals who are redeeming prescriptions from multiple physicians and who are abusing the system and posing harm to themselves. EHRs may also be used for audit purposes and could streamline program integrity review processes. By more effectively understanding these activities and patient behaviors, Medicaid programs would be able to support targeted interventions with beneficiaries and providers to strengthen the integrity of the overall program.

5.4 Physician Participation

Medicaid beneficiaries' access to providers is critical to Medicaid's ability to provide and ensure high-quality care. However, several state Medicaid programs struggle with retaining sufficient numbers of providers. Medicaid involvement with an HIE has the potential to promote physician participation and retention. Through EHR-focused projects, HIE initiatives can give providers ready access to information on Medicaid beneficiaries at the point of care and can streamline Medicaid's administrative and claims processes, which can facilitate provider payment. HIE initiatives also have the potential to help align Medicaid's claims systems with other payer systems regularly used by providers.

6 Mechanisms to Increase Medicaid Involvement in HIE

Interviewees identified several vehicles in place today that can facilitate Medicaid's involvement in HIE initiatives, including transformation grants, waivers, IT infrastructure initiatives, managed care and disease management initiatives, and CMS-focused quality initiatives. Some activities generated more interest among interviewee stakeholder groups and provide the opportunity for Medicaid to collaborate with ongoing activities in a new way, whereas others may facilitate Medicaid engagement over the longer term. This section will discuss these opportunities in more detail.

6.1 Medicaid Transformation Grants

As referenced earlier in this report, Medicaid Transformation Grants are considered a popular and new strategic opportunity for HIE initiatives to work with and on behalf of state Medicaid programs. Of the more than 165 applications submitted to CMS, more than half are estimated to include HIT components. Some proposed projects include promoting electronic prescribing, developing electronic medication profiles, and facilitating the use of broadband activity in rural areas.

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6.2 Waivers

Although states do not have demonstration authority outside of waivers, they may use waivers specifically to support investments and participation in HIE. Waivers are a mechanism for states to propose and implement alternatives to standard benefit design, cost sharing, and eligibility requirements. However, waiver proposals must be budget neutral and incur no new net cost to the Medicaid program. Section 1115, on research and demonstration projects specifically, test policy innovations that are likely to further the objectives of Medicaid programs. Waivers could be used to support HIE investment and implementation costs where there is demonstrable, positive ROI. States, however, have not yet taken advantage of this creative opportunity.

6.3 MMIS and MITA

FFP associated with the development, implementation, and maintenance of MMIS is one opportunity in which states can receive financial assistance with their investments. MITA specifically provides a framework that states should use when designing and procuring new systems to ensure interoperability with other entities. Upgrading systems by using MITA principles, the state Medicaid program would receive up to 90% FFP. Although these funds could improve Medicaid's IT infrastructure, with appropriate design changes, they could also facilitate their participation in an HIE initiative. Matching funds may be enticing to some Medicaid programs; however, this approach may not be feasible for programs that still struggle to secure the necessary capital for the FFP.

In addition, although the MITA framework holds potential to modernize Medicaid's IT systems and incorporate clinical data components, the framework is still under development, and it will likely be at least five to eight years before the framework is complete and ready for broad implementation. Although some states are early adopters of initial components of the MITA framework, they are unlikely to realize benefits or cost savings until much further into the future. The current level of involvement and progress varies by state.

6.4 Leveraging Current Contracts

States could also use the existing technological infrastructure and construct their contracts to foster HIE. States with high managed care penetration or disease management contracts or those where outside contractors implemented HIE demonstration projects could work with these contractors to engage in community-based HIE and leverage their experience through new programs that target Medicaid beneficiaries. Partnering with managed care, for example, would also allow state agencies to use data for pay-for-performance programs, programs that are not widely established in fee-for-service Medicaid.

6.5 Collaboration around Dually Eligible Beneficiaries

State Medicaid agencies may also collaborate with the Medicare program and leadership to focus on quality of care for dually eligible beneficiaries. One way is through Programs of All-Inclusive Care for the Elderly (PACE). Discussions around Medicare's approach to HIE cite differences with Medicaid's approach. Medicare addresses the issues as part of a dialogue around quality, whereas

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Medicaid frames it as standards and interoperability. Ultimately, Medicaid may choose to replicate demonstration programs currently under way in Medicare.

6.6 Medicaid as a Partner with the Medicare Program

CMSO, in its August 2005 memo on the Medicaid/State Children's Health Insurance Program Quality Initiative,³ states that it will work with partners to promote the use of HIT. Specifically, CMSO indicated that it would join the CMS Quality Council HIT Workgroup to develop models for states to invest in HIT. Moreover, the Division of Quality, Evaluations, and Health Outcomes was charged with compiling information for and providing technical assistance to states on HIE. This is a new division, however, and to date CMS has focused first on issues related to quality performance measures, not HIE. Fostering transfer of knowledge across states on HIE remains a priority for the division, but more time is needed to see how the division will address it specifically.

7 Recommendations

This section presents recommendations on how HIE initiatives and Medicaid can address the barriers and challenges described throughout the report and work together to advance HIE. These recommendations, which target HIE initiatives, Medicaid agencies, and CMS, are based on interviewee and AHIMA Steering Committee input and contractor expertise and are not prioritized. Some recommendations can be achieved in the short term, but others will require action over the longer term.

7.1 HIE Initiatives

Interviewees from HIE initiatives and state Medicaid agencies alike cited the lack of a sufficient business proposition as a major barrier to Medicaid engagement. Short-term recommendations focus on selecting projects for Medicaid collaboration that are well suited to the needs of both parties. Long-term recommendations direct HIE efforts toward participation in state Medicaid planning activities.

Short Term

- Identify successful HIE case studies and begin to identify best practices for the principles of HIE as they relate to Medicaid
- Explore what Medicaid needs from an HIE initiative
 - Develop and target value propositions that fit with Medicaid's top business needs or reform priorities
- Develop HIE champions within Medicaid agencies
 - o Engage early, educate Medicaid leadership and staff, be persistent, and collaborate

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- Include Medicaid leaders in HIE initiatives' governance, planning, and leadership activities
- Pursue assistance and support from the governor and legislators
- Enlist the support of physician leaders and HIT champions to articulate how Medicaid's involvement in HIE initiatives could increase physicians' willingness to work with Medicaid

- Successful engagements should:
 - o Meet the needs of both parties
 - May start with more discrete, targeted projects (e.g., medication lists, electronic prescribing, laboratory data) before expanding to widespread data exchange supporting Medicaid beneficiaries
 - o Focus on what will be most readily understood by Medicaid
 - o Build a case on the basis of previous success and demonstrated ROI

Long Term

- Promote and position the benefits of HIE in the context of the state's overall health goals, programs, and needs to increase buy-in for Medicaid's involvement in HIE
- Demonstrate ROI to show HIE cost savings and/or efficiencies for Medicaid
- Demonstrate how Medicaid involvement is critical to coordination of care and long-term care
- Monitor and report on the results of transformation grants that promoted HIE

7.2 State Medicaid Programs

These recommendations push state Medicaid programs to use and leverage existing relationships and infrastructure to lay the groundwork for further and future investment in HIE. Long-term recommendations suggest working with external stakeholders. Additional initiatives like MITA may require additional time for development before they are truly suitable and offer direct benefits and opportunities for Medicaid to work with HIE initiatives.

Short Term

- Explore managed care and disease management organizations and programs as levers to increase HIE engagement and use of HIT
- Explore potential to participate in demonstration programs or develop demonstration-like programs to test HIE in Medicaid
- Consider collaboration with other states that share Medicaid contractors engaged in privatesector HIE

Long Term

- Work with the state to identify and articulate state needs and to coordinate HIE interests across state programs and agencies
- Work with CMS and other state agencies on shared priorities for underlying HIE capabilities
- Look for opportunities where HIE could facilitate collaboration across agencies
- Use MITA to incorporate HIE initiatives into MMIS upgrades
- Collaborate with CMS to develop a more coordinated Medicaid/Medicare HIE strategy to better manage dually eligible beneficiaries

7.3 CMS

Recommendations to CMS call on the agency to demonstrate strong national leadership by defining a clear position on HIE in and across state Medicaid programs, while also serving as a clearinghouse for information and guidance about the collaboration process.

• Issue policy statements that support Medicaid's involvement in HIE, clarify the appropriate

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- sharing of data, and are consistent with other agency HIE priorities
- Help develop state-based and national-level business cases for Medicaid's involvement in HIE initiatives
- Issue a policy statement that supports and defines FFP for state Medicaid investment in HIE
- Assemble a tool kit with best practices and instructions for states to incorporate HIE successfully into MMIS to receive FFP
- Create a central point of contact for HIE and Medicaid issues that could serve as a knowledge base and provide leadership
- Foster increased dialogue between Medicaid officials and staff on the topic of HIE
- Circulate best practices for legal and contracting templates that promote HIE (e.g., successful waiver applications and legal contracts)
- Explore opportunities for Medicaid to build on Medicare quality and HIE work under way (e.g., the Doctor's Office Quality—Information Technology [DOQ-IT] program, the Personal Health Record [PHR] Feasibility Test, and the beneficiary portal focusing on engagement of physicians working with dually eligible beneficiaries
- Examine outcomes and disseminate findings from grant programs, particularly transformation grants and MITA implementation

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⁴ The DOQ-IT project is a national initiative that promotes the adoption of EHR systems to improve quality and safety for Medicare beneficiaries in small- and medium-sized physician offices.

⁵ The PHR Feasibility Test is a component of a larger CMS PHR action plan that describes a number of ways that CMS can help promote the growth of PHRs and ensure that beneficiaries have private and secure access to their own healthcare information.

⁶ The Medicare Beneficiary Portal (MyMedicare.gov) is an Internet portal allowing registered beneficiaries the ability to view eligibility and entitlement information, as well as enrollment information including prescription drug plans, deductible, and address of record information. Role of State Medicaid Programs with HIE Initiatives Task #3 - Page: 13

Appendix A—Interviewees

The opinions expressed by those interviewed for this project are their own and may not reflect the opinions of their respective organizations.

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Appendix B—About the Authors

The Avalere Health project team for Task #3 included: Gregory Fuller, Project Manager Madeleine Konig Shannah Koss Sheera Rosenfeld

Avalere Health is a leading strategic advisory firm in the healthcare field. The company provides strategy, research, and educational products to a range of commercial and nonprofit customers with interests in improving the healthcare system. Founded in 2000, the company was initially known as The Health Strategies Consultancy. The name was changed in 2005 to reflect the unique nature of the firm's products and services.

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Appendix C—HIE Interview Guide

Interview Questions

1. How important is Medicaid involvement to the following formative activities for HIE initiatives identified in AHIMA's *Development of State-Level Health Information Exchange (HIE) Initiatives* report?

	Importance					
Formative Activity		None	Mini mal	Moderate	Significant	
Assessing Market Characteristics						
Identifying Champions and Key Stakeholders						
Determining the Role of the HIE Initiative						
Establishing Governance Structure						
Developing Financial Model for Sustainability,						
Formulating Policies, and Setting Up Operations						
Identifying Short- and Long-Term Priorities						
Reassessing Original Assumptions and Plans						

	Reassessing Original Assumptions and Plans
I.	Medicaid Involvement in Your HIE Initiative
2.	Is your state's Medicaid agency currently involved in your HIE initiative? Yes (Skip to Question #6) No
3.	Has your organization been involved in discussions with your state's Medicaid agency regarding potential involvement in your HIE initiative? Yes No Unsure Intend to
4.	Is your state Medicaid agency considered a key stakeholder for your current or future HIE initiatives? Yes (Please identify why Medicaid, as a key stakeholder, is not currently involved) No (Please identify why Medicaid was not identified as a key stakeholder) Lack of perceived Medicaid interest/support Lack of other stakeholder interest/support to pursue Medicaid Limited funding (by whom?) Unwilling to share data Other:
5.	How knowledgeable are you about Medicaid and HIE in your state? Not knowledgeable (Skip to Question #25) Slightly knowledgeable (Skip to Question #20) Moderately knowledgeable (Skip to Question #20) Very knowledgeable (Skip to Question #20)
6.	How knowledgeable are you about the Medicaid participation in your HIE initiative? Not knowledgeable Slightly knowledgeable Moderately knowledgeable Very knowledgeable
7.	How closely do you work with the Medicaid representative in your HIE initiative? \[\sum \text{Not at all} \sum \text{Frequently} \] \[\sum \text{Occasionally} \sum \text{Regularly}
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8.		parison to other stake processes (e.g., in t More				
9.	How is apply:	your state's Medicaid	d agency currently in	volved in your HIE	initiative? Please i	ndicate all that
	арріу.	☐ Data source ☐ Data recipient ☐ Funder	What type: What type: Of what: pilot project		echnology, other:	
		☐ Board member ☐ Workgroup/com ☐ Advocate/repres	HIE initiative (planni mittee member: Wh entative for Medicaio nts are target popula	ich committee		
10.	How lo	ng has Medicaid bee	☐ Initial im	pacity? plementation (pilot ementation)	
11.	Why w	☐ Medicaid identifi☐ Medicaid identifi☐ Medicaid recipie	cutive Order	ng source source ential target popular	tion for HIE (e.g., c	hronic illness)
12.	Who in	External facilitate	representative rom Medicaid agencor or convener (e.g., as contractor or other	state); Please spe	cify:	
13.	Has the	e nature of the Medic Yes (please des No Unsure	aid relationship char cribe why, if possible			
14.	How, if	at all, has the level of Increased Decreased	f Medicaid involvem	ent changed?	☐ No change ☐ Unsure	

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II. Medicaid and HIE: Effect and Lessons Learned

15. How has the relationship with Medicaid affected the HIE initiative? Please indicate all that apply.

	Type of Effect					
Effect on HIE Initiative	Improved/ Increased	Hindered/ Decreased	No effect/ No change	Unsure/ N/A		
Availability of funding for HIE						
Pace of initiative planning, development, or implementation						
State representation on HIE initiative's board						
Visibility of HIE initiative						
Credibility with other stakeholders						
Access to patient data for HIE						
Exchange of data on vulnerable populations						

16. Given your experience, what strategies should other HIE initiatives use to engage Medicaid?
17. When should these types of activities occur? From the outset of the HIE initiative During HIE initiative's early planning and development phase During HIE initiative's implementation phase Other:

III. Barriers

18. A list of potential challenges to engaging Medicaid in HIE is provided below.

Given your experience, which of these challenges have been a factor for your HIE initiative?

Please indicate the severity of each potential challenge and rank the most significant ones indicated in the first column (1=most significant).

	Degree of Challenge						
Challenge	Significant		Manageable	Modest	None		
		Rank	V	√	$\sqrt{}$		
ROI/Value proposition							
Funding/Medicaid "crisis"							
Privacy and security							
Lack of political will							
Lack of HIE champion							
Medicaid engagement in competing/other state HIE initiatives							
Medicaid's competing priorities							
Data-sharing restrictions							
Lack of flexibility of Medicaid program/waiver							
Other:							

19. Given your top two barriers (identified in the first column from the table on page 3), what do you see as the key role(s) of the following stakeholders in addressing these issues?

See table on next page for list of stakeholders.

	Key Role for Stakeholder					
Stakeholder	Barrier #1	Barrier #2				
CMS						

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Medicaid/	
Medicaid Director	
State Legislature/Governor	
Leadership/	
Governance of HIE initiatives	
Federal Government/US	
Congress	
Other:	
edicaid and HIE in Your State	

IV. M

recipients? Yes No Unsure	1
21. Are there other HIE efforts in your state currently working with the Medicaid agency? Yes (Please explain in what way) No Unsure	
22. Is there an "HIE Champion" in your state's Medicaid agency or state government? Yes (Please identify who and their title) No Unsure	
23. Has your state's Medicaid agency pursued waiver options (e.g., 1115) to support HIE activities? Yes (Please describe, if possible) No Unsure	1

24. How much flexibility does your state Medicaid agency have to make decisions around the following areas?

		Degree of Flexibility				
Decision Area	Un	Un None Low Moderate Sub				
	sur					
	е					
Investment in HIE						
Promotion of HIE						
Requiring HIE						

V. Other Federal Public Payer Structures

25. Which, if any, of the following federal public payers have played a role in your HIE initiative? Where relevant, please indicate the degree of involvement and briefly characterize its nature.

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See table on next page for list of federal public payers.

	Degree of Involvement			
Federal Public Payer		Low	Moderate	Substantial
Medicare				
Veterans Affairs (VA)				
Department of Defense (DoD)				
Federal Employees Health Benefits Program (FEHB)				
Other				

Nature of involvem	nent:								
26. What role(s), if any initiatives?	,, should the federal gov	ernment play in coordina	ting state Medicaid ar	nd HIE					
☐ Set sta	Set standards for Medicaid information systems								
	Require states seeking Medicaid waivers to incorporate HIT								
	Offer incentives for states to incorporate HIT in Medicaid waivers								
	Require state Medicaid agencies to demonstrate investment (direct or indirect) in and								
	orate with local HIE initia		(4	,					
	e federal financial suppor								
	s privacy and data-shari								
		dicaid agencies around F	liF						
Other:		_							
									
VI. MITA									
enterprise. MITA will e Medicaid program adm	establish national guidelii ninistration. It includes ar	grated business and IT trans nes for technologies and n architecture framework, t common objectives with	processes that can en processes, and plant	nable improved ning guidelines					
MITA's common busin	ace and tachnology visic	on for state Medicaid agei	nciae amphaeizae:						
		t constrained by organiza							
			illoriai barriers						
	standards (with, but not I		d coroso statos co w	مال مع بييناه					
		dicaid agencies within an	d across states, as we	en as with					
	olved in healthcare delive	• /							
	d access and integration	1							
5. Software r		Setting (COTO)							
	mmercial Off-the-Shelf S	Software (CO15)							
7. Integration	n of public health data								
☐ Not kno	v, how knowledgeable we owledgeable (Skip to Qu v knowledgeable		tive? derately knowledgeat hly knowledgeable	ble					
28. Is your HIE initiativ	ve involved with MITA in	vour state?							
Yes			□ No V	Vhy not?					
	this involvement?		Insure	,					
Trataro or			7110410						
29. How do you think a	adopting MITA will affect	each of the following?							
		Hinder	No Affect	Advance					
HIE in your state									
Your HIE initiative									
Medicaid's involvement in	n HIE generally								
Medicaid's involvement in									
1111 : 1 () 1 1									

30. What role(s) could HIE initiatives play in advancing the adoption of the MITA framework and principles?

31. How would you characterize the level of support/political buy-in for MITA from the following stakeholders?

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	Deg	ree of	Support/Polit	ical Buy-In
MITA Stakeholder	None	Low	Moderate	Substantial
Your HIE initiative				
The state Medicaid agency				
CMS				
Other:				

VII. Additional Comments or Recommendations

32.	Should a Medicaid official be included in the governance structure Yes No Why or why not? If yes, when should this happen? When interests of both parties align (e.g., when HIE is versa) From the onset of the HIE initiative During HIE initiative's early planning phase During HIE initiative's implementation phase Other:	
33.	Is there anything else that you think would be helpful to know abo addressed by this survey?	ut Medicaid and HIE that was not
VIII	.Background Information on Your HIE Initiative	
34.	Please identify the type of legal entity that best describes your HIE Not-for-profit 501(c)(3) charitable organization Not-for-profit 501(c)(4) social welfare organization Not-for-profit 501(c)(6) mutual benefit organization Virtual HIE that is linked contractually but with no sepa Quasigovernmental entity State agency Partnership or limited liability corporation (LLC) pass-tl Special joint powers authority Cooperative	arate new entity
35.	What was your HIE initiative's initial priority for data exchange? Medication management EHRs ePrescribing Clinical messaging	Long-term care Emergency departments Other:
ass	Who are your initiative's key stakeholders? Please check all that a Hospital or health system Academia/research groups Clinicians Vendor State government Local government Federal government Payers (nongovernmental) Health professional sociation Long-term care facilities PBMs Pharmacies Quality/safety organizations Ancillary services (e.g., oratories) Consumers Employers	
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TASK #4

Health Information Exchange and Quality and Transparency Initiatives: Toward Strategic and Operational Coordination

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1 Overview of Task #4 Scope

Task: Explore the relationship between state-level health information exchange (HIE) and quality and transparency initiatives.

Deliverables:

- 1. Describe current efforts to integrate quality and transparency initiatives into state-level HIE.
- 2. Identify key principles for involving state-level HIE in quality and transparency initiatives.

1.1 Introduction

The momentum for collecting and reporting performance data about healthcare providers is accelerating. Data about quality and cost supports healthcare purchasing and contracting by employers and their intermediaries. It can also be used to help make personal choices about healthcare. Healthcare consumers are no longer passive recipients of services. They require reliable information from credible sources to inform their own choices and improve the value of the system as a whole. Because of greater consumer engagement, quality and transparency initiatives are expanding in the private and public sectors.

On August 22, 2006, President Bush signed an Executive Order supporting the promotion of quality and efficient healthcare in healthcare programs administered or sponsored by the federal government. The president requested that federal agencies implement health information technology (HIT) for the direct exchange of health information, as well as programs measuring the quality of services provided to beneficiaries or enrollees of the federal healthcare system.

During the September 12, 2006, meeting of the American Health Information Community (AHIC), Secretary Michael Leavitt asked for recommendations regarding the role of state-level HIE organizations in quality and transparency initiatives and their role and relationship to other organizations working to achieve these goals. The Office of the National Coordinator for Health Information Technology (ONC) requested that the state-level HIE Steering Committee explore this important and timely question as part of its work under the *Development of Consensus Best Practices for State-Level Regional Health Information Organizations* contract. The American Health Information Management Association's (AHIMA's) Foundation of Research and Education (FORE):

- Surveyed the nine state-level HIEs participating in the state-level HIE project, and
- Convened the Steering Committee for discussion of survey findings and formulation of recommendations.

Appendix A contains the full list of interviewees, their organizations, and relevant contact information. Appendix B is the survey tool, and Appendix C lists the FORE project team that administered the survey and prepared this report.

