The Community

American Health Information Community

July 31, 2007
9:00 a.m. - 3:45 p.m.

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

TABLE OF CONTENTS

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July 31, 2007

9:00 a.m. - 3:45 p.m. (EDT)

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

9:00 a.m. **CALL TO ORDER** - *Secretary Leavitt*

9:05 a.m. **Introductory Comments** - *Secretary Leavitt*

9:15 a.m. **Comments** - *Robert M. Kolodner, National Coordinator*

9:30 a.m. **AHIC Standing Committee of the Whole: Successor**

- *Secretary Leavitt and Rob Kolodner*

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

12:00 p.m. **Workgroup Recommendations**:
Personalized Healthcare Workgroup

- *Douglas E. Henley, American Academy of Family Physicians, Co-Chair*
- *John Glaser, Partners Healthcare, Co-Chair*

12:30 p.m. **Use Case/Priority Setting Process**

- *John Loonsk, Office of the National Coordinator*

1:15 p.m. **Health Information Security & Privacy Collaborative (HISPC) Report**

- *Linda Dimitropoulos, RTI International*
- *Lori M. Evans, State of New York*
- *Jonathan Sugarman, State of Washington*
- *Kristen Rosati, State of Arizona*

2:15 p.m. **BREAK**

2:30 p.m. **Certification Commission for Health Information Technology -- In-Patient & Ambulatory Care Certification Criteria**

- *Mark Leavitt, CCHIT, Chair*

3:15 p.m. **Workgroup Update:**
Consumer Empowerment Workgroup Recommendation Status Report

- *Rob Kolodner, National Coordinator*
- *Nancy Davenport-Ennis, National Patient Advocate Foundation, Co-Chair*
- *Karen Bell, Office of the National Coordinator for Health Information Technology*

3:30 p.m. **Public Input**

3:45 p.m. **ADJOURN**

Meeting Report

American Health Information Community
June 12, 2007

The American Health Information Community (AHIC), a federally chartered commission formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within 10 years, held its 14th meeting on June 12, 2007, at the Department of Health and Human Services (HHS), 200 Independence Avenue, SW, Washington, DC, 20201.

The purpose of the meeting was to bring together Community members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to HHS on how to make health records digital and interoperable, and ensure that the privacy and security of those records are protected in a smooth, market-led way. The meeting focused on: (1) a discussion of the AHIC successor entity and presentations from the three contractors that have developed models for the proposed successor entity; (2) an update on standards and the Healthcare Information Technology Standards Panel (HITSP); (3) recommendations from the Chronic Care, Electronic Health Records, and Confidentiality, Privacy, and Security Workgroups; (4) a discussion about a privacy and security framework; and (5) an AHIC recommendation implementation status report.

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

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

Call to Order

Joining Secretary Leavitt around the table were:

Robert Kolodner, MD, National Coordinator for Health Information Technology and Vice-Chair, AHIC

Kevin Hutchinson, CEO of SureScripts

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

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

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (Dr. Gerberding participated in a portion of the meeting by teleconference; she was represented onsite by Steven Solomon, MD, Director of the Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention)

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

Leslie Norwalk, Acting Administrator, Centers for Medicare and Medicaid Services (Ms. Norwalk was represented by Tony Trenkle, Director of E-Health Standards and Services, Centers for Medicare and Medicaid Services, for part of the meeting)

Adele Morris, Senior Economist, U.S. Treasury (Ms. Morris represented Dr. Phillip Swagel, Assistant Secretary for Economic Policy, U.S. Treasury)

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

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

S. Ward Casscells, MD, Assistant Secretary for Health Affairs, Department of Defense (Dr. Casscells was represented by Robert Foster, Chief Information Officer of the Department of Defense's Tricare Management Activity, for part of the meeting)

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

Craig Barrett, PhD, Chairman of the Board, Intel

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

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

Linda Dillman, Executive Vice President of Risk Management and Benefits Administration (Ms. Dillman represented John Menzer, Vice Chairman, Wal-Mart)

Rosi Sweeney, Vice President for Public Policy and Practice Support, American Academy of Family Physicians (Ms. Sweeney represented Douglas Henley, MD, Executive Vice President, American Academy of Family Physicians)

Approval of Minutes

Minutes from the April 24, 2007, AHIC meeting were distributed, reviewed by Community members, and approved unanimously with no changes.

Introductory Comments

Secretary Leavitt welcomed Community members to the 14th AHIC meeting, informing members that Dr. Brailer has stepped down from the position of AHIC Vice-Chairman. The Secretary recognized Dr. Brailer for his tremendous contributions to AHIC's mission, and thanked him for his efforts. Secretary Leavitt also pointed to the progress AHIC has made, noting that 20 months ago, one could not buy an ambulatory EHR product from a vendor that has been certified by common standards—this product can connect to others in the health care community.

Before starting on the day's agenda, Dr. Kolodner also recognized and thanked Vic Eilenfield, who has spent the last year supporting AHIC's activities—especially Dr. Kolodner's transition to his current positions of AHIC Vice Chair and National Coordinator for Health Information Technology—while on detail from the Department of Defense (DoD). In closing, Dr. Kolodner explained that the next AHIC meeting will feature a presentation on a strategic plan for the Community.

AHIC Standing Committee of the Whole

Kelly Cronin, Director of the Office of Programs and Coordination, Office of the National Coordinator (ONC), began this session by reminding Community members that, as presented at the last AHIC meeting, three contracts have been awarded to three different firms to initially explore how best to design a governance structure and develop a business model for AHIC's successor. The contractors had six weeks to prepare and submit deliverables to the ONC; these deliverables were received by the Office a few days before this meeting. Ms. Cronin explained that today, Community members were being asked to reach agreement on the evaluation criteria and principles being proposed.

In June/July 2007, there will be a three-week period for public input. Following public comments and internal input, the July 31 AHIC meeting will include a presentation on a prototype organization based on the best ideas put forward by the three contractors during this session. Over the summer, this prototype will be refined, based on Community input as well as expert comment. It is hoped to have a final prototype for review and consideration by Community members in September 2007. In the last quarter of 2007, ONC intends to support the formation of this new entity, identify funding sources, and begin the transition of responsibilities from this Federal Advisory Committee to that new entity as it becomes formed and operational.

Dr. Kolodner presented six principles for successful governance being advanced by the ONC. These principles are:

- The entity should exist for the purpose of individual/consumer benefit.
  - Is the purpose of the proposed entity to advance the health and well-being of all residents of the United States?
  - Are there provisions in the governing documents, structure, and operations of the proposed entity that ensure the privacy of consumer and provider data?

- The entity should establish and enhance trust among stakeholders.
  - Will the proposed entity be operated to ensure that decisions can be made in an informed, fair, and equitable manner?
  - Are the rights and obligations of members common across industry sectors and equitable between industry sectors?
  - Do decisions made by the proposed entity have mechanisms to ensure that they incorporate the views of all sectors of the health industry, and cannot be dominated or controlled by any?

- The entity should have broad participation across the health care industry stakeholders.
  - Does the proposed entity allow membership by individuals and organizations from all sectors of the health community?
  - Is participation voluntary, with simplicity of entry and ease of exit that result in minimal impact on the ongoing activities of the members?

- Can existing federal, state, and private-sector health information technology initiatives participate as a smoothly functioning whole in the proposed entity with minimal disruption and in a way that enhances their capacity and progress?
- Does the proposed entity have a clearly delineated power to set fees, if any, with sufficient restrictions on that power to prevent inequity or abuse?

- The governing bodies of the entity should have necessary authority to make decisions, but only the authority that is necessary to do this.
  - Does the proposed entity have a clear delineation between rights and responsibilities of members and those of any of its governing bodies, and whether governing bodies are elected by, and fairly represent, members of the entity?
  - Do governing bodies of the proposed entity have sufficient authority to create necessary rules and procedures to guide their own operations and functions, determine conformity with them, and enforce compliance when necessary, with sufficient restraints on that authority to prevent abuse?
  - Are the decisions, actions, and regulations of the proposed entity limited to that which is essential for the successful collaborative development and operation of the entity, and are all other decisions, actions, and regulations reserved to the independent action of its members?

- The entity should be feasible to establish and operate, and sustainable into the future.
  - Is the proposed entity consistent with applicable laws and regulations, and is it governed in a manner which ensures that its decisions and actions will not place members in violation of laws and regulations to which they are subject?
  - Is there a clear, practical plan to bring the proposed entity into being and commence initial operations by December 2007?
  - Is there a clear, practical plan of action for the first 3 years operation ending December 2010, and for financial sustainability after that?
  - Does the proposed entity have a practical plan for attracting a sufficient mass of members at inception from key industry sectors?
  - Can the proposed entity attract and adequately reward outstanding leadership and staff?

- The entity should be adaptable over time and across future circumstances.
  - Is the proposed entity durable with respect to purpose and principles over time, yet malleable in form and function, allowing it to evolve in response to changes in technology, communications, and the environment in which it must operate without harming its objectives?
  - Can the proposed entity ensure that all members can self-organize at any time, at any scale, for any reason consistent with its charter, purpose, and principles, and that the resulting organization can have a right of membership without depriving its constituency of theirs?
  - Can the proposed entity ensure continual delineation between decisions, actions, and rules necessary for the degree of collaboration and cooperation required to function effectively, and those necessary to preserve freedom of action and competition between members? Are the powers necessary for the effective functioning of the entity vested in the successor organization and all others vested in the members?

Dr. Kolodner noted that the three contractors will be explaining potential business models, with consideration given to these principles and a number of factors, such as the appropriate role of government; the short-, mid-, and long-term goals of the entity; mechanisms to ensure diverse and voluntary membership representing all stakeholders and health care; a transition plan; and a path to sustainability. In addition to the three contractors, the services of an expert advisor have been obtained. Dee Hock, founder and first CEO of Visa International, will be serving as an advisor to ONC on these potential business models. Ms. Cronin added that following presentations by the three contractors, Community members would be asked to discuss their thoughts on the appropriate governance structure,

revenue sources for this entity, the appropriate role for government, and how this entity interfaces with governance organizations that oversee quality measurements or data aggregation for the purposes of quality measurement and public reporting.

Discussion Highlights

"[We should] make sure that what we're doing is not somehow hindering innovation…and ensure there is a balanced purpose where we're establishing…a foundation for the sharing of health information but we're not…somehow hindering innovation in the sharing of health care information, the development of technology to be able to do that, because that obviously is not the purpose of this organization, nor would it be the purpose of its successor." -- Mr. Hutchinson

"There are a few places where we tried to capture that. For example, under the necessary authority, there is the restriction where there is enough power to accomplish the organization, but only that much power, and that all the rest of the actions are left to the members or to others. But it is not meant to restrict that. And I think we'll capture that and make sure that we have that explicit, about the innovation." -- Dr. Kolodner

"This organization needs to be about standards to achieve interoperability. And I think in some ways, one of the things we'll have to decide is whether its relationship is with CCHIT and HITSP and potentially others. But its purpose and mission needs to be clearly focused and defined, and I don't see that in the principles. I suspect that will be somewhere in the mission, but we ought to focus on the mission as well as the principles." -- Secretary Leavitt

"I think consumers are going to be very interested to see how the new entity is going to deal with secondary use of data, and what protections are in place for the consumer moving forward. As we look at the initiation of these principles…there has to be a sensitivity to 'how do we incent the consumer?'" -- Ms. Davenport-Ennis

"What is the structure of this new successor organization? Are we assuming it will not be an organization under the Federal Advisory Committee Act? It matters a lot to the process and governance of the organization." -- Ms. Morris

"If it takes government to do it, then we ought to decide what government's role and what its relationship is, but I still believe that our default position ought to be getting it out of government so that it's able to function more as a direct functionary of the larger medical family and consumers." -- Secretary Leavitt

"I agree, theoretically and conceptually, with Secretary Leavitt's notion of [AHIC's successor entity] being private, and I think it ought to be private. But at the end of the day, I think authority and responsibility, ultimately so much falls back to the government, and because I believe that we need at least partial broad-based financing, if not total broad-based financing. The government is going to play a very important role here." -- Mr. Kahn

"The Medigap model is one that could be very relevant to this…It's a nonfederal government entity…the Secretary is involved in the process and signs off on it, and there is a regulation promulgated. So at the end of the day, the recommendations of the entity, the policies that the entity proposes, in a sense have the power of law." -- Mr. Kahn

"This is always going to be such a national priority, at least in the foreseeable future, that I think any Secretary would have to take very seriously what was recommended to him, from such a body, and it really enhances the authority of that body, everyone knowing that at the end of the day, the Secretary is

going to have to take their recommendations and do a regulation one way or the other on them." -- Mr. Kahn

"Somewhere in those principles [of governance] should be a bias toward action. I think the biggest problem we run into is a debating society, and so I think the principles should be very clear that there is a bias of this group to act." -- Mr. Serota

"This is a case where the private sector is lagging behind the government sector in terms of health IT. Clearly. So it scares me a little bit to put a model solidly in the court of a private sector when the private sector is lagging so much behind the federal health care system's interoperability and health IT capability." -- Ms. Gelinas

"I really think there are two [roles for government in this situation], and they are intertwined…The first is to provide some kind of regulatory authority so privacy is established…And then there is a market weight that HHS brings to bear." -- Mr. Roob

"To say that you're going to divorce government as the purchaser of 50 percent of the health care in America from this process, I think is a mistake, because we lose that throw weight that the federal government brings to those choices. You, *de facto*, set the standard when you're 50 percent of the marketplace, and no one else has more than one percent of the market." -- Mr. Roob

"It's not a private-sector entity, it's a public-private entity in the private sector. So the intention is…to see how we structure a public-private entity so that the government representatives and government agencies can, in fact, participate as one of those sectors, so that as you say, the full weight of the purchasing power is there." -- Dr. Kolodner

"How does government play a role? We can play a role as a regulator, and by the force and power of regulation and law, given the right construct, we can create finality with law. The other role we can play is to add substantial weight to a private organization with our purchasing power. We have, in previous months, attempted to bring the purchasing power of the federal government behind this effort by committing that we will follow the pattern of interoperability." -- Secretary Leavitt

"I've come to the conclusion that we don't want to be using government regulation as a means of being able to set the course on what has to be a highly nimble, fast market-efficient process of adapting. On the other hand, we have to reach enough finality that it is, in fact, the northbound train…We have got to decide not if government plays a role, but what its role is, and which of its tools do we use or some combination thereof to reach market adaptability." -- Secretary Leavitt

"This entity should exist in principle for the benefit of the individual who is actually having the record used for them…The notion that I was looking for was something that recognized…that the doctors, and hospitals and other health care providers, are actually going to have to purchase, use, and be responsible for this record that the future AHIC is going to provide policy for…I was looking for something that just recognized that the role of the entities and people providing the care, in a sense, is as much as something that needs to be benefited by this process as the individual consumer, because without those people, the individual consumer won't get the benefit." -- Mr. Kahn

"All of us around this table have computers. We still depend on suppliers, and experts and other people to make it all work. And at the end of the day, we can do a lot, but we can't do it all, unless we're expert in it…That needs to be recognized in a way here, because it's those people, whoever they are, in the current world or the new world, that are really going to be as important as the individual, because the individual is going to depend on it." -- Mr. Kahn

"CMS plays a couple of different roles. Certainly as the largest purchaser, we play a huge role in what happens because of the regulations that the Secretary mentioned. But we have another set of regulations…How do CMS and the successor organization play with the HIPAA transaction and code sets regulations? How do the Designated Standards Maintenance Organizations interact with this successor body, and how is it that we can put it all together so that CMS, as a regulator of transactions and code sets for the entire industry, separate and apart from the Medicare payment regulations or what we do on the Medicaid side of the house, how do those all come together?" -- Ms. Norwalk

Presentations From the Three Contractors

Booz Allen Hamilton

Bob Hutchens, Vice President of the Group Health Practice Group at Booz Allen Hamilton, presented the following draft mission statement for a successor to AHIC:

- Achieve the widespread adoption of interoperable health information technology by providing a forum where member organizations, a full-time staff, and the public sector work collaboratively, effectively, and efficiently.

Mr. Hutchens added that proposed goals of the successor organization include: (1) govern a nationwide strategy and roadmap that establishes the specific priorities for the short, mid, and long term; (2) provide a clearinghouse for product certifications, interoperability specifications, and best practices; and (3) coordinate among dispersed health information initiatives to maximize reuse of successful approaches. He noted that the proposed mission statement and goals could be a topic for in-depth Community discussion, possibly at a future AHIC meeting. He also emphasized that in discussions with the Community and outside experts, two important themes emerged. First, the government must be involved in this effort. AHIC's success to date has been achieved largely because the government is leading this. Second, there is a desire for broader participation and broader representation in this group; the private sector wants to play a bigger role, and there needs to be a balance across sectors and across interested participants.

The governance model being proposed by Booz Allen Hamilton includes the following five primary elements:

- ***Member Organizations.*** Booz Allen recommends a membership model that is open and dues-based, representing a community of organizations, not individuals, with unique and independent interests and an overlapping interest in health information exchange. Government would be a member of this entity, subject to the same bylaws as private industry membership. Booz Allen also recommends that when members join, they self-select a stakeholder identity used in determining the balance of representation when selecting Board membership. Mr. Hutchens explained that, for example, if there were five categories of members, each group would elect the same number of Board members, so there would be equal representation.

- ***Board.*** The Board of this entity will balance the need to follow best practices with the need for wide representation; Board members will be elected through a formal and transparent process that ensures a balanced set of voting members. To encourage the private sector to take on a more significant role in these efforts, the Board's Chair and Vice-Chair positions will be filled by private-sector representatives and will be selected by Board members from among Board members. This Board will strive for consensus in descisionmaking; when consensus cannot be reached, the root causes of disagreements will be further analyzed by a subgroup. If a consensus still cannot be reached, the final decision will be based on a majority vote, with dissenting views noted.

- ***Advisory Groups.*** The entity's Board may periodically establish advisory groups with very specific targeted audiences to generate and obtain specific input to further support the Board's decisionmaking. These primarily "audience-based" groups will include five to eight members and will advise Board members from a particular stakeholder perspective (e.g., the nursing industry, pharmaceutical industry, etc.). These advisory groups will provide counsel, but will not make decisions; they will strive for consensus in input to encourage buy-in from all stakeholders. Root causes of disagreements will be noted for Board consideration.

- ***Workgroups.*** Mr. Hutchens indicated that AHIC's Workgroups have been successful; the workgroups associated with this proposed successor entity will operate similarly, with the inclusion of non-profit organization employees. The workgroups will serve as a key mechanism to adapt to market needs and will be co-led by public and private-sector leaders. The workgroups will be launched at the request of the Board to conduct research and analysis on specific issues, and to recommend a set course of action to the Board. They will focus on specific charges for a pre-determined period of time, disbanding at the end. The workgroups will include a mix of volunteer and paid staffing, depending on the topic and duration of effort; they will see recommendations through to implementation, to the extent practical.

- ***Management Organization.*** The entity's management organization will include a number of key operational and service units, including:
  - External Liaison to coordinate with the full range of related efforts in the federal, state, and private sectors
  - Member Services to proactively recruit new members through targeted outreach and communication and administer current member relationships.
  - Workgroup Drivers to provide full-time leadership, project management, and facilitation capabilities to the workgroups, and to provide subject matter expertise and other staff as appropriate.
  - Board Secretariat to support Board activities.
  - Standards Harmonization to drive harmonization of standards aligned with AHIC's roadmap for interoperability.
  - Nationwide Health Information Exchange (NHIE) Products and Services to promote revenue-earning products and services that support implementation of NHIE.