2 Survey Findings

Survey findings reveal much about the role of state-level HIEs and other organizations in quality and transparency initiatives. However, it should be noted that this is a survey of a limited number of HIE organizations. No data were collected from any of the other organizations that are leading quality and transparency initiatives in these states. Aside from conversations during the Agency for Healthcare Research and Quality (AHRQ)-sponsored data collection and reporting conference held November 8-9, 2006, national experts in quality and transparency did not have input into the recommendations. The survey findings served primarily as a stepping off point for the Steering Committee discussion about how HIE organizations can best contribute to quality and transparency initiatives to serve the public good.

2.1 The HIE's Role and Authority for Quality and Transparency

All of the state-level HIEs have quality improvement as an element of their organizational mission. This is not a tangential issue; it is mission critical for these organizations.

When participants were asked to describe their organization's current or planned role in supporting quality initiatives, their responses varied from being a supplier of data for performance reporting (55%) and disease or chronic care management (33%) to reporting actual performance to purchasers or payers (33%) or the public (22%). Some see their role as advising and overseeing initiatives being managed by other entities (33%).

The authority for a quality and transparency mission and leadership role generally originates from action of the HIE's governance (66%). Action of governors or legislatures is the source of authority for some of the HIEs (33%). Authority also comes from other state agencies, public or private sources of funding, private stakeholders, or community consensus (55%).

2.2 Stakeholders Leading Quality Initiatives

When participants were asked to list all the types of organizations currently leading quality initiatives in their states, the list reveals the diversity. The most common organizations perceived to be quality initiative leaders are Quality Improvement Organizations (QIOs) (88%), health plans (88%), and hospital associations (78%). The next tier includes self-insured employers (55%), medical societies, business coalitions for health and state-level HIEs (each at 44%). Other organizations include private quality measurement and data organizations, state and local health departments, community-based coalitions, consumer advisory groups, universities, and other nonprofit provider and pay-for-performance groups (33% or less).

2.3 Coordinating Quality and Transparency and HIE initiatives

On the survey, HIE leaders confirmed the importance of coordination and suggested the following strategies at the state and local levels:

- Convene leaders from quality and HIE organizations to promote long-term working relationships, shared visions and goals, and coordinated strategies
- Have HIEs serve as neutral data suppliers to reduce redundant data collection, particularly when HIEs have clinical data
- Develop models that demonstrate the value of state-level HIEs in providing valuable data while lowering duplication of effort

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- Have quality and HIE organizations agree to use nationally recognized standards and valid measures to reduce data variation and to adopt uniform privacy and security practices
- Educate stakeholders about the value that state-level HIE can bring to these efforts
- Educate consumers regarding the value of coordinating HIE and quality initiatives

2.4 Coordinating Quality and Transparency and HIE Initiatives with National Initiatives

When asked to share ideas for how state-level HIE and quality organizations might coordinate with national initiatives, HIE leaders suggested:

- Encourage collaboration between state-level HIE and the federal government to reduce data silos and encourage consolidation of data for multiple uses
- Coordinate the use of data from federal data sources (for example, Centers for Medicare and Medicaid Services, Department of Defense, Veterans Affairs, etc.)
- Have HIE initiatives participate in defining, testing, and prioritizing quality and transparency measures to fully leverage available data
- Appoint leaders from state-level HIE and quality organizations to national committees
- Align funding and initiatives to accelerate technology adoption and remove barriers
- Create incentives that reward providers who participate in HIE initiatives
- Create incentives that reward HIE organizations that execute and support quality and transparency objectives
- Establish standard quality measures and metrics

2.5 State-Level Quality and Transparency Oversight

HIE leaders were asked about the need for a state-level oversight body for quality and transparency. Responses ranged from recommending a formal multi-stakeholder body recognized by state law or Executive Order (55%) to an advisory body to encourage coordination (22%) or no separate formal entity for quality and transparency (22%). All agreed that this decision should reflect state and local characteristics. There was also consensus that whatever the organizational form, states should take responsibility for articulating healthcare performance improvement goals and for helping to educate consumers and keep stakeholders engaged and committed to the priorities.

3 Analysis and Implications

The project Steering Committee underscored that this is a critical time for HIE and for quality and transparency initiatives. They share a focus on improving healthcare through effective use of health information, and they exist to serve a public good. They are generally multi-stakeholder entities with fairly complex governance to balance stakeholder interests. And they must develop sustainable business models if they are to succeed at their missions.

Data and information are their key products. HIEs ensure that clinical data are available where needed to support patient care. Quality and transparency initiatives use aggregated information to identify cost and quality outcomes to drive performance improvement and consumer choice. The Steering Committee discussed opportunities for collaboration including:

• Engaging stakeholders

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- Sound planning for data and information
- Leveraging information
- Information stewardship
- Continually improving the data and processes

Stakeholders—provider, payer, governmental and consumer stakeholders must be engaged in and shape HIE and quality and transparency governance, policy, and technology. Within the same state or locale, obviously the same stakeholders must be involved in both HIE and quality and transparency initiatives. The Steering Committee urged at minimum joint planning so planning is comprehensive—from HIE to public health and quality reporting.

Data and information planning—Although it is a simplistic model, Figure 1 shows the clusters of activities required for HIE and quality reporting. Activities 1 and 2, data capture/collection and HIE, are fundamental roles for HIEs. Patient-specific data are exchanged for patient care, but the data are not retained by the HIE. This is one of the models being tested in Nationwide Health Information Network pilots.

Some HIEs also aggregate data streams into databases for secondary uses such as reporting to public health, maintaining disease registries, and supporting research. They may set up the technology operations to be the aggregator or they may subcontract this function. State-level HIEs may subcontract to regional health information organizations or to third-party aggregators.

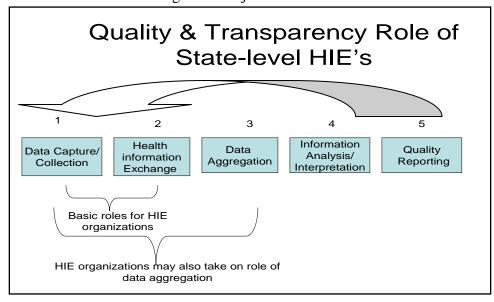


Figure 1. Major Data Activities

Members of the Steering Committee cautioned that the role of aggregator is not a neutral role. Data aggregation does change data, if only through structuring it into the data model and editing it for data errors. Thus, HIEs that move from exchange to exchange and aggregation take on a greatly expanded role, but one that has potential for increasing the sustainability of the HIE.

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The members of the Steering Committee agreed that information analysis and reporting are generally not roles for HIE organizations. Analysis is best done by application experts. So, for example, analysis for quality reporting is performed by quality and performance measurement experts, and public health trend reports are prepared by public health experts. However, the HIE should serve as an advisor because of its knowledge of the data's attributes.

Leveraging information—This model obviously requires unified governance and planning, but it offers the potential to minimize siloed and redundant data collection, the most costly part of HIE and quality and transparency. There is also a growing cost burden for healthcare providers who must provide data to a growing number of organizations each with different reporting requirements and poorly tested and nonstandard measures.

Information stewardship—Critical data stewardship functions include security, access, attribution management, protocols for making data anonymous, data quality management, version control on terminologies and analytical tools, and so on. Siloed and redundant data increase the cost and complexity of these practices exponentially.

Continually improving data and processes—There must be an improvement loop built in so data capture, HIE, aggregation, analysis, stewardship, and reporting processes, as well as the data, are assessed and improved. The feedback loop should extend to the provider and other organizations that are the source for the data. All of these are relatively new activities for which best practices do not yet exist and standards are relatively untested.

4 Recommendations

It is very important to bring the HIE and quality initiatives into closer alignment, and the state-level HIE Steering Committee offers the following recommendations to the Secretary of Health and Human Services (HHS) and the AHIC and offers to continue this dialogue:

- 1. National, state, and local health IT and quality agendas are generally not now aligned, despite their shared mission of improving quality and value and their essential reliance on healthcare data to carry out their missions. HHS and AHIC should clearly articulate the need for explicit coordination between state-level HIE and state quality and transparency initiatives. To support a network of Quality and Price Information Collaboratives (QPICs) without clarifying the relationship to HIE could set back HIE.
- 2. State-level HIEs should support quality and transparency data requirements and be an active, funded partner in QPICs. This involvement and funding could contribute to a sustainable business model for state-level HIE.
- 3. A more integrated model such as that described above should be further developed and should be tested. Other emerging models that demonstrate effective coordination and collaboration between HIE and quality and transparency should also be encouraged and studied. There should be financial support and programmatic incentives (e.g., access to Medicare data) for effective governance, streamlined models for managing data, effective stewardship, and other practices that emanate from integrated planning.

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- 4. Strategies need to be top down and bottom up. That is, HIE and quality organizations must work together on national committees such as the National Quality Forum (NQF), Ambulatory Care Quality Association/Hospital Quality Association (AQA/HQA), Agency for Healthcare Research and Quality (AHRQ), and American Health Information Community (AHIC) activities to design integrative strategies. At the same time, working relationships need to be strengthened at the state and local levels. Working from both perspectives will improve their effectiveness. The quality community must be at the table when information exchange decisions are being made, and the HIE community must be at the table when decisions are being made about data capture, exchange, and aggregation for quality.
- 5. Although each state must determine its preferred model for data capture and aggregation, state-level HIEs are best positioned to facilitate cost-effective access to statewide data for quality initiatives. State-level HIEs should assist with data standardization to reduce duplicate data acquisition efforts. State-level HIEs should not be responsible for establishing or enforcing quality and transparency requirements; however, HIE organizations should play a role in assisting community stakeholders with identifying, collecting, and aggregating data required for quality and transparency initiatives. This function should include establishing a definitive plan for moving from claims-based quality measurement to quality measurement that incorporates both claims and clinical data.
- 6. The Steering Committee recommends ongoing efforts to expand and discuss these principles further with a broader array of stakeholders in the near future. Future efforts should include:
 - Conducting an environmental scan of states that have successfully integrated state-level HIE with quality and transparency initiatives
 - Developing models that demonstrate the ability of state-level HIEs to share information for quality initiatives
 - Developing business models that support state-level HIE involvement in quality and transparency initiatives, incorporating the long-term cost savings from reduced data variations and collection and aggregation burdens
 - Discussing and clarifying the governance structures required to support the relationship between state-level HIE organizations and quality initiatives

Appendix A—Survey Participants

- 1. California Regional Health Information Organization (CalRHIO) San Francisco, CA
- 2. Colorado Regional Health Information Organization (CORHIO)
 Denver, CO
- 3. Florida's Agency for Health Care Administration Tallahassee, FL
- 4. HealthInfoNet Manchester, ME
- 5. Indiana Health Information Exchange (IHIE)/Regenstrief Institute, Inc. Indianapolis, IN
- 6. Massachusetts Health Data Consortium Waltham, MA
- 7. Rhode Island Quality Institute (RIQI) Providence, RI
- 8. State of Tennessee eHealth Council Nashville, TN
- 9. Utah Health Information Network (UHIN) Murray, UT

Appendix B—Survey Tool

Quality Initiatives in State-Level Health Information Exchange

In conjunction with work under HHS Contract # HHSP23320064105EC to study state-level Health Information Exchange (HIE), the Foundation of Research and Education of AHIMA is exploring the relationship between HIE and state-level quality initiatives. The information collected through this short survey will be utilized to facilitate discussions during the next project steering committee meeting on October 23 and 24, 2006. *Please complete the survey and fax or e-mail it to the address below by October 16, 2006.*

State:	Person Completing the Survey:	
Organ	zation Name:	
1.	Do the vision and/or mission statements of your organization contemplate a supporting quality initiatives? Yes (skip to question 1b)	role in
	No (proceed to question 1a) Unknown (proceed to question 1a)	
	a. If no (or unknown) was selected for question 1, does the charter for organization contemplate quality initiatives as a future focus?	r your
	Yes (proceed to question 1b)	
	No (skip to question 2)	
	Unknown (skip to question 2)	
	b. If yes was selected for question 1/1a, describe your organization's or planned role in supporting quality initiatives. (check all that apply and proc question 1c)	
	Quality performance reporting for purchasers or	payers
	Quality performance reporting for the public	
	Disease or chronic care management services	
	Advisory or oversight role	
	Supplier of Data to quality performance reporting organization	9
	Supplier of data to disease or chronic care mana service	agemen
	Other (please specify)	

	c. Where does the HIE's authority for quality flow from?
	(check all that apply and proceed to question 2)
	Governor's executive order
	Action by state legislators
	Action of the HIE's governance
	Other (please specify)
2.	Which organizations are currently leading quality initiatives in your state? (check all that apply and proceed to question 2a) State-level Health Information Exchange
	Regional health information organizations at the local level Quality Improvement Organization (QIO)
	Hospital Association
	Business Coalition for Health
	☐ Health Plans
	Health PlansSelf insured Employers
	Private data analysis/quality measurement company
	Pay-for-performance entity
	Other
	Unknown
	No Current Leadership (skip to question 3)
	a. For each organization selected in question 2, please provide the name of the specific organization(s) leading quality initiatives in your state. (skip to question 4)
3.	If no organization(s) has yet emerged to lead quality initiatives in your state, where do you anticipate the leadership for quality initiatives will come from? (check all that apply and proceed to question 4)
	State-level Health Information Exchange
	Regional health information organizations at the local level
	Quality Improvement Organization (QIO)
	Hospital Association
	Medical Society
	Business Coalition for Health
	☐ Health Plans
	Self insured Employers
	Private data analysis/quality measurement company
	Pay-for-performance entity

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	Other (please specify)
	Unknown
4.	Please share your ideas for how best to integrate quality initiatives with your HIE efforts in your state. (proceed to question 5)
5.	Please share your ideas for how entities or organizations overseeing state-level HIE, quality, or health care transformation efforts can actively coordinate with federal or national initiatives. (proceed to question 6)
6.	What would be the ideal scope of responsibility for a state-level entity with oversight or coordination of health care transformation, including quality and HIE initiatives? (proceed to question 6a)
	 a. What would be the relationship of this state-level entity to state government? (proceed to question 6b) Advisory body Supported by the Governor's office Formally recognized and authorized by state statute Comprised of state government leaders and private sector health care leaders Other (please specify)
	b. How would this state-level entity coordinate with private sector stakeholders? (proceed to question 6c)
	c. Which private sector stakeholders should be represented? (proceed to question 6d)
	d. What characteristics would make these entities similar or different from existing governance entities for state-level HIE or quality initiatives?

Appendix C—Project Team

The project team for this task included:

Crystal Kallem, RHIT Manager, Practice Leadership American Health Information Management Association (AHIMA)

Linda Kloss, MA, RHIA Chief Executive Officer American Health Information Management Association (AHIMA)

Eileen Murray, MM, CFRE, CAE Vice President and Executive Director, Foundation of Research and Education American Health Information Management Association (AHIMA)

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American Health Information Community

Health Information Exchange Business Models: Perspective from Industry, Academia, and the Field

Kelly Cronin
Office of the National Coordinator

January 23, 2007

ONC Sponsored HIE Business Model Projects

- NHIN Cost and Revenue Models
 - NHIN will be a network of networks cost models keep this perspective.
 - Four different models proposed by each of the four consortia.
- Review of Financially Sustainable HIE Services
 - Identify, examine, and analyze health information exchange (HIE) services that have achieved financial sustainability.
 - Six case studies of existing HIEs.
 - Recommendations based on what is working and feasible in terms of growth of services overtime.

Panel Discussion Today

- Overview of NHIN Cost and Revenue Models
 John Glaser
 - Summary of potential services
 - Common themes and differences across models
 - Conditions for sustainability
- The Economic Proposition for Financial Sustainability Steve Parente
- Review of Existing Financially Sustainable HIE Services
 Viki Prescott
 - Summary of real-world experience with financially viable services
 - Recommendations on initially and secondary services



American Health Information Community

The Nationwide Health Information Network Initiative Cost and Revenue Models

John Glaser Partners HealthCare System

January 23, 2007

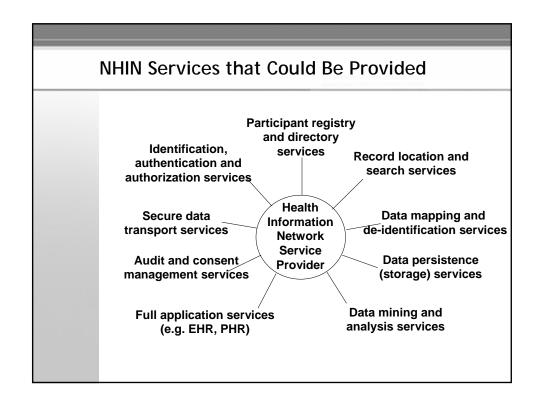
Nationwide Health Information Network Initiative

- ...foster widely available services that facilitate the accurate, appropriate, timely, and secure exchange of health information
- ...information that follows the consumer and supports clinical decision making

Nationwide Health Information Network Initiative

Shared assumptions

- Vision for the NHIN is a network of networks
- The organizations that provide network services may take several forms
- There are some basic network services necessary for connecting health records, security, record look-up and routing
- Many other network services may be considered valuable in local settings



Creation of these Models Presented Significant Challenges

- Defining the business model (services, governance, pricing and adoption) for a very complex IT infrastructure for which there is very little market experience
- Defining a model for which many of the base conditions may not be in place, e.g., extensive EHR adoption and quality-based financial incentives
- Basing the model on hundreds of variables and dozens of assumptions

NHIN Framework Alternatives - Financial Sustainability

- Revenue and cost models were based on very different business models and approaches
 - Balance between NHIN services and "sub-networks"
 - NHIN governance structures
 - Revenue strategies and sources
- All models projected breakeven within 8 years
 - Ranging from very near term to 7 years
 - Financial sustainability did require progress on several NHIN conditions

NHIN Framework Alternatives - Financial Sustainability

- All of the models:
 - Required an active government role
 - · Developer of standards and certification,
 - · Formation of policy,
 - · Provider of initial capital and/or
 - Employer/payer funder of NHIN services
 - Identified secondary uses of data as a critical contributor to sustainability (often accounting for over 50% of revenues)

Conditions for NHIN Adoption

- Financially viable participant networks and organizations
- Conformance of participant networks and organizations to necessary NHIN standards and policies
- Methods for addressing mis-aligned financial incentives and care improvement externalities
- Sufficient base of EHR adoption
- · Broad adoption of standards
- Robust privacy and security policies and mechanisms
- Legal and policy approaches to anonymized, secondary uses of data

Open Questions/Issues

- What else should government and the private sector do to facilitate progress on the conditions for NHIN adoption?
- How well do we understand the business tradeoffs between services that support inter-network exchange and exchange within participant networks?
- What are the differences in effectiveness of various revenue models?
- How viable is secondary uses of data as a source of NHIN revenue?



American Health Information Community

The Economic Proposition of Financially Sustainable Health Information Exchange Services

Stephen T. Parente HSI Network LLC

January 23, 2007

Overview

- Defining Financial Sustainability
- The Economic Benefits of Achieving Sustainability
 - Economies of Scale
 - Economies of Scope
 - Public Good as Network Externalities
 - Economic Incentives for Innovation
- Identifying Sustainable Revenues
- Sustainable for the Long Run

Defining Economic Sustainability

- 'Sustainability': A firm, venture, or enterprise operates where it can breakeven at a certain point in the future and can grow to where marginal revenue equals marginal cost.
- Key factors
 - Size of enterprise
 - Time from start-up to sustainability
 - Source of revenues
 - Expected tenure/type of revenue sources
 - Stakeholder expectations: profit-sharing or other
 - Barriers to entry/intellectual property rewards
 - Technological opportunities/constraints
 - Rate of technological progress & redundancy threat

Economics of Information Technology

- Applicable Conceptual Model developed by Erik Brynjolfsson from MIT and Lorin Hitt from University of Pennsylvania.
- Three Different Measures of IT Value:
 - Productivity
 - Profit
 - Consumer Welfare
 - Opportunity for public good creation

Sustainability Benefits - Scale Economies

- Economies of Scale from Single Products:
 Reductions in the average cost of a single product in the long run (e.g., clinical messaging) resulting from an expanded set of output (e.g., avoided clinical wait times and complications).
- In application:
 - Clinical messaging can yield reductions in medical error and higher productivity.
 - Higher productivity yields additional revenue to more than offset the cost of the message fee or marginal cost of the messaging provider.
 - These savings will be long-run savings and (ideally) increasing over time (e.g., more aging boomers, more complications, better high quality patient volume).

Sustainability Benefits - Scope Economies

- Economies of Scope for Multiple Products:
 Conceptually similar to economies of scale. But economies of scope look at efficiencies from combining different types of products through changes in pricing, marketing and distribution.
- In application:
 - Bundle worth more than sum of single products.
 - Bundle clinical messaging, medication history, eprescribing, and clinical data sharing on common webbased platform.
 - Market to physicians with high broadband access and consider adding a diagnostic imaging component.
 - High ROI (i.e., sustainable) single products can crosssubsidize lower ROI single products.

Sustainability Benefits - Network Externalities

- Network Externalities: Externality generating activity (e.g., shared clinical database) raises the production or well-being of an externally affected party. Positive externalities creates the public good.
- In application:
 - Shared Clinical Data services provides a national data repository to readily identify high potential success of a vaccine for a future pandemic flu strain.
 - Katrina Health results from prescribing utilizing previous Rx exchange infrastructure that was tapped for a national emergency.

How to Optimize the Public Good

- Support Adoption of Technologies that:
 - Produce single products that optimize positive 'scale' externalities.
 - Produce even greater 'scope' positive externalities for product bundle combinations.
- Balance public/private investment to get best network externality ROI.
- If the private sector can profit and create a
 positive externality, identify whether the public
 sector can provide bridge financing or temporary
 exclusive property rights to mitigate the
 risk/reward.

Incentives for Innovation

- Standard assumption is that IT cannot yield profits, only reduce costs.
- Assumption is not true if an industry has high barriers to entry.
- Health care has many barriers to entry, so providers & insurers should buy IT not just as a tool to control cost but to profit as well.