  In terms of management, the successor entity under Booz Allen's proposal would be led by a Chief Executive Officer that also sits on the Board. A Chief Operating Officer would oversee the majority of day-to-day activities. A senior-level management staff will lead all revenue- and funding-level activities as well as the workgroup process.

Mr. Hutchens indicated that Booz Allen's rough estimate for the cost of this proposed successor entity is $10 million per year. Anticipated revenue is expected to start at approximately $5 million per year, with the entity becoming self-sustaining with a $10 million annual revenue within a relatively short period of time. He noted that these projects assume a membership of between 300 and 500 members, with an assumed annual membership cost of $1,000 to $25,000. Annual conferences are envisioned, partly to serve as fundraisers but also to enhance the entity's public credibility by being seen as the leading thought organization focused on these issues. Training and publications will have an important, albeit smaller role in creating awareness in the public.

While the successor entity's short-term potential revenue is focused on member organizations, the longer-term revenue sources focus on Nationwide Health Information Network (NHIN) participants. Mr. Hutchens indicated that a number of products and services are envisioned. These include consulting services, certification services, etc. He noted that these types of products and services likely are at least

three years away, however, and that preliminary analyses indicate that these would be revenue-neutral activities (i.e., they would not be a source of profit).

In terms of transitioning from AHIC in its current form to this proposed successor entity, Mr. Hutchens explained that Booz Allen is suggesting that between now and the fourth quarter of 2007, design activities occur to further develop: (1) a prototype, (2) detailed designs based on the prototype, (3) detailed transition plans, and (4) performance measures. In 2008, standup activities would include staffing key leadership positions, building out the infrastructure and processes, assembling and transitioning to an interim Board, and beginning to build membership. January 2009 through December 2010 would constitute "Operating Phase 1," during which time Board elections would be held, advisory groups would be assembled, working group oversight would be transitioned, membership would expand, a suite of member services would be developed, initial NHIE products and services would be developed, and performance would be measured. "Operating Phase 2" would occur from January 2011 through December 2012. This phase would involve expanding the portfolio of NHIE products and services. Mr. Hutchens explained that the primary difference between Operating Phase 1 and Operating Phase 2 is the role of the government—the government will have a bigger role, both in terms of leadership and funding during the first phase. In the first few years, it is expected that this entity will operate at a loss and will require federal dollars to sustain itself during that time. During Operating Phase 2, the entity is expected to be a revenue neutral, self-sustaining organization (i.e., a "self-funding private sector-led AHIC").

Discussion Highlights

"Do you see the principle mission of this organization as an organization that's intended to [be] interoperability standard setting, or is it to become a stand-alone business entity, in and of itself? I got a little concerned…that the organization may evolve into one which is more interested in selling product because it needs to sell product to fund its operations, than the principle mission which we articulated." -- Mr. Serota

"If you go back and look at the actual revenue numbers, the vast majority of revenues are coming from memberships and conferences, so those will be the two primary sources…We walked into this and still believe that ultimately, this is about standard setting and coordinating the activities that are already out there." -- Mr. Hutchens

"If the successor organization is going to have a mission that parallels what [AHIC] has done so far, then it's good to be clear that this is an organization that's going to make policy recommendations to the federal government and perhaps state and local health care agencies. So if it's a policy advisory organization, then we should really be thinking about what kind of structure is the best structure to provide the best possible advice to the government. If it's…about bringing people together and fostering some kind of clearinghouse or coordinating something…then I think we need a lot more clarity about what those functions are going to be, because that's not what we've been doing." -- Ms. Morris

"This has been relatively unique, in terms of what this group has done, and what we didn't want to lose the momentum that this group has achieved. And if we come back to the principle that…a lot of that success has been because of the role of the government to date…Let's build on what we've done, and again [have] a slow transition out of that." -- Mr. Hutchens

"Did you also consider…the role that ONC would play in this process as well, where does that fit in your thinking?" -- Mr. Hutchinson

"Frankly, they would only support the government delegation in effect to this. It would be limited to that. We are actually ultimately pulling out all of those functions that support the AHIC Board into the separate organization." -- Mr. Hutchens

"I have a question about the makeup of the board. Why did you give member category equal weight? There are other splits that could happen; economic size, some value judgment about impact on the system." -- Mr. Kahn

"We had a lot of internal debate, even within the Booz Allen team, about that. At the end of the day, the principle we tried to adhere to was…the need for balanced participation, and the need for balance, and that every group got heard." -- Mr. Hutchens

Avalere

Shannah Koss, a Vice President and head of the Health IT Practice Group at Avalere, explained that her company's vision for AHIC's successor, which they have termed the Partnership for Health and Care Improvement (PHCI, or Partnership), is an interconnected U.S. health system that enables real-time, secure, authorized access to health information by each relevant stakeholder, when and where it is needed. PHCI's primary mission is to prioritize, enable, and synchronize health information technology (HIT) needs and activities in the United States. The Partnership has the following three core components of its mission, which are consistent with the combined needs of health industry stakeholders:

- Prioritize the expanded information needs of the health system. The Partnership will determine health system goals to improve information capabilities that require industry-wide collaboration, focusing on quality, consumer empowerment, and population health.

- Enable the generation, transmission, and use of information at the individual and population level. This will be accomplished through delegation, collaboration, and development as needed, and with the identification of barriers and solutions to enable needed capabilities.

- Synchronize the array of related activities across the public and private sectors, identifying how activities and initiatives are interrelated or interdependent and how to coordinate them.

Ms. Koss emphasized that the PHCI, as a public-private partnership, would embrace and maintain the momentum that the Community has already started. These efforts are dependent on not only maintaining, but in many ways expanding the value proposition that the Community has had to date. The first phase in transitioning AHIC to the Partnership involves a Transition Board that will create some of the necessary buy-in and value proposition for the entire health care stakeholder community. It will be important to define this Board's own mission consistent with what the Community already has accomplished and with the recognition of an open, transparent, trusted, and equitable structure that would have all voices at the table. Ms. Koss noted that the Transition Board would have, as one of its first tasks, to revisit the prioritized focus areas for health system improvement, and determine which of the existing AHIC Workgroups need to be stood up immediately to ensure a smooth transition from where the Community and the Workgroups are working today.

Avalere's design of the successor entity does not involve a membership organization in the sense that was discussed during the Booz Allen Hamilton presentation. Avalere's design will leverage some very critical membership organizations, but the notion is to help foster and facilitate; it is hoped that these activities will begin in the fourth quarter of this year. Avalere is attempting to establish health industry sector councils (HISCs) across key constituencies throughout the stakeholder community of health care modeled after the Critical Infrastructure Partnership Advisory Council, a Federal Advisory Committee Act

(FACA) group that advises the Department of Homeland Security. These HISCs provide a structure that promotes broad stakeholder representation and direct input to the PHCI. Examples of HISCs include those in the areas of long-term care, providers, HIT and health information exchange (HIE), employers, state and local government, etc. Under Avalere's proposal, initial nominations for the Transition Board would come from the HISCs, which each would nominate two or three representatives; the Secretary then would select transition board membership from among these nominations.

Ms. Koss explained that Avalere's model includes affiliate organizations with related objectives that will plan an essential role in supporting the PHCI. Some likely affiliates already have been identified, such as the Certification Commission for Healthcare Information Technology (CCHIT), HITSP, National Quality Forum (NQF), the Ambulatory Care Quality Alliance, the Hospital Quality Alliance, and others. These organizations are capable of supporting other needed development components (e.g., research, standards development, certification, quality metric specifications). Affiliates could be asked to form *ad hoc* workgroups or technical advisory panels to focus on key areas. As the Transition Board determines priorities and gaps in current information capabilities, it also will consider what these affiliate organizations could accomplish—this offers an alternative to creating a new workgroup or duplicating existing efforts. The Transition Board would develop Memoranda of Understanding with affiliate organizations that that establish the relationships and expedite consideration of PHCI recommendations. These affiliates will be recognized as expert resources from which input should be regularly sought.

Ms. Koss noted that each federal entity involved in the PHCI will play a different role and offers differing value. She explained that Avalere approached this not as a FACA, but with guidance from ONC without required federal legislation, to quickly develop this public-private partnership. The Partnership will be predominantly recommending policy, both to the private and public sectors, with the government playing some critical and ongoing roles. First and foremost, both the current Community and ONC would provide the underpinnings for how sector councils are established and the creation of the Transition Board is fostered. Once the Partnership is put unto place, Avalere is recommending that there be an Executive Order to shift the federal activities of the current AHIC to an interagency Council for Health Care Improvement (CHCI), which would maintain the federal components of the Community to advance similar goals on behalf of the federal government and explicitly work as a counterpart to the PHCI. Ms. Koss added that all federal agencies subject to the transparency Executive Order would incorporate recommendations from the Transition Board and PHCI consistent with the Executive Order and CHCI guidance. ONC would: (1) work with federal agencies to facilitate government-wide adoption; (2) work with contractors to implement and advance agreed-upon standards, supporting pilots, and recommended policies; and (3) channel funding, existing contracts, and staffing as needed and appropriate. Also included in Avalere's vision for the role of federal entities, the National Center for Vital and Health Statistics would provide a mechanism to direct recommendations to the Secretary, HHS, and provide ongoing support for public hearings and other FACA processes, offering technical expertise as needed.

Avalere envisions three primary ways that key relationships and processes will ensure that the Partnership is coordinated with the states: (1) a state and local government HISC to provide Board/workgroup nominations, input, and ongoing feedback on recommendations; (2) a state affiliate help the PHCI address state-level HIT issues including barriers to interoperability, privacy and security issues, and state law and regulatory barriers; and (3) a state and community public forum to obtain regular input from an array of state and local representatives. In addition, Ms. Koss noted, the PHCI will coordinate and direct workgroups to state-based input mechanisms.

In terms of the timeline for transitioning to the PHCI, Ms. Koss explained that fostering the HISC creation is a critical first step. AHIC members will work with sector associations to hold town hall meetings and foster HISC formation. Interim principles will be established for HISC operations based on open and inclusive processes. Town hall meetings also will be conducted for individuals, companies,

organizations, and associations that represent the designated sectors. Once the HISCs are formed, each will develop a list of two or three Transition Board nominees, ensuring equitable balance in industry representation and transparent selection. In terms of funding for these activities, current AHIC and ONC dollars will be leveraged, along with government grants and contract/support for transition support and town hall meetings.

In terms of the Transition Board itself, an 18-member commission is envisioned, with ten HISC representatives, four Congressional appointees, four federal representatives recommended by non-federal members of the current AHIC, and five initial staff (an Executive Director, Deputy Director, General Counsel, and two support staff). Once formed, the Transition Board will re-evaluate the structure and priorities of the current AHIC to determine what, if any, realignment process is necessary to promote and maintain industry support/buy-in. The Board will prioritize future PHCI activities using an open and transparent process, establish an Executive Committee, and set up priority workgroups. The Transition Board also will have the authority to create technical advisory panels; Avalere is recommending that there be a standing Community Health Information Exchange Panel. Once the Partnership's three-year agenda with explicit goals, milestones, tasks, and a revised structure (insofar as the Transition Board believes it to be necessary) has been vetted and revised, a new nomination of the formal Board for the mature organization would proceed.

Ms. Koss noted that from the second phase of transition on, Avalere anticipates obtaining private-sector funding through a small percentage of association dues that would help to support the Board and the HISCs. The percentage would be scalable to the size of the association. She explained that with broad participation, a very small amount of membership dues that all of these associations have coming in to help support both the Board and the councils would actually be a sizeable amount of money, and could support a sustained portion of the Partnership. Avalere also is recommending a minimum of five-year, 50 percent funding from federal sources. Ms. Koss noted that the estimated cost for the first phase, establishing the HISCs, is $1-2 million; the second phase is expected to cost $5-6 million on an annual basis, with closure expected in early 2009. Once the Partnership has reached a mature state (phase three), an annual budget of $15-16 million is expected. The first two phases are more heavily funded by the government. Phase three is funded more evenly, but still includes an ongoing role for federal funding.

Before closing her presentation, Ms. Koss explained that the mature PHCI, when formed, will also offer various operational services that support the NHIN. One example of such a self-funded activity would be certifying trusted local networks to join onto the NHIN. This activity would not replace CCHIT's efforts, which focus on certifying the system; rather it addresses the policy and the nature of how these local networks are being supported from both a policy and organizational standpoint, and indicating whether they have covered all that is necessary to ensure that theirs is a trusted network. Ms. Koss summarized her comments by noting that once it has reached maturity, the PHCI will have used a broad and inclusive approach to redefine priorities, target areas, and supporting infrastructure.

Alchemy

Alchemy principal Dr. Sharon Benjamin opened her comments by noting that a series of assumptions drove the recommendations being presented by Alchemy. The first assumption is that the process and consideration before AHIC is "all about the network"—the Community is embedded in a very complex network of stakeholders and activities—this assumption drove Alchemy's process and structural recommendations. For example, Alchemy recommends that AHIC: (1) broker connections, (2) catalyze innovation, and (3) facilitate communications. Each of these recommendations is tied to a different structure. In addition, there are legitimate roles for government to continue to play as the guardian of Americans' interests in this area.

Another assumption is that the future is unknown; to that end, Alchemy is recommending that the Community accept an unforeseeable future. Dr. Benjamin explained that conversations with AHIC members and knowledgeable observers had indicated that many of the recommendations and considerations about structure are predicated on the ability to know the future. The future is not knowable, however, and change in the technical arena particularly is nonlinear, resulting in a complex adaptive problem and leading to an appropriate application of some of the principles of complexity science.

Dr. Lisa Kimball, founder and Executive Producer of Group Jazz, explained that Alchemy considered three different key models in focusing on the key functions necessary to create a system of standards that would establish an interoperable HIT system:

- ***The Health Information Roundtable.*** This mechanism is similar to AHIC as it currently exists and to some parts of the other proposals. It involves the process by which stakeholders are brought together to determine how best to synthesize and prioritize ideas so that recommendations can be made, not only to HHS, but to the other possible entities that might take in recommendations and act on them.

- ***The Innovation Fund.*** This mechanism is needed to catalyze the creative development of technical and other innovations required. Stakeholder representative mechanisms are not widely known for moving quickly. Alchemy believes that a mechanism to create the fast-moving technological innovation needed will not be achieved through a system of stakeholder representative councils or meetings; this Innovation Fund would ignite that kind of change towards targeted development.

- ***The Diffusion Network.*** Dr. Kimball indicated that the ability for people to actually take in and use new technical developments is not about telling them what they are. There are thousands of local and individual adaptations and problem-solving strategies that need to be developed and deployed; and so a mechanism to help use at the end of the process is required.

In addition to these three mechanisms, Alchemy recommends that ONC and other HHS functions continue their important roles as representatives of the public at large.

Dr. Kimball noted that there is a large chasm between what is necessary to get people who are in the early adopter end of the adoption curve to take in, use, and deploy any new innovation, particularly technology, and what it takes for the mainstream to do that. Even if the right standards are developed and the technology to support them is there, there is still that chasm acting as a barrier to making this system work widely. Addressing this issue within the context of AHIC's successor is critical.

Dr. Benjamin reviewed a series of short-term activities and goals associated with AHIC's successor. These include: (1) creating roadmaps owned by the communities involved that identify and define shared objectives; (2) kick-starting technical development to open standards by a target date; (3) taking advantage of ongoing pilots and launching multiple new experiments and pilots; (4) nurturing the key relationships among stakeholders; and (5) establishing a vigorous, aggressive, and responsive technical assistance network. She noted that some of these activities are somewhat outside the current comfort zone of both AHIC and ONC. As part of the transition, learning to undertake those activities and monitor them represents an educational opportunity for the Community.

Dr. Benjamin discussed the Health Information Roundtable, which will:

- Set bold direction and catalyze the conversation about the role and power of HIT in the community of stakeholders.

- Create and manage roadmaps.

- Establish "min specs" for technology development and certification.

- Identify and use leverage points (e.g., government policy, industry incentives, sector engagement).

- Delegate key authorities (for example to CCHIT for certification).

- Coordinate with local, regional, and federal government bodies with related oversight responsibilities for privacy and security issues.

Alchemy is suggesting that in forming the Health Information Roundtable, the Internet Corporation for Assigned Names and Numbers (ICANN), the governance body for part of the Internet, be considered as a model. Dr. Benjamin also noted that Alchemy recommends that the Roundtable be created with distributed control (i.e., the control for this successor organization should be distributed across the community and not owned by a single entity). She commented that distributed control will accelerate the use and relevance of the Health Information Roundtable. Alchemy recommends a fairly high tolerance for the coexistence of order and disorder or chaos, noting that in a healthy adaptive system, order and disorder coexist.

Dr. Kimball noted that Alchemy is interested in the notion of how a functional network develops—the four stages of network development are: (1) Stage 1 -- scattered clusters and unconnected individuals; (2) Stage 2 -- hub and spoke; (3) Stage 3 -- multi-hub small world; and (4) Stage 4 -- core-periphery network or smart network. She explained that AHIC currently is at Stage 2, and for interoperability across an HIT system to work, there needs to be a Stage 4 network. Alchemy envisions the Health Information Roundtable as being the mechanism for moving through to Stage 4.

Dr. Kimball discussed how AHIC's successor might influence the system that is already in place with regards to standards development, and target the system towards the things in which there is the greatest public interest. There is going to be a lot of development, but there might not be enough development fast enough to address some of the privacy or other issues that arise. These issues might be examples of ones that get prioritized for the Innovation Fund described previously.

With regard to the Diffusion Network, Dr. Kimball commented that one model that might be worth exploring is the Department of Education's methodology for providing technical assistance to follow the No Child Left Behind initiatives and regulations. Alchemy is recommending the creation of a network of regional and local technical assistance providers that can be a combination of something funded by government or by a public-private sector entity, and a way of linking up many of the mechanisms that are already out there independent of this new entity. She explained that in terms of diffusion of innovation, best practices generally do not work very well—they are hard to manage, expensive, and must be locally adopted and adapted. Alchemy is recommending creating this Diffusion Network as a network of regional and local entities that can support adoption and adaptation. This Network will help close gaps, such as the gap between what needs to happen relative to EHRs and the actual use of them.

Dr. Kimball summarized by emphasizing that Alchemy is recommending that AHIC powers its transition with multiple simultaneous actions across four frames: (1) the creation of a Health Information Roundtable; (2) the creation of an Innovation Fund; (3) the recognition that AHIC currently is a diffusion

network that must be a smart network that operates in some particular ways; and (4) HHS should continue to play the guardian roles that it plays currently, while it divests itself of some of the things for which it is not particularly well suited.