Identifying Sustainable Revenues

Best case sustainable revenues:

- Per transaction user fee
- Substitutable 'staple' commodity
- Subscription services with sustainable fixed base pricing and variable add-on pricing.
- Bundled as part of software purchase/lease contract
- Multi-year most favored trade partner status through opportunity cost savings.

Less advantageous revenues for sustainability:

- Grants for quality improvement/IT prototypes
- Venture capital without established revenue sources in start-up.

Summary - To Get the Value of Sustainability

- Seek long run efficiencies (returns to scale).
- Have multiple revenue sources lined up and balance your portfolio.
- Identify revenues that are expected to survive in the future and continuously renew and update.
- Look for bundling and channeling opportunities to get economies of scope.
- Be forward looking and either plan for redundancy or develop a new product to replace future lost revenues.



American Health Information Community

Task #2:

Financially Sustainable Health Information Exchange Services

Victoria M. Prescott, Esq. Primary Investigator

January 23, 2007

Project Overview

- Define parameters for inclusion
 - •"HIE": umbrella term for several different types of specific exchanges of clinical or administrative data
 - •"HIE Services":
 - A service, not the whole organization
 - · Not limited to state-level HIE services
 - Exchange of health info between multiple stakeholders
 - · Not merely increase use of EHRs
 - Not merely increase use of telemedicine
 - "Financially Sustainable":
 - Having sufficient revenue for ongoing operations
 - Assessment did not include start-up costs
- Describe sample HIE services meeting parameters
- Make recommendations

Outcomes of the Project

- Analysis of Specific HIE Services
- Recommendations for HIEs
- Overall Observations

Clinical Messaging

Definition Delivery of electronic clinical results (such as lab test results, radiology reports, or transcribed reports) from the source system (e.g., lab, radiology center) to the intended recipients (e.g., ordering physician, primary care physician)

Key Rationale

- ROI easy to understand
- · Establish connections between clinical data providers and physician offices
- Master Patient Index not necessary
- Clinical relevance of data
- Physicians receive test results faster

Medication History

Definition Electronically sharing a patient's medication history obtained from multiple sources with the clinician or institution treating the patient.

Key Rationale

- Attractive to hospitals to help comply with JCAHO medication reconciliation requirements
- Eligibility and formulary typically included which can reduce drug costs and increase efficiencies
- Clinical relevance of the data

ePrescribing

Definition Automates the process for the clinician to prescribe medications for patients by electronically delivering the Rx to the retail pharmacy or mail order service.

Kev Rationale

- Reduce physician's administrative expenses re: legibility of Rx & processing refills
- · Positive impact on many stakeholders
- This project could include med Hx, eligibility & formulary, but need this info before prescribing

Hurdles

- However, implementation challenges include:
 - Need critical mass of pharmacies covered
 - Need software physicians use (& often certified)
 - Need critical mass of med history data

Sharing Patient Clinical Data at Point of Care

Definition Gathers and provides electronic clinical information (e.g., patient's med Hx, lab test results, diagnoses) from multiple sources on a patient when the patient presents for care

Key Rationale

- High value to treatment
- Standardized repository of clinical data can also serve to benefit public health, researchers, pharma
- The addition of clinical decision support and reminders functionality can further aid providers

Hurdles

- However, implementation challenges include:
 - Large scale project
 - Need Master Patient Index
 - Difficult to project value across stakeholders and hence hesitancy to invest
 - Standardization of data needed to be of real value

Quality Measurement Reporting

Definition Share healthcare information (clinical and claims) between multiple data sources for the purpose of quality measurement that can support provider quality initiatives and also serve as a basis for determining incentives to providers from payers.

Key Rationale

- Consistent set of quality measures:
 - Pavers recognize improvements in efficiency and quality of care, and will have more influence by banding together
 - Providers only have to comply with one set of quality measures; they receive information and incentives to help them improve
- As quality increases, patient have better outcomes

Hurdles

- However, implementation challenges include:
 - Need critical mass of data and participation
 - Consensus needed on: quality metrics, how to analyze them, and who has access to results
 - Standardization of data needed
 - Master Patient Index needed

Recommendations for HIEs

- Leverage any infrastructure built and data collected (re-use of data to build other services)
- Recommended Initial Services (less complex):
 - Clinical Messaging (HB, INHS, RI)
 - Medication History (RI)
- Recommended Later Services (more complex):
 - ePrescribing (RI)
 - Sharing Patient Clinical Data at Point of Care (RI)
 - Quality Measurement (RI)

Overall Observations

- No single approach
- Market factors are not well understood
- Enablers
- Common Challenges
- There are sustainable models



American Health Information Community

AHIC Priorities and Use Cases - 2007

John Loonsk, Office of the National Coordinator Rose Marie Robertson, American Heart Association Blackford Middleton, Partners HealthCare Systems John Lumpkin, The Robert Wood Johnson Foundation Carolyn Clancy, Agency for Healthcare Research & Quality

January 23, 2007

AHIC Priorities and Use Cases

Use Cases

- Use cases are descriptions of events that detail what a system (or systems) needs to do to achieve a specific mission or stakeholder goals
- Use cases convey how individuals and organizations (actors) interact with the involved systems and strive to provide enough detail and context for follow-up activities to occur
- Usually, the follow-up from a use case is work that leads to the development or implementation of a specific software system

AHIC Priorities and Use Cases

AHIC Use Cases

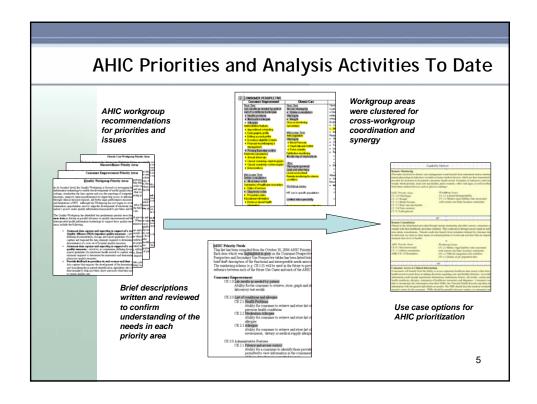
- ONC has been using high-level use cases that are not about the development of a specific software system, but are about the needs of many systems, stakeholder organizations, and individuals
- The use cases are based on the priorities expressed by the American Health Information Community workgroups and describe involved stakeholders, information flows, issues, and systems needs that apply to the multiple organizations participating in these areas
- The use cases strive to provide enough detail and context for standards harmonization, architecture specification, certification consideration, and detailed policy discussions to advance the national HIT agenda
- These high-level use cases focus, to a significant degree, on the exchange of information between organizations and systems rather than the internal activities of a particular organization or system

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AHIC Priorities and Use Cases

2007 AHIC Priorities and Use Cases

- For 2007, AHIC workgroups have identified over 120 priorites and issues for consideration
- ONC has tried to cluster like priorites and issues among the different workgroups and organize them so that as many can be attended to as possible, and that there are opportunites to reuse (or "extend") existing use case work
- Clustering has led to three high-level categories of use cases (Consumer, Provider and Population), and several options for immediate attention in each category
- We are now asking the AHIC members to prioritize the possible use cases in each high-level category and have attached suggested critieria for supporting this prioritization



High-Level Use Case Categories

Consumer

Existing Use Cases

Consumer
 Empowerment Registration and Medication History

New Possibilities

- a) Remote Monitoring
- b) Remote Consultation
- c) Consumer Access to Clinical Information

Provider

Existing Use Cases

- EHR Labs
- Emergency Responder EHR

New Possibilities

- a) Medication Management
- b) Referrals and Transfer of Care

Population

Existing Use Cases

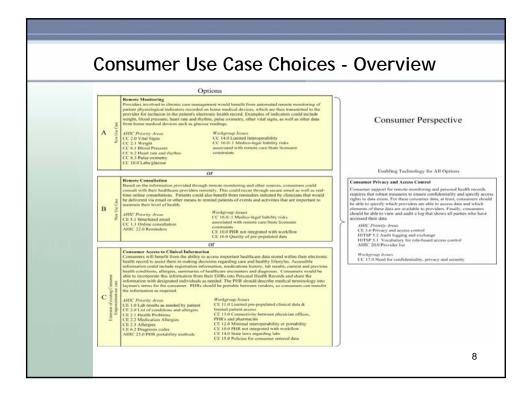
Biosurveillance

New Possibilities

- a) Quality
- b) Public Health Case Reporting
- c) Response Management

Use Case Possibilities

- Options for 2007 use cases are expressed in the following charts
- The "overview" charts provide the options for a particular category (Consumer, Provider and Population) and the enabling technologies that are necessary to support any of those options
- The individual "choice" charts show each individual possibility and detail which AHIC priority areas and issues are associated with that choice
- Although not all priority areas and issues will be immediately and fully attended to in 2007, we can expect many others to be addressed in the next round of use cases



Choice A: Remote Monitoring

Remote Monitoring

Providers involved in chronic care management would benefit from automated remote monitoring of patient physiological indicators recorded on home medical devices, which are then transmitted to the provider for inclusion in the patient's electronic health record. Examples of indicators could include weight, blood pressure, heart rate and rhythm, pulse oximetry, other vital signs, as well as other data from home medical devices such as glucose readings.

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AHIC Priority Areas CC 2.0 Vital Signs

CC 2.1 Weight CC 6.1 Blood Pressure

CC 6.2 Heart rate and rhythm CC 6.3 Pulse oximetry CC 10.0 Labs/glucose Workgroup Issues

CC 14.0 Limited Interoperability CC 16.0/.1 Medico-legal liability risks associated with remote care/State licensure

constraints

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Choice B: Remote Consultation

Remote Consultation

Based on the information provided through remote monitoring and other sources, consumers could consult with their healthcare providers remotely. This could occur through secure email as well as real-time online consultations. Patients could also benefit from reminders initiated by clinicians that would be delivered via email or other means to remind patients of events and activities that are important to maintain their level of health.

В

AHIC Priority Areas

CE 5.1 Structured email CC 1.1 Online consultation AHIC 22.0 Reminders Workgroup Issues

CC 16.0/.1 Medico-legal liability risks associated with remote care/State licensure constraints

CE 10.0 PHR not integrated with workflow CE 16.0 Quality of pre-populated data

Choice C: Consumer Access to Clinical Information

Consumer Access to Clinical Information

Consumers will benefit from the ability to access important healthcare data stored within their electronic health record to assist them in making decisions regarding care and healthy lifestyles. Accessible information could include registration information, medications history, lab results, current and previous health conditions, allergies, summaries of healthcare encounters and diagnoses. Consumers would be able to incorporate this information from their EHRs into Personal Health Records and share the information with designated individuals as needed. The PHR should describe medical terminology into layman's terms for the consumer. PHRs should be portable between vendors, so consumers can transfer the information as required.

C ansion of existing Empowerment us

AHIC Priority Areas

CE 1.0 Lab results as needed by patient

CE 2.0 List of conditions and allergies

CE 2.1 Health Problems CE 2.2 Medication Allergies

CE 2.3 Allergies

CE 6.2 Diagnosis codes

AHIC 25.0 PHR portability methods

Workgroup Issues

CE 11.0 Limited pre-populated clinical data & limited patient access

CE 13.0 Connectivity between physician offices,

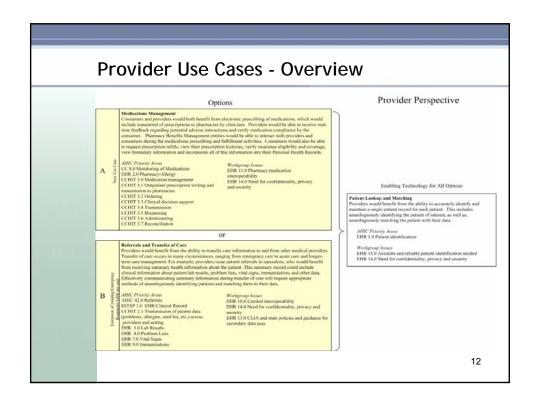
PHR's and pharmacies

CE 12.0 Minimal interoperability or portability

CE 10.0 PHR not integrated with workflow

CE 14.0 State laws regarding labs

CE 15.0 Policies for consumer entered data



Choice A: Medications Management

Consumers and providers would both benefit from electronic prescribing of medications, which would include transmittal of prescriptions to pharmacies by clinicians. Providers would be able to receive real-time feedback regarding potential adverse interactions and verify medication compliance by the consumer. Pharmacy Benefits Management entities would be able to interact with providers and consumers during the medications prescribing and fulfillment activities. Consumers would also be able to request prescription refills, view their prescription histories, verify insurance eligibility and coverage, view formulary information and incorporate all of this information into their Personal Health Records.

AHIC Priority Areas CC 8.0 Monitoring of Medications EHR 2.0 Pharmacy/Allergy CCHIT 3.0 Medication management CCHIT 3.1 Outpatient prescription writing and

transmission to pharmacies CCHIT 3.2 Ordering CCHIT 3.3 Clinical decision support CCHIT 3.4 Transmission

CCHIT 3.5 Dispensing CCHIT 3.6 Administering CCHIT 3.7 Reconciliation

Workgroup Issues EHR 11.0 Pharmacy/medication interoperability EHR 14.0 Need for confidentiality, privacy

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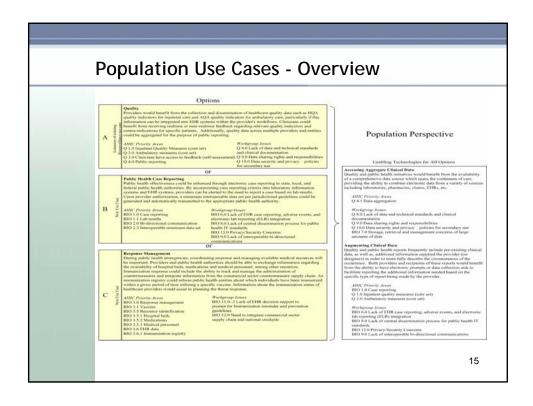
Choice B: Referrals and Transfer of Care

Referrals and Transfer of Care

Providers would benefit from the ability to transfer care information to and from other medical providers. Transfer of care occurs in many circumstances, ranging from emergency care to acute care and longerterm care management. For example, providers issue patient referrals to specialists, who would benefit from receiving summary health information about the patient. This summary record could include clinical information about patient lab results, problem lists, vital signs, immunizations and other data. Effectively communicating summary information during transfer of care will require appropriate methods of unambiguously identifying patients and matching them to their data.

AHIC Priority Areas AHIC 42.0 Referrals HITSP 1.0 EHR/Clinical Record CCHIT 2.1 Transmission of patient data (problems, allergies, med list, etc.) across providers and setting EHR 3.0 Lab Results

EHR 4.0 Problem Lists EHR 7.0 Vital Signs EHR 9.0 Immunizations Workgroup Issues EHR 10.0 Limited interoperability EHR 14.0 Need for confidentiality, privacy and EHR 13.0 CLIA and state policies and guidance for secondary data uses



Choice A: Quality Providers would benefit from the collection and dissemination of healthcare quality data such as HQA quality indicators for inpatient care and AQA quality indicators for ambulatory care, particularly if this information can be integrated into EHR systems within the provider's workflows. Clinicians could benefit from receiving realtime or near-realtime feedback regarding relevant quality indicators and contra-indications for specific patients. Additionally, quality data across multiple providers and entities could be aggregated for the purpose of public reporting. Workgroup Issues AHIC Priority Areas Q 1.0 Inpatient Quality Measures (core set) Q 8.0 Lack of data and technical standards Q 2.0 Ambulatory measures (core set) and clinical documentation Q 3.0 Clinicians have access to feedback (self-assessment) Q 9.0 Data sharing rights and responsibilities Q 10.0 Data security and privacy - policies Q 4.0 Public reporting for secondary use 16

Choice B: Public Health Case Reporting

Public Health Case Reporting

Public health effectiveness could be enhanced through electronic case reporting to state, local, and federal public health authorities. By incorporating case reporting criteria into laboratory information systems and EHR systems, providers can be alerted to the need to report a case based on lab results. Upon provider authorization, a minimum interoperable data set per jurisdictional guidelines could be generated and automatically transmitted to the appropriate public health authority.

AHIC Priority Areas

BIO 1.0 Case reporting BIO 1.1 Lab results

BIO 2.0 Bi-directional communication BIO 2.3 Interoperable minimum data set Workgroup Issues

BIO 6.0 Lack of EHR case reporting, adverse events, and electronic lab reporting (ELR) integration

BIO 8.0 Lack of central dissemination process for public

health IT standards

BIO 13.0 Privacy/Security Concerns BIO 9.0 Lack of interoperable bi-directional communications

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Choice C: Response Management

Response Management

During public health emergencies, coordinating response and managing available medical resources will be important. Providers and public health authorities should be able to exchange information regarding the availability of hospital beds, medications and medical personnel, among other resources. Immunization response could include the ability to track and manage the administration of countermeasures and integrate information from the commercial sector countermeasure supply chain. An immunization registry could inform public health entities about which individuals have been immunized within a given period of time utilizing a specific vaccine. Information about the immunization status of healthcare providers would assist in planning the threat response.

AHIC Priority Areas

BIO 3.0 Response management

BIO 3.1 Vaccine

BIO 3.5 Resource identification BIO 3.5.1 Hospital beds

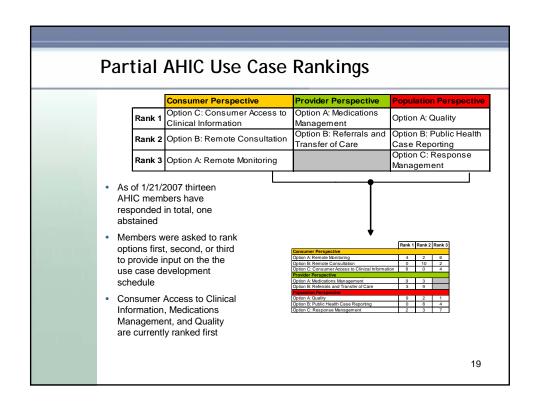
BIO 3.5.2 Medications BIO 3.5.3 Medical personnel

BIO 3.6 EHR data

BIO 3.6.1 Immunization registry

Workgroup Issues
BIO 11.0-.2 Lack of EHR decision support to prompt for Immunization reminder and prevention guidelines

BIO 12.0 Need to integrate commercial sector supply chain and national stockpile





American Health Information Community

Confidentiality, Privacy, and Security Workgroup Recommendations

Paul Feldman, The Health Privacy Project Jodi Daniel, Office of the National Coordinator

January 23, 2007

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

• Co-Chairs:

Paul Feldman The Health Privacy Project
 Kirk Nahra Wiley Rein & Fielding LLP

Members:

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 Jodi Daniel
 Steven Davis
 Oklahoma Department of Mental Health and Substance Abuse Services

Don Detmer American Medical Informatics Association

Flora Terrell Hamilton
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 Family and Medical Counseling Service, Inc.
 National Committee on Vital and Health Statistics, and

 John Houston National Committee on Vital and Health Statistics, an University of Pittsburgh Medical Center

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Susan McAndrew
 David McDaniel
 HHS/Office of Civil Rights
 Veterans Health Administration

Deven McGraw
 National Partnership for Women and Families

- Alison Rein National Consumer League

Tony Trenkle
 Paul Uhrig
 HHS/Centers for Medicare and Medicaid Services
 SureScripts LLC

Thomas Wilder America's Health Insurance Plans

Office of the National Coordinator:

CPS Workgroup 01/23/07

CPS Workgroup Overview

Broad Charge:

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

Specific Charge:

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

CPS Workgroup 01/23/07

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Patient Identity Proofing Recommendations General Statements

- Patient identity proofing is defined as the process of providing sufficient information to correctly and accurately establish and verify a patient's identity to be used in an electronic environment.
- The purpose of these recommendations is to advance the specific charges of the Chronic Care, EHR, and Consumer Empowerment Workgroups. More widespread application of these recommendations may necessitate further review.
- All data included in secure messaging, EHRs, and PHRs should be considered sensitive. Appropriate policies and supporting security measures must be in place to mitigate the risks of unauthorized or unintended data disclosure.
- Patient identity proofing is just one part of an overall process (e.g., validation, revocation) for issuing and maintaining electronic identity credentials. All parts of the process are interdependent and, if they do not achieve comparable levels of security, the overall strength of the electronic identity credential may not be adequate.

CPS Workgroup 01/23/07

Patient Identity Proofing Recommendation #1

- Recommendation 1: Entities that offer health care consumers or their authorized proxy(ies) electronic access to data and services through secure messaging, PHRs, or EHRs should perform, or rely upon, identity proofing performed by the entity or an accountable trusted third party that meets or exceeds one of the following options (1.1, 1.2, 1.3).
 - Note: If the primary method chosen by an entity does not apply in some instances, one of the other methods should be chosen. Failure to meet identity proofing requirements for electronic access to health information should not impede patient access to health care.

CPS Workgroup 01/23/07

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Patient Identity Proofing Recommendation #1 (Continued)

- 1.1: When it is practical and feasible for a health care consumer or his/her authorized proxy to present themselves in-person, in-person identity proofing should be performed by the health care entity. Identity proofing can be achieved by using, at a minimum a valid, government issued, picture-ID to verify identity. Examples of such documents include: A passport; driver's license or state issued ID; permanent resident card; military ID.
- 1.2: When the healthcare consumer or his/her authorized proxy has an established and durable relationship (e.g., long-standing, trusted) with an entity, this relationship could be used to confirm the consumer or proxy's identity on the basis of that relationship. Examples of confirmation may include: inperson or telephonic dialogue, etc., where confirmation occurs at the time of the request. (i.e., a voicemail or message left for the entity to confirm at later time would not be acceptable).

CPS Workgroup 01/23/07

Patient Identity Proofing Recommendation #1 (Continued)

- 1.3: When the healthcare consumer or his/her authorized proxy is unable to meet the criteria necessary to satisfy 1.1, the entity determines that 1.2 is not viable, and a relationship exists between the consumer or proxy and the entity, identity proofing should consist of a method that verifies a person's identity based on information they know or can produce about themselves when asked. The entity or trusted third party should 1) request basic identity data (e.g., name, address, date of birth, etc.), and 2) require the individual to provide some personal information specific to that relationship (e.g., last prescription, electronic device).

Accept	Table	Reject

CPS Workgroup 01/23/07

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Patient Identity Proofing Recommendation #2

 Recommendation 2: For the purposes of secure messaging and accessing data through a PHR or EHR, document(s) and the information therein or other information used solely for purposes of identity proofing a health care consumer or their authorized proxy(ies), if kept, should be securely maintained separate from the health care consumer's clinical data.

Accept	Table	Reject

CPS Workgroup 01/23/07

Patient Identity Proofing Recommendation #3 • Recommendation 3: Converting from a paper-based health care practice to one that uses EHRs does not require a health care entity to identity proof their patients. Where this conversion also provides patients with access to data within the EHR (such as via flash drive, Internet, or remote access), health care providers should follow the identity proofing recommendation schema noted in Recommendation #1.

Patient Identity Proofing Recommendation #4	
Recommendation 4: Entities that provide patient access to personal health information via secure messaging or a PHR (such as via a flash drive, populating data records stored on the Internet, or remote access), should follow the identity proofing recommendation schema noted in Recommendation #1. Accept Table Reject	
CPS Workgroup 01/23/07 9	

Patient Identity Proofing Recommendation #5

 <u>Recommendation 5:</u> Where applicable, the Certification Commission for Healthcare Information Technology (CCHIT) should develop certification criteria for the systems and networks they certify to support the identity proofing practices in these recommendations.

Accept	Table	Reject

CPS Workgroup 01/23/07

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Next Topic Candidates

- Identity proofing in instances where no prior relationship exists.
- Criteria for next topics:
 - Tactical / Impact.
 - Quantity of work-in-progress / Avoiding duplication.
 - Recommendations to CPS from other workgroups.
- · Possible future topics:
 - An analysis of the effects consumer choice and control could have on the benefits of electronic health information exchange.
 - Identification and analysis of changes in the health IT environment since HIPAA.
 - Activities of non-covered entities.
 - With respect to EHRs, PHRs, and health information exchanges.
 - Privacy protections for information held by non-covered entities in collaboration with the Consumer Empowerment (CE) Workgroup per CE Recommendation 2.1.

CPS Workgroup 01/23/07



American Health Information Community

Consumer Empowerment Workgroup Recommendations

Nancy Davenport-Ennis National Patient Advocate Foundation

Rose Marie Robertson American Heart Association

January 23, 2007

Consumer Empowerment Workgroup

Co-Chairs:

- Nancy Davenport-Ennis Rose Marie Robertson

National Patient Advocate Foundation

Members:

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Centers for Medicare and Medicaid Services

SureScripts Department of Veterans Affairs

Markle Foundation RxHub

DHHS/Office for Civil Rights

Department of Defense American Medical Association

National Institute of Standards and Technology American Medical Informatics Association

Blue Cross Blue Shield Association Microsoft

Office of Personnel Management

Palo Alto Medical Foundation Medical Group Management Association National Health Council

Paul Tang Robert Tennant Myrl Weinberg

Office of the National Coordinator:

Consumer Empowerment Workgroup 01/23/07

Broad Charge: What are we trying to accomplish?

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

Consumer Empowerment Workgroup 01/23/07

2

Broad charge issues to be addressed

- Ideally, personal health data can be exchanged among PHRs and sources of personal health information (e.g., electronic medical records, payer or pharmacy systems) under the control of the patient while preserving the meaning of the data.
- 2. Privacy protection and security safeguards are paramount, and timely access for all consumers to their personal health information should be ensured.
- 3. Appropriate incentives to encourage consumer and provider adoption of PHRs should be identified and promoted.
- 4. Research on effective messaging for consumers and providers should guide broad educational efforts to engage them.

Consumer Empowerment Workgroup 01/23/07

1. Interoperability and Portability
Recommendation 1.1: HHS should promote consumer access to their personal health information in the trial implementations of the NHIN.
Accept Table Reject
Consumer Empowerment Workgroup 01/23/07 4

2. Privacy and Security
 Recommendation 2.1: The AHIC Confidentiality, Privacy and Security Workgroup, in collaboration with the Consumer Empowerment Workgroup, should develop principles and identify best practices for privacy policies for consumers' PHR data that are interoperable, (i.e., protections that follow the consumer as his or her data moves or is shared). These recommendations should apply to all individuals and entities, including both covered and non-covered entities under HIPAA.
Consumer Empowerment Workgroup 01/23/07 5

2. Privacy and Security
Recommendation 2.2: The HHS Office for Civil Rights should provide guidance to clarify the protections provided under HIPAA regarding the rights of consumers and their proxies to timely access to their electronic personal health information requested from covered entities. Accept Table Reject
Consumer Empowerment Workgroup 01/23/07 6

2. Privacy and Security
Recommendation 2.3: CMS, in collaboration with the HHS Office for Civil Rights and other interested agencies, should develop policies and guidelines for HIPAA-covered entities and business associates for authorization of data release to and from PHRs, including the development of HIPAA-compliant standardized authorization language, no later than December 28, 2007.
Accept Table Reject
Consumer Empowerment Workgroup 01/23/07 7

2. Privacy and Security	
 Recommendation 2.4: The State Alliance for elegative to State privacy laws and PHRs and share their findings with the Community and HHS. The Consumer Empowerment Workgroup intends to provide the State Alliance for e-Health with background information and a detailed explanation for this request. 	e
Accept Table Reject	
Consumer Empowerment Workgroup 01/23/07	8

3. Incentives for Adoption	
Recommendation 3.1: HHS, through AHRQ, and in collaboration with the Indian Health Service, CMS, the Department of Veterans Affairs, and the Office of Person Management, should develop an evaluation framework can assist in the systematic assessment of PHR offering federal employees and beneficiaries, by December 28, 2007. Evaluation criteria may include the effect of PHR services on health outcomes, level of consumer engagement in their health care, economic impact, data security, and other measures.	that ngs to
Accept Table Reject	
Consumer Empowerment Workgroup 01/23/07	9

3. Incentives for Adoption

 Recommendation 3.2: In 2007, HHS, through AHRQ when appropriate, should conduct evaluations that will provide useful information needed to develop the evaluation framework for assessing PHRs specified in 3.1. Specific study topics include the impact of data sharing through health information exchange, the comparative value of various data sources, and the impact of various architectural models.

Consumer Empowerment Workgroup 01/23/07

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3. Incentives for Adoption

 Recommendation 3.2.1: HHS should assess how the sharing of personal health information with consumers through the use of PHRs impacts health care quality and patient satisfaction, including the results of private sector efforts as available.

Consumer Empowerment Workgroup 01/23/07

3. Incentives for Adoption

Recommendation 3.2.2: HHS, through AHRQ, should conduct a study to assess the comparative value of and challenges related to using data on diagnoses and medication derived from claims, administrative, clinical, laboratory, pharmacy, and consumer-based sources to populate and maintain PHRs, including evaluations of the current availability of each source of data and of consumer and clinician reactions to and decisions based on the use of these data. Because of the low rate of EHR adoption by providers, the study should begin with an examination of experiences with currently available PHRs based on claims and administrative data as well as consumer-based sources, then move to clinical and other data over time, with interim results reported back to the Community by December 28, 2007, and final results reported back by June 30, 2008.

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3. Incentives for Adoption

 Recommendation 3.2.3: HHS, through AHRQ, should fund evaluations of the impact on health care quality and patient satisfaction of various architectural models of PHRs (e.g., stand-alone, integrated, networked) and delivery methods (e.g., web-based, compact disc, flash drive) to consumers.

Accept Table Reject

Consumer Empowerment Workgroup 01/23/07

3. Incentives for Adoption
Recommendation 3.3: The Department of Veterans Affairs should conduct an evaluation of the benefits of their My HealtheVet PHR in the 2007 calendar year, and report back to the Community about the status and results to date no later than December 28, 2007. Based on the evaluation, the Department of Veterans Affairs should communicate the value of their PHR to veterans and stakeholders to encourage adoption. Accept Table Reject Reject
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3. Incentives for Adoption
• Recommendation 3.4: HHS, through the Centers for Medicare & Medicaid Services and the Indian Health Service, should develop plans to offer portable PHRs with privacy protections to their beneficiaries, and report back to the Community about their plans as available. The plans should take into account the results of the studies and best practices from 2.1 and 3.2, as they become available.
Accept Table Reject
Consumer Empowerment Workgroup 01/23/07 15

3.	Incentives for Adoption	
	Recommendation 3.5: In 2007, the Consumer Empowerment Workgroup should identify a range of incentives intended to increase adoption of PHRs, and report on their findings to the Community. These incentives may include financial benefits accruing to providers or othe PHR offerors, financial benefits accruing to patients and consumers, or other forms of economic benefit of established effectiveness (e.g., employee productivity, customer loyalty). The Consumer Empowerment Workgroup should include in its report any available evidence documenting the effectiveness of each type of incentive and how that incentive might best be deployed encourage PHR adoption.	ner
	Accept Table Reject	
	Consumer Empowerment Workgroup 01/23/07	16

4. Education and Outreach
 Recommendation 4.1: In 2007, the Consumer Empowerment Workgroup should continue to study public and private sector activities to increase consumer awareness of PHRs, including the convening of an expert panel on consumer engagement and social marketing, and report on their findings to the Community.
Accept Table Reject
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January 23, 2007

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

Dear Mr. Chairman:

The American Health Information Community has given the following Broad Charge to the Consumer Empowerment Workgroup:

Broad Charge for the Workgroup: To make recommendations to the Community to gain widespread adoption of personal health records (PHRs) that are easy to use, portable, longitudinal, affordable, and consumer-centered.

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

- 1. Ideally, personal health data can be exchanged among PHRs and sources of personal health information (e.g., electronic medical records, payer or pharmacy systems) under the control of the patient while preserving the meaning of the data.
- 2. Privacy protection and security safeguards are paramount, and timely access for all consumers and their proxies to their personal health information should be ensured.
- 3. Appropriate incentives to encourage consumer and provider adoption of PHRs should be identified and promoted.
- 4. Research on creating effective messages for consumers and providers should guide broad educational efforts to engage them.

This letter provides both context and recommendations for how these issues can be addressed in 2007.

FINDINGS

Empowering consumers to take an active role in managing their health through engaged management of their personal health information has been the overarching goal for this Workgroup. This theme is consistent in spirit with many positive trends visible in the U.S. health care system today. Sixty percent of Americans support the creation of secure, online personal health records (Markle Foundation, 2005) and additional research supports the belief that consumer commitment to PHRs would result in increased efficiencies in the health care system, lower overall costs and improved health care information access (Kaiser Permanente Institute for Health Policy Roundtable Summary Report, 2006). Patients using comprehensive PHR systems find increased access to their health information and health care team to be transformative (Tang and Lansky, 2006). However, this consumer support has yet to translate into large-scale

movement toward managing one's own personal health information through personal health records.

The research and testimony collected by the Workgroup to date have illustrated both the challenges and opportunities within this landscape. The main challenges include concerns about health data privacy and security, data accessibility, lack of interoperability between PHRs and electronic health records (EHRs), payment mechanisms, and evolving technologies and standards. Additional challenges include low health literacy, lack of PHR awareness, asymmetrical state-level policies on health data sharing, lack of a clear value proposition and incentives for mass adoption, and tensions between assuring minimum standards while ensuring maximum flexibility.

A variety of PHR products and sponsors have emerged to address these challenges and to meet the needs of various populations. While some stand-alone web-based PHRs find that many of their subscribers are the "worried well," users of integrated PHR systems are more often those with chronic diseases (Tang, Black, and Young, 2006). Additionally, some employers and health plans are offering PHRs to their employees and plan members in the hope that the use of these tools will improve health behaviors and patient care while slowing rising health care costs (Reuters, 12/6/06). Within the last year, there have been significant large-scale personal health record planning efforts and implementations. Some notable projects include the open-source Indivo Personally-Controlled Health Record, which demonstrates access to personal health information across state lines within the NHIN construct, CMS's evaluation of the use of claims data to populate PHRs for Medicare beneficiaries, the AHIP/Blue Cross Blue Shield Association model for portable PHRs, and Omnimedix's proposed Dossia personal health information network. These activities will introduce increasing numbers of consumers in the U.S. to PHRs, will show the potential utility and value of PHRs, and will demonstrate the promise of interoperable, portable PHRs.

Certification of PHRs may be a useful tool available to help address some of the main challenges of the PHR marketplace and better protect the consumer. The Consumer Empowerment Workgroup had extensive conversations about the potential benefits of certifying PHRs and EHR connectivity to PHRs as well the challenges related to achieving a meaningful certification process that support consumers in making informed choices about PHRs. There are at least two major prerequisites to creating a meaningful certification process for PHRs that empowers consumers rather than stifles innovation. First is the establishment of standards and specifications against which a vendor's PHR could be assessed. Second is the development of adequate industry experience in real-world settings to ensure the standards and specifications are sufficiently mature as to warrant certification. The Workgroup notes that, for example, while HITSP recently approved an interoperability specification for the exchange of patient medication history and registration summary information, there is limited industry experience with adopting the specification. Much work remains in establishing privacy and security policies that could be used as benchmarks for certification. The Consumer Empowerment Workgroup agreed that the establishment of standards, specifications, and privacy policies must be addressed before market implementation of certification. The Workgroup concluded that testing of standards and specifications in the marketplace was also necessary before they are included in a certification process.

One area where certification could fill a current gap in the marketplace relates to PHR privacy and security policies. An analysis of privacy and security policies for PHRs estimates that, while nearly all of the PHR vendors surveyed had these in place, only half of these PHR vendors are sharing these policies with consumers (Altarum, 2006). Another privacy concern is that many PHR vendors and service providers are not considered to be covered entities or business associates under the Health Insurance Portability and Accountability Act (HIPAA), so the protections provided under HIPAA may not extend to the consumers of these products. Certification of PHRs for security could potentially enhance the protections afforded to the consumer's personal health information. A second area where certification could fill a gap in the marketplace is that of interoperability between EHRs and PHRs. Currently, few incentives exist to motivate the sharing of information between systems, but it is in the best interest of the consumer that they be able to access their personal health information stored in an EHR or other system and be able to populate their PHR with these data. Several vendors and payers have testified that minimum certification of EHRs and PHRs for interoperability would improve data liquidity and increase trust in the products, thereby encouraging adoption of PHRs.

While progress is being made, significant attention and work is still needed in order to realize the transformational promise of increased personal health information management by consumers and the greater adoption of PHRs. The recommendations below identify initial strategic steps that could leverage ongoing activities and address prioritized challenges to address this Workgroup's Charge of gaining widespread adoption of a personal health record that is easy to use, portable, longitudinal, affordable, and consumer-centered. We suggest that these recommendations, if accepted by the AHIC, be considered by the Department of Health and Human Services (HHS) for adoption as HHS policy regarding current and future activities, including appropriate federal contracts, pilot, and demonstration projects as they relate to the Workgroup's Charge.

Furthermore, it is the Workgroup's intention that these recommendations apply more broadly to the health care system, and that public and private sector organizations would parallel HHS in their implementations. While their roles are different, the public and private sectors each play important parts in the new and emerging PHR marketplace. The federal government role is to create policies that address public concerns and increase data liquidity. The private sector is focused on understanding the value proposition and innovating to meet the needs of consumers. Both sectors need to collaborate in order to realize the vision of widespread adoption of PHRs.

RECOMMENDATIONS

The Workgroup identified the following actionable recommendations that could be initiated in 2007 to begin to address the Broad Charge.

1. Interoperability and Portability

Previously, most PHR products were stand-alone products that have little connectivity with electronic data sources. Currently, new PHR products have established connectivity with at least one electronic data source, e.g., a provider system or health plan.

However, when a consumer's PHR is tethered to an entity such as a health plan or a provider group, in the absence of interoperability standards, the data typically cannot be transferred to a different PHR if the consumer switches to another health plan or provider. If the consumer wishes to share the data with another provider or a new health plan, there is currently no consistent way for this data exchange to occur, and there has not been consensus on the data elements or information to be collected, maintained, and shared in a PHR.

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

Recommendation 1.2: HHS should support CCHIT in identifying a pathway and timeline for certification of PHRs after adequate industry experience has been achieved in this market. Such certification should include: specifications for PHR privacy and security, interoperability between PHRs and personal health information data sources (including EHRs) consistent with HITSP-identified standards, and PHR portability. CCHIT would need to develop expertise and reexamine its charter in preparation for these activities.

2. Privacy and Security

The Consumer Empowerment Workgroup recognizes its work is expected to bring millions of new users into a nationwide health information network, raising numerous questions about privacy, data security, consumer control, and trust. Survey data and early user experience confirm that Americans believe that their personal health information is highly sensitive, and they demand strong protections regarding its proper management, sharing, and use. Consumers should be able to control access to and secondary use of personal health information in PHRs. However, consistent, enforceable policies for release of data to PHRs, for disclosure of data to third parties, and for secondary use of data do not exist for entities not covered by the HIPAA regulations. Furthermore, such polices, where they exist, may not encourage the release of data in an electronic format, hindering interoperability and portability of data, and limiting use of PHRs in a treatment setting.

Because privacy and security policy issues are essential to achieving the AHIC Workgroups' charges, a cross-cutting Workgroup was formed in 2006 to handle these issues, the Confidentiality, Privacy and Security (CPS) Workgroup. Because the Consumer Empowerment Workgroup has considerable knowledge of personal health records, it would be appropriate for these two Workgroups to collaborate in the development of recommendations on privacy policies to protect consumers. Additionally, task forces within the new State Alliance for e-Health are currently considering privacy and liability issues.

Recommendation 2.1: The AHIC Confidentiality, Privacy and Security Workgroup, in collaboration with the Consumer Empowerment Workgroup, should develop principles and identify best practices for privacy policies for consumers' PHR data that are interoperable, i.e., protections that follow the consumer as his or her data moves or is shared. These recommendations should apply to all individuals and entities, including both covered and non-covered entities under HIPAA.

Recommendation 2.2: The HHS Office for Civil Rights should provide guidance to clarify the protections provided under HIPAA regarding the rights of consumers and their proxies to timely access to their electronic personal health information requested from covered entities.

Recommendation 2.3: CMS, in collaboration with the HHS Office for Civil Rights and other interested agencies, should develop policies and guidelines for HIPAA-covered entities and business associates for authorization of data release to and from PHRs, including the development of HIPAA-compliant standardized authorization language, no later than December 28, 2007.

Recommendation 2.4: The State Alliance for e-Health should consider exploring issues relative to State privacy laws and PHRs and share their findings with the Community and HHS. The Consumer Empowerment Workgroup intends to provide the State Alliance for e-Health with background information and a detailed explanation for this request.

3. Incentives for Adoption

Currently, there is a lack of incentives for PHR adoption and utilization by consumers. Enabling federal employees and beneficiaries to become early adopters in government-sponsored PHR pilot programs could encourage adoption while providing valuable feedback and lessons learned about how to implement a PHR and about the benefits such a tool provides. The PHRs may be offered directly by the agencies to their beneficiaries, through contracts with health care providers or plans, or through incentives that encourage individuals to gain access to PHRs on their own. Government agencies, such as the Department of Veterans Affairs, the Indian Health Service Office of Personnel Management, and CMS are also working on projects that could provide valuable information for future PHR implementations.

In the coming year, there is a need to evaluate current PHR offerings and incentives in order to develop a framework for offering PHRs to federal program populations in subsequent years. The framework could address both the criteria for the selection of the PHRs to be offered and the range of incentives that may encourage user adoption. The selection criteria could be used across federal agencies in making decisions about providing PHR services to its beneficiaries. Such criteria may include security and privacy practices, portability, interoperability, usability or other considerations.

Recommendation 3.1: HHS, through AHRQ, and in collaboration with the Indian Health Service, CMS, the Department of Veterans Affairs, and the Office of Personnel Management, should develop an evaluation framework that can assist in the systematic assessment of PHR offerings to federal employees and beneficiaries, by December 28, 2007. Evaluation criteria may include the effect of PHR services on health outcomes, level of consumer engagement in their health care, economic impact, data security, and other measures.

Recommendation 3.2: In 2007, HHS, through AHRQ when appropriate, should conduct evaluations that will provide useful information needed to develop the evaluation framework for assessing PHRs specified in 3.1. Specific study topics include the impact of data sharing through health information exchange, the comparative value of various data sources, and the impact of various architectural models.

Recommendation 3.2.1: HHS should assess how the sharing of personal health information with consumers through the use of PHRs impacts health care quality and patient satisfaction, including the results of private sector efforts as available.

Recommendation 3.2.2: HHS, through AHRQ, should conduct a study to assess the comparative value of and challenges related to using data on diagnoses and medication derived from claims, administrative, clinical, laboratory, pharmacy, and consumer-based sources to populate and maintain PHRs, including evaluations of the current availability of each source of data and of consumer and clinician reactions to and decisions based on the use of these data. Because of the low rate of EHR adoption by providers, the study should begin with an examination of experiences with currently available PHRs based on claims and administrative data as well as consumer-based sources, then move to clinical and other data over time, with interim results reported back to the Community by December 28, 2007, and final results reported back by June 30, 2008.

Recommendation 3.2.3: HHS, through AHRQ, should fund evaluations of the impact on health care quality and patient satisfaction of various architectural models of PHRs (e.g., stand-alone, integrated, networked) and delivery methods (e.g., web-based, compact disc, flash drive) to consumers.

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

Recommendation 3.4: HHS, through the Centers for Medicare & Medicaid Services and the Indian Health Service, should develop plans to offer portable PHRs with privacy protections to their beneficiaries, and report back to the Community about their plans as available. The plans should take into account the results of the studies and best practices from 2.1 and 3.2, as they become available.