Discussion Highlights

"In your vision of this [Innovation] fund, what is the market failure that this fund could address that wouldn't [otherwise] be existent?" -- Mr. Foster

"There might be some market lags, if not failures, in some of the things in which there is a keen public interest. For example, underserved categories or particular aspects of privacy and those kinds of things…The incentive for the private sector money is that everybody gets to play in setting priorities and, in some cases, private sector funders may feel that they would like to develop something they anticipate will be required, such as a privacy module, but they themselves don't want to have to pay for the whole thing. But if they pool in an innovation fund this becomes possible." -- Dr. Benjamin

"The larger the constituency that the structure represents, that is, the more members it has, the slower it always moves, by definition…I'm very concerned about setting up any structure which represents a 2 trillion dollar industry in the United States, and in principle, impacts every citizen in the United States. So there are 300 million people who are going to be interested in the output as well." -- Mr. Barrett

"I think absent a very active role of HHS with its purchasing power, the system suggested will probably set back any progress by, I'd be conservative, 5 or 10 years, because you'll go back to ground zero, and you'll try to get agreement between two trillion dollars worth of parochial revenue, and you won't get agreement." -- Mr. Barrett

"The first thing the Transition Board does is identify the priority areas where it wants to stand up workgroups that are arguably counterparts to the current Workgroups of the Community….the other [activity] is to formalize the go-forward strategy…with very explicit milestones and goals." -- Ms. Koss

"HHS should issue a tech manifesto about its position on technical development of interoperable software so that the community at large knows where we stand as a payer…Have innovation funds been granted, in areas of particular promise?…Has the Diffusion Network begun to meet and can you map that change?" -- Dr. Benjamin

"The first time I saw the membership of [AHIC], I was very surprised about the very small private-sector representation on this. I acknowledge the government's half the market but there is another half to that. So for me, the other piece of this is whatever mechanism we use, do we have a broader base of representation on the committee, or in the group, whatever the successor is, to do this." -- Mr. Hutchens

"At the end of the day, if we're going to drive standards, there is going to have to be a role for the government." -- Mr. Hutchens

"I'd like to hear from each of you the lessons from the current AHIC and how to avoid speed bumps going forward." -- Ms. Gelinas

"Probably the most prominent [lesson] that we heard was around scope creep, to use the vernacular, and the notion that a lot faster, more exciting progress can sometimes be made, the more narrow you focus. And that tracks with what we know from complexity that sometimes, small changes have big effects; that rather than thinking it's a big problem so you need a big program or a big organization, maybe you don't. Maybe it's very small targeted acupuncture-like focused attacks." -- Dr. Benjamin

"I think the Community is perceived as trying to work with the various organizations that are also undertaking activities, but not necessarily always heeding or hearing what is sort of the on-the-ground experience. And consequently, some of the recommendations aren't viewed as really being implementable or necessarily going to be embraced." -- Ms. Koss

"It's the frontline, it's ensuring that we're hearing from all interested parties, and again, recognizing you don't want to turn this into "analysis paralysis,"+ but we need to make sure we've got balanced representation." -- Mr. Hutchens

"What would you do to give the patient more choices, more control, which will lead to ownership and accountability? This is not trivial in DoD, and I need your help with it, but we are trying to drive it in that direction to get more ownership, and I think that's a very important issue." -- Dr. Casscells

"We do not know the answer to that, and we know we don't know the answer to that. But one of the things that we do suggest is that perhaps a way to find the answer to that question is to begin a demonstration project on a particularly difficult chronic disease, because people who suffer from chronic diseases have very difficult health records." -- Dr. Benjamin

"There are certainly some private sector self-insured employers that are incenting and providing a set of tools that are helping and encouraging consumers to get more engaged and take control. Obviously, the whole U.S. population doesn't have that advantage, and it is the larger self-insured employers that can offer choices." -- Ms. Koss

"We certainly think you can have incentives. You can envision staggered co-pays. If you're already using a physician who is using electronic health records, there is a lower co-pay. Something as simple as that." -- Mr. Hutchens

"So if the patient comes in with their personalized health record all filled out on their home computer, or even on a scannable document, you could waive the co-pay and they could say, 'I want to go to a participating provider who waives the co-pay if I have filled out the electronic record'." -- Dr. Casscells

"Or the co-pay is $10 instead of $50 or whatever, yes." -- Mr. Hutchens

"I still am a firm believer that it is the purchasers who are going to drive this change...The technology is not going to drive the change. The implementation of that technology can support the change, but we're going to have to drive those reimbursements. I still get concerned that we don't have a clear understanding of how we keep the momentum going forward of the purchasers' involvement in this process." -- Mr. Hutchinson

"We do believe that incentives, consumer-directed health care, is going to be something that not only causes this change, but may actually help us control overall medical costs…In the particular model we have proposed, we could envision the private sector payer community, the Blue Cross Blue Shields of the world, being one of the groups represented on the board. We could also envision consumer advocacy groups playing a major role in this as well. " -- Mr. Hutchens

"One of the things that we recommend is a consideration of the model offered by the Department of Commerce and the creation of ICANN, and we recommend that for a couple of reasons. First, there is a divestiture of control from the Department of Commerce to ICANN, and that is a model that we are recommending in this case…And secondly, given the incredible influence of the large payers, including HHS in this field, it would be a pretty dumb organization that didn't understand that it needed to stay in very close sync in relationship with HHS." -- Ms. Koss

"I'd like to suggest a challenge to each of the groups who presented today. And consider that when we define consumer, or individual, that we also include, in our language and dynamics, special populations…I would like to invite you to…provide to us a simple descriptor of how you feel your presentation, indeed, will bring benefits to the consumers for whom we are trying to develop this translational entity." -- Ms. Davenport-Ennis

"It's one of the reasons that we suggested that the Innovation Fund be both a public and private partnership, partly to serve those special populations that may not meet market criteria for innovation, but whose needs absolutely need to be protected, and interests need to be advanced." -- Dr. Benjamin

"We believe our model is broad enough that it could represent any number of stakeholder constituencies." -- Mr. Hutchens

"We need to make sure that as we push this boat forward, that the one or two things we're going to do, everybody understands it, and it passed the 'mother-in-law test.' Otherwise we're going to…end up screwing things up. Because we're going to set up a lot of process, and then they're going to get into a lot of different things, and we're going to have trouble." -- Mr. Kahn

"If 150 companies come up with a predominant standard for chronic disease monitoring, we ought to adopt it, and we ought to use it as a piece of this larger puzzle…Our task here is to create a mechanism to reach conclusions on technical standards, and to organize that into a thoughtful system that the marketplace can then operate within." -- Secretary Leavitt

"What we're experiencing right now is how hard it is to collaborate. But we ought to acknowledge the fact that in many other industries and settings, this has been done very successfully. The IEEE is an example where standards have been established. I don't know how hard the collaboration was, but there are standards on 1,300 or 1,400 different things that they have begun to coordinate. [Visa] has 90,000 members who somehow come up with a means by which they're able to create standards that drive, and allow an entire financial community, not just in the United States, but across the world, to do this." -- Secretary Leavitt

"The government, in my judgment, needs to play an organizing role, and we also need to play a role as a participant and a vendor, and we need to put our market force behind this. We need to put our dollars behind it and we need to invite others. Let's not make this too complex. We can do this. Lots of others have. Our goal isn't to be the overall orchestrator of all health care." -- Secretary Leavitt

Standards Timeline and HITSP Interoperability Specifications Version 2.0

Dr. John Loonsk, Director of Interoperability and Standards, ONC, presented a chart illustrating the work that has been accomplished and the work that has yet to be done relative to the AHIC priorities and use case roadmap. The first three breakthroughs have been advanced (in the areas of Consumer Empowerment, Electronic Health Records, and Biosurveillance). An additional four priority areas or use cases have been clustered from a variety of different priorities and issues that the AHIC and its Workgroups have advanced. These four areas, or use cases, are Consumer Access to Clinical Information, Emergency Responder EHR, Medication Management, and Quality. Dr. Loonsk noted that these four use cases will feed into the next steps of the process. AHIC has asked HITSP to begin working up a series of possible use cases for a December 2007 deliverable, representing the next step of priorities

to be advanced. Dr. Loonsk indicated that HITSP will be bringing these possible use cases back to the Community at its next meeting to confirm that these are in fact the priorities to move forward.

HITSP Chair Dr. John Halamka presented Version 2.0 of the work of HITSP, noting that it represents more than 20,000 hours of work by 300 organizations and more than 300 technical experts. The process was built by vendors, standards development organizations (SDOs), consumers, payers, providers, etc. In March of 2006, HITSP was given the three initial use cases (Consumer Empowerment, Biosurveillance, and Laboratory Electronic Health Record Interoperability). HITSP turned those use cases into very detailed requirements documents and then examined more than 700 standards that would meet those requirements and assessed their readiness and appropriateness. From those 700 standards, HITSP named 30. Those 30 standards required very detailed implementation guidance; that guidance was presented to the Community as Version 1.2 in October 2006. Secretary Leavitt accepted the interoperability specifications in December 2006 with the intent to recognize Version 2.0, presuming that changes would be minimal or of a technical nature. The HITSP Panel approved the Version 2.0 interoperability specifications on May 11, 2007. No additional constructs or standards were added to Version 1.2 as a result of implementation testing feedback. All changes between Versions 1.2 and 2.0 were minor or of a technical nature to the implementation guidance. Dr. Halamka explained that AHIC is being presented with 28 of 30 standards are complete for this round; two are still being balloted by SDOs in July.

Consumer Empowerment -- Registration and Medication History Version 2.0

The scope of this specification to "eliminate the clipboard" involves deploying to targeted populations a pre-populated, consumer-directed and secure electronic registration summary. It also includes deploying a widely available pre-populated medication history linked to the registration summary. This specification addresses core consumer empowerment enabling "connecting PHRs." Dr. Halamka noted that this work required a historical collaboration between HITSP and member organizations such as the American Society for Testing Materials (ASTM), the Council for Affordable Quality Health Care, Centers for Disease Control and Prevention, the Federation Management Tool, Health Level-7 (HL-7), etc. It also resulted in harmonization to the Continuity of Care Document (CCD) medical summary record; ASTM has been working on the Continuity of Care Record, while HL-7 has been working on the Clinical Document Architecture. HISTP membership, without objection, agreed to support the best of both worlds, the CCD. Dr. Halamka explained that the consumer empowerment specification is complete and includes all of the implementation guidance necessary to implement and the final balloted work products of all the standards development organizations involved.

Biosurveillance Version 2.0

The scope of this specification involves transmitting essential ambulatory care and emergency department visit, utilization, and laboratory result data from electronically enabled health care delivery and public health systems in a standardized and anonymized format to authorized public health agencies with less than one day lag time. HITSP achieved the following accomplishments related to the Biosurveillance v.2.0 specification:

- Maximizes data sources and provides stringent data management to ensure proper routing, security, privacy, and timely reporting.

- Provides support for different architectural environments.

- Addresses gaps with referrals to SDOs through the Foundations Committee.

- Aligns with other public health initiatives.

- Uses the same result message as is used for clinical reporting, which should improve the number of public health cases reported.

Dr. Halamka noted that there was not a standard in this country for describing hospital bed availability and utilization. If there is a mass casualty incident, and someone or some group needs to know how many beds are available at a given hospital, other than sending a spreadsheet, there has not been an interoperable standard developed by an SDO. The Oasis International, one of the American National Standards Institute-recognized SDOs, has in ballot the Hospital Availability Exchange Standard in July 2007. It is believed that this will meet that final last element of the use case for reporting on hospital utilization and availability.

Electronic Health Record -- Laboratory Results Reporting Version 2.0

The scope of this specification is to deploy standardized, widely available, secure solutions for accessing laboratory results and interpretations in a patient-centric manner for clinical care by authorized parties. Dr. Halamka commented that this specification takes into account two basic types of data transmission, machine-level transmission between a laboratory and EHR, as well as human-readable transmission or documents that may go with a patient and a PHR, or may be an EHR or a regional health information organization (RHIO). Version 2.0 of this standard addresses the lack of harmonization among data interoperability standards including vocabulary and laboratory and other messaging standards. Version 2.0 also accommodates both laboratory message transaction and document-sharing paradigms. In addition, HL-7 and the HITSP Laboratory Workgroup are coordinating activities to complete a laboratory message implementation guide to meet AHIC use case requirements. Dr. Halamka noted that a messaging standard for laboratories, HL-7 2.51, will be balloted in July. Comments are expected in August, with final implementation guidance to be incorporated into the HITSP specifications by September.

Dr. Halamka acknowledged that change in vendor products is not immediate. HITSP will develop standards, but there needs to be a logical timeline by which the vendor products, laboratories, pharmacies, and doctors in the United States change their systems to use these standards. HITSP and CCHIT have developed a roadmap together that includes moving from the heterogeneous standards of HL-7 2.2 and 2.3 to 2.51 in 2008 as well as using controlled terminologies such as LOINC codes and SNOMED vocabularies (in 2009). Using standard units of measure in every laboratory of this country is a particularly changing body of work and, therefore, is slated for 2010.

HITSP's next step is to finalize privacy and security standards by October of this year. There are nine different classes of privacy and security standards; HITSP will return to AHIC in October with nine different kinds of security and privacy constructs that will work across all of the use cases presented today as well as future use cases. HITSP also is moving forward on the Emergency Responder EHR specification and the three new use cases referenced by Dr. Loonsk (Consumer Access to Clinical Information, Quality, and Medication Management).

Discussion Highlights

"We have received our use cases…and we've broken those use cases into what I'll call the 'low hanging fruit.' Standards already exist. There is relatively mature implementation guidance that we can incorporate, and we'll bring those back to you in October. We will follow the March through October guidelines. But we also recognize that because the timeframes are so tight, that there is going to be additional work post-October on some of the gaps, and some of the areas that aren't yet quite

mature…There is no question we will be back in October with privacy and security, and emergency first responder, and some low hanging fruit, phase one materials on the other three use cases." -- Dr. Halamka

"HITSP is essentially getting the use cases six months later than they would have liked to, and the commitment represented in its timeline is one that they probably should be given some flexibility with the next step of deliverables, whether that be to February of this coming year or of next year. If we do prioritize the six next round, we can have those for them in December of this year, and that from henceforth, they can have a regularly expected deliverable in December that can feed their process and get onto a much more regular cycle, which is important for not just HITSP, and the amount of time they need to do their work, but also for all the dependencies of the other processes that cascade from that as well." -- Dr. Loonsk

"We also need to align our work with CCHIT, because as you can see, there is a clear dependency, and if CCHIT has a June-to-June cycle, the timing is quite delicate to make sure that this is incorporated and, therefore, certification can occur in a timely way." -- Dr. Halamka

"I see the Community as the Board of Directors, and I get to serve as your CEO or COO, and together we will deliver what you prioritize." -- Dr. Loonsk

"We have what would be called a Harmonization Readiness Committee that looks at what the industry has done, or standards development organizations have done, and asks, 'is it applicable for the purpose of a use case? Does it have an open, transparent process that was used to develop it? Is it going to be maintained going forward?' And if it passes through that sieve, we say, 'this is great. This is something that now we incorporate into an interoperability specification.' Because we do not want to write standards nor maintain implementation guides ourselves. We would much rather point to the work of an SDO, or a group that has decided to create implementation guidance that's going to help us." -- Dr. Halamka

"Are you aware of other similar organizations…that could accelerate the pace of our work? We started with three, we went up to four, now we're looking at six. Are we going to be able to see an acceleration of this process over time?" -- Secretary Leavitt

"Not only are we trying to encourage looking for those groups, as this process moves forward, but we're also trying to encourage the Working Groups to guide the development, to fill gaps as early as possible, so that they can be harmonized, or advanced in this context moving forward." -- Dr. Loonsk

"We ought not to allow our view of AHIC to become too complex. The complex work happens at HITSP and CCHIT. Our job is to find a way to bring conclusions and to prioritize what happens next." -- Secretary Leavitt

"As you get into lab result standard in the reporting, this unified code of units of measure, this UCUN, is getting into some standardization and medical terminology that the concern is a patient safety concern. How do we transition, for example, milligrams? In medicine it's 'Mg,' as an abbreviation. In the UCUN standard it's 'G-3.' So how do we get into a transition to where a position is not interpreting the information incorrectly because of unknown new vocabulary terms?" -- Mr. Hutchinson

"This is why we set with CCHIT, a 3-year roadmap for working through these issues, because you might imagine, the machine-to-machine communication takes place with that G minus three, but the human readable communication may very well have a visual mapping, which is more consistent with what a doctor is used to seeing. The word 'milligrams,' for example. So that is work that still would need to be done in the future. We're simply saying we need to standardize units of measure so that every machine in

the world spits out the same information so a computer can interpret it, and the roadmap to begin that process starts in 2007, with 2010 as a likely implementation date." -- Dr. Halamka

"The 2008 possible use cases, the one that just really stands out is under remote consultation, structured e-mail reminders and online consultation. I think we're moving from fog to concrete. But that is going to beg the whole reimbursement issue, that as we get that finalized, the ugly issue of paying for e-visits, electronic communication with patients, that type of thing, it really strikes me as an important component to tackle with the reimbursement aspect." -- Ms. Gelinas

"In Massachusetts…Blue Cross has taken an early lead in pilot programs to reimburse e-visits, and so there is some learning, I think both in California and in Massachusetts on this. So I hope the lessons learned will be there by the time the standards are implemented." -- Dr. Halamka

"Many of the standards I presented to you today are semantic Web-based, so the CCD standard is, in fact, an XML construct. The notion of transporting that securely, via the Web, in an encrypted way, certainly is a common mechanism of sending that from place to place. So I think with this particular UCUN example, it's not so much a technology challenge, it's just making sure there is an unambiguous mapping between what the computer is using as a unit of measure, and what the person sees. And implementing it, using a transform such as a semantic Web may be a very logical way to do that." -- Dr. Halamka

Chronic Care Workgroup Recommendations

AHIC member and Chronic Care Workgroup Co-Chair Craig Barrett reminded Community members that the Workgroup's broad charge is to make recommendations to the Community to deploy widely available, secure technologies solutions for remote monitoring and assessment of patients and for communication between clinicians about patients. The Workgroup's specific charge is to 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. In reviewing progress to date, Mr. Barrett reminded the Community that the Workgroup has already made several categories of recommendations in the areas of compiling and assessing various reimbursement methodologies for secure messaging between clinicians and patients, looking for evidence, and continuing to contribute to the information database on that topic. An additional set of Chronic Care Workgroup recommendations focused on having HHS work with the states to discuss cross-state licensure and facilitate telemedicine across states. The Workgroup also made recommendations to HITSP to define standards for secure patient-clinician messaging transactions, and also to examine remote monitoring. These are possible 2008 use case topics. Additional Workgroup recommendations made previously focus on having AHRQ look at studies of information technology in the elderly, ill, and underserved populations; and on the issue of broadband access as a necessary infrastructural item to move forward for remote monitoring, diagnostics, and consultation.

Following this review, Mr. Barrett presented the current round of Chronic Care Workgroup recommendations, which fall into two categories:

Use Case Development: Secure Messaging

- ***Recommendation 1.0:*** Given that the HITSP interoperability standards and certification criteria for secure messaging and advanced electronic technologies for clinical monitoring have not been included in the development of either of the first two sets of use cases and that interoperability

between patient and clinician electronic health products is critical for improving quality of care, the Secretary should make a use case for interoperability with respect to remote care a top priority.

Business Case Alignment

- ***Recommendation 2.0:*** In order for a clinician to be reimbursed by Medicare for providing services delivered through advanced electronic technologies, current statute requires the patient to be in a specific clinical setting. The Secretary should develop legal guidance that defines the clinical setting by the information collected, diagnostic services performed and treatments rendered. This guidance should take into account potential concerns with fraud and abuse, violation of Stark laws, HCPCS codes, and other possible mitigating factors.

- ***Recommendation 2.1:*** The Secretary should conduct demonstration projects to determine the value of telehealth services in clinical settings beyond those listed in federal statute in order to make informed decisions about expansion of that list.