Health care providers (especially primary care physicians) are key partners in realizing widespread adoption of PHRs. Surveys of consumers have identified their health care providers as the most trusted sources of health data. Consumers with PHRs that are integrated with provider EHRs are finding value in having a PHR but the percentage of the overall population with access to such integrated PHRs is very small. Providers find it difficult to justify the expense of the necessary infrastructure and the impact of the workflow changes necessary to interact with PHRs. It is important that incentives are properly aligned so that providers realize benefits from encouraging PHR adoption among their patients and so that portability of data between PHRs is encouraged.

Recommendation 3.5: In 2007, the Consumer Empowerment Workgroup should identify a range of incentives intended to increase adoption of PHRs, and report on their findings to the Community. These incentives may include financial benefits accruing to providers or other PHR offerors, financial benefits accruing to patients and consumers, or other forms of economic benefit of established effectiveness (e.g., employee productivity, customer loyalty). The Consumer Empowerment Workgroup should include in its report any available evidence documenting the effectiveness of each type of incentive and how that incentive might best be deployed to encourage PHR adoption.

4. Education and Outreach

Consumer awareness and engagement in PHRs today is fairly low. Current interest in PHRs is found largely among providers, employers, health plans and software vendors, rather than among consumers. Consumer awareness and engagement could be increased through education initiatives about the benefits and value of PHRs.

A broad variety of private-sector organizations regularly provides health education to their constituents. Examples include organizations such as patient advocates, chronic disease advocates, provider associations, and umbrella entities that are trade associations composed of many consumer groups. These private-sector organizations are positioned to effectively identify ways to segment and reach consumer groups for education purposes. They have established grassroots networks with proven track records for communicating information and providing education to their members.

Recommendation 4.1: In 2007, the Consumer Empowerment Workgroup should continue to study public and private sector activities to increase consumer awareness of PHRs, including the convening of an expert panel on consumer engagement and social marketing, and report on their findings to the Community.

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

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

Sincerely yours,

Nancy Davenport-Ennis

Co-chair, Consumer Empowerment

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Workgroup

Sincerely yours,

Rose Marie Robertson

Co-chair, Consumer Empowerment

Pose Mari Planto

Workgroup



American Health Information Community

Quality Workgroup Update

Carolyn Clancy HHS/ Agency for Healthcare Research and Quality

January 23, 2007

Workgroup Member List

Co-Chairs:

Carolyn ClancyRichard (Rick) Stephens HHS/Agency for Healthcare Research and Quality

The Boeing Company

Members:

- Abby Block
- Janet Corrig HHS/Centers for Medicare and Medicaid Services

National Quality Forum

Janet Corrigan Helen Darling National Business Group on Health U.S. Office of Personnel Management Anne Easton Nancy Foster American Hospital Association George Isham HealthPartners and AQA alliance

First Consulting Group
Hospital Corporation of America Jane MetzgerSusan Postal Gerald Shea AFL-CIO

 Barry Straube Jonathan Teich

HHS/Centers for Medicare and Medicaid Services Brigham & Women's Hospital Phyllis Torda National Committee for Quality Assurance

Reed V. Tuckson United Health Group

- Charlene Underwood Siemens Medical Solutions and HIMSS EHR Vendor Association

- Margaret van Amringe Joint Commission on Accreditation of Healthcare Organizations

 Josie Williams Quality and Patient Safety Initiatives

Office of the National Coordinator:
 Kelly Cronin

Quality Workgroup 01/23/07

Broad Charge: What are we trying to accomplish?

Make recommendations to the American Health Information Community so that health IT can provide the data needed for the development of quality measures that are useful to patients and others in the health care industry, automate the measurement and reporting of a comprehensive current and future set of quality measures, and accelerate the use of clinical decision support that can improve performance on those quality measures. Also, make recommendations for how performance measures should align with the capabilities and limitations of health IT.

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Current state: Where are we today?

- No unified, national quality agenda.
- Reporting is manual, expensive, and time consuming.
- Focus is on reporting measures that are widely available, as opposed to high priority.
- Most measures lack detailed data specifications, limiting potential for automation or easy data capture.
- Multiple stakeholders retain relevant data with minimal data exchange.
- Varied (often proprietary) data formats and poor data quality hamper data aggregation efforts.

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Current state: Where are we today?

- Clinical Decision Support (CDS) has limited penetration and is not closely aligned with quality reporting.
- Public reporting is fractured, inconsistent, and infrequently used to support choice of providers.
- Extensive innovation in the private sector with pay for performance, but not yet broadly scaled.
- Privacy and security policy gaps exist for non-covered HIPAA entities' use of electronic health information.

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Vision for the future

- Quality is integral to all aspects of health care. Every citizen expects consistently high-quality, safe, and efficient care.
- Performance information is timely, comprehensive, and trusted as an accurate measure of the nation's ability to address high-priority gaps in quality and safety.
- Information technology and information sharing support consumers' information needs and assist providers in delivering evidence-based care.
- The national quality agenda promotes all of the above, and is:
 - Aligned with state and regional health care reform policies
 - Reinforced by public reporting on metrics
 - Supported by a payment framework that aligns expectations with resources

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End state: Where do we want to end up?

- Widespread awareness of national quality agenda.
- Significantly reduced administrative burden of performance measurement due to adoption of national consensus metrics and unified data stewardship.
- Needs for data to support measurement and quality improvement largely met by EHRs, PHRs, and other network technologies. Common services allow small practices to participate more effectively.
- Rapid diffusion of new guidelines, metrics, and best practices into EHRs facilitated by harmonized standards and distribution services.
- CDS routinely available and supports improved quality of care.

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End state: Where do we want to end up?

- Reporting and feedback provided in near real-time. Data collection is a natural by-product of care, and data quality is high.
- Consumers routinely use provider performance information to help make health care provider decisions, and providers begin to differentiate on safety, quality, and cost. More health care spending can be performance-based due to better reliability and availability of quality improvement metrics and tools.
- A national framework for the secondary use of health data for multiple purposes provides for appropriate privacy and security protections.

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Mid-state: Where will we likely be in 4-6 years?

- National Quality Forum and measure developers have established consensus around national goals for quality and a common measures framework for development and maintenance of measures.
- A body governed by multiple stakeholders (data steward) establishes uniform operating rules and standards for sharing and aggregating public and private sector data on quality and efficiency.
- Quality reporting is largely supported by existing HIT. EHRs increasingly support data capture and reporting for consensus measures, using interoperable platforms.
- Quality metric development organizations have developed an expanded, basic set of metrics. Data standards exist for common data elements required for quality reporting.

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Mid-state: Where will we likely be in 4-6 years?

- Standardization of CDS methodologies is complete, with certification requirements for robust use of CDS in EHR systems.
- Consumer engagement strategies are more mature and tied to transparency of price and quality.
- · Increased alignment of reimbursement and quality.
- State, regional, and national privacy and security policies enable appropriate secondary uses of clinical data for quality management (and other applications or purposes).

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Key enablers for reaching the mid-state

- Quality alliances producing uniform standards for sharing, aggregating, and reporting data and metrics.
- Measures that span care delivery.
- NHIN/RHIO collaboration on quality measurement initiatives.
- Quality use case guiding standards harmonization and inpatient and ambulatory EHR certification criteria in 2007.
- Quality use case guiding NHIN contracts.
- Scalable open source software development to reduce costs of multiple approaches to data aggregation.

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Key enablers for reaching the mid-state

- Availability of knowledge management repository in public domain.
- Clarification of the role of a national health data stewardship entity to oversee appropriate use of data.
- Additional pilot projects for a national framework to link public and private data sets and to assess clinical quality, cost of care, and patient experience.

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Near-term key needs to be addressed

- Automate data capture and reporting to support core sets of AQA clinician-focused and Hospital Quality Alliance (HQA) inpatient quality measures.
- Provide feedback to providers in real or near-real-time.
- Enable data aggregation to allow public reporting of quality measures based on comprehensive clinical data that is pooled across providers and merged, as appropriate, with other data sources.
- Align performance measurement with the capabilities and limitations of health information technology.

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Quality Workgroup Executive Summary of the End State Vision

In the future, stakeholders, including consumers, purchasers, providers, policymakers, researchers, accrediting and oversight bodies, will rely on transparent reporting of quality performance and quality improvement to inform their decision making about care. Information technology and the sharing of health information across a network of regional health information entities using data from electronic health records (EHRs), personal health records (PHRs), and strong clinical decision support (CDS) systems will assist providers in ensuring that the right care is delivered to the right patient – every time. Consumers and policymakers will use these same systems to understand how well the nation as a whole and individual providers are doing in improving care and health status in accordance with national, regional, and local priorities.

Achieving this vision will radically transform the way health care information is shared among various stakeholders and, in particular, how it is used by consumers. Consumers will be empowered to take a more active role in their health care. Transformational change among stakeholder groups and within various dimensions of today's health care system will be required to achieve this vision. A strong public – private partnership and a joint commitment to producing value to health care consumers are critical. Responsibility for improving quality and value in health care transcends any one stakeholder group, and true alignment of incentives across the health care value chain requires active participation and engagement from each link in that chain.

The envisioned changes in the defining attributes and characteristics of today's health care system are described below, illustrated by their impact on key stakeholders.

Consumers: Consumers will be better educated, more empowered, and more engaged in their health care through the increased availability of personal health records and use of electronic health records by their providers. Growing awareness of provider performance information will enable informed decision making about their choice of providers. Access and

Defining Characteristics or Attributes of the Health Care System with Respect to the Quality Enterprise

- Receiving Care
- Managing Clinician-Patient Interactions
- Managing Health of Defined Populations
- Coordination of Care
- Improving Quality
- Measuring and Reporting Quality
- Reimbursement

utilization of cost and quality information along with education in how to interpret both will strengthen their experience. The capacity to gather evidence as a by-product of clinical interactions will enhance the availability of evidence-based information on treatment options, permitting customization of care to individual needs and preferences.

Providers: Providers will have access to performance information, coordinated guidelines and protocols. Market differentiation will occur based on safety, quality and cost performance. Linking information networks will enhance care coordination and allow easy communication between providers. Utilizing EHR's at the point of decision making along with other interventions, like clinical decision support tools, will help address a wide range of condition-specific guidelines and patient safety. Providers will receive incentives to continually improve through payment as well as non financial recognition such as maintenance of professional certification and Continuing Medical Education (CME).

Payers: The adoption of national consensus metrics and unified data stewardship will significantly reduce the administrative and economic burden of physician performance measurement. More of healthcare spending will be performance-based, due to better reliability of metrics and widespread adoption of health information technology and evidence to improve quality. Benefit design, provider relations and consumer strategies will all promote transparency and value.

Quality Workgroup Executive Summary of the End State Vision

Employers: National consensus quality goals and standards for quality performance reporting will provide a comprehensive basis for employee awareness and incentives. The choice of health plans, physicians, and hospitals will be enhanced by the availability of performance data.

Research Community: Guideline developers and clinical researchers will collect performance measurement data and refine the evidence base and practice guidelines in near real-time. Measures will be dynamically adjusted based on refinements by guideline developers and the clinical research community.

Policymakers: Health care policy will be unified around the national quality agenda and will incorporate gaps identified in the National Healthcare Quality and Disparities Report. Policy decisions will be reviewed annually based on population-based reporting and analysis of outcomes enabling modifications, enhancements or discontinuation of policies as appropriate.

Accreditors: Accreditors will incorporate a robust measurement set based on a strong evidence base. Continuous evaluation of providers will be based on informative, easily accessible data. Tools for improvement will be tailored to individual providers and care settings.

To support the envisioned changes to the health care system, there are specific obstacles that must be overcome as well as various aspects of the national quality infrastructure that must be bolstered, and, in some cases, developed *de novo*. These barriers and enablers are summarized in the following table:

Barriers Enablers

Clear business model for health information Clear value preparation currents the use

- Lack of a clear business model for health information exchange
- Lack of a clear business model for quality
- Limited set of national consensus measures; robust measures not yet developed for all physician specialties
- Lack of standards for data collection and aggregation
- Lack of standardized mechanisms for external reporting including data stewardship
- Lack of alignment of payment with quality performance
- Gaps in regulations and practices relating to privacy/security and secondary use of data
- Slow translation of research into practice at the point of care
- Quality assessment tightly linked with site of care or individual clinicians; few integrated or episode-based metrics
- Lack of coordination in quality measurement
- Gaps in quality management capabilities of EHRs
- Clinical documentation unstructured using non-standardized nomenclature
- HIE operational in few regions
- Poor provider economics- higher costs of doing business, declining reimbursement and the expectation of implementing information technology solutions
- Lack of a complete medical record to support CDS

- Clear value proposition supports the use of HIT capabilities for quality assessment, quality improvement and informed decision making
- Collaboration between providers, purchasers, consumers and accreditors produce uniform standards for sharing and aggregating health data and for public reporting
- Collaboration between regional quality measurement initiatives and RHIOs or NHIN service providers
- Standard approach for EHRs to routinely produce quality data based on approved measures that span care delivery
- Designation of a national health data stewardship entity to oversee appropriate use of data
- Comprehensive medical record across points of care obtained via health information exchange networks to enable intelligent alerts to providers
- Measure developers identify data and HIT requirements in order to implement measures into clinical care and software
- Certification of HIT based on criteria to enable reporting of an expanded set of AQA and HQA quality measurement in EHRs
- Education of consumers on how to obtain data and assess quality of care along with sharing of data with patients' PHRs will increase consumer stake in quality measurement
- Overall payment system that provides incentives for quality and safe care
- Cultural change that encourages performance reporting
- Certification of clinical decision support capabilities in EHRs
- Additional pilot projects that provide leadership for a national framework and act as learning laboratories to link public and private data sets and assess clinical quality, cost of care and patient experience

Quality Workgroup Vision Summary

In response to the American Health Information Community (the Community), the Quality Workgroup prepared the following document to address the needs and expectations of health care stakeholders by the year 2014. The Workgroup's vision is predicated on the idea that performance measurement is integral to all aspects of health care in the United States, and that every citizen has the right to expect consistently high-quality, safe, and efficient care. Furthermore, stakeholder education must occur to gain a common understanding of the nation's unified quality agenda and to work toward a common goal. Consumers, in particular, will require additional information on what is being measured and the rationale behind those decisions.

Desired Future Vision

In the future, stakeholders, including consumers, purchasers, providers, policymakers, researchers, accrediting and oversight bodies will rely on transparent reporting of quality performance and quality improvement to inform their decision making about care. Information technology and the sharing of health information across a network of regional health information entities using data from electronic health records (EHR), personal health records (PHR), and strong clinical decision support (CDS) systems will assist providers in ensuring that the right care is delivered to the right patient – every time. Consumers and policymakers will use these same systems to understand how well the nation as a whole and individual providers are doing in improving care and health status in accordance with national, regional, and local priorities.

Ideally, the national agenda will be in alignment with state and regional health care reform and policies. Performance information will be timely, comprehensive, and trusted as a true measure of how well the nation is addressing high-priority gaps in quality and safety. Performance and quality improvement are accelerated because information systems increase the ability to make optimal care decisions. Finally, results will demonstrate significant progress on the nation's quality goals reinforced by public reporting on metrics and a payment framework that aligns expectations and resources among providers, employers, public and private payers.

Realizing the Vision: Impact on Today's Health Care System

Achieving this vision will require a transformation in the information necessary to evaluate provider performance and will radically shift the way health care information is shared among various stakeholders and, in particular, how it is used by consumers.

In the future, consumers will be empowered to take a more active role in their health care. Providing more information in the form of comparative data will afford consumers the opportunity to make informed choices. To achieve this vision, however, requires transformational change among stakeholder groups and within various dimensions of today's health care system. A strong public–private partnership combined with a joint commitment to increasing value to health care consumers is critical. The issue of quality and value in health

care transcends any one stakeholder group, and true alignment of incentives across the health care value chain requires active participation and engagement from each link in that chain.

Defining Characteristics of the Health Care System in the Context of a National Quality Enterprise

Changes to the defining characteristics of the health care system within the context of a National Quality Enterprise (Quality Enterprise) must be present to achieve the high-level vision described above. The Quality Enterprise represents the nation's quality infrastructure, quality goals, and incorporates the roles, responsibilities, and expectations of key stakeholders.

In the future, national goals will be realized through comprehensive measure sets that address all of the Institute of Medicine's (IOM) "Six Aims for Improvement." Meaningful and consistently refined consensus measures, such as those emerging from the AQA and the Hospital Quality Alliance (HQA) consensus process will be harmonized across settings and level of analysis and all stakeholders will have access to information on "value" (i.e., cost and outcomes associated with different medical interventions and provider settings). The data necessary to describe performance based upon these standards will be efficiently collected, aggregated, and analyzed through the widespread adoption of health information technology that facilitates electronic access to clinical information. The Workgroup recognizes that transition to clinical data will be lengthy, and that a hybrid of claims and clinical data will be required to measure quality for the foreseeable future.

In the context of the Quality Enterprise, the various characteristics of today's and the future state's health care system are described below, taking into account the impact the transition from the current to future state will have on key stakeholder's experience and expectations.

Receiving Care

Today, the average *consumer* needs more information to make a more educated choice about which providers they want to use, what treatments they want to receive, and the cost, quality and efficiency of the care available. The lack of consistency in available information makes provider and care comparisons difficult, and the public is becoming increasingly aware of gaps in care and safety issues for themselves and their family members.

In the future state, a national quality agenda reflecting patient needs will be disseminated to ensure widespread consumer awareness. Consumers will be more educated, empowered and confident in their health care through the increased availability of PHRs and the rapidly growing use of EHRs by their providers. Consumers will routinely use provider performance information to make decisions about their choice of providers and, with access to useful information, will expect dialogue with providers. Technology will be leveraged to coordinate health information across delivery systems, patients will be allowed to add input, and tailored self-care programs and guidelines will be available.

Additionally, *providers* will further participate in the performance evaluation process to match a patient's clinical needs and personal preferences with the appropriate care, based upon

demonstrated expertise, quality, safety, efficiency, and other relevant characteristics. Networks will link providers to enable easy communication with each other in order to provide coordinated care. Providers will be more engaged and more motivated to improve. Routine use of clinical decision support and internal quality improvement will be aligned with the national quality agenda. The *payer* community will provide benefit design and consumer strategies that promote availability and accessibility of quality and cost information, and *employers* will provide choice of health plans to consumers based on enhanced availability of performance data.

Managing Clinician-Patient Interactions

Today, *providers* struggle with assembling a comprehensive view of a patient's health care needs due to the way information is collected and stored. Productivity pressures and the reimbursement structure impede the opportunity for providers to have sufficient dialogue with patients, stifling communication and information sharing. Documentation is largely manual and not geared for tracking, quality improvement, or quality reporting, resulting in an additional burden on providers to collect and report measurement data.

To improve on the current state, measurement and quality improvement will largely rely on EHRs and other network technologies. In the future, national quality metrics and a unified set of operating rules and standards for collecting and using public and private sector quality data ("data stewardship") will help to simplify quality measurement; thereby reducing the burden of external reporting by providers and focusing efforts on internal quality improvement. Distribution systems will keep EHRs up-to-date with best practice clinical decision support (CDS) based on latest knowledge, allowing for feedback to *providers* in real or near-real time. EHR support at the point of care will be common practice along with other interventions to address a wide range of condition-specific guidelines and patient safety. Data from interoperable EHRs will be available to the *research community* to better assess and prioritize national quality metrics and guidelines.

Additionally, consumers will have access to tools that enable a more informed dialogue between patient and provider with regular channels to report their experience with care. Employers will continue to support patient empowerment and linkage of payment to performance ensuring consumers have a choice of physicians and hospitals that are enhanced by the availability of performance data. Payers will significantly reduce an administrative burden of reporting provider performance due to adoption of national consensus metrics and unified data stewardship; spending will be performance-based; and provider strategies will promote quality and cost transparency. Furthermore, the research community will be able to dynamically update existing measures based on changes in evidence base, and national priorities.

Managing Health of Defined Populations

Currently, the ability to track the quality of care received by groups of similar patients, commonly referred to as populations, is limited by the nation's reliance on paper medical records and a lack of standardized, relevant information. Population-based health management, population-based health interventions and communications and outreach to subsets of the population are not fully realized as a result of information gaps.

In the future, *consumers* will experience reduced gaps in care due to improved EHR support. EHR functionality will support the availability of patient lists, identifying more easily those consumers with urgent needs, and communications (via secure clinical messaging) to enable outreach to patients with gaps in care. *Providers* will leverage the incorporation of CDS in EHRs to allow for appropriate care to be provided directly at the time of the patient encounter, with limited requirement for alerts and reminders. Improved systems will facilitate better coordinated care of patients with multiple chronic problems. *Payers* will be able to tailor and target care and prevention programs to defined populations and design specialized incentive programs for providers treating specific subpopulations.

The future will bring the opportunity for the *research community* to more effectively study populations, and refine or advance the evidence base by utilizing data capture and reporting enabled by population health management. Finally, the increased use and reporting through EHRs will allow *policymakers* to focus on improving quality of care for defined populations and populations at-large through ready access to accurate quality and clinical data at the population level.

Coordination of Care

Today, effective coordination of care across settings and along the continuum of care is limited by site- and venue-specific medical records (both paper and electronic), and manual processes are needed today to communicate relevant health care information. Clinicians have limited access to information on how to most effectively transition patients along an episode of care and how to coordinate with other care providers when patients have multiple chronic conditions. As a result, the transition of patients between settings is characterized by a lack of continuity directly impacting the quality of care a patient receives.

In the future, *providers* will experience widespread adoption of interoperable EHRs and PHRs, enabling information sharing across sites and settings of care, allowing networks of practitioners to communicate easily with one another. *Providers* will have access to coordinated guidelines and protocols will be widely-used along with the inclusion of multi-practice care process in quality metrics. Referral information systems will facilitate the transfer of critical information needed for care coordination and continuity.

To support improved coordination of care, the *National Quality Enterprise* will encourage the alignment of measures across settings as well as the use of interoperable EHRs and PHRs that allow for measurement of episode-based care. The *research community* will develop guidelines and measures that promote efficient, quality, coordinated care, and will continue to identify gaps and refine and update existing measures as more information is gathered on coordination of care. As a result of these efforts, *payers* will implement payment programs that reward effectiveness and coordination of care and *consumers* will remain engaged and empowered, and utilize quality information to strengthen their experience and undertake a vested interest in care across settings.