- ***Recommendation 3.0:*** The Secretary should evaluate the benefits of remote store and forward technology as currently employed in Alaska and Hawaii to determine if these services should be expanded beyond these two states.

- ***Recommendation 4.0:*** The Secretary should conduct demonstration programs through the Special Needs plans and Medicare Advantage plans that specifically evaluate the use of home-based, remote care monitoring for the management of specific chronic conditions by clinicians of record.

Discussion Highlights

"From my own view, all of these are AHIC acceptable. But it's important that I acknowledge that when AHIC forwards those to the Secretary, that in many cases, I'll be able to deploy, and not just have them accepted, but act on them. In other cases, I will have to act on them by modifying them in some way. In other situations, they won't be practical for reasons that may not be entirely seen or even, for that matter, agreed with by members of AHIC." -- Secretary Leavitt

"With respect to changing the way we pay to acknowledge electronic monitoring, and to focus on the delivery of the service as opposed to the proximity, that makes a lot of sense to me. It would have a profound impact on the business model of HHS. And I suspect everyone at this table believes that it would, in the long run, maybe even the short run, produce a net gain for HHS." -- Secretary Leavitt

"The group did find it rather amusing when we came to realize that if you are an average citizen in the United States, you fall into a substantially different category than if you happen to be a member of the armed services, an American Indian, a convict, or an astronaut. Those four categories of people all have opportunities and capability for remote diagnostics, remote consultation. If you're an average American citizen, you do not." -- Mr. Barrett

"The wording that 'the Secretary should develop legal guidance that defines,' [in Recommendation 2.0]…I think that the Secretary just sort of outlined the question of demonstration, and I think even before you get to demonstration, there needs to be sort of exploration here of the possibilities of payment policy. Because the trouble is, particularly if you're thinking with a budget neutral principle underlying it, that you've already got a stressed system and budget neutrality isn't necessarily helpful, although I understand it's mandatory." -- Mr. Kahn

"Any kind of fee for service here, unless it's a hundred percent co-payment, which maybe it ought to be, is not going to work. And if it's one hundred percent co-payment, then does the government come in and set a fee schedule? You don't want the government to set a fee schedule because that's not market oriented…You've got have to some kind of capitation model or something that you're going to experiment with, and it seems to me that you've got to have more than legal guidance. You've got to have some policy development that has to be done here. I would suggest that we expand this to say that there be some kind of policy development because the legal guidance would be that you probably can't do it without legislation, whereas if there is policy development, that could lead to demonstrations which could lead to either legislative action eventually or action if the Secretary did have any authority." -- Mr. Kahn

"It would be very helpful to us if private insurers, who have less arduous standards in terms of changing their business model, were leading in being able to say 'let's figure out ways to demonstrate that this works, it would be very helpful to HHS in designing our demonstrations and hence our rule making." -- Secretary Leavitt

"We could throw in language saying 'working with private sector.' I just think there has got to be thinking done about it, and it can't be fee for service. It's just not going to work. It's got to be something else." -- Mr. Kahn

"I welcome your additional language…I think this is a place where government could be substantially assisted by private payers and providers. If you have ways of doing this, show us the way. We'll have a big impact when we move, but we'll move faster if we can be shown that, in fact, this works." -- Secretary Leavitt

"When you look at policies, you can't ignore the Congressional Budget Office and OMB…We've got to think about that." -- Mr. Kahn

"Common sense tells you that if you're doing this remote monitoring, that there are some potential efficiencies, but before we change our business model in a way that costs the treasury billions of dollars, we need to know what those impacts are, because as has been suggested, it doesn't always save money." -- Secretary Leavitt

"That's why we combine 2.0 with 2.1. 2.0 was to define the change, 2.1 was, in fact, to carry out the pilot projects, to see, in fact, what makes sense as you move forward." -- Mr. Barrett

"From the Blue's point of view, we will certainly help to put information on the table to evaluate what is going on, what is working, and what the barriers are." -- Ms. Handelman

"Certainly we are restrained by regulation and statute. In general, when we do change payment policies, it's done through a process whereby we look at what's going on in the private sector. We have certain processes in place. Then we do demonstration projects…In the Medicare population, of course, it's not as technology savvy as a lot of the major other population groups. And I think that also needs to be taken into consideration." -- Mr. Trenkle

"I wonder if there is an intermediate step here to really compile the lessons learned…Are there age-limiting factors in this, is it more helpful in some diseases than others? We would certainly be willing to participate." -- Ms. Graham

"The target of all of this is, in fact, to keep hospitalizations down, catch chronic illnesses as they're deteriorating early, and treat them as opposed to waiting until the hospitalization occurs. So it's kind of

the shift left mentality, shifting out of the hospital into the pre-hospital remote monitoring, catch it early and treat it…The remote monitoring is relatively inexpensive compared to a single night in a hospital for anyone with chronic illness. And that's where the savings comes." -- Mr. Barrett

"We haven't talked about the time that family members must take to take their loved ones to see health care providers, and that's an economic cost that doesn't appear on any budget, but it can be extraordinary, both for those who miss work and for their employers...As the AHIC sets its priorities going forward, have a very broad view of what the benefits of society might be from these things, and not worry too much just about the particular budget implications of any one particular initiative." -- Ms. Morris

"The one thing that I would ask us to expand our thinking on, and in the recommendation 2.0…is making sure we're all on the same page with this concept of advanced electronic technologies, and the use through those advanced electronic technologies. We're not just simply talking about traditional services…So from a demonstration project, things like making sure patients are taking their medications, staying on their medications, or taking the preventive test to ensure that they're catching things early on, I think are more critically important as part of the demonstration project, to prove the cost benefit you're looking for." -- Mr. Hutchinson

"As a self-insured employer…we are all over this, it is part of our wellness program, so we're not viewing it as traditional health care plan. Contrary to rumors, we also have to be budget neutral in our environment; there's that bottom line focus. But we believe it will actually be a positive impact, when you look at the total well being of the associate. We can look beyond just the health care environment, and look at things like how well are you, what is productivity, what does it do to sick days? But everything we learn, we will share." -- Ms. Dillman

"As we are shifting responsibilities to consumers and engaging them more directly in the therapy, as we look at the Recommendation 2.0…there is the opportunity to amend the last sentence, to add one phrase. It would simply read, 'as well as benefits to consumers with cost sharing identified within the pilot.' I think to the point made earlier, that consumers understand the financial advantage to families if e-health could, indeed, be available, and that cost sharing for consumers would probably be supported in that particular area and would be helpful in that budget neutrality." -- Ms. Davenport-Ennis

"Would you be talking about both 2.0, 2.1, and 4.0 for this?" -- Dr. Kolodner

"Yes…I think consumers are understanding more that they do have a responsibility within the area of cost, and that this is a savings to families when they can actually stay at home and have the benefit of e-health technology." -- Ms. Davenport-Ennis

"I would just presume that there is ultimate flexibility in terms of any reimbursement program, in terms of co-pays, cost sharing, what have you; and that that would logically come out of the deliberations and the pilot programs you would run." -- Mr. Barrett

"And I think the only amendment, Craig, to your comment would be that on behalf of the patients that we represent, we would strongly urge that it not be at a 100 percent co-payment for these services." -- Ms. Davenport-Ennis

"Just so I'm clear in terms of the recommendations for moving forward, we can either have it with your comments reflecting and informing the recommendations, or are you suggesting we still need to modify the recommendations?" -- Dr. Kolodner

"I think my recommendation can stand, and Craig's recommendation that it be with the full flexibility possible, and my further amendment that hopefully we will not be at one hundred percent." -- Ms. Davenport-Ennis

Following these discussions, consensus was declared on the Community accepting Recommendations 1.0 and 3.0. Recommendations 2.0, 2.1, and 4.0 also were accepted by the Community by consensus, with the amendments presented by Ms. Davenport-Ennis and Mr. Barrett.

Electronic Health Records Workgroup Recommendations

The Electronic Health Records Workgroup has the following broad charge: to make recommendations to the Community on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers. The Workgroup's specific charge is to make recommendations to the Community so that within 1 year, standardized, widely available and secure solutions for accessing current and historical laboratory results and interpretations is deployed for clinical care by authorized parties.

Community member Lillee Gelinas, Workgroup Co-Chair, noted that the Electronic Health Records Workgroup previously made eight recommendations to the Community. Five of these recommendations have been carried out, one is "on target," and progress on the remaining two is underway. She noted that one study has found that 80 percent of medical errors began with miscommunication, missing or incorrect information about patients, or lack of access to patient records. She reminded Council members that all of the Workgroups are functioning under five major areas around which recommendations are made: business case alignment, workflow and cultural concerns, medical-legal issues, privacy and security, and state of the technology.

Ms. Gelinas noted that the Workgroup heard testimony indicating that in the ambulatory physician practice area, only about 9 percent of physician practices have adopted EHRs, and in the inpatient setting in hospitals, only 10-20 percent. With regard to the prevalence of electronic claim systems, physician's offices are at 80 percent, pharmacies are at 93 percent, and payers are at 94 percent. She also reminded Community members that the Workgroup's Recommendation 2.0 (focusing on workflow and cultural concerns) have been accepted by AHIC, as have Recommendations 3.0 and 3.1 (which deal with medical-legal issues). After presentation at a previous AHIC meeting, the Electronic Health Records Workgroup was asked to revise Recommendations 1.0, 1.1, and 4.0. Ms. Gelinas presented revised recommendations as follows:

Business Case Alignment

- ***Recommendation 1.0:*** As the federal government develops language in its contracts with health plans and insurers to support the widespread adoption of HITSP interoperability standards, this language should foster, to the maximum extent possible within existing authority, the use of financial incentives or pay-for-use programs to incent the adoption and effective utilization of CCHIT-certified EHRs. Structural measures should be included in these programs, which may be limited to a specific timeframe with the ultimate goal of using process and outcome measures to assess performance.

- ***Recommendation 1.1:*** These pay-for-use programs should use reliable, standardized, and validated tools which are currently available to assess structural measures: for example, the NCQA's Physician's Practice Connections or CMS' publicly available Office System Survey. When the National Quality Forum endorses a set of structural measures, these should be employed by these programs.

- ***Recommendation 1.2:*** HHS should evaluate pay-for-use programs with respect to quality, cost, and adoption.

Discussion Highlights

"The issue of how we pay for this is obviously one that the industry has struggled with for some time. And there is no question that at least in the early stages, there is a disconnect between those asked to make the investment. And I think what you said was correct about when there are incentives, people respond…We're going to have to see the macroeconomics of this change over time, and the question is, who bears the burden of it? And how do we go about it?" -- Secretary Leavitt

"It's unlikely that we'll see any system go from where we are today to pay for use. But I think it is quite likely that you'll see, in fact, that we have now in the market just starting in four metropolitan areas where HHS is going, essentially, pay for use, using AHIC systems that are CCHIT certified. That's in four markets…I have invited the major insurers to do things on their own that would mirror that. If we end up with a dozen markets where we are starting with pay-for-use, migrating to pay-for-reporting and then going to pay-for-performance, we're likely to see that change." -- Secretary Leavitt

"The principle here is that once we discover a way in which interacting with providers, or hospitals and doctors, in particular, save us money, we ought to be, then, willing to share that. But we'll initially go in this gradual process, until we can get critical mass." -- Secretary Leavitt

"At the end of the day, all of the benefits from where the EHR will lead will go back to the patients, and to the premium payers, and that's where they ought to go. But…at the end of the day, you're going to take money away from the hospitals, because hopefully there will be less hospitalizations, and you're going to take money possibly away from physicians, because hopefully there will need to be less encounters, which is a good thing. But on the other hand, there are going to be expectations about the hospitals and the physicians and the providers having all the technology, which has capital expense." -- Mr. Kahn

"All of us have to believe that there are huge savings here, or we wouldn't be here. And it's a function of how we transition the macroeconomics to the point that you can't do business without having health IT. We're not there yet….This is about finding that process of changing the macroeconomics of the system and I agree, it's going to require a little bit of risk and reward being balanced, and over time, we'll make it." -- Secretary Leavitt

"One health care process where this has already been deployed in a private industry mode is around prescribing. And we've seen a number of payers in the last six months begin to deploy, not just simply giving away devices, but encouraging and putting incentives in place for use of those devices. And not only the uptake in the number of physicians that are beginning to adopt those technologies for electronic prescribing, but also the number of prescriptions that are written electronically versus by paper, by an individual physician, because it is focused on use…I really do believe that all three of these recommendations are something that we, as an organization, should adopt." -- Mr. Hutchinson

Following these discussions, consensus was declared on the Community accepting Recommendations 1.0, 1.1, and 1.2.

Confidentiality, Privacy, and Security Workgroup Recommendations

The broad charge of the Confidentiality, Privacy, and Security Workgroup is the make recommendations to AHIC regarding the protection of personal health information in order to secure trust, and support appropriate interoperable electronic health information exchange. The Workgroup's specific charge is to make actionable confidentiality, privacy, and security recommendations to the AHIC on specific policies that best balance the needs between appropriate information protection and access to support, and accelerate the implementation of the consumer empowerment, chronic care, and electronic health record-related breakthroughs.

Mr. Kirk Nahra, Workgroup Chair, noted that the Workgroup has added a new member from the Hawaii Department of Health, bringing a genetics focus to the Workgroup. He presented two related recommendations intended to move significantly forward on some of the bigger-picture issues being addressed by the Confidentiality, Privacy, and Security Workgroup. The two related recommendations are:

- All persons and entities, excluding consumers, that participate directly in, or comprise, an electronic health information exchange network, through which individually identifiable health information is stored, compiled, transmitted, modified, or accessed should be required to meet enforceable privacy and security criteria at least equivalent to any relevant Health Insurance Portability and Accountability Act (HIPAA) requirements (45 CFR Parts 160 and 164).

- Furthermore, any person or entity that functions as a *Business Associate* (as described in 45 CFR § 160.163) and participates directly in, or comprises, an electronic health information exchange network should be required to meet enforceable privacy and security criteria at least equivalent to any relevant HIPAA requirements, independent of those established by contractual arrangements (such as *Business Associate Agreement* as provided for in HIPAA).

Mr. Nahra noted that the Workgroup will be attempting to answer two key questions as it moves forward. First, what constitutes a "relevant" HIPAA requirement for particular "direct participants" in the network? Some persons or entities may have an appropriate reason for not needing to meet a particular requirement. It is hoped to evaluate the need for exceptions based on testimony, Workgroup discussion, and responses to questions posed in the Federal Register. The second key question is what, if any, additional confidentiality, privacy, security protections may be needed beyond those already contained in the HIPAA privacy and Security Rules? The Workgroup plans to consider whether there are important differences in the operation of health information exchange networks that require a baseline standard that is more stringent than the existing HIPAA Privacy and Security Rules.

Discussion Highlights

"I was wondering what you meant by 'enforceable privacy and security criteria,' since obviously HHS would have no statutory authority to do anything beyond covered entities." -- Mr. Trenkle

"We did not view our recommendation as something that could be just adopted and implemented, per se. There would need to be some kind of change in the future…We do recognize that there is going to need to be some kind of implementation step, and we did not make a recommendation on what that would be. But we think it's a rule or a statute, not simply policies, not simply best practices. And for business associates, it's not simply contracts to be enforced." -- Mr. Nahra

"We struggled with how to define sort of what our mandate was. For example, we didn't want to limit it just to PHRs. We didn't want to limit it just to EHRs. We tried to use that phrase as essentially a proxy for what's often called the NHIN, but we're recognizing that there's also state versions, regional versions, so it's the type of entity that is the NHIN." -- Mr. Nahra

"I'm really intrigued by the comments here, which stored, compiled, transmitted, modified or accessed, and what I'm trying to do is to get you to a remote location where information is being communicated from that remote location to someplace else, and ask you if every local telephone company, etc., etc., is HIPAA compliant." -- Mr. Barrett

"Well, that's certainly not our intention to go that far…It's not the computer network…It's essentially like the NHIN, or you can use a RHIO as a model. The RHIO organization would be a network that would fit this." -- Mr. Nahra

"I just want to register a concern that if, in fact, I read this literally, my doctor in Darby, Montana is going to access this network from a very remote location, it's going to go through all sorts of entities to transmit that information that you don't want to be HIPAA compliant." -- Mr. Barrett

"Our recommendation is that in this environment, that distinction doesn't make sense, and that that doctor, accessing the network, this regional health information network or the NHIN, is no different than a doctor in any other place. The other doctors, if they happen to bill electronically, already would have to meet these standards. We want to make sure that there is not someone who doesn't have to meet those standards, simply because of the accident of how they bill for their patient treatment." -- Mr. Nahra

"What we can do is to see maybe what sort of clarification we can get in passing it forward. It's not the communication and telecommunications network. It is a network of individuals, and companies, and others working together to exchange information." -- Dr. Kolodner

"I would support both of these in the sense that we do view ourselves, even though we don't fall under the official guidelines of HIPAA, that's how we operate, as if we do. And in fact, every software company, and we have hundreds of software companies contracted into the network, are required to do business associate type of agreement to pass that through." -- Mr. Hutchinson

"The one concern that I do have…is a follow up item to understand the relevant HIPAA requirements, and the definition of 'relevant,' because as you know, not being a care provider, there are many aspects of HIPAA that would not pertain to an entity that's not actually providing care…I would support both of these recommendations and put our company underneath that requirement. But the definition of 'relevant' is very, very important." -- Mr. Hutchinson

"The idea of 'relevant' is…clearly a next step. Now, our assumption is that it's going to essentially meet all standards, unless there are particular ones that don't make sense. So it's going to be sort of an opt-out kind of thing. We're not going to be starting at ground zero and say, 'all right, you've got to do this one and this one.' It's going to be, 'you follow everything unless we decide there are a handful of things that you don't meet.'" -- Mr. Nahra

"If [consumers are] participating with someone currently not defined as a business partner within the HIPAA law and constraints, that consumer, indeed, may not enjoy enforceable privacy and security. I wonder if, in the earlier discussion, when we were talking about the fact that what this recommendation is trying to get to is really a network, that would be governed by these privacy and security criteria, as identified, if perhaps it would be better to omit the word 'excluding consumers,' and just cast the

language again, so that it more clearly defines your addressing participants within a network." -- Ms. Davenport-Ennis

"Our group had exactly the opposite concern, which was, if we took out 'excluding consumers,' there was a sense that an individual patient now is obligated to follow enforceable privacy and security standards, and that the individual patient could be prosecuted. We wanted to say, 'no, we're not talking about the level playing field and all of these rules being applied to individual patients'." -- Mr. Nahra

"What I will look forward to is the recommendation that may be coming from you after you have future hearings on the matter, that will identify, more specifically, what protections and safeguards will be for consumers." -- Ms. Davenport-Ennis

"Your concern was exactly what drove some of this recommendation. For example, we were very concerned about consumers who would, without going through a hospital or a health insurer, build a PHR, and that that PHR would be linked up to the networks. Absolutely. Today, that PHR vendor is not required to follow anything related to HIPAA. This recommendation would say, 'yes, that PHR vendor does, in fact, have to follow HIPAA.' It would give you exactly the kinds of protections that are not there today. That's a core purpose of this recommendation." -- Mr. Nahra

"What's the enforceable mechanism that's going to be used for these two recommendations?" -- Mr. Hutchinson

"We did not make a recommendation on what that should be. We clearly recognized there needs to be another step. HHS may have some options, but we can't just wave a wand and make this happen. The most straightforward way…would be a new law that's relevant to this situation. I don't know if that's viable, we haven't made a recommendation on that one way or the other." -- Mr. Nahra

Following these discussions, consensus was declared on the Community accepting these two recommendations, with the understanding that the language will be revised to clarify the intent and what should be excluded.

Developing a Privacy and Security Framework

Dr. Kolodner reminded the Community that the responsibilities of the National Coordinator, as specified in Executive Order #13335, include addressing privacy and security issues related to interoperable HIT and recommending methods to ensure appropriate authorization, authentication, and encryption of data for transmission over the Internet. Almost 25 years ago, the Fair Information Practices of 1973 were developed by HHS' predecessor; these foundational principles have served not only as a framework for the development of privacy and security laws (most notably the Privacy Act of 1974 and HIPAA), but also as a springboard for developing principles by a variety of organizations that tailor their fair information practices concepts to specific audiences or applications, some of which are health related, some of which are not.

Dr. Kolodner explained that HIPAA serves as a legal floor for privacy and security in the health care sector. The privacy and security principles that AHIC hopefully will agree on, with input from the public and private sectors and from the public at large, will serve as a guide to the development of business practices and requirements for the HIT agenda that will instill the public trust necessary for its adoption. Dr. Kolodner emphasized that the privacy, security, and confidentiality of the ongoing system is fundamental for achieving success in adoption. The objective in developing a privacy and security

framework is to build consensus around a set of privacy and security principles to guide the use and disclosure of individual health information in the public and private sectors.

Dr. Kolodner listed the following recognized privacy and security instruments: (1) the Organisation for Economic Co-operation and Development's Guidelines on the Protection of Privacy and Transborder Flows of Personal Data, (2) the Federal Trade Commission's Fair Information Practice Principles, (3) the Markle Foundation's Model Privacy Policies for Health Information Exchange, (4) the Coalition of Consumer Organizations' Health information Technology -- Consumer Principles, and (5) the International Security Trust and Privacy Alliance's Common Terminology in Privacy Requirements. The ONC reviewed this broad set of privacy and security instruments and found multiple examples of similarities in the names of principles across the instruments. ONC then looked within each of the principles across all of the instruments and began identifying various themes that emerged (e.g., accountability/oversight, collection limitation, data integrity/quality, etc.).

Dr. Kolodner described the principle harmonization methodology used by ONC staff in analyzing this information. Staff conducted cross-instrument mapping at the specific wording level (while accommodating variations in wording). They considered each set of wording, using the source documents for context, which led to specific concepts. Staff then determined whether to include or exclude the wording/concept in a specific principle. There were few exclusions; the primary reason for exclusion was that the wording/concept appeared in another principle and did not warrant duplication. ONC staff currently are building a harmonized set of principles using the harmonized set of wording/concepts and the source documents for context. ONC will work with public and private stakeholders to build consensus around a harmonized set of principles that will be posted for comment and vetted through the AHIC Workgroups as well as experts in the private sector.

AHIC Recommendations-Implementation Status Report

Dr. Kolodner presented an update on the status of AHIC Workgroup recommendations made to date, noting that Ms. Gelinas' presentation included an update on the Electronic Health Records Workgroup's recommendations. He briefly overviewed the recommendations put forth by the Chronic Care and Population Health and Clinical Care Connections Workgroups. In terms of process, ONC is taking each recommendation and discussing it with the appropriate Workgroup Co-Chairs to ensure that the wording is correct and that the assessment of progress is accurate before taking it to the Workgroup overall. Mr. Barrett commented that a revised scoring index may be more helpful than simply indicating progress using terms such as "some progress," "progress on target," etc. He suggested using a zero, one-half, one type of scoring system. Ms. Gelinas noted that a color scheme where red indicates "zero," yellow indicates "progress, and green indicates "done" also might be helpful. Dr. Kolodner clarified that under the current system, the color blue is used to denote recommendations that are done, while green indicates recommendations for which progress is moving along.

Public Input Session

Speaker Number 1 -- Carol Bickford of the American Nurses Association asked about the implications of the Chronic Care Workgroup's recommendation that focused on expanding services provided and diagnostic activities. She explained that this has major implications for those participating in interstate licensure discussions that the state governors are attending to for across-state practice types of activities. Ms. Bickford also asked about privacy and confidentiality—are standards bodies participating in this initiative? There has been work done by ASTM, in relation to some of the principles and

implementations for security, privacy, and confidentially. Are those entities part of that conversation? Dr. Kolodner indicated that these comments would be passed on to the Workgroups for discussion.

Speaker Number 2 -- Jay Sanders, a member of the Chronic Care Workgroup, applauded ACIC for its receptiveness to the recommendations presented by Mr. Barrett. He also suggested that, with respect to the issue of further demonstration projects, that there have been thousands of projects already reported in the peer-reviewed literature that might be looked at to help develop policy rather than going through another cycle of demonstration projects. Dr. Sanders also discussed the issue of quality, noting that taking a patient's blood pleasure at home is a much better determination of what their true blood pressure is than taking it in a physician's office. Similarly, conducting pulmonary function tests in a child with asthma at home is a much better reflection of what their true pulmonary function tests are than in the totally different environment of a physician's office.

Closing Remarks

Dr. Kolodner thanked Community members and speakers for their efforts and participation, and adjourned the 14th AHIC meeting.

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

American Health Information Community

Long Term Succession Update

Robert M. Kolodner, MD
National Coordinator for Health Information Technology

July 31, 2007

AHIC Successor Update

The AHIC successor will address the need for

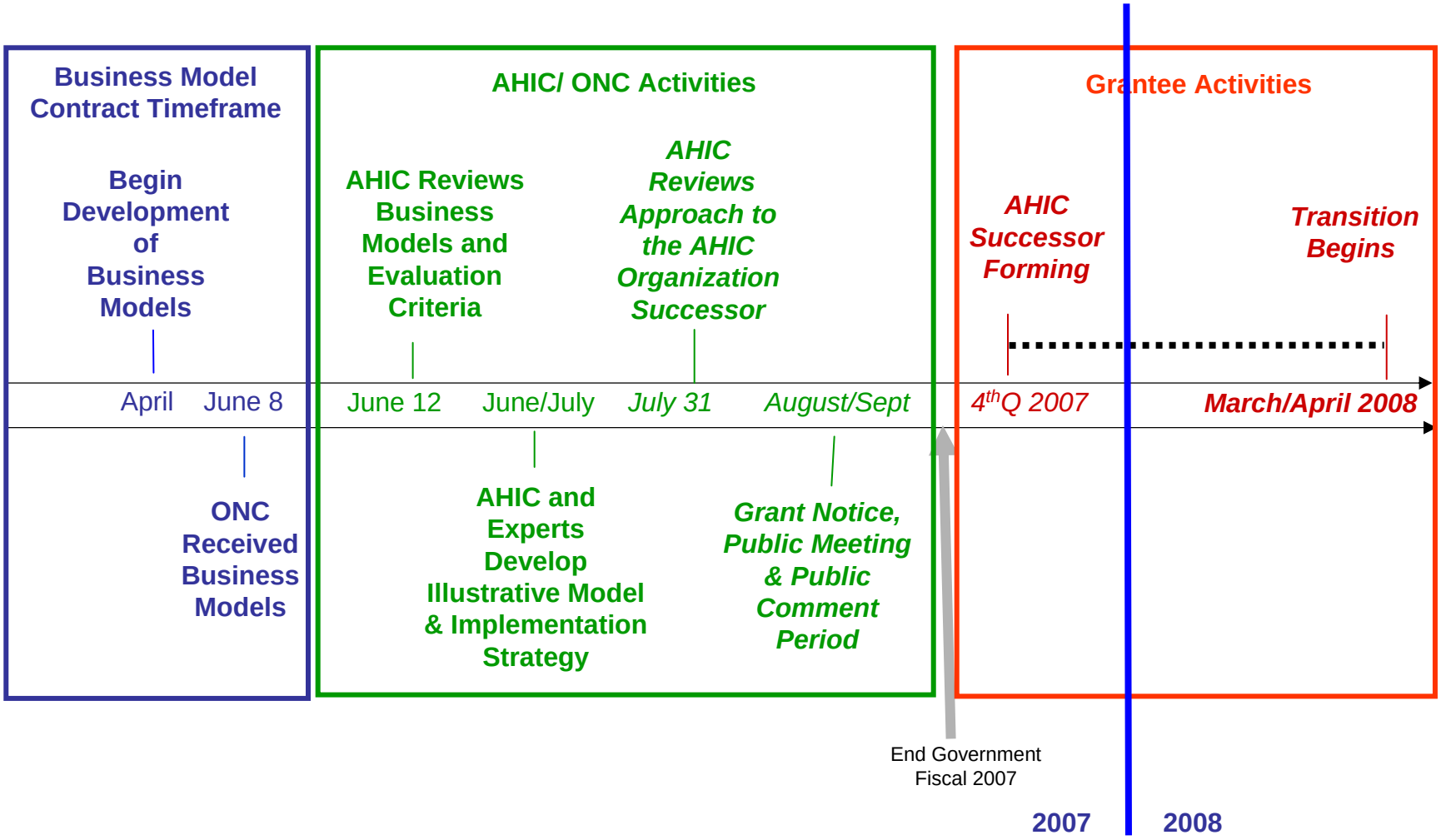
- Interoperability in a secure, trusted environment
- An inclusive, participatory entity that is efficient and results oriented

- Progress to date:
  - Requested Business and Governance Model Proposals
  - Presented proposed models to AHIC at June 12th meeting
  - Synthesized concepts and developed illustrative prototype
  - Vetted concepts with individual industry leaders
  - Developed strategy for realizing successor organization

Principles for Successful Governance

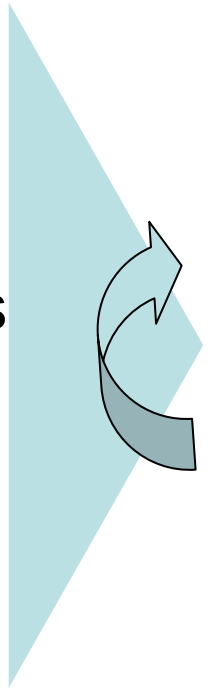
- The entity should exist for the purpose of individual/consumer benefit.
- The entity should establish and enhance trust among stakeholders.
- The entity should have broad participation across the health care industry stakeholders.
- The governing bodies of the entity should have necessary authority to make decisions, but only the authority that is necessary to do this.
- The entity should be feasible to establish and operate, and sustainable into the future.
- The entity should be adaptable over time and across future circumstances.

Work Process for Developing the AHIC Successor



Vetting Process

- Key attributes to be vetted today include the following:
  1. Vision at a glance
  2. Membership
  3. Governance Body
  4. Rights and Obligations
  5. Protections and Incorporations
  6. Management and Staffing



Vetting Process

- Present one attribute
- Illustrate it using the prototype model
- Solicit your feedback

1. Successor Vision

- The successor is an independent and sustainable public-private membership organization.
- It brings together public and private entities and resources into a trusted, decisive, effective organization.
- Its goal is the creation and use of an interoperable nationwide health information system to serve the health and well-being of all individuals in the United States.

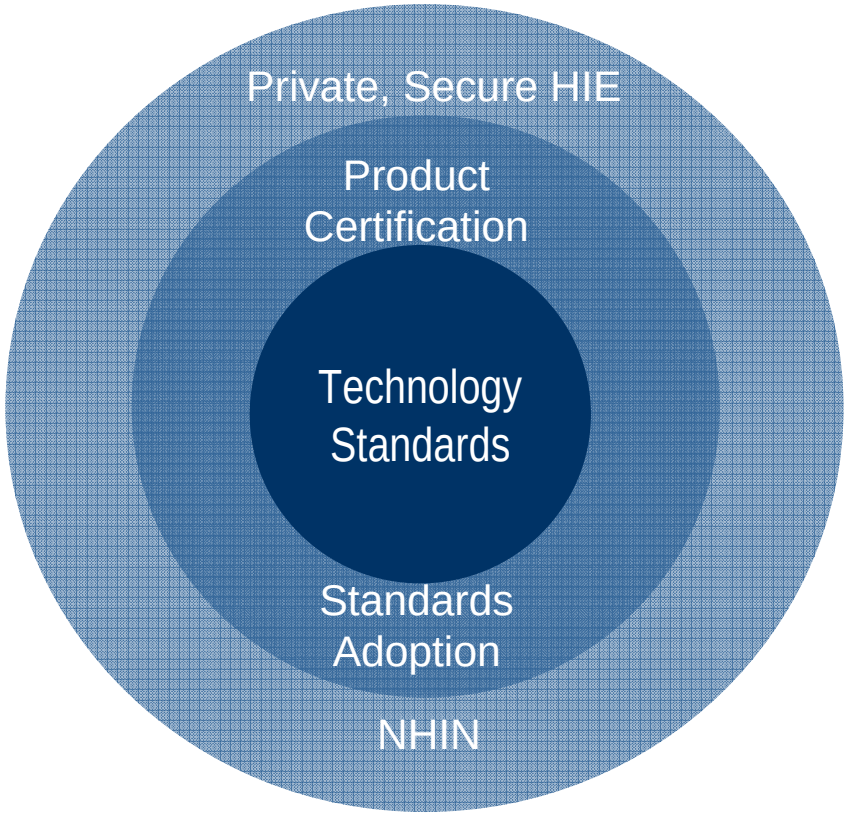
1. Successor Vision - Functions

- Accelerate and coordinate current AHIC interoperability initiatives including standards harmonization and certification of health IT
- Prioritize stakeholder requirements for nationwide health IT interoperability
- Advance the harmonization of technology standards and policies, including those to protect confidentiality, privacy, and security
- Oversee and facilitate the Nationwide Health Information Network (NHIN – a network-of-networks), including necessary governance and/or accreditation of participant organizations
- Advance the certification of products, network participants, and/or operations

1. Successor Vision - Interoperability Initiatives

- Initiatives that identify and remove obstacles to exchange of health information nationwide
- Obstacles can be
  - **technology based**, such as a lack of harmonized technology data exchange standards
  - **business based**, such as a lack of shared business rules and agreements that enable confidential and secure health information exchange

Spectrum of Interoperability Initiatives



2. Membership

- The successor should be **open** to membership (direct or participating) by all organizations and individuals in all sectors of the health community
- The health community would likely be **organized into sectors** such that all relevant and affected parties are included
- The successor should define differing **classes of membership** with differing rights and obligations

2. Membership Sectors - illustrated

Sector Name	Sector Descriptions
Ancillary Health Services	Those engaged in developing analysis, data or other tools relevant to health care, and those engaged in the retail dispensing of drugs and/or devices which legally require prescriptions (labs, pharmacies).
Clinicians	Physicians or medical groups, nurses, or other providers licensed or certified by an appropriate authority.
Consumers	Individuals who agree to seek medical or other health care from participating members.
Employers/ Purchasers	Organizations that purchase/arrange for medical or other health care or assistance.
Government	Representatives of Federal, State, City, Community, and Tribal governments.
Health Information Exchange	A multi-stakeholder entity that enables the movement of health-related data within state, regional, or non-jurisdictional participant groups.
Institutional Providers	Hospitals, long term care facilities, home health agencies, clinics, and other facilities licensed or certified by an appropriate authority.
Payers / Health Plans	Organizations providing/administering resources to sustain or improve health and well-being through payment of the costs of health care.
Pharmaceuticals & Devices	Organizations engaged in the research, manufacture or wholesale distribution of drugs and/or devices which legally require prescriptions.

THIS DIAGRAM ILLUSTRATES A CONCEPT AND IS NOT INTENDED TO BE DEFINITIVE

2. Membership Classes - illustrated

- Main Street Physicians is a **Direct Member** in the **Clinician Sector**
- Elm Street University is a **Direct Member** in the **Institutional Provider Sector**
- Main Street Physicians is a part of Elm Street University and so they are also a **Participating Member** of the **Institutional Provider Sector**

Illustrative Membership Classes

	Direct	Participating
Voting	Yes	No
Fees	Yes	No
Obligations / Rights	Always	Limited to formal relationship with Direct Member

- A **Direct Member** may be affiliated with multiple Participating Members
- **Participating Members** agree to participate and abide by AHIC successor standards through the Direct Member
- **Only the Direct Member** will have voting rights in the AHIC successor

THIS DIAGRAM ILLUSTRATES A CONCEPT AND IS NOT INTENDED TO BE DEFINITIVE

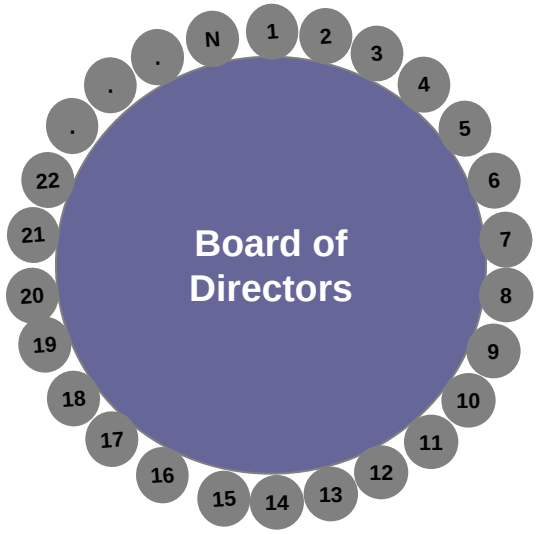
3. Governance Body

- The successor board should be selected by elective or appointive **methods that equitably represent all members** in all sectors.
- The structure of the successor should ensure that the views of all sectors will be adequately conveyed to any governing body and that its deliberations and **decisions are neither dominated nor controlled** by any interest or sector.
- **Eligibility** to be elected or appointed to the board should be **clearly defined**.

3. Governance Body - illustrated

Membership Sectors

Ancillary Health Services	Health Information Exchanges
Consumers	Institutional Providers
Clinicians	Payers/Health Plans
Employers/ Purchasers	Pharmaceuticals/ Devices
Government/Public Health	



Members sectors elect x number of Board Members for their sector

Sector Name	No. Seats
Ancillary Health Services	x
Clinicians	x
Consumers	x
Employers/ Purchasers	x
Government/Public Health	x
Health Information Exchange	x
Institutional Providers	x
Payer/ Health Plans	x
Pharmaceuticals & Devices	x
At Large	x
AHIC Successor CEO	1

THIS DIAGRAM ILLUSTRATES A CONCEPT AND IS NOT INTENDED TO BE DEFINITIVE

4. Rights and Obligation

- AHIC successor bylaws should have clear delineation of **voting rights**, if any, of members and clear delineation between voting rights of members and the board.
- **Fiduciary duty** of board members should be specified, whether to the constituency (sector) from which they were appointed or elected, or once appointed and elected, to the best interests of the whole.
- **Authority** of the AHIC successor board and rights and obligations of members should be clearly delineated.
- **Decision making process** should specify use of quorums, and decisions requiring double majorities or super majorities of the board for adoption

5. Protections and Incorporation

- The AHIC successor should operate under a certificate of incorporation, detailed bylaws, and initial operating regulations and membership agreement(s) that reflect the most appropriate type of legal entity for the successor organization.
- Protection of the AHIC successor structure should be built into the certificate of incorporation and bylaws to prevent changes that would radically alter the structure and operations of the board or the protection of members who were relying on it as a condition of their membership.