Quality Improvement

Today, public reporting requirements are helping to advance quality improvement, yet remains constrained by the intensity and burden of data collection. Performance measurement is reliant on labor-intensive chart reviews, and manual data extraction activities remain a limiting factor in making the necessary information available to impact improvement in care delivery. EHRs, where implemented, support care delivery but have not been designed to facilitate improvement and assessment of quality of care delivered across patient groups. Providers receive feedback reports on quality retrospectively, with at least a four-month lag from the date of care delivery, and the use of clinical decision support at the point of care is low.

The future will require automated data collection through EHRs for the HQA and AQA quality measures, thereby reducing a *provider* burden of collection and reporting. Event detectors within EHRs will identify significant variances and hazards, highlighting for providers important health details and include the ability to integrate patient-specific care and safety recommendations into EHR-supported tasks and workflow. Improved CDS will be selectively concentrated toward the highest-frequency/highest-severity quality issues in addition to allowing for automated collection of adherence, non-adherence, and exclusion criteria.

Furthermore, *consumers* will remain engaged and empowered, and will realize the benefit of true quality improvement; becoming more comfortable with initiating dialogue with providers about their health care. *Payers* will implement payment programs that reward quality improvement and transparency of quality information. The *research community* will leverage outcomes data and continually refine practice guidelines and quality measures to further quality improvement efforts, and to build or extend the evidence base.

Measuring and Reporting Quality

There is no unified national agenda for measuring quality today. Current measurement efforts are limited by what is measurable, rather than focused on what is important to measure. Measure development activities focus on provider encounters and, thus, occur in silos. Many measure developers use differing standards for evidence grading, differing approaches to measure specifications, and have varying capabilities for measure development and maintenance, resulting in inconsistencies in the way measures are developed, implemented and maintained.

In the future, *All Stakeholders* will have a robust set of standardized quality measures to use, including specialty care settings. *Providers'* reporting efforts will largely be supported by health information technology and real or near-real time feedback. EHRs will support data capture and reporting for consensus measures leading to quality reporting as a natural by-product of care. Common services will allow small practices to participate more effectively in reporting.

In addition, by increasing reporting participation, *accreditors* will increase reliance on robust, easily-accessible data, including performance measurement, in the evaluation for accreditation. Using the same information, *consumers* will be able to discern quality of care through consistent information with which they can make informed choices and *payers* will be able to reward

efficiency and quality of care, based on reporting of reliable and consistent quality measures. *Policymakers* will become unified around a national quality agenda and incorporate into this agenda the performance gaps identified in the AHRQ National Healthcare Quality and Disparities Report.

Payment

Today's payment system is largely driven by financial compensation for utilization of encounter-based services, regardless of patient outcome. There has been an increase in pay-for-performance pilots and programs are increasing in number but studies on the effectiveness of such programs remain mixed. Measurement of quality performance is done largely through claims data because electronic clinical information is generally lacking and performance information is insufficient for payers to determine true under- and over-utilization of services. Currently, the market perceives the cost of quality reporting to be higher than the benefit or incentives, but generally supports movement toward payment based on value.

In the future, payment reform will exist when incentives are aligned. To improve the current system, *payers* will use financial incentives to promote higher levels of quality across diverse health care settings. Easier, more consistent reporting will lead to more reliable performance measures combined with wider availability of tools to improve overall quality. This system will also allow for increased reimbursement drivers based on quality. Adoption of national consensus metrics and a unified data stewardship will significantly reduce the payers' administrative burden of provider performance measurement and lead to a comprehensive basis for quality performance incentives.

In addition, *providers* will continually improve, and will receive incentives to do so through payment, while *consumers* will recognize value and quality. Consumers will have access to cost information and will be educated on how to interpret both quality and cost data. At this time pay-for-performance strategies will evolve from rewarding high quality clinical care to rewarding care that is not only high quality but patient-focused and efficient. *Policymakers* will support legislation and programming that link "performance" to payment, and *employers* will recognize benefits from alignment of incentives and payment across the health care value chain. These changes will afford employers the opportunity to manage shared cost programs with employees due to the availability of valuable, understandable and applicable health care quality performance reporting.

Building Blocks for Change: National Quality Infrastructure Requirements

To support the envisioned changes to the health care system, there are various components of the national quality infrastructure that must be bolstered, and, in some cases, developed *de novo*. These components represent interdependent building blocks, working together to create the defined future vision. For example, a robust health information exchange (HIE) is dependent on solid policies for appropriate data use, stemming from a unified data stewardship and clearly-defined and accepted privacy and security policies with data supplied by interoperable electronic health records. Each one of these building blocks is critically dependent on the development and maintenance of a strong public-private partnership. Without shared

responsibility, commitment and investment, we will not be successful in achieving the milestones discussed below.

Metrics

Today, national priorities for quality measurement are not defined and metrics are currently limited to what is measurable rather that what is important to measure. Developed by multiple organizations with differing perspectives, experience, and objectives; metrics have limited standardization of targets and limited commonality in how similar terms are defined for numerators and denominators. Operational and IT challenges of metrics create tension with the need to drive measurement forward.

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

Electronic Health Record Adoption

Recent surveys suggest that adoption rates in ambulatory settings range between 15 and 18 percent¹. In 2005, 10 percent of hospitals had implemented all functions of an EHR; 36 percent were just getting started; 27 percent had low usability; and 27 percent had moderate usability (usability defined as the number of functions and the percentage of which the hospital had fully implemented)².

In the future, EHR adoption will increase because of the financial incentives related to improved quality and external reporting, and a reduction in purchaser uncertainty due to product certification, which will require high quality, highly-functional EHR products.

Electronic Health Record Products

Today, capabilities of EHR products lag behind the needs of external performance reporting and quality improvement. CDS capabilities in existing inpatient EHRs consist mostly of alerts and order sets as part of computerized physician order entry systems. In ambulatory EHRs, CDS is limited to some medication checking and age- and sex-based wellness prompting but limited support for disease management. CDS is difficult to implement without disrupting clinician workflow, and is not explicitly synchronized with quality measurement. Utilization

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¹ Gans D, Kralewski J, Hammons T, Dowd B. Medical groups' adoption of electronic health records and information systems. Health Affairs 2005; 24(5):1323-33.

¹ Burt CW, Sisk JE. Which physicians and practices are using electronic medical records? Health Affairs 2005; 24(5):1334-43.

² http://www.ahapolicyforum.org/ahapolicyforum/resources/content/FINALNonEmbITSurvey105.pdf

and benefits are inconsistent at different sites because the knowledge and tools are not interoperable (each vendor / provider recreates the wheel) and adoption is limited and difficult.

In order for change to occur there needs to be increased availability of EHR capabilities to include data capture, measurement, and reporting due to product certification and market pressures. A common performance measurement infrastructure must include standardized data sets, and the wide-spread use of HIT including EHR platforms and interoperability throughout the systems. This unified platform will be able to monitor and improve quality performance. Standardization of CDS methodologies will be completed through harmonization of US and international Standard Development Organizations. EHRs containing effective CDS tools will address a full range of quality improvement goals: health maintenance, chronic disease management, patient safety, and effectiveness and cost of care. Effective EHRs combined with change management will build local and national capacity to work toward the nation's quality improvement priorities. CDS and related process improvements will be supported by reimbursement structure and certification.

Health Information Exchange (HIE)

Currently, there are at least nine state-level HIEs, with 55 percent of these planning to be suppliers of performance data. However, vehicles for support and knowledge sharing among state-level HIE initiatives are lacking along with financial models for a sustainable HIE structure. Mechanisms are needed to promote strategic synergy among states and between state and federal efforts, with additional clarity on how state policymakers and governmental agencies should be involved in HIE. Public and private payers will need to be engaged and leveraged.

In order to leverage HIE capabilities, broader stakeholder dialogue must

- conduct an environmental scan of states that have successfully integrated state-level HIE with quality and transparency initiatives;
- develop business models that support state-level HIE involvement in quality and transparency initiatives; and
- discuss and clarify the governance structures that are required to support the relationship between state-level HIE organizations and quality initiatives.

In the future, these activities will position state-level HIEs to facilitate cost-effective access to statewide data for quality initiatives and assist with data standardization to reduce duplicate data acquisition efforts. HIE representatives will be involved in national committees and coordinating efforts (NQF, AQA, HQA, etc.) while strengthening relationships with quality organizations at the state and local levels.

Data Stewardship

Currently, there is no consensus regarding utility of centralized *vs.* decentralized strategies for aggregating data for quality assessment, resulting in multiple stakeholders holding relevant

data with limited access to others'. In addition, there are no uniform rules regarding data access and use, contributing to privacy concerns.

To create consensus, a collaborative of measure developers, clinical system vendors, providers and practitioners must begin to apply research and hold discussions to generate principles for guidance on implementation of operating rules and standards. A data steward body will reconcile and enhance operating rules and standards based on lessons from AQA pilots and emerging data exchanges. Stewardship will be consistent across aggregators, with some variation, where necessary, to be sensitive to regional priorities, and some variation over time as the national agenda for improving quality evolves. Technical assistance will be available for data aggregators and international standards will be harmonized where appropriate to encourage adoption and implementation.

Data Aggregation

In the present environment, clinical data is aggregated by providers and payers in proprietary databases that are not interoperable, or into stand-alone registries and related databases. These individual initiatives do not comprehensively assess provider performance since the data collected are often insufficient to reliably measure quality and efficiency performance.

In order to improve data aggregation practices, it must be enhanced by the structuring of documented data either through direct entry of structured information, or through focused and standardized free text searching and parsing techniques, seamlessly to clinical users. This will allow for patient-centered data, aggregated across providers and payers to support longitudinal quality measurement at the patient, physician, physician group, plan and hospital level. Longitudinal measurement systems will capture the performance of multiple providers caring for a patient, will examine how well care is provided across transitions to different settings (e.g., hospital to nursing home), and most important, will evaluate patient outcomes over time. The same data will also be used to report to population health reporting and surveillance (e.g., real time biosurveillance; cancer registries; vital statistics).

Population Reporting and Feedback

Today providers utilize proprietary information systems for performance improvement and physician feedback.

In the future, quality reporting modules or systems will provide closer to real-time performance data to local organization managers or individual practitioners to allow timely implementation of performance improvements through benchmarking and peer comparison. EHRs will support transfer of quality data to these quality reporting modules or systems that can support automated and standardized quality reporting. An established nationwide interoperability will enable population reporting and feedback and will coordinate public and private health.

Public Reporting

Today, public reporting is fractured and inconsistent with multiple measures and data display approaches. As a result, the public infrequently uses reported data to support choice of providers. NQF, in partnership with measure developers, need to define consensus set of measurement priorities to support public reporting, and ensure that public reporting is focused on national priorities.

In the future, research must be done to understand consumer preferences around data display. The quality data that is displayed needs to be pertinent, valid, reliable, and understandable to enable informed choices across the care continuum (e.g., hospitals, physicians, SNF, etc). Information on performance data, payment policies, and performance improvement processes will require timely public disclosure to providers (both clinicians and institutions), purchasers, and beneficiaries, to promote accountability among providers.

Privacy and Security Policies

The Health Insurance Portability Accountability Act of 1996 (HIPAA) applies to health information created or maintained by health plans, health care clearinghouses, and health care providers who engage in certain electronic transactions, but there is a potential lack of protection of personal health information (PHI) when used by entities not explicitly covered by HIPAA legislation or regulations. In fact, there may be mistaken perceptions that HIPAA assures protection of all secondary use of PHI by users, beyond those covered entities specifically noted in HIPAA.

In the future, a national framework for the secondary use of health data must include a robust infrastructure of policies, standards, and best practices to facilitate the broad and multiple purpose collection, storage, aggregation, linkage, and transmission of health data with appropriate protections for legitimate secondary use. Rules and guidelines will be put in place early on in the process in order to enable quality programs to continue uninterrupted by secondary data issues. Appropriate confidentiality protections will be in place for the submission of patient data that are in strict compliance with HIPAA regulations. Potential problems of patients opting out of having their data included in a data repository will be addressed and impacts on accurately assessing the quality of care on both the national and community levels will be understood.



American Health Information Community

Biosurveillance Workgroup Update

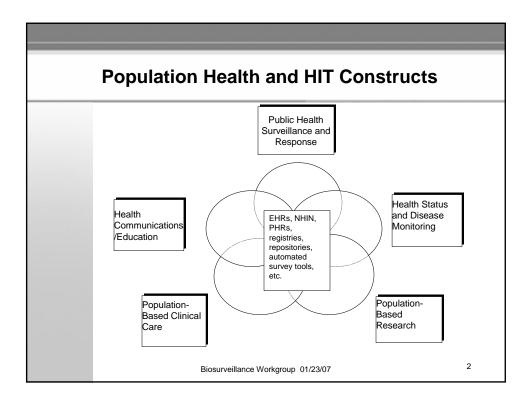
Charles Kahn, Federation of American Hospitals John Lumpkin, The Robert Wood Johnson Foundation

January 23, 2007

Background

- AHIC approves Biosurveillance Workgroup-November, 2005.
- HHS Health Information Technology Policy Council recognizes gap in population health needs across AHIC workgroups.
- Population health needs presented at October 2006 AHIC Meeting.
- AHIC asks Biosurveillance Workgroup to expand scope.

Biosurveillance Workgroup 01/23/07



Population Health – Five Main Areas

- Public Health Surveillance and Response
 Ongoing systematic collection, analysis and
 interpretation of public health data essential to the
 planning, implementation, and evaluation of public
 health practice closely integrated with the timely
 dissemination of these data to those responsible
 for prevention and control, and management of the
 appropriate response.
- Health Status/Disease Monitoring
 Accurate, periodic assessment of community and patient-level health status.

Biosurveillance Workgroup 01/23/07

Population Health – Five Main Areas (Continued)

Population-Based Clinical Care

Health and functional status for populations of people (e.g., income-based, ethnicity-based, agebased, gender-based, others defined as needed).

Population-Based Research

Research for new insights and innovative solutions to health problems on a population level.

Health Communications/Health Education

Inform, educate and empower providers, consumers, and others about health and wellness issues.

Biosurveillance Workgroup 01/23/07

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Expanded Scope - Proposed

New Name

Population Health and Clinical Care Connections (PH/CCC) Workgroup.

Broad Charge

Make recommendations to the Community that facilitate the flow of reliable health information among population health and clinical care systems necessary to protect and improve the public's health.

Biosurveillance Workgroup 01/23/07

Biosurveillance Workgroup Member List

Co-Chairs:
- Charles Kahn Federation of American Hospitals The Robert Wood Johnson Foundation CDC John Lumpkin Julie Gerberding

Members:

- Michael Barr Michael Barr Scott Becker Larry Biggio Art Davidson Leah Devlin Thomas Frieden Shawn Fultz Shaun Grannis Lamas Hadler

American College of Physicians
Association of Public Health Laboratories
State of Wyoming
Denver Public Health Department
NC Department of HHS
NYC Dept. of Health and Mental Hygiene
Department of Veterans Affairs
Regenstrief
Connecticut Department of Health (CSTE)
Agency for Healthcare Research and Quality
American College of Emergency Physicians
Minnesota DoH
HHS/ONC
CDC/NCPHI
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- Michelle Meigs – APHL Paula Soper – NACCHO
 John Abellera – CSTE

Biosurveillance Workgroup 01/23/07

BACKGROUND DOCUMENT FOR EXPANDED SCOPE: POPULATION HEALTH AND CLINICAL CARE

Population health is broadly described in this document (and depicted in Figure 1) using five interrelated and overlapping domains: public health surveillance and response; health status and disease monitoring; population-based research; population-based clinical care; and health education/communications.

Population health is an approach to improve the health of an entire population, where the health of the population is measured by health status indicators and influenced by: social, economic and physical environments; personal health practices; individual health capacity and coping skills; human biology; early childhood development; and health services. Numerous entities involved in health care and public health contribute to population health. As such, it is recognized by this Workgroup that many of the bullets falling under the five domains described below are either shared or exclusive responsibilities of other existing or future AHIC Workgroups. Examples of shared activities are highlighted in the text below (though not exhaustively).

The Workgroup also recognizes that there is a need to develop measures and to assess how well public health and health care systems and programs are working to improve the health of populations. An aspect of this includes development of indicators to evaluate how effectively research outcomes are translated into practice. While the overall evaluation of systems is not detailed within the sections below, it is recognized as an overarching need associated with population health.

Figure - 1 below depicts the five concepts used to describe population health as five concentric and overlapping circles. Health information technology is represented in the rectangular box in the middle of the diagram and it supports, interacts with, and underlies the other five areas.

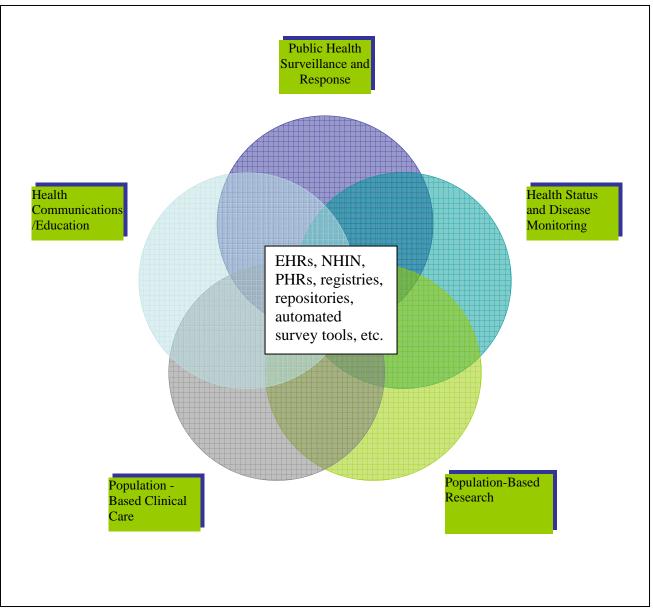


Figure - 1

Public Health Surveillance and Response

- Ongoing, systematic collection, analysis and interpretation of public health data essential to the planning, implementation and evaluation of public health practice closely integrated with the timely dissemination of these data to those responsible for prevention and control, and management of the appropriate response
- Situational Awareness
- Event Detection, including outbreaks, epidemics and pandemics
- Active Surveillance (e.g., for unexplained deaths or for disease)
- Notifiable Condition Reporting
- Response Management (e.g., outbreak management, countermeasure allocation, distribution, and administration)
- Adverse Events Reporting (e.g., MedWatch, NNIS, VAERS, etc.)
- Data collected by a public health surveillance system can be used for immediate public health action, program planning and evaluation, and formulating research hypotheses. For example, data from a public health surveillance system can be used to:
 - o Guide immediate action for cases of public health importance
 - Monitor and report birth and death vital events and associated information (e.g. cause of death, prenatal care, etc.)
 - Guide the response to prevent and control disease, injury, or adverse exposure
 - o Enable assessment of the effectiveness of control measures and evaluation of public health programs

Health Status/Disease Monitoring - Accurate, Periodic Assessment of Community and Patient-Level Health Status

- Identification of health risks (determinants of health and functional status) and determination of health service needs
- Attention to the vital statistics, health status and functional status indicators of groups, including groups that are at higher risk than the total population
- Identification of community assets that support the LPHS in promoting health and improving quality of life
- Monitor trends in the burden of a disease or condition for particular populations (e.g, quality adjusted life years for persons with diabetes, mental health status of veterans, etc.)
- Detect changes in health practices and the effects of these changes on populations of interest
- Support development of disease modeling approaches

• Examples include:

- o Environmental monitoring (e.g., asthma levels and air quality)
- o Examining vital statistics in areas near recovery sites
- The collection of health and functional status data (qualitative and quantitative) of relevance to communities
- Monitoring for environmental hazard exposures (e.g., lead, asbestos or radiation)
- o Food Safety monitoring and water quality monitoring
- o Monitoring chronic conditions such as obesity and diabetes
- Monitoring birth defects
- o Monitoring prenatal alcohol exposure
- Evaluate trends in disease virulence and antimicrobial resistance, including emerging pathogenic agents.

Population-Based Clinical Care

- Health and functional status for populations of people (e.g., income-based, ethnicity-based, age-based, gender-based, and others defined as needed)
- Genomics and population health
- Health disparities determinants
- Chronic diseases management
- Observation of adverse events (e.g. adverse reactions to vaccination, vaccine resistant disease prompting change in vaccine, etc.)

Provision of care

- o Identifying populations with barriers to health and related services
- o Identifying health and health-related services (e.g., long-term care, social services, etc.) needed by populations with limited access to a coordinated system of clinical care
- O Assuring the linkage of people to appropriate health and related services through coordination of provider services and development of interventions that address barriers to care (e.g., culturally and linguistically appropriate staff and materials, transportation services, etc.)

• Evidence-based clinical care

- Developing evidence-based guidelines for individual episodes of care and systems of care
- Developing patient (individual), practitioner (individual) and populationbased (aggregated) measures of quality
- o Delivering evidence to the point of care (clinical decision support)
- Measuring quality / efficiency for patients, practitioners (individual) and health care systems (aggregate)
- Measuring disparities in care for defined populations across specialties and/or sites of care
- Developing feedback loops to ensure the outcomes of measures are incorporated into subsequent guidelines and measures

Population-Based Research – Research for New Insights and Innovative Solutions to Health Problems on a Population Level

- Ensure that all people, especially those who experience health disparities, will achieve their optimal lifespan and experience the best possible health in every stage of life.
- Includes field-based efforts to foster improvements in public health practice and other population health management activities. Examples of population-based research include:
 - Development and evaluation of new vaccination programs for new vaccines and populations of people to be vaccinated (e.g., adolescents and persons in high-risk groups).
 - o More efficient tools for outbreak detection, investigation, and reporting that integrate clinical, epidemiologic, and laboratory data obtained from various sources (e.g., health care providers and public health institutions at the national, state, and local levels).
 - o Clinical trials and records-based research to assess the efficacy and safety of medical products.
- Infrastructure, policies and internal capacity to perform timely population-based, epidemiologic and economic analyses and conduct needed health services research
- Strategies to develop and conduct evaluation to determine the effectiveness of health services and systems
- Developing indicators to measure disparities in quality of care
- Research to inform the understanding of mechanisms of disease on the health and functional status of populations

Health Communications / Health Education - Inform, Educate and Empower Providers, Consumers and Others about Health and Wellness Issues

- Health information, health education, and health promotion activities designed to reduce health risk, promote better health, and improve and/or maintain health and functional status using methods such as health alerts, Web sites, collaboration forums, risk communications
- Communication between public health and clinical care (Bi-directional Communications)
- Health communication plans and activities such as media advocacy and social marketing
- Accessible health information and educational resources.
- Health education and health promotion program partnerships with schools, faith communities, work sites, providers, and others to implement and reinforce health promotion programs and messages
- Workforce development and education

• Examples include:

- o Prevention guidelines (e.g. flu, diabetes, obesity, asthma, etc.)
- o Vaccination schedules, guidelines, warnings
- o Case definitions, syndrome definitions, diagnostic guidelines and criteria
- o Drug recalls, drug interactions and side effects
- o Notifications of disease outbreaks or environmental hazards
- o Safety measures
- Wellness promotion

PROPOSED BROAD CHARGE FOR EXPANDED SCOPE

Workgroup Name: POPULATION HEALTH AND CLINICAL CARE CONNECTIONS

Broad Charge for the Expanded Scope:

Make recommendations to the Community that facilitate the flow of reliable health information among population health and clinical care systems necessary to protect and improve the public's health.

As reference – Charges for current Biosurveillance Workgroup:

- Broad Charge for the Workgroup: Make recommendations to the Community to implement the informational tools and business operations 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 for the Workgroup: Make recommendations to the Community so that, within one year, essential ambulatory care and emergency department visit, utilization, and lab 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.



American Health Information Community

NHIN Prototype Architecture Demonstrations
January 23, 2007

Demonstration Objectives / What to Expect

- NHIN Prototype architectures
 - Consumer Émpowerment
 - Electronic Health Record
- Put a "face" on NHIN and breakthroughs
 - Specificity and possibilities
- Prototypes represent part of the NHIN effort
 - Software validation of the architectures
 - "Applications" are not the architectures

Demonstration Objectives / What to Expect

- Limited demonstrations
 - Fit into time period (e.g. no biosurveillance)
- Full demonstrations of prototypes at 3rd
 NHIN Forum:

Prototypes and Business Models

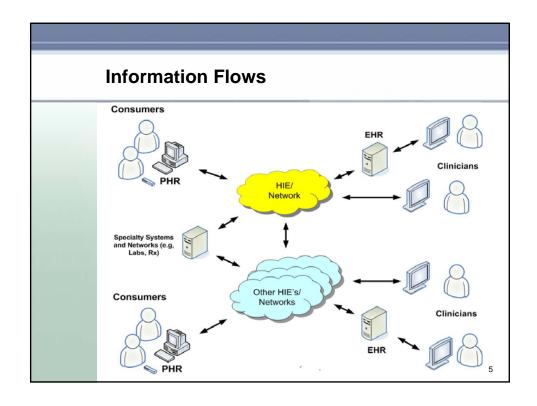
Grand Hyatt Washington Hotel - January 25-26th

www.hhs.gov/healthit/NHIN_Forum

3

Demonstration Objectives / What to Expect

- Each consortia:
 - live or test systems not simulations
 - demonstrate specific parts of the scenario
 - some redundancy
- Two video screens
 - Left screen describes where we are in the demonstration
 - Right screen shows the actual demonstration



The Patient

- 89 year old female with diabetes
- Recent total knee replacement surgery
- Moved in with her daughter (in a different state) to get help with her rehabilitation
- New primary care physician
- Will also visit a specialist
- Has a personal health record

Scenario – Consumer Empowerment

Part 1: Consumer views and updates registration and medication history information

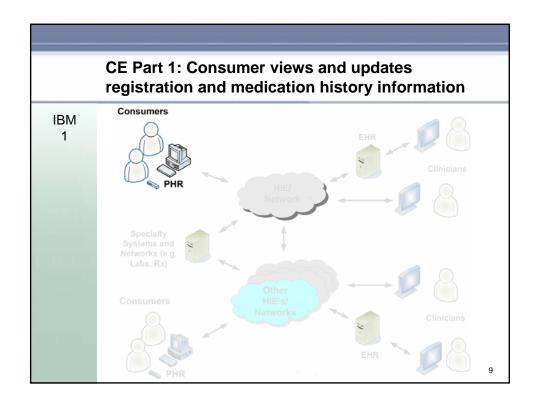
Part 2: Consumer establishes provider permissions to view data

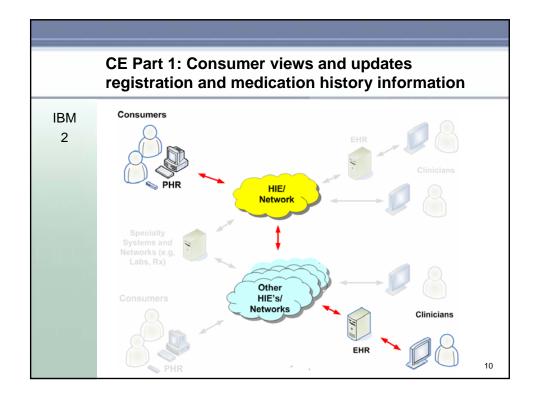
Part 3: Provider retrieves registration and medication history data

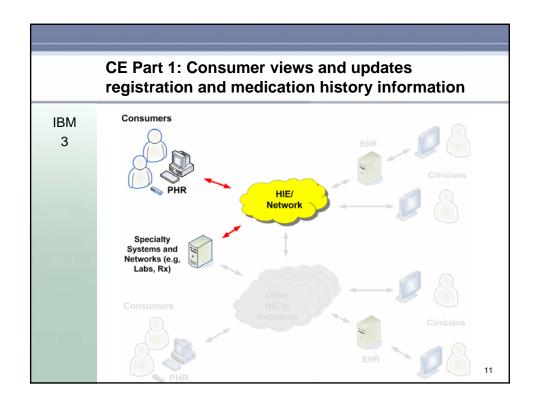
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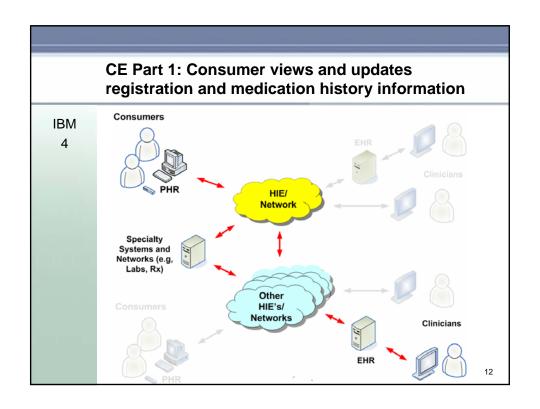
Key Issues To Look For In CE

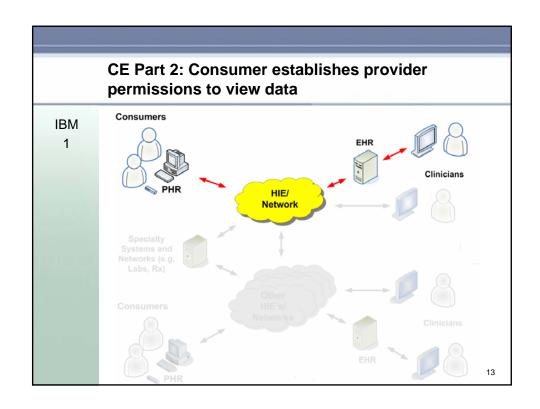
- Connection of commercial and "tethered" PHR's to the NHIN
- Opportunities for consumer management of PHR data
- Consideration for how consumer's could influence the exchange of data on the NHIN
- Needs for tracking providers associated with patients

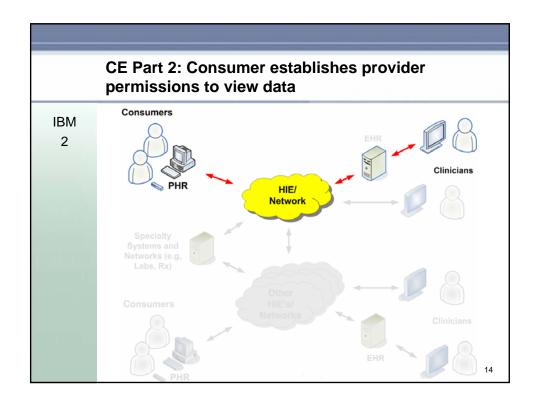


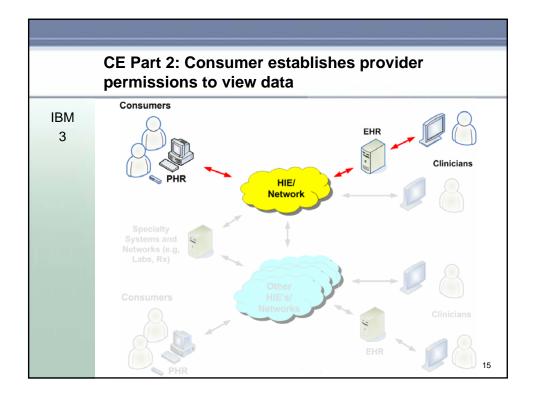






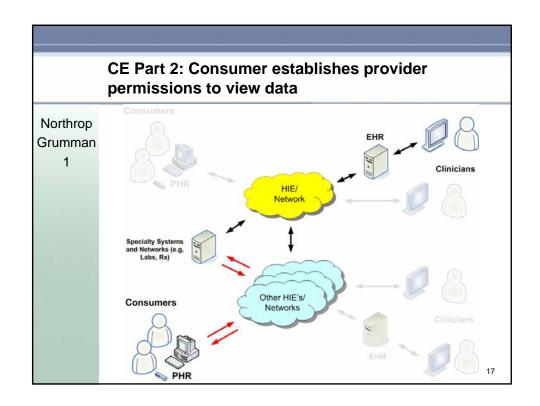


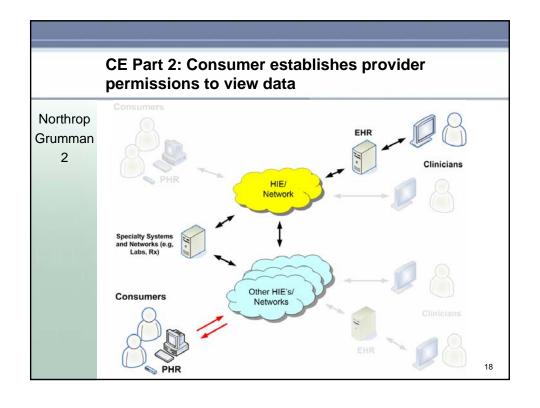


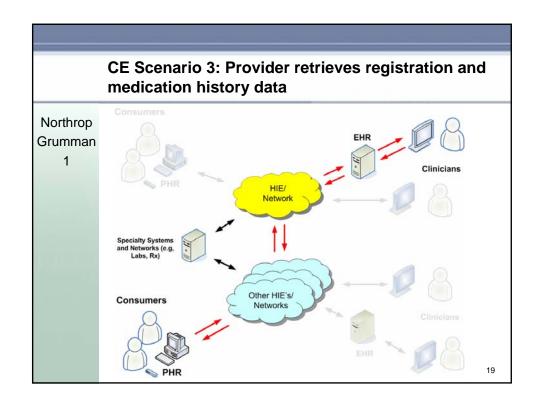


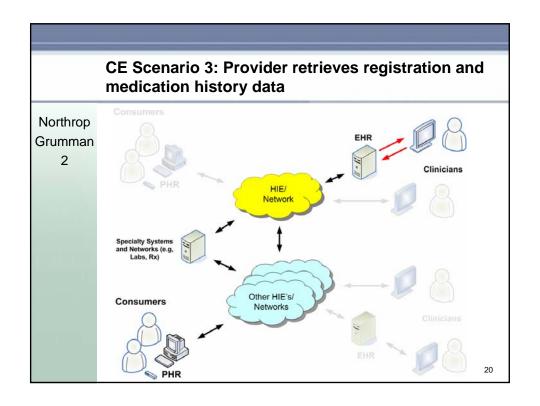
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- Consideration for how consumer's could influence the exchange of data on the NHIN
- Needs for tracking providers associated with patients









Questions and Discussion of Consumer Empowerment Scenario Consumers Part 1: Consumer views and updates registration and medication history information HIE/ Part 2: Consumer establishes provider permissions to view data rks (e.g, Part 3: Provider retrieves registration Other HIE's/ Consumers and medication Networks history data

Scenario – Electronic Health Records

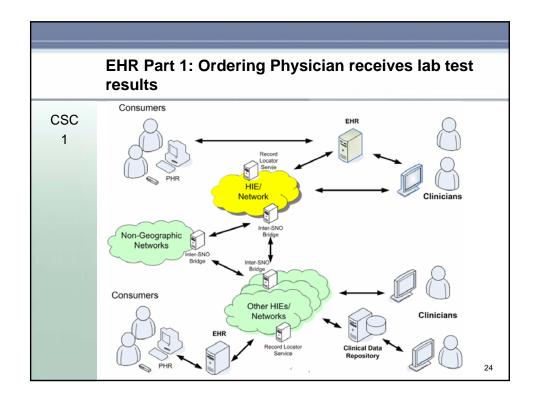
Part 1: Ordering Physician receives lab test results

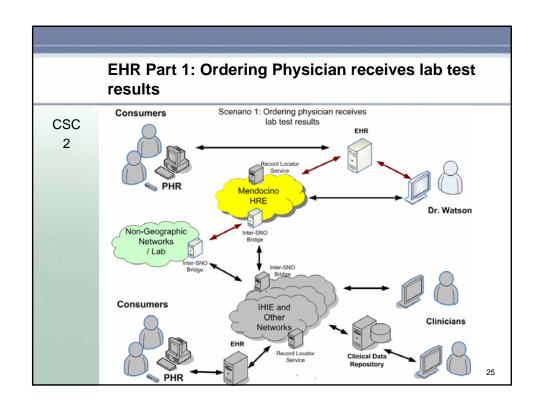
Part 2: Physician retrieves historical results

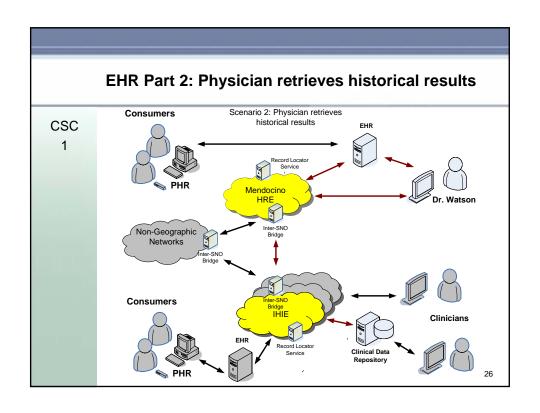
Part 3: Non-ordering clinician receives lab test results or notification

Key Issues To Look For In EHR

- Routing of lab data to the appropriate EHR
- Portal and EHR based retrieval of historical lab results
- Notifications of when new lab data are available
- Lab result routing to "non-ordering" providers of care
- Comparability of data across provider sites

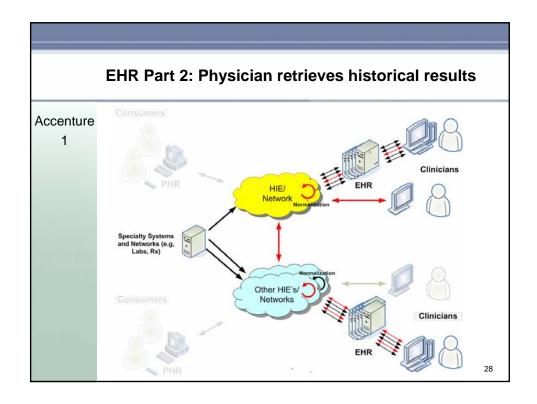


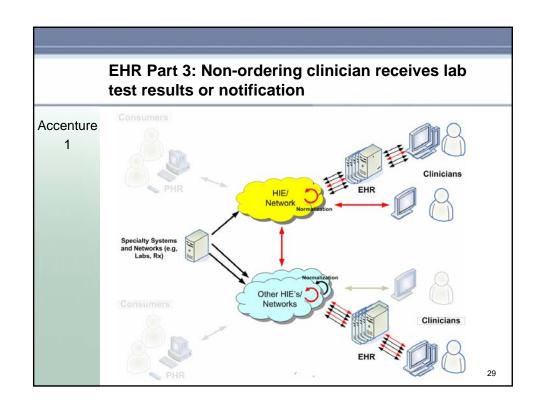


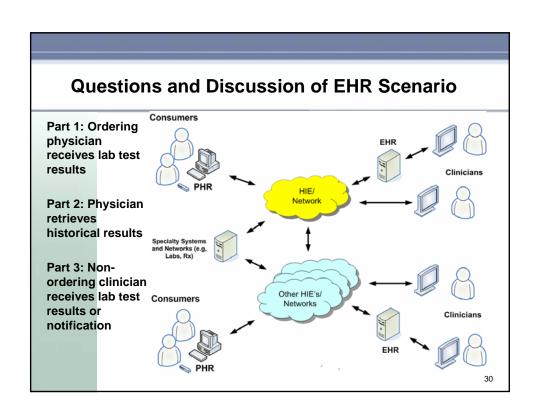


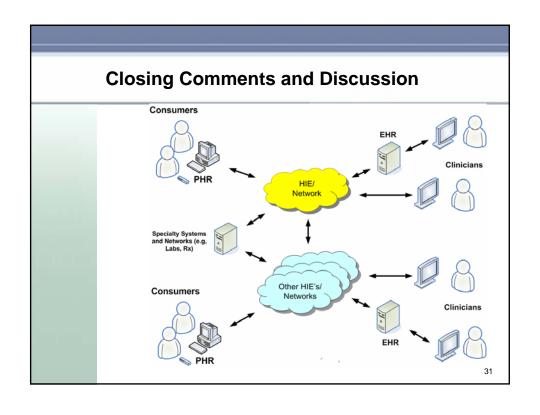
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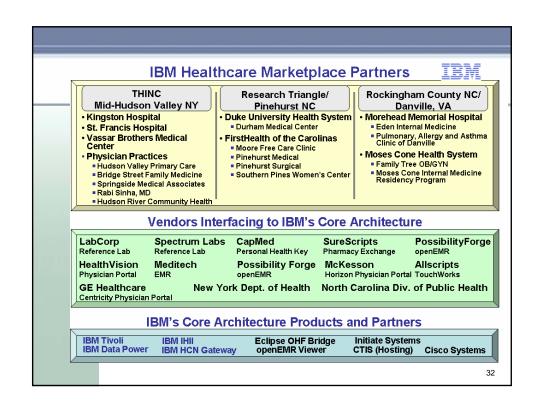
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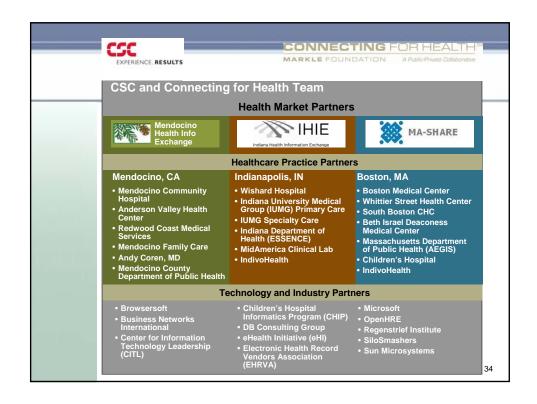






Northrop Grumman Consortium

- Demonstrating Clinical Partners
 - Physicians Medical Group and Western Medical Associates, Santa Cruz County, California
 - University Hospitals, Cleveland, Ohio
 - Quality Health Network, Grand Junction, Colorado
- Other Contributing Clinical Partners
 - Greater Cincinnati HealthBridge, Cincinnati, Ohio
 - Waterbury Health Access Program, Waterbury, Connecticut
- Technology Partners
 - Axolotl and First Consulting Group
 - RxHub
 - Client/Server Software Solutions and SphereCom Enterprises
 - Oracle and Sun SeeBeyond (formerly SeeBeyond Technologies)



Accenture Healthcare & Technical Partners

West Virginia Medical Institute

- New River Health Association Beckley
- Cabin Creek
- ARH-Beckley
- ARH Summers County
- AMFM-Beckley
- WV University Physicians of Charleston

The Commonwealth of Kentucky's Eastern Region Health Community

- ARH-Hazard Regional Medical Center and Family Health Services
- University of Kentucky Clinic
- University of Kentucky HealthCare Chandler Medical Center
- Kentucky River District Letcher County Health Dept
- Kentucky River District Perry County Health Dept

CareSpark

- Holston Medical Group
- Mountain States Health Alliance
- Johnston Memorial Hospital
- Sullivan County Regional Health Dept.

Core Technical Components

- · Cisco Systems
- Initiate Systems
- Oracle
- Orion
- Quovadx
- · Sun Microsystems

Technical Partners

- Apelon
- AMA
- BEA
- CCSi
- · CGI Federal
- Intellithought
- LucentGlow
- Oakland Consulting Group
- Reactivity
- Red Hat

Consumer Empowerment Use Case Scenario

Part 1: Consumer views and updates registration and medication history information

Ms. Patricia Walker is an 89 year old diabetic. Her daughter, Mary, who lives in another state, helped her create a PHR account during a visit last year. Following total knee replacement surgery Patricia has decided to move in with her daughter so that her daughter can help with her rehabilitation. Dr. Douglas will become Patricia's primary care physician in her daughter's home town.