6. Management Structure

- Chief Executive Officer
- CFO, Counsel, Secretariat, Operations Officer
- Senior Membership Officer including membership and recruitment, publicity, advertising, marketing, public relations
- Senior Technology Officer for standards harmonization, certification, NHIN services, and technology related services
- Senior Data Uses Officer for data stewardship, privacy policy, accreditation, and uses of data for purposes such as public health, quality, research, and all other related activities

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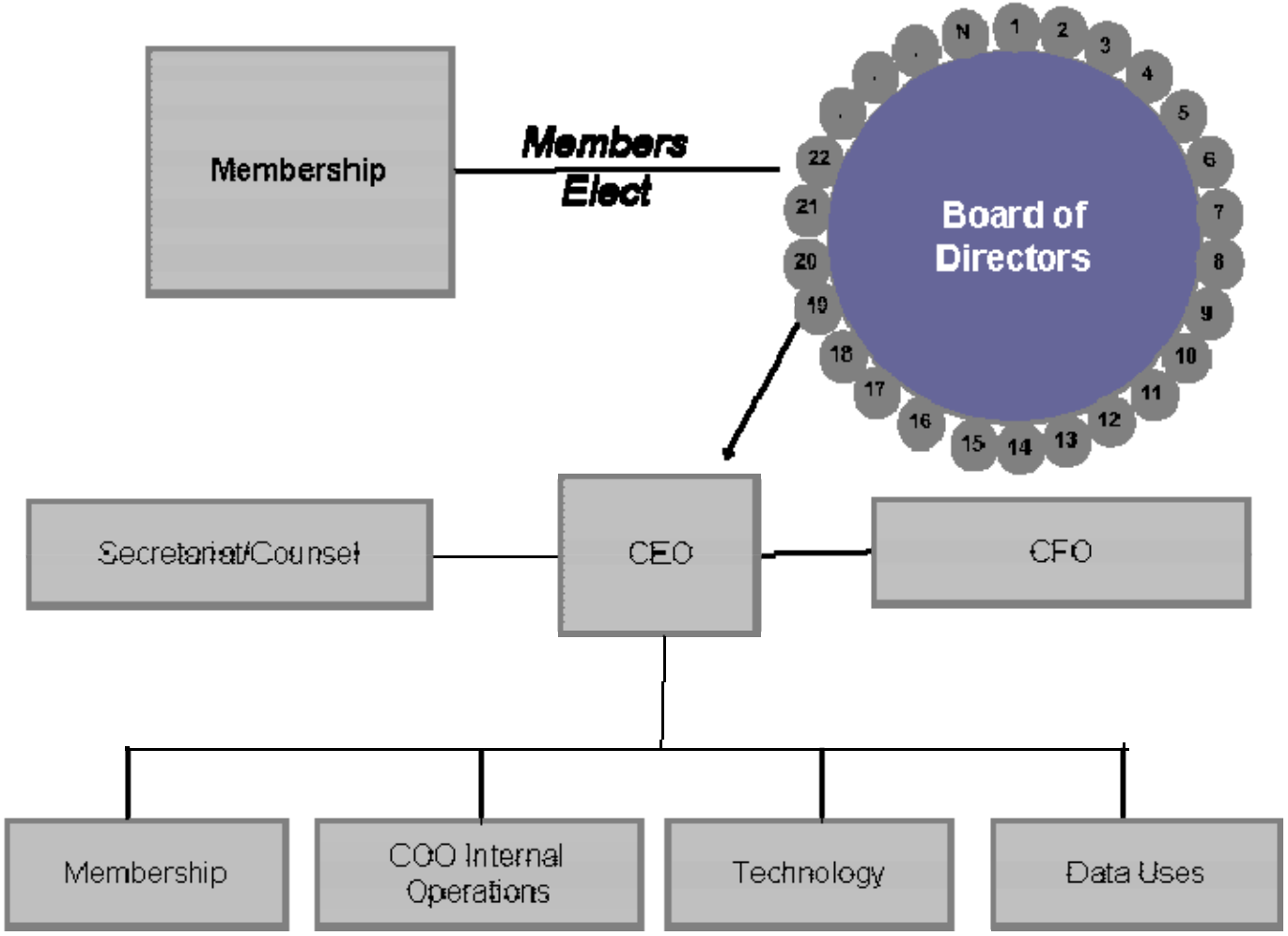
6. Management Structure - illustrated



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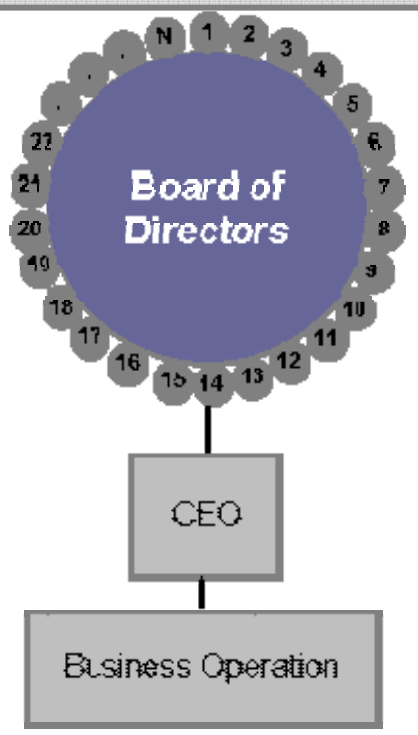
AHIC Successor Attributes

1. Vision
2. Membership
3. Governance Body
4. Rights and Obligations
5. Protections and Incorporations
6. Management and Staffing

Membership Sectors

Ancillary Health Services	Health Information Exchanges
Consumers	Institutional Providers
Clinicians	Payers/Health Plans
Employers/ Purchasers	Pharmaceuticals/ Devices
Government/Public Health	



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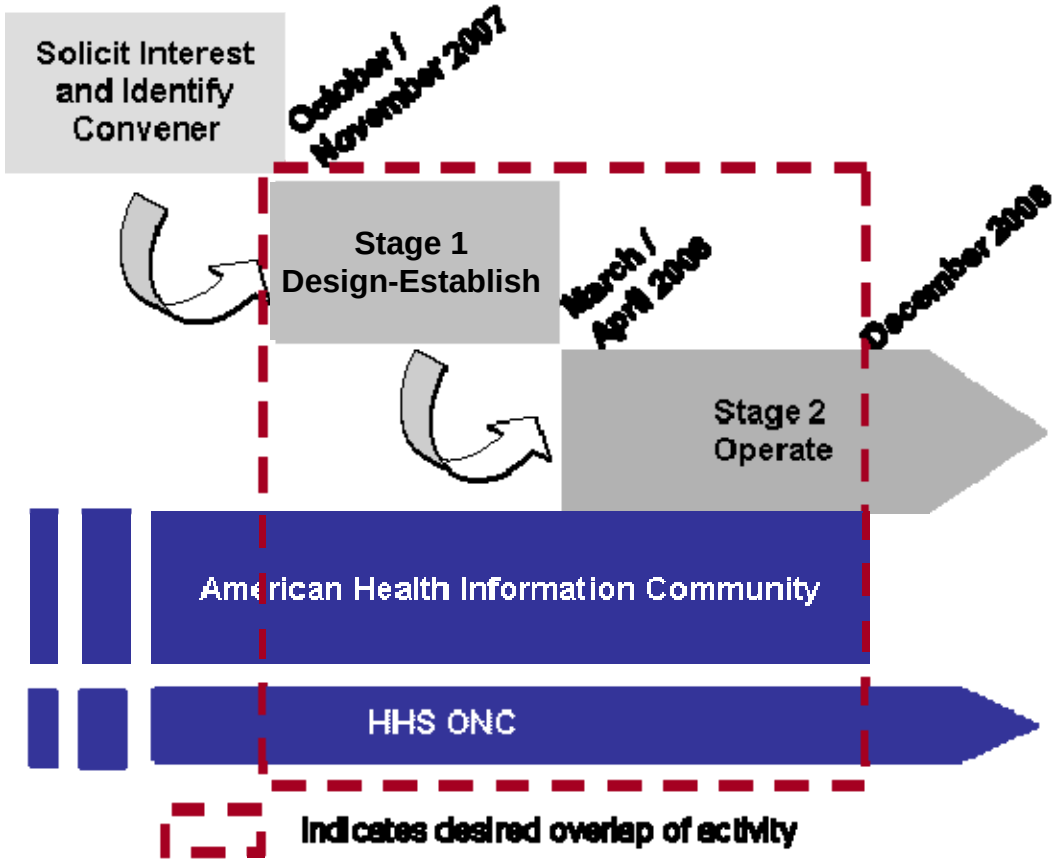
Strategy and Milestones

- Solicit interest and award a grant to a convener entity
  - Collaborate with the convener entity to design and build the successor organization
- Award a grant to the new legal entity
  - Collaborate in the initial operation of the new legal entity
  - Government organizations as Direct members with Board representation



Next Steps

- Early August publish a white paper that describes the successor organization attributes and request public comment
- August publication of a notice of funding availability requesting interested conveners to respond
- In Mid-August, Secretary Leavitt will lead a public meeting to raise awareness of the implementation strategy encourage collaboration
- Review responses and negotiate a cooperative agreement that defines a specific role for Government
- Award the grant by November 2007

Early Success Factors

- Continued strong Federal government participation
  - Secretary HHS will “recognize” harmonized standards and agencies must adopt them
- Nationally recognized leader seen as an honest broker by a wide constituency of the health community
  - Will attract other outstanding leadership and staff
  - Will engender trust needed to build a membership base
- Clearly articulated list of accomplishments for the first year or two
- Adequate public and private resources needed to meet the short and mid-term goals
- Broad participation and commitment from public and private sector leaders

DRAFT White Paper

American Health Information Community Successor

July 2007

Introduction

This white paper describes the vision for and attributes of a successor to the American Health Information Community (AHIC). Specifically, it describes the purpose and scope of a successor entity, presents governance and operating objectives, and highlights several legal considerations associated with the formation of the AHIC successor.[FN2]

American Health Information Community

The American Health Information Community (AHIC) is a federal advisory body chartered in 2005 to make recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) on how to accelerate the development and adoption of health information technology. The advisory nature of AHIC and its Workgroups has been invaluable in creating a forum to seek input and guidance to understand key issues and policy implications necessary to achieve President Bush's goal for most Americans to have access to secure electronic health records by 2014.

The AHIC charter requires responsibilities to be transferred to a successor. Therefore, the AHIC is embarking upon a project that will take the Community to the next level. The AHIC successor will be an independent and sustainable public-private partnership bringing together the best attributes and resources of public and private entities. This new public-private partnership will develop a unified approach to realize an effective, interoperable nationwide health information system[FN1] that supports the health and well-being of individuals and communities in the U.S.

The AHIC seeks public comment on the contents of this white paper. Specific instructions for providing comments are available on the AHIC successor web page: http://www.hhs.gov/healthit/community/background/AHICsuccessor.html.

Recognizing that interoperability is critical to realizing both improvements in quality and efficiency in the U.S. health system, and understanding the importance of continuity of leadership to maintaining the AHIC's momentum toward achieving interoperability, the Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) will engage with the private sector to seamlessly transition the locus of activity from a Federal advisory committee to an independent public-private partnership that is focused on achieving interoperability across the health care system.

Between now and the Spring of 2008, AHIC members and AHIC Workgroups will continue efforts to identify obstacles to the adoption of interoperable health information technology (IT) and make specific recommendations to the Secretary of (HHS). At the same time, HHS has embarked upon an effort that will take AHIC to the next level by facilitating the development of an independent public-private partnership that is results-oriented, inclusive, and coordinated with quality and transparency initiatives. The new entity will build on the AHIC achievements and will require exceptional leadership as well as a broad base of both public and private support to realize the vision of an interoperable health care system.
The AHIC successor will bring together both public and private, not-for-profit and for-profit entities that represent all sectors of the health community. It is essential that the Federal government play a substantial role in order to accelerate the emergence of an interoperable nationwide health information system. Designing and establishing an AHIC successor is neither an effort to privatize the role of AHIC, nor is it Federal Government preemption. Instead, it is an effort to establish a balanced, effective, public-private collaboration among organizations and individuals in all sectors of the health community.

Vision and Attributes

At their meeting in June 2007, the AHIC approved a set of principles to guide the work of defining and implementing the AHIC successor. Between April and June of 2007, ONC requested and received input[FN3] from three organizations on potential business models and an organizational design for an AHIC successor. Between June and July of 2007, ONC reviewed the input and, working with an industry subject matter expert, consolidated the recommendations from the three proposals. This process led to the development of the vision and key attributes of the AHIC successor that are presented in this white paper.

Design Guiding Principles

- The entity should exist for the purpose of individual/consumer benefit.
- The entity should establish and enhance trust among stakeholders.
- The entity should have broad participation across the health care industry stakeholders.
- The governing bodies of the entity should have necessary authority to make decisions, but only the authority that is necessary to do this.
- The entity should be feasible to establish and operate, and sustainable into the future.
- The entity should be adaptable over time and across future circumstances.

The AHIC successor will be designed, established, and ready for operation by Spring 2008. The process and schedule for designing and establishing the new entity is described in later sections of this white paper.

A. Purpose and Scope

The AHIC successor will be an independent and sustainable public-private partnership bringing together the best of the public and private sectors into a trusted, decisive, effective organization for the creation and use of an interoperable nationwide health information system to improve and maintain the health and well-being of all individuals and communities in the United States.

The proposed scope of responsibility for the AHIC successor includes, but is not limited to, the following:

- Accelerate and coordinate current AHIC interoperability initiatives including standards harmonization and certification of health IT[FN4]
- Prioritize stakeholder requirements for nationwide health IT interoperability
- Advance the harmonization of technology standards and policies, including those to protect confidentiality, privacy, and security
- Oversee and facilitate the Nationwide Health Information Network (NHIN – a network-of-networks), including necessary governance and/or accreditation of participant organizations
- Advance the certification of products, network participants, and/or operations

The key attributes, objectives, and/or considerations related to governance, business and operations, transition, and legal issues of the envisioned AHIC successor are presented in the following sections.

B. Governance Objectives

The following statements of objectives pertain to processes that determine how authority will be exercised, how members of the organization will be classified and represented, and how decisions will be made on issues of nationwide concern.

Membership

The AHIC successor should be open to membership by all individuals and organizations in all sectors of the health community. The health community should be organized into membership sectors that may be defined in any way the AHIC successor chooses but must be inclusive of all relevant and affected parties in the health community.

The concepts described in this white paper were refined using an illustrative prototype business model. Figure 1 presents the membership sectors that were identified as part of the AHIC successor prototype. These sectors were designed to support the creation of a governance body that includes all relevant stakeholders, and to inform decisions made by a governance body, such that no single sector controls or dominates the governance.

Figure 1. Illustration of Membership Sectors and Definitions

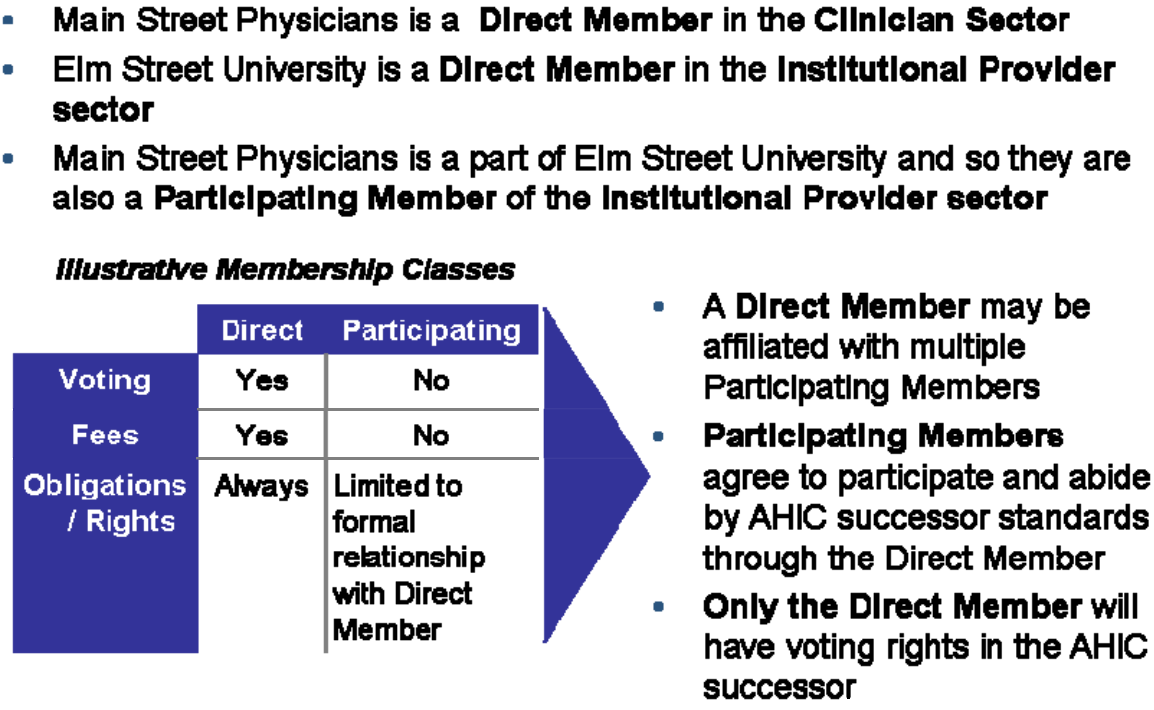
Sector Name	Sector Descriptions
Ancillary Health Services	Those engaged in developing analysis, data or other tools relevant to health care, and those engaged in the retail dispensing of drugs and/or devices which legally require prescription (labs, pharmacies)
Clinicians	Physicians or medical groups, nurses, or other providers licensed or certified by an appropriate authority
Consumers	Individuals who agree to seek medical or other health care from participating members.
Employers/ Purchasers	Organizations that purchase/arrange for medical or other health care or assistance.
Government	Representatives of Federal, State, City, Community, and Tribal government
Health Information Exchange	A multi-stakeholder entity that enables the movement of health-related data within state, regional, or non-jurisdictional participant groups.
Institutional Providers	Hospitals, long term care facilities, home health agencies, clinics, and other facilities licensed or certified by an appropriate authority.
Payers / Health Plans	Organizations providing/administering resources to sustain or improve health and well being through payment of the costs of health care.
Pharmaceuticals & Devices	Organizations engaged in the research, manufacture or wholesale distribution of drugs and/or devices which legally require prescriptions.

The AHIC successor should have differing classes of membership with differing rights and obligations to provide for both *loosely*-bound and *tightly*-bound members.

Classes of membership are used in conjunction with membership sectors to provide as many pathways as possible for stakeholder participation. There will be situations when an organization will be a Direct Member of the AHIC successor, and situations where the same organization will be a Participating Member. For example, as illustrated in Figure 2, the Elm

Street University System is a Direct Member representing the Institutional Provider Sector. The doctors, labs, pharmacies, and patients that comprise that system would be "loosely" bound to the AHIC successor through the Direct Members commitments. These Participating Members would not have separate voting rights or membership fees, and their obligations would be limited to the obligations of the member hospital system. Yet a Direct Member, such as the hospital system in this example, is not likely to always represent the exact interests of all of the affiliated participating members. Therefore, each of the Participating Members has multiple ways to directly connect to the successor organization. For example, the Main Street Physicians could also be a Direct Member through affiliation with the Clinician Sector. This complexity of membership mitigates the risk of any single sector dominating decisions that have nationwide impact. An illustration of member classes and their rights and obligations is presented in Figure 2.

Figure 2. Illustration of Membership Classes



Governing Body

The governing body (i.e., Board of Directors) should be selected by elective or appointive methods that result in a balanced representation of members in all sectors.

The structure of the AHIC successor should ensure that the views of all sectors will be adequately conveyed to any governing body and that its deliberations and decisions are neither dominated nor controlled by any single interest or sector.

Eligibility to be elected or appointed to the board should be clearly defined.

Figure 3 illustrates one method used to constitute a board that could represent all member sectors in a balanced manner. In this illustration, members self-select a membership sector

and each sector's members play a role in filling a specific number of "seats" assigned to their sector.

Figure 3. Illustration of Membership Sectors and Board Composition

Members sectors elect x number of Board Members for their sector

Sector Name	No. Seats
Ancillary Health Services	x
Clinicians	x
Consumers	x
Employers/ Purchasers	x
Government/Public Health	x
Health Information Exchange	x
Institutional Providers	x
Payer/ Health Plans	x
Pharmaceuticals & Devices	x
At Large	x
AHIC Successor CEO	1

Decision-Making Process

AHIC successor bylaws should have clear delineation of voting rights, if any, of members and clear delineation between voting rights of members and the board.

Fiduciary duty of board members should be specified, whether to the constituency (sector) from which they were appointed or elected, or once appointed and elected, to the best interests of the whole of the AHIC successor.

Authority of the AHIC successor board as well as the rights and obligations of members should be clearly delineated. Specifically, the following should be delineated:

a. Authority of the board, if any, to set service fees or pricing of services to set service fees binding on members including limitations and methods to prevent abuse of such authority;

b. Authority of the board, if any, to adopt operating procedures and standards binding on members;

c. Authority of the board, if any, to adopt sanctions, fines, and/or penalties for violation of operating procedures;

d. Whether or not different classes of members should have different rights and obligations and, if so, whether they should be common within each class.

In order to ensure proper restraints on authority and protection of member rights and proper obligations of Members, the decision-making process of the AHIC successor should specify the use of quorums of board members, board voting procedures, and types of issues and decisions that require double majorities or super majorities of the board for adoption.

C. Business and Operating Objectives

The following statements of objectives pertain to protections, incorporation, financial considerations, and legal aspects of an operating business entity.

Protections and Incorporation

1. The AHIC successor should operate under a certificate of incorporation, detailed bylaws, and initial operating regulations and membership agreement(s) that reflect the most appropriate type of legal entity for the successor (e.g., for-profit, not-for-profit, stock, membership, partnership, government instrumentality).

2. Protection of the AHIC successor structure should be built into the certificate of incorporation and bylaws to prevent changes that would radically alter the structure and operations of the board or the protection of members who were relying on the structure as a condition of their membership.

3. The AHIC successor should identify and address all relevant attributes of business operations, including but not limited to, corporate law, best jurisdictions for incorporation or other legal formation, securities law, antitrust law, trademark and intellectual properties law, Federal and state law regarding membership by government entities and other legal issues affecting legal and successful operation.

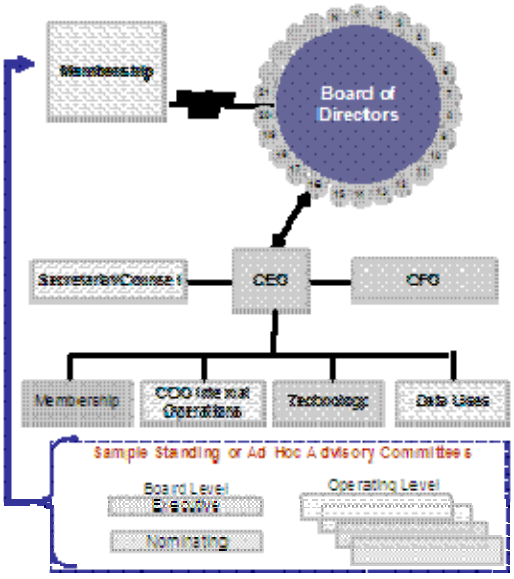
4. The AHIC successor structure should allow for and encourage self-organization of members into health information exchange entities (HIEs) or other types of sub-organization at any time, at any scale, for any reason consistent with AHIC successor policy and procedures without loss of the member rights and obligations of their constituent parts.

Management and Staffing

5. The AHIC successor operating structure could include, but not be limited to, (a) Chief Executive Officer; (b) Treasurer, CFO or equivalent for accounting, budgeting, financial control, capital formation to support automation at the clinical and institutional level, and all other similar or related activities; (c) Secretary and Counsel for legal advice and coordination of outside counsel, Board and Board committee minutes, evolution of bylaws and other corporate documents, voting lists and procedures, elections, and all similar or related activities; (d) Senior Membership Officer for membership and recruitment, publicity, advertising, marketing, public relations, and all other related activities; (e) Chief Operating Officer for personnel, internal operating matters, security, fraud, system operating procedures and all other related activities; (f) Senior Technology Officer for standards harmonization, certification, network services, and all other related activities; (g) Senior Data Uses Officer for data stewardship, privacy policy, accreditation, and uses of data for purposes such as public health, research, quality, and all other related activities.
6. The AHIC successor should establish standing or ad hoc advisory committees to bring the best possible expertise of members to bear on substantive matters in all areas of activity. The AHIC successor should identify methods whereby Management, under the direction of the board, can define the committees by establishing the charter, appointing committee members, determining the functions, and coordinating the activities of new committees.

Figure 4 depicts the operating structure described in the preceding paragraphs.

Figure 4. Illustration of AHIC Successor Management and Staffing Structure



7. The AHIC successor structure and operations should be, at a minimum, as innovative, decisive, and operationally efficient and effective as any private or public sector organization.
8. The structure and operations should be reliable and durable in purpose and principles of organization, yet malleable in form and function in order to evolve as rapidly as the technology it must use and the conditions in which it must operate.
9. The AHIC successor, to ensure its successful implementation, balanced governing structure and sustained operating success, should recruit a substantial portion of organizations in each sector of the health community, secure their membership agreement and accept them as members in 2nd quarter 2008.
10. The AHIC successor should provide methods by which all organizations and individuals eligible to become members could be accommodated, if and when and if they voluntarily choose to become members, as well as multiple paths and choices for participating.
11. The AHIC successor should document a simple, non-punitive method by which members can choose to leave the system should they decide the benefits do not substantially exceed the obligations of membership.

Revenue, Costs, Budgets and Capital

12. The AHIC successor should, no later than 1st quarter 2008, identify and obtain secure commitments for the necessary funding for operation throughout 2008 and 2009.
13. The AHIC successor should, by the middle of 2009, have developed methods and means to become financially and operationally sound and secure for the years 2010 through 2014.

D. AHIC to AHIC Successor Transition Objectives

The transition objectives will ensure an orderly hand-off from AHIC to the AHIC successor, and that the highly successful work of standards harmonization and adoption will be sustained. AHIC Workgroup activities will be ongoing until their charges are met in the months between now and 4th quarter 2008, and a future path has been charted. AHIC recommendations resulting from workgroup efforts are expected to continue and will be addressed by Secretary Leavitt.

The following statements of the AHIC successor objectives pertain to an initial operating period defined by the transition of leadership and priority-setting from the Federal Advisory Committee effort (i.e., AHIC) to the new, independent public-private partnership.

General Transition

1. The AHIC successor should obtain a majority of eligible charter members from each sector who have applied for and met the criteria for membership, or at least a sufficient number to demonstrate that the AHIC successor will become a balanced, multi-stakeholder entity that includes all relevant and affected parties.
2. The AHIC successor should document the anticipated accomplishments in each of its first three years of operation to clearly establish its credibility and enhance its ability to attract members, secure resources and increase the rate of accomplishment in subsequent years through 2014.

Continue and Accelerate Current AHIC Interoperability Initiatives (Initial Operations Stage)

3. The AHIC successor should analyze current AHIC initiatives and functions to determine the best method and means to assume responsibility for interoperability initiatives between March 31, 2008 and October 31, 2008, the initial AHIC successor operations stage.
4. The AHIC successor should be structured, staffed, and operated so that assumption of revenue streams and/or direction of present AHIC activities will not only be effectively transferred and continued, but also improved and accelerated.

Identify and Address Obstacles

5. Upon successful transition of AHIC responsibilities related to the advancement of the harmonization and adoption of standards and acceleration of efforts to achieve interoperability, the AHIC successor should identify existing obstacles to the emergence of an effective interoperable nationwide health information system, including but not limited to:

- Limited technical capacity for harmonization and specification of standards
- Disincentives
- Legislative or regulatory impediments
- Conflicting state and Federal laws or regulations
- Availability of capital needed by members for implementation and adoption of electronic health information systems
- Absence of critical infrastructure needed to connect members.

6. The AHIC successor should prioritize identified obstacles in order of importance, and identify means and methods to overcome each.
7. The AHIC successor should identify the time and resources required to remove each obstacle, and demonstrate how the AHIC successor would be effective in obtaining resources and removing obstacles.
8. The AHIC successor should document which obstacles the AHIC successor could remove in each of its first three years of operation that would clearly establish its credibility and increase the rate of accomplishments in subsequent years through 2014.

Identify and Realize Opportunities

9. Based upon a sound policy framework to ensure confidentiality, privacy, and security, the AHIC successor should identify opportunities to create and use interoperable health information for informing direct clinical care and for purposes in addition to informing direct clinical care. These uses of health information may include but are not limited to: clinical care, biosurveillance, mobilization of clinical and related response to emergencies, post-market surveillance of medical products, clinical research including clinical trials for medical products, tracking of fraud and abuse in health care, remote delivery of clinical care, population and health services research, measurement and reporting of provider performance, and personal health management.
10. The AHIC successor should prioritize opportunities in order of importance, and identify means and methods to realize each.
11. The AHIC successor should identify the time and resources required to realize each opportunity and demonstrate how the AHIC successor could be effective in obtaining resources and realizing the opportunities.

E. Legal Considerations

In order to successfully implement the vision described in this paper, the AHIC successor will need to consider organizational issues which have legal implications in three primary areas: the successor organization's status and structure, anti-trust, and government participation.

Organizational Issues

In the planning and design phase, options relating to formation, tax status, governance structure, and relationships with participating organizations and individuals will need to be considered in establishing a successor organization.

1. Formation
   The entity's form and tax status will be determined as the organization is being designed in accordance with the well worn adage that "form follows function." There could be reason to consider forming the AHIC successor as a non-profit (non-stock) membership corporation. Some of the factors related to this consideration are:
   - the principal purpose of the public-private partnership;
   - governance rules are more established for a corporate entity than they are for an unincorporated association or partnership;

- membership (non-stock) corporations are a recognized form that afford an opportunity for participation to a broad array of participants, yet flexible enough to enable the structuring of a governing body, once elected, that is empowered to make timely decisions;
- the members are not likely to invest funds in the AHIC successor for purposes of a direct financial return (so that non-profit status should not adversely affect access to capital); and
- some of the early funding may need to come from foundations and others who will be required to make initial funding available to a non-profit.

2. Membership
   The membership would consist of those organizations, entities and persons who want a voice in the running of the AHIC successor and a vote in its affairs (including the election of its governing board), who would become members of an applicable stakeholder sector and agree to pay dues and make initial capital contributions (members). All members in all categories would be expected to sign Participation Agreements that bind them to using the AHIC successor's standards, policies, and procedures when transacting business with the AHIC successor or another member of the AHIC successor. In order to induce broad and robust membership in the AHIC successor, any member would have the right to withdraw from the AHIC successor at any time in its discretion, on designated written notice, without adverse economic consequences to that member.

3. Board
   The AHIC successor would be governed by a board consisting of high-level representatives of the multiple stakeholder interests, preferably senior executives with experience in running organizations, developing innovative new models, and participating in board-level activities. Directors would be expected to serve in both representative and fiduciary roles – with responsibilities to consult with their sector constituencies and, at the same time, expected to make determinations in the course of Board deliberations in what they determine to be in the best interests of the AHIC successor, and the broad public and stakeholder interests to be served.

4. The Timetable
   Not later than the Spring of 2008, the AHIC successor, with its governing documents, will need to be formed/documented after vetting with a broad array of stakeholder sectors and interest groups, together with an in-place budget, a sustainable business plan, and actual realizable funding commitments that assure the financial and operational viability.

Antitrust Issues

Many of the AHIC successor's members will be competitors or potential competitors. This means that competitors will be collaborating in numerous ways. Such collaborations raise the possibility of violations of the antitrust laws by the AHIC successor and/or some of its members. However, given the pro-competitive benefits of an interoperable nationwide health information system and assuming that the AHIC successor is structured carefully and correctly, the federal antitrust laws should not be a problem for the AHIC successor.

Antitrust law would likely treat the AHIC successor as a joint venture. Integrated joint ventures which promise pro-competitive benefits such as the AHIC successor are evaluated under the rule of reason. Rule of reason analysis focuses on the state of competition with, as compared to without, the relevant agreement. The central question is whether the joint venture is more likely to benefit or harm competition. In an efficiency-enhancing joint venture, participants collaborate to perform one or more business functions, such as research and development or production, and thereby benefit consumers by reducing price or enhancing quality, service, or innovation. Typically such a joint venture combines technology or other complementary assets to achieve pro-competitive benefits that the participants could not achieve separately. Such is the situation here. The AHIC successor is intended to create a unified platform to accomplish a task – creation of an interoperable nationwide health information system – that no single entity could coordinate on its own.

Government Participation

The Federal Government does not intend to establish the AHIC successor, nor does it anticipate that the functions of the AHIC successor include any that are inherently governmental. The Federal government though does intend to participate in the anticipated activities of the AHIC successor, such as those pertaining to voluntary consensus standards, consistent with its statutory authority. In fact, the National Technology Transfer and Advancement Act of 1995 (NTTAA) is relevant to the proposed purpose and actions of the AHIC successor by providing that all Federal agencies and departments shall use, unless inconsistent with applicable law or impractical, data and technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments. The Office of Management and Budget (through OMB Circular A-119, as amended) has defined voluntary consensus standards bodies as domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. Further, they have the following attributes:

1. Openness
2. Balance of interest
3. Due process
4. An appeals process, and
5. A Consensus process

To increase the likelihood that the standards named or recognized will meet both public and private sector needs, both the NTTAA and the Circular encourage the participation of federal representatives in these bodies, to the extent it is compatible with the agency's mission and authorities and in the public interest. In the planning stages of the AHIC successor and as governing documents are developed, these attributes can be considered in consultation with the Federal Government to ensure the compliance with the OMB definition of a voluntary consensus standards organization.

There are a number of existing public-private partnerships that involve the participation of the Federal Government as a member of a non-governmental organization and the service of government employees as board members. In some cases, government employees

play a formal role in governance as representatives of government agencies; in other cases, they serve as board members on a more informal basis. Examples of such organizations include the National Quality Forum, the American National Standards Institute, and the North American Energy Standards Board. Please refer to Appendix A for more information.

Federal employees participating in the AHIC successor would remain subject to the applicable ethics laws, including those pertaining to conflict of interests and appearance of partiality, as they would be taking such actions in their official capacity as Federal employees. Federal employees who participate with the AHIC successor as board members may have certain fiduciary obligations to the successor organization. This may give rise to certain conflict of interest issues with respect to their actions as Federal officials. These employees should consult with their agency ethics officials prior to participating in such actions.

Value Proposition

Historically, there has been a competitive and growing market for health IT. There is a market emerging, to a lesser degree, for regional and specialty HIEs. The dynamics and forces at work in these markets are producing health information network elements but are not yet converging into an interoperable nationwide network-of-networks on their own. These regional and specialty markets need a catalyst to leverage existing economic market influences. The President's call for most Americans to have access to electronic health records (EHRs) by 2014 and the formation of the AHIC and the Office of the National Coordinator for Health IT have acted as this catalyst. As a result, through June 2007, several major milestones have been achieved. Specifically, the HHS Secretary is poised to recognize 30 interoperability standards and detailed implementation guidance that have been harmonized through the work of the Health Information Technology Standards Panel (HITSP), and he has recognized the Certification Commission for Healthcare Information Technology (CCHIT). Subsequently, CCHIT has certified over 80 ambulatory EHR products, which can now be donated to health care providers as specified in final regulations that create a Stark exception and an anti-kickback safe harbor. This progress clearly demonstrates the value of a focused set of nationwide priorities and provides the incentive to take the AHIC process to the next level and refine priorities and accelerate actions. Moreover, the successor entity will have the full support of the Secretary of HHS and the necessary participation of government executives and experts.

In addition, future progress will be supported through the broad reach of Federal procurement. As specified in *Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs* on August 22, 2006, recognized interoperability standards will be required for use by each agency that implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities. Similarly, each agency will require compliance with interoperability standards in contracts or agreements with health care providers, health plans, or health insurance issuers such that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards.

Through the AHIC successor, all organizations in the health community will have an unprecedented opportunity to continue the role of community leader and change agent that was initiated by the Secretary of HHS. Through the AHIC successor, organizations from across the health care community will have a direct opportunity to set priorities for the nation as part of balanced public-private collaboration. With the expanded role of the private sector and its best practices, the AHIC successor can accelerate decisions on health IT. With the continued strong participation of the public sector, the AHIC successor will have a high likelihood of successfully securing government actions to adopt these same standards. The AHIC successor can ensure alignment of certification criteria with nationwide priorities to achieve interoperability, and accelerate adoption of best practices and policies to ensure privacy and security.

To be successful, the AHIC successor must overcome a significant barrier: how to demonstrate the value that could accrue from interoperability and the sharing of information across EHRs, HIEs, and the NHIN. Most stakeholders have preconceived notions about the value of health IT, and many views are based on anecdotal evidence. Studies exist on the return on investment of health IT, but most are narrow in scope and focused on the providers of care. Demonstrating that value can be created and captured more broadly across stakeholder groups is critical to widespread adoption and use. Based on anecdotal evidence and expert opinion, the nature and level of benefits that can be achieved with a fully interoperable nationwide health information system will vary across health care sectors, as illustrated in the following figure.