Before going to the first appointment with Dr. Douglas, Patricia and Mary decide to review Patricia's registration and medications history information in the PHR. They also want to update Patricia's address information with her daughter's home address. While reviewing the medication history information, Mary notices that Patricia's prescription for Acetaminophen oxycodone HCl is out-of-date because Dr. Norton, her primary care physician where she used to live, changed the dosage during a recent telephone call to the office. Mary submits a request to have the medication history information updated.

Part 2: Consumer establishes provider permissions to view data

After reviewing the medication history information, Patricia asks Mary if it will be accessible to Dr. Douglas. Mary then adds Dr. Douglas to Patricia's list of providers and grants Dr. Douglas access to Patricia's information.

Part 3: Provider retrieves registration and medication history data

During the visit to Dr. Douglas' office, Lois, who is the office manager, requests Patricia's address and insurance information. Mary grants permission for Lois to access the registration information in Patricia's PHR. Lois accesses the PHR, retrieves Patricia's registration information, reviews it on-line, then decides to bring it into the office system.

While reviewing Patricia's case, Dr. Douglas decides to review her medication history. Dr. Douglas uses the access provided by Mary to retrieve Patricia's medication history via her PHR.

EHR Use Case Scenario

Ms. Patricia Walker is an 89 year old diabetic. Her daughter, Mary, who lives in another state, helped her create a PHR account during a visit last year. Following total knee replacement surgery Patricia has decided to move in with her daughter so that her daughter can help with her rehabilitation. Dr. Douglas is Patricia's new primary care physician in her daughter's home town.

Patricia is having some difficulty managing her diabetes as a result of her change in exercise following her knee replacement surgery. Her daughter, Mary, has arranged an appointment with Dr. Watson, an Endocrinologist who specializes in the management of diabetes. Before going to the first appointment with Dr. Watson, Mary updates the list of providers in Patricia's PHR to include Dr. Watson. She also adds Jane, a home health nurse who is helping Patricia manage her diabetes.

Part 1: Ordering physician receives lab test results

During Patricia's office visit, Dr. Watson decides to order a new HbA1c test. The test is completed by the laboratory and the test result is made available to Dr. Watson in his local EHR. Dr. Watson receives notification that test results are available and views the new test result

Part 2: Physician retrieves historical results

After receiving the new lab results, Dr. Watson decides to review her prior laboratory results, including the HbA1c results in the months before she had surgery. Using the EHR in his local practice, Dr. Watson queries for the available laboratory results, views them, decides to incorporate them into his EHR and compare them to the new result.

Part 3: Non-ordering clinician receives lab test results or notification

Dr. Douglas, Patricia's new primary care physician, also needs to be aware of Patricia's HbA1c results. The Laboratory sends the test results to Dr. Douglas. Jane, the home health nurse who helps Patricia manage her diabetes, receives notification that updates to Patricia's information are available and views them using a web browser.



THE SECRETARY OF HEALTH AND HUMAN SERVICES WASHINGTON, D.C. 20201

JAN 2 2 2007

Dear Community Members:

On behalf of the Department of Health and Human Services (HHS), I wish to express my deep appreciation for your efforts in accelerating the implementation of health information technology (IT) standards and advancing the national health IT agenda.

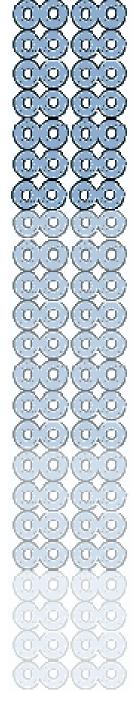
I have accepted the Community's recommendations on the Health Information Technology Standards Panel's (HITSP) Interoperability Specifications as presented at the October 31, 2006, Community meeting. These HITSP Interoperability Specifications were advanced in a public consensus process that included more than 265 industry stakeholders who contributed more than 12,000 hours of effort to make these specifications available. Having accepted these recommendations for version 1.2 of the HITSP Interoperability Specifications, I now envision a period of one year for implementation and testing in software systems and refinement of their implementation guidance in that process. I plan to recognize version 2.0 of these Interoperability Specifications in December of 2007, presuming that all revisions are minimal or of a technical nature.

The recommendations for three sets of Interoperability Specifications that I have accepted will advance health information technology (IT) standards toward implementation and facilitate the use of secure, interoperable health information systems. The Interoperability Specifications were based on the three Use Cases previously established by the Community in the areas of Electronic Health Records, Biosurveillance, and Consumer Empowerment.

The Community's dedication, professionalism, and thoroughness were evident throughout this complex engagement. Please accept my gratitude - and that of the Department - for your contributions supporting the advancement of the national Health IT agenda.

Sincerely,

Michael O. Leavitt



U.S. Department of Health and Human Services

Health Information Technology Initiative

Major Accomplishments: 2004-2006

"In 2006, HHS achieved several major milestones to meet the President's call for most Americans to have access to electronic health records by 2014. These significant accomplishments will provide tangible value to health-care consumers - helping to reduce costs and medical errors with better information technology."

> — Michael O. Leavitt Secretary of Health and Human Services



Background: A Historical Perspective

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Over the past 30 years, nearly every sector of the American economy has undertaken a sweeping transformation in the way information is collected, managed, and transmitted. The result has been consistently increased productivity and efficiency, and this shift has helped to secure America's place at the top of the economic leader board.

Yet today, health care—one of the most significant sections of the American economy—has not made this transformation. However, this is beginning to change.

Today, evidence that use of secure, standards-based, electronic health records can improve patient care and increase administrative efficiency is overwhelming.¹ This use of interoperable health information technology (IT) will benefit individuals and the health-care system as a whole in profound ways.

Benefits to the health-care consumer:

- Higher quality care
- Reduction in medical errors
- Fewer duplicate treatments and tests
- Decrease in paperwork
- Lower health-care costs
- Constant access to health information
- Expansion of access to affordable care

Benefits to public health:

- Early detection of infectious disease outbreaks around the country
- Improved tracking of chronic disease management
- Ability to gather de-identified data for research purposes
- Evaluation of health care based on value, enabled by the collection of price and quality information that can be compared

These benefits led President Bush to call for most Americans to have access to an interoperable electronic health record by 2014, in his 2004 Technology Agenda, Promoting Innovation and Competitiveness. Since that time, HHS has made rapid and significant progress to meet this goal.

2004: Laying the Foundation

The President, by Executive Order, established the position of National Coordinator for Health Information Technology.² The National Coordinator for Health IT is the chief advisor to the Secretary of HHS on the actions needed to meet the President's call for widespread availability of secure, interoperable health IT.

In November, 2004, the National Coordinator issued a request for information to gather public input on the development of a Nationwide Health Information Network (NHIN). In analyzing the more than 500 responses in early 2005, the Office of the National Coordinator for Health IT (ONC) found that a lack of uniform standards was a key obstacle to the success of a NHIN.

- 1. Walker, Pan, Johnston, Adler-Milstein, Bates, and Middleton: Health Affairs Online: January, 2005.
- 2. Presidential Executive Order 13335, April 27, 2004.

"By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care."

—President George W. Bush, State of the Union Address, January 20, 2004

2005: Initial Steps and Progress

More than 1.5 million Americans are injured every year by drug errors in hospitals, nursing homes, and doctors' offices. On average, a hospitalized patient is subject to at least one medication error per day.

— Preventing Medication Errors, Institute of Medicine, July 20, 2006

American Health Information Community (AHIC)

In 2005, Secretary Leavitt announced the formation of the American Health Information Community (AHIC), a federal advisory committee made up of public and private sector leaders who represent a broad spectrum of health-care stakeholders. The AHIC was established to make recommendations to the Secretary on how to accelerate adoption of interoperable electronic health IT in a smooth, market-led way.

HHS Contracts

The Office of the National Coordinator for Health Information Technology (ONC) was established within the Office of the Secretary at HHS in 2005. That year, the Department awarded nine contracts to conduct work in several key areas of the health IT initiative:

- Health Information Technology Standards Panel (HITSP) To harmonize industry-wide health IT standards
- Certification Commission for Healthcare Information Technology (CCHIT) – To develop a certification process for health IT products
- Privacy and Security To enhance safety of health information by addressing variations in policies and State laws affecting privacy and security practices
- Anti-Fraud for Electronic Health Records To identify ways to enhance health-care anti-fraud activities with the use of health information technology
- Nationwide Health Information Network (NHIN) To create prototype architectures for widespread health information exchange
- Adoption of Electronic Health Records To develop a standardized way to measure adoption of electronic health records
- **Clinical Decision Support** To form a group of qualified experts to advise federal activities concerning clinical decision support
- Health Information Exchange³ To develop consensus for bestpractice guidelines from existing, state-level efforts to exchange health information
- Hurricane Katrina Information Network and Digital Health Information Recovery Project – To foster widespread use of interoperable health IT in Gulf Coast regions affected by hurricanes in 2005

HHS' progress on health IT in 2005 provided momentum to produce many tangible results in 2006.

^{3.} This work was initially funded by the HHS Agency for Healthcare Quality and Research.

2006: Major Accomplishments

HHS' many accomplishments on the health IT initiative in 2006 are already beginning to provide tangible value to health-care consumers today, while continuing to build momentum for the rapid advancement of interoperable health IT into the future.

American Health Information Community (AHIC)

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In May, 2006, the American Health Information Community (AHIC) delivered its first set of recommendations to the Secretary of HHS. The Secretary officially accepted these unanimous recommendations in four work group areas:

- Consumer Empowerment To create a consumer-directed and secure electronic health-care registration information and medication history for patients
- **Chronic Care** To use secure messaging, such as email, for communication between patients and their health-care providers
- Electronic Health Records To create standardized, secure records of past and current laboratory test results that is accessible by health professionals
- **Bio-surveillance** –To enable the transfer of standardized and anonymized health data to authorized public health agencies within 24 hours

Standards Harmonization

In August, the AHIC recommended three sets of "Interoperability Specifications" approved by the Health Information Technology Standards Panel (HITSP)—a standards panel established by the American National Standards Institute (ANSI)—an organization contracted by HHS to develop a process for harmonizing hundreds of competing standards. Secretary Leavitt accepted these standards that form the basis of interoperability. He also accepted the AHIC's recommendation for federal health-care delivery systems, which provide direct patient care, to develop an adoption plan to integrate these standards into their software systems by December, 2007.

Executive Order on Value-Driven Health Care

In August, 2006, the President issued an Executive Order committing federal departments and agencies that purchase and deliver health care to require the use of health IT that is based on interoperability standards recognized by the Secretary of HHS as new upgrades or systems are implemented within the federal system.⁴

Product Certification

In 2006, the Certification Commission for Healthcare Information Technology (CCHIT) certified the first 37 ambulatory—or clinician office-based—electronic health record products. The CCHIT seal of approval is awarded to products that meet base-line criteria for functionality, security, and interoperability. This certification encourages adoption of health IT by assuring providers that their systems can be a part of the future of health IT.

- In 2000, the Institute of Medicine estimated that between 44,000 and 98,000 Americans die each year from preventable medical errors.
- —To Err Is Human: Building a Safer Health System, Institute of Medicine, 2000

4. Presidential Executive Order 13410, August 22, 2006. Federal departments and agencies are required by the Executive Order to act to the extent permitted by law.

2006: Major Accomplishments (contd)

Changes to Regulations

HHS issued new regulations to allow certain arrangements in which a hospital or other health-care entity donates health IT and training services to health-care providers. These new regulations will accelerate adoption by health-care providers by giving them access to increased financial assistance in implementing health IT.

Health IT Adoption Measurement

Through a contract with HHS, George Washington University conducted a health IT adoption survey of physician offices to establish the baseline for current physician use of electronic health records at 10 percent. The survey also provided the criteria necessary to measure success in encouraging further adoption.

Results

These accomplishments will encourage broad, standards-based adoption of health IT that will improve the health and health care of all Americans. Already, markets are responding to federal leadership.

- 1. Just one month after HHS published rules allowing for increased donations of interoperable health IT to providers, health IT vendors were reporting substantial increases in buyer interest.
- 2. The CCHIT received and evaluated dozens of applications for product certification as buyer interest in certified systems dramatically increased.
- 3. Nearly 200 public and private health-care purchasers, including several States, counties, and cities, have agreed to implement the principles of the President's Value-Driven Health Care Executive Order in their health-care procurement programs. This includes the first corner stone: to do business exclusively with those who adopt health IT systems that use interoperability standards recognized by the Secretary of HHS as their systems are updated.

2007: Next Steps

HHS accomplishments leading up to 2007 have laid the foundation of a robust health IT initiative that is already bringing value to health-care consumers and providers. With the organizations and contracts in place and a standards process established, additional progress for the year ahead will be rapid.

Nationwide Health Information Network (NHIN)

Four prototype architectures for a Nationwide Health Information Network (NHIN) were delivered in January, 2007. These prototypes were developed with functional requirements and security and business models for health information exchange. Their delivery marks the beginning of the next phase of NHIN work – to connect the prototypes and state and regional health information exchange efforts in "trial implementations" that will make up the "networks of networks" of the NHIN.

"In nearly one in seven visits, [primary care clinicians] reported that clinical information important for the patients care was missing.... Clinicians who reported having full [electronic medical records] were significantly less likely to report missing clinical information."

— Missing Clinical Information During Primary Care Visits, The Journal of the American Medical Association, February, 2005

5. Links to the relevant regulations are available here:
www.oig.hhs.gov/fraud/safeharborregulations.html and
www.cms.hhs.gov/physicianselfreferral/05 Regulations.asp

2007: Next Steps (contd)

American Health Information Community (AHIC)

The American Health Information Community formed workgroups in 2006 that will make recommendations to the AHIC in the following areas:

- The Confidentiality, Privacy and Security Workgroup To address privacy and security policy issues for nation-wide use of health IT
- **The Quality Workgroup** To identify the role of health IT in the development of health-care quality measures, their automation, and the use of clinical decision support to improve their performance
- The Personalized Health Care Workgroup To plan for standardized integration of genomic test information into electronic health records

Privacy and Security across State Lines

To ensure that every patient's privacy is consistently protected no matter where they receive care, a regular forum will convene state leaders to reach consensus on cross-border issues of privacy, security, physician licensure and health-care practice, and the states' roles in health information exchange. In addition, a nation-wide summary of state privacy and security assessments, solutions, and implementation plans will be presented and used to consider national policy issues.

The Federal Health Care Delivery System

Plans will be completed across the federal government to implement the requirements of the President's 2006 Executive Order on Value-Driven Health Care in a consistent and effective manner. These plans will apply to the federal government's adoption of interoperable health IT within its own delivery system and the contracts it negotiates.

Product Certification

The Certification Commission for Healthcare Information Technology will expand certification to inpatient—or hospital—electronic health record products. This will significantly increase patients' (and their subsequent providers') access to the health information generated during a hospitalization.

Summary

Each of these efforts is significant individually, and taken together, they will accelerate adoption of interoperable health IT and will form the basis of a health-care system that provides better care at lower cost to more Americans.

A study found that 80 percent of medical errors began with miscommunication, missing or incorrect information about patients, or lack of access to patient records.

—A String of Mistakes: The Importance of Cascade Analysis in Describing, Counting, and Preventing Medical Errors, Annals of Family Medicine, 2004

> To learn more about HHS' health IT initiative, visit: www.hhs.gov/healthit

January 23, 2007

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

Dear Mr. Chairman:

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

Broad Charge for the Workgroup: Make recommendations to the Community regarding the protection of personal health information in order to secure trust, and support appropriate electronic health information exchange.

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

BACKGROUND AND DISCUSSION

The following recommendations were developed by the American Health Information Community (AHIC) Confidentiality, Privacy and Security (CPS) Workgroup on the topic of patient identity proofing. They seek to advance the Specific Charges of the Consumer Empowerment, Electronic Health Record (EHR), and Chronic Care Workgroups and are not intended to introduce barriers to the efficient and effective provision of health care.

Furthermore, the recommendations below intend to establish a baseline for patient identity proofing in the electronic health information exchange environment. Where a particular recommendation presents a range of possible options for patient identity proofing, those options should be evaluated in the context of the specific environment to ensure the appropriate confidentiality, privacy, and security protections are put in place.

We suggest that these recommendations, if accepted by the AHIC, be considered by the Department of Health and Human Services (HHS) for adoption as HHS policy regarding current and future activities, including appropriate federal contracts, and pilot and demonstration projects as they relate to the specific Workgroup charges listed below and their broad charges where appropriate. Furthermore, it is the Workgroup's intention that these recommendations

apply more broadly to the health care system, and that public and private sector organizations would parallel HHS in their implementations.

GENERAL STATEMENTS

- 1) We defined patient identity proofing as the process of providing sufficient information (e.g., identity history, credentials, documents) to correctly and accurately establish and verify an identity to be used in an electronic environment (e.g., via the Internet).
- 2) The purpose of these recommendations is to advance the specific charges of the Chronic Care, EHR, and Consumer Empowerment Workgroups. The Workgroup discussions and these recommendations are related solely to the following issue areas. More widespread application of these recommendations may necessitate further review.
 - a. Chronic Care Make recommendations to the Community so that within one year, widespread use of secure messaging, as appropriate, is fostered as a means of communication between clinicians and patients about care delivery.
 - b. EHR Make recommendations to the Community so that within one year, standardized, widely available and secure solutions for accessing current and historical laboratory results and interpretations are deployed for clinical care by authorized parties.
 - c. Consumer Empowerment Make recommendations to the Community so that within one year, a pre-populated, consumer-directed and secure electronic registration summary is available to targeted populations. Make additional recommendations to the Community so that within one year, a widely available pre-populated medication history linked to the registration summary is deployed.
- 3) All data included in secure messaging, EHRs, and Personal Health Records (PHRs) should be considered sensitive. Appropriate policies and supporting security measures must be in place to mitigate the risks of unauthorized or unintended data disclosure.
- 4) It is important to understand that patient identity proofing is just one part of an overall process (e.g., validation, revocation) for issuing and maintaining electronic identity credentials. All parts of the process are interdependent and, if they do not achieve comparable levels of security, the overall strength of the electronic identity credential may not be adequate.

RECOMMENDATIONS

Recommendation 1: Entities that offer health care consumers or their authorized proxy(ies) ¹ electronic access to data and services through secure messaging, PHRs, or EHRs should perform, or rely upon, identity proofing performed by the entity or an accountable trusted third party² that

¹ The Workgroup would assume that establishing authority to act as a proxy would mirror the HIPAA Privacy Rule's provisions for personal representatives (45 CFR §164.502 (g)), applicable state law requirements, or would require patient authorization.

²A trusted third party is an entity that both the health care consumer or their authorized proxy and health care entity trust or can reasonably rely upon, for the purpose of performing identity proofing on behalf of the entity.

meets or exceeds one of the following options (1.1, 1.2, 1.3). Note: If the primary method chosen by an entity does not apply in some instances, one of the other methods below should be chosen. Failure to meet identity proofing requirements for electronic access to health information should not impede patient access to health care.

1.1:

When it is practical and feasible for a health care consumer or his/her authorized proxy to present themselves in-person, in-person identity proofing should be performed by the health care entity. Identity proofing can be achieved by using, at a minimum, a valid, government issued, picture-ID to verify identity. Examples of such documents include: A passport; driver's license or state issued ID; permanent resident card; military ID.

1.2:

When the healthcare consumer or his/her authorized proxy has an established and durable relationship (e.g., long-standing, trusted) with an entity, this relationship could be used to confirm the consumer or proxy's identity on the basis of that relationship. Examples of confirmation may include: in-person or telephonic dialogue, etc., where confirmation occurs at the time of the request. (i.e., a voicemail or message left for the entity to confirm at later time would not be acceptable).

1.3:

When the healthcare consumer or his/her authorized proxy is unable to meet the criteria necessary to satisfy 1.1, and the entity determines that 1.2 is not viable, and a relationship exists between the consumer or proxy and the entity, identity proofing should consist of a method that verifies a person's identity based on information they know or can produce about themselves when asked. The entity or trusted third party should 1) request basic identity data (e.g., name, address, date of birth, etc.), and 2) require the individual to provide some personal information specific to that relationship (e.g., last prescription, electronic device).

The CPS Workgroup recognizes that some entities may offer PHRs and related services to health care consumers with whom they have no prior relationship. These may include PHRs that are not in any way connected to other information, or can include more "integrated/interoperable" PHRs. The Workgroup began to explore this difficult issue in its public meetings and has considered oral and written testimony, but needs further information before it can make recommendations with regard to identity proofing in these situations.

We have concluded that option 1.1 above - in-person identity proofing – might be used in some of these circumstances. In other cases, option 1.1 may not be practicable. We will be exploring alternative mechanisms to identity proofing by the entity itself (e.g., through a trusted third party) to enhance the opportunities for identity proofing in these circumstances. The Workgroup did not reach a consensus on other options that could provide a sufficiently protective method to identity proof in circumstances when the credentialing cannot take place inperson. We will continue to consider this issue in future discussions to examine whether appropriate alternatives offering similar protections exist (or are expected to emerge).

Recommendation 2: For the purposes of secure messaging and accessing data through a PHR or EHR, document(s) and the information therein or other information used solely for purposes of identity proofing a health care consumer or their authorized proxy(ies), if kept, should be securely maintained separate from the health care consumer's clinical data.

Recommendation 3: Converting from a paper-based health care practice to one that uses EHRs does not require a health care entity to identity proof their patients. Where this conversion also provides patients with access to data within the EHR (such as via flash drive, Internet, or remote access), health care providers should follow the identity proofing recommendation schema noted in Recommendation #1.

Recommendation 4: Entities that provide patient access to personal health information via secure messaging or a PHR (such as via a flash drive, populating data records stored on the Internet, or remote access), should follow the identity proofing recommendation schema noted in Recommendation #1.

Recommendation 5: Where applicable, the Certification Commission for Healthcare Information Technology (CCHIT) should develop certification criteria for the systems and networks they certify to support the identity proofing practices in these recommendations.

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

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

Sincerely yours,

Sincerely yours,

/Kirk J. Nahra/ /Paul Feldman/
Co-chair Co-chair Co-fidentiality Privacy and Security Confidentiality

Confidentiality, Privacy, and Security

Confidentiality, Privacy, and Security

Workgroup Workgroup