Figure 5. Value Proposition Across the Health Care Community Sectors

Stakeholders	Value Proposition
Ancillary Health Services	• Advanced interoperability between EHRs, NHIN, and specialty networks specific to ancillary services (e.g., labs, radiology and pharmacy) • Decreased operating costs due to automated interactions directly with providers
Clinicians	• Interoperable health IT (Clinical Decision Tools) that allow them to deliver the highest quality health care to their patients • Unprecedented opportunity to participate in priority setting, ensuring that priorities are informed by clinically relevant expertise and advance the level and quality of patient care • Mitigation of risks to clinicians associated with liability, privacy, and security stemming through advancement of the appropriate exchange of data
Consumers	• Recipient of markedly improved quality, safety, efficiency, and convenience of health care; dramatically increased continuity of care across their care providers • Increased ability to manage their health and well-being • Defined and influential role in advancing interoperability of health IT • Increased role in the development of privacy and security policies and practices • Robust, comprehensive, and interoperable Personal Health Record
Employers and Other Purchasers	• More efficient, higher quality, lower cost care for their employees resulting in significant reductions in the rate of increase in health care premiums • Increased participation in setting unified nationwide health IT priorities • Improved ability to manage constituents' health and associated costs through incentives for preventative treatment of chronic conditions • Healthier employees and their families will result in less sick days and use of family leave for health related issues, thereby improving employee productivity

Stakeholders	Value Proposition
Government Agencies	• More efficient, higher quality, lower cost care for their employees and beneficiaries resulting in significant reductions in the rate of increase in health care costs paid for with public funds • Vastly improved Public Health information systems, with highly effective surveillance and emergency response capabilities resulting in healthier populations and communities • Reduced entitlement costs due to fraud detection (CMS)
Health Information Exchanges	• Increased voice in nationwide decision-making • Increased ability to share aggregated data for quality measurement and reporting, which is an element of sustainable business models for HIEs • Development of a competitive marketplace for HIE technology and services
Institutional Providers	• Health IT solutions that allow them to deliver the highest quality health care to their patients • Improve ability to measure and manage provider performance through certified EHRs and HIE • Accelerated development of interoperable network services to share data across care settings to improve continuity and quality of care
Payers/ Health Plans	• More efficient, higher quality, lower cost care for their beneficiaries • Improved ability to measure and manage provider performance • Ability to facilitate disease management and provide other value-added services
Pharmaceuticals/ Devices	• Reduced cost for research due to rapid access to standardized, interoperable data in clinical trials • Potential to automate enrollment of patients in clinical trials from EHRs and/or PHRs • Potential to expedite development of targeted therapies • Enhanced post-marketing surveillance and risk management of marketed products

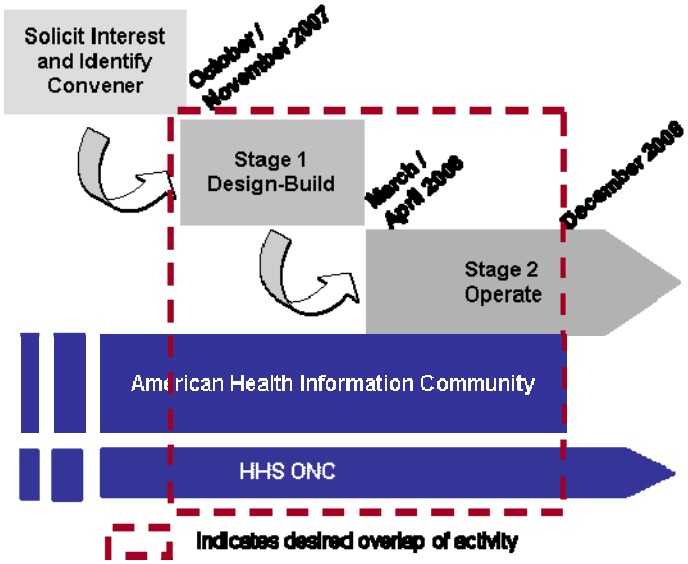
From a cross-sector perspective, the AHIC successor will provide a forum outside of Government, but with the active participation and input of Government, that allows members to build on progress made and expand the priorities to align with market demand and at the same time to improve the health and well-being of individuals and communities. As an independent public-private partnership, the AHIC successor can move swiftly to make decisions (not just recommendations) and with public sector input, the decisions that are acted upon can have a significant market impact. Consequently, the AHIC successor can act as a guarantor of the efficiency and integrity of an interoperable nationwide health information system, mitigating risk to adopters of health IT.

The AHIC successor must recognize that there are different perspectives on the value of health IT and acknowledge the constructive tensions that exist among different sectors. Although an interoperable nationwide health information system should bring substantial benefits to all sectors, no member of the AHIC successor can expect that on every occasion, decisions that need to be made will be beneficial to every sector. The problems of the health care system simply cannot be addressed without some effort and temporary sacrifices for the common good. For example, if approximately 20% of lab tests are needlessly repeated due to lack of interoperable, transportable information, then loss of volume due to reducing redundancy will have a negative impact on the revenue of laboratories and providers. In addition, in the institutional provider and clinician sectors there is a questionable business return on the investment associated with adopting technology to enable interoperability in certain circumstances.

To be credible, the AHIC successor must fully appreciate and openly acknowledge that member rights cannot be ensured without obligations, and that the public good associated with interoperable health information cannot be obtained without effort and sacrifice.

AHIC Successor Implementation Strategy

Figure 6. AHIC Successor Implementation Strategy



For the purposes of facilitating the establishment of the AHIC successor and convening a planning board, HHS will award a Cooperative Agreement that allows for substantial involvement by the Federal Government. HHS will solicit interest through public comment on this white paper and through a public meeting on August 16, 2007. HHS will then select a grantee that includes or will convene representatives from the private and public sectors to design and establish the AHIC successor. HHS and other Federal Agencies and Departments will participate in the design process and fully leverage the prior and on-going work of HHS and AHIC. The public input received from this white paper will also inform this process. Once a new legal entity is established and after certain conditions are met, HHS will support that entity through additional funding that will enable initial operations and transition of specific AHIC responsibilities by Fall 2008.

1 The nationwide health information system refers to the National Health Information Network (NHIN), certified Electronic Health Records (EHRs) used across settings of care, personal health records, public health and other data intermediaries that enable health information exchange across the health care and public health entities.

2 **Disclamer:** This document is intended to provide general information to assist in discussions regarding an AHIC successor entity. The document may contain general legal information and should not be construed as legal advice to be applied to any factual situation. HHS makes no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the information contained in this white paper.

3 Materials prepared by Alchemy LLC, Avalere Health LLC, and Booz Allen Hamilton, Inc. are available at http://www.hhs.gov/healthit/community/background/AHICsuccessor.html.

4 The relationship between the AHIC successor, Health Information Technology Standards Panel (HITSP), and Certification Commission for Healthcare Information Technology (CCHIT) will be determined as the organization is designed.

APPENDIX A

The following organizations are relevant models for the Federal Government's participation as a member of the AHIC successor and the service of Government employees as AHIC successor board directors.

- National Quality Forum (NQF). NQF is a not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting. Established in response to a formal recommendation from the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry in 1998, it has broad participation from all parts of the health care system, including government. Its functions include endorsing voluntary consensus standards and it explicitly relies on the NTTAA in performing its functions relative to government. *See* McLean, *The Implications of Patient Safety Research & Risk Managed Care*, 26 S.Ill.U. L.J. 227, 241-2 (Winter 2002). Its Board includes the Administrator of the Centers for Medicare and Medicaid Services, the Director of the Agency for Healthcare Research and Quality, and the Under Secretary for Health in the Veterans Health Administration.

- American National Standards Institute (ANSI). ANSI oversees the creation, promulgation, and use of thousands of norms and guidelines across nearly all business sectors. Founded in 1918 by five engineering societies and three government agencies, it is a private, nonprofit membership organization "supported by a diverse constituency of private and public sector organizations." Its Board includes the Standards Executive for the Environmental Protection Agency.

- North American Energy Standards Board (NAESB). NAESB serves as an industry forum for the development and promotion of standards that will lead to a seamless marketplace for wholesale and retail natural gas and electricity. It was created as a result of an order of the Federal Energy Regulatory Commission (FERC) in 1992. There are no Federal Government employees on the Board at this time, although the Board does include state government representation.

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

American Health Information Community

Personalized Health Care Workgroup Recommendations

Douglas E. Henley
American Academy of Family Physicians

John Glaser
Partners HealthCare

July 31, 2007

Personalized Health Care (PHC) Workgroup Member List

Co-Chairs:

–John Glaser	Partners HealthCare
–Douglas Henley	American Academy of Family Physicians

Staff Co-Chair:

–Gregory Downing	Office of the Secretary, HHS

Members:

–Carolyn Clancy	Agency for Healthcare Research and Quality
–Beryl Crossley	American Clinical Laboratory Association, Quest
–Paul Cusenza	23andMe
–Andrea Ferreira-Gonzalez	Virginia Commonwealth University
–Becky Fisher	Patient Advocate
–Felix Frueh	Food and Drug Administration
–Emory Fry	Department of Defense
–Alan Guttmacher	National Institutes of Health/NHGRI
–Kathy Hudson	Genetics and Public Policy Center
–Betsy Humphreys	National Institutes of Health/NLM
–Charles Kennedy	WellPoint
–Joel Kupersmith	Department of Veterans Affairs
–Stephen Matteson	Pfizer
–Deven McGraw	National Partnership for Women and Families
–Amy McGuire	Baylor College of Medicine
–Mark Rothstein	University of Louisville
–Steve Teutsch	Merck
–Janet Warrington	Affymetrix
–Andrew Wiesenthal	Permanente Federation
–Marc Williams	Intermountain Healthcare

PHC Workgroup Senior Advisors

Senior Advisors:

–Mary Beth Bigley	Office of the U.S. Surgeon General
–Greg Feero	National Institutes of Health/NHGRI
–Joseph Kelly	Centers for Medicare & Medicaid Services
–Muin Khoury	Centers for Disease Control and Prevention
–Katherine Kolor	Centers for Disease Control and Prevention
–Michele Lloyd-Puryear	Health Resources and Services Administration
–Elizabeth Mansfield	Food and Drug Administration
–Clement McDonald	National Institutes of Health/NLM
–Armando Oliva	Food and Drug Administration
–Dina Paltoo	National Institutes of Health/NHLBI
–Jonathan Perlin	HCA, Inc.
–Gurvaneet Randhawa	Agency for Healthcare Research and Quality
–Lisa Rovin	Food and Drug Administration
–Maren Scheuner	RAND Corporation
–Jean Slutsky	Agency for Healthcare Research and Quality
–Reed Tuckson	UnitedHealth Group; SACGHS
–Mollie Ullman-Cullere	Harvard Partners Center for Genetics and Genomics
–Grant Wood	Intermountain Healthcare

PHC Workgroup Overview

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 to facilitate the incorporation of interoperable, clinically useful genetic/genomic information and analytical tools into electronic health records to support clinical decision-making for the clinician and consumer.

Specific Charge:

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

PHC Vision and Priorities

- Personalized Health Care is a consumer-centric system in which clinicians customize diagnostic, treatment, and management plans

- Four perspectives were identified as important to the vision
  - Consumer
  - Clinician
  - Researcher
  - Health Plan/Payer

- Four priority areas across each perspective
  - Genetic/Genomic Tests
  - Family Health History
  - Confidentiality, Privacy, and Security
  - Clinical Decision Support

Overarching

Recommendation 1.0:

The Community should advance the area of Personalized Health Care as a Priority for Use Case Development.

- **Accept**
- **Table**
- **Reject**

Overarching (continued)

Recommendation 1.1:

Priorities for use cases in the area of Personalized Health Care should be developed in conjunction with work performed by the genetic/genomic test workgroup and the family health history workgroup described in Recommendations 2 and 3. The use cases should additionally leverage the work in related activities including: the AHIC Electronic Health Record (EHR), Confidentiality, Privacy, and Security (CPS), and Consumer Empowerment (CE) Workgroups; the Harmonized Use Case for EHRs (Laboratory Results Reporting); the Consumer Access to Clinical Information Use Case; and others.

- **Accept**
- **Table**
- **Reject**

Genetic/Genomic Tests

Recommendation 2.0:

An extension to the Harmonized Use Case for EHRs (Laboratory Results Reporting) should be developed to address the specific information needs in the pre-analytic, analytic, and post-analytic phases of genetic/genomic tests. This extension to the use case should additionally address the need for integrated data flow across the pre-analytic, analytic, and post-analytic phases of genetic/genomic testing and address both the EHR and Laboratory Information Systems.

- **Accept**
- **Table**
- **Reject**

Genetic/Genomic Tests (continued)

Recommendation 2.1:

A multi-stakeholder workgroup, including the private sector, federal health care providers, and federal Public Health Service agencies, should be formed to identify what types of data and information are generated when performing genetic/genomic tests, and to identify standard metrics, terminology, language, and processes. This work should inform the extension to the Harmonized Use Case for EHRs (Laboratory Results Reporting) developed for genetic/genomic tests.

- **Accept**
- **Table**
- **Reject**

Genetic/Genomic Tests (continued)

Recommendation 2.2:

Research activities that increase the knowledge base regarding genetic/genomic test results need to be supported. The National Institutes of Health (NIH) should continue to work with public and private partners to support, develop, and enhance public reference databases that enable more effective and efficient genetic/genomic testing and incorporation of test results that can be aggregated in electronic health records.

- **Accept**
- **Table**
- **Reject**

Family Health History

Recommendation 3.0:

A multi-stakeholder workgroup, including the private sector, federal health care providers, and federal Public Health Service agencies, should be formed to develop a core minimum data set and common data definition available for primary care collection of family health history information.

- **Accept**
- **Table**
- **Reject**

Family Health History (continued)

Recommendation 3.1:

Additionally, studies should be performed as part of this collaboration as an evidence-base to determine the validity and utility of family health history risk assessment and management tools, clinical decision support tools, and how clinicians view this information as helpful for informing their medical decisions.

- **Accept**
- **Table**
- **Reject**

Family Health History (continued)

Recommendation 3.2:

Federal agencies in conjunction with private health care organizations with similar interests and expertise sponsoring pilots in the area of family health history should be used to evaluate the core minimum data set and evidence-base developed through Recommendations 3.0 and 3.1. Health care providers involved in these pilots should also examine the feasibility of consumer-clinician exchange of family health history information between PHR and EHR systems. When possible, the pilots should test and implement the standards and architecture identified in the HITSP developed use case.

- **Accept**
- **Table**
- **Reject**

Next Steps

- Ongoing and Future PHC Subgroup Activities
  - Confidentiality, Privacy, and Security (CPS):
    - Consider if aspects of genetic/genomic test results and family health history information may raise different concerns relative to other types of medical data
    - Discuss the Genetic Information Nondiscrimination Act (GINA)
  - Clinical Decision Support (CDS):
    - Survey commercial CDS tools
    - Examine evidence development
    - Survey user perspectives

July 31, 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 (AHIC) has given the following broad charge to the Personalized Health Care Workgroup:

> **Broad Charge for the Workgroup:** Make recommendations to the AHIC for a process to foster a broad, community-based approach to establish a common pathway based on common data standards to facilitate the incorporation of interoperable, clinically useful genetic/genomic information and analytical tools into electronic health records to support clinical decision-making for the clinician and consumer.

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

1. Genetic/Genomic Tests
2. Family Health History
3. Clinical Decision Support
4. Confidentiality, Privacy, and Security

This letter provides both context and recommendations for how the issues of genetic/genomic tests and family health history can be addressed in the next twelve months.

BACKGROUND

The Workgroup's vision of Personalized Health Care (PHC) is a consumer-centric system in which clinicians and consumers work together to customize diagnostic, treatment, and management plans based on a variety of factors, including the consumer's culture, personal behaviors, preferences, family health history, and the individual's unique genetic/genomic makeup. In this desirable future, consumers and clinicians both have ready access to information needed to identify and assess individualized treatment options as well as the resources and reimbursement mechanisms necessary to support implementation of a more extensive menu of tests and treatments.

Underpinning this vision is the confluence of two powerful forces, the development of Health Information Technology (HIT) and the rapid advances in the basic understanding of the relationships between health, disease, genetics/genomics, and prevention and treatment options. Knowledge of an individual's genetic/genomic makeup appears to have an exceptionally powerful ability to assist with disease prediction, diagnostic accuracy, targeted treatments, medication dosing, and health management.

The PHC Workgroup has held six meetings since its formation in October 2006. Testimony from a wide variety of experts in standards development, genetics/genomics, laboratory testing procedures and systems, privacy concerns, tools and standards for family health history, and commercial and government electronic health record (EHR) systems has informed the Workgroup's discussions. In March 2007, the Workgroup developed a vision of PHC from four perspectives: the consumer; the clinician; the researcher; and the health plan/payer. Following this visioning session, the Workgroup outlined its priorities in the areas of: genetic/genomic tests; family health history; clinical decision support; and confidentiality, privacy, and security. The vision summary and priorities documents were presented to the AHIC on April 24, 2007. Subgroups of the Workgroup were formed to address each of these four priority areas. Two of these subgroups, genetic/genomic tests and family health history, have developed recommendations that are being advanced to the AHIC by the PHC Workgroup.

If accepted by the AHIC, these recommendations should be considered for adoption by the Department of Health and Human Services (HHS) as HHS policy regarding current and future federal activities as they relate to the Workgroup's charge.

INITIAL RECOMMENDATIONS

I. Overarching

With the completed sequence of the human genome, genetic/genomic testing and its possibilities have moved from the sidelines into mainstream medicine. There are over 1,400 diseases for which genetic/genomic tests are used in current clinical practice, and several hundreds more are available in a research setting.[FN1] A genetic/genomic test can be performed on a wide variety of tissue samples and across the human lifespan, providing information on predispositions for a disease, presence of a disease, the risk of passing a disease onto offspring, and potential positive or adverse responses to therapeutic interventions.

In addition to the increasing adoption of genetic/genomic testing in medical practice, clinicians have always used a basic and important genetic/genomic tool in everyday practice: family health history. Combined with the power of genetic/genomic testing results, family health history adds value and provides useful predictive information. Broadly stated, genetic/genomic information has the potential to identify and predict the health outcomes of individuals and their families.

Consumers today are concerned that their health information may be used for unintended purposes or without their authorization. Compounding this concern are the limited understanding of new genetic/genomic tests for heritable disorders, the immutability of this information across the consumer's entire lifetime, the predictive abilities attributed to genetic/genomic information, and the potential for unintended informing of relatives because of a common genetic/genomic background. However, if consumers avoid genetic/genomic tests because of fear, they are potentially at risk by not having information available to them that could substantially and beneficially alter their health care. Therefore, maintaining the public's trust in the use of their personal health and genetic/genomic information, by developing technical and policy guidelines to ensure the security of their genetic/genomic data, is key to maximizing utility and health benefits. Consumer authorization of access to their genetic/genomic information should be taken into consideration as these use cases are developed. Therefore, the PHC Workgroup will work with the Confidentiality, Privacy, and Security (CPS) Workgroup to

consider if aspects of genetic/genomic test results and family health history information may raise special concerns about confidentiality, privacy, and security relative to other types of medical data.

The Workgroup identified the following actionable recommendations for the next twelve months that begin to address one aspect of the broad charge, incorporating clinically useful genetic/genomic information into the EHR.

> **Recommendation 1.0**: The Community should advance the area of Personalized Health Care as a Priority for Use Case Development.
>
> **Recommendation 1.1**: Priorities for use cases in the area of Personalized Health Care should be developed in conjunction with work performed by the genetic/genomic test workgroup and the family health history workgroup described in Recommendations 2 and 3. The use cases should additionally leverage the work in related activities including: the AHIC EHR, CPS, and Consumer Empowerment (CE) Workgroups; the Harmonized Use Case for Electronic Health Records (Laboratory Results Reporting); the Consumer Access to Clinical Information Use Case; and others.

II. Genetic/Genomic Tests

Inclusion of genetic/genomic test results in the EHR or personal health record (PHR) could enable the personalization of health care decisions through avoidance of adverse reactions, selection of optimal interventions, and beginning the transition of the health care sector from a reactive to a predictive enterprise. Standardized electronic recording of data associated with laboratory performance of genetic/genomic tests and, in parallel, inclusion of relevant results from genetic/genomic tests in the EHR have been identified as immediate priorities for recommendation by the PHC Workgroup.

Genetic/genomic testing in humans generally falls into two categories: molecular and biochemical. A molecular genetic/genomic or cytogenetic test may be defined as an analysis performed on human DNA, RNA, and chromosomes to detect heritable or acquired disease-related genotypes, mutations, or karyotypes for clinical purposes. A biochemical genetic/genomic test may be defined as the analysis of human proteins and certain metabolites, which are predominantly used to detect inborn errors of metabolism, heritable genotypes, or mutations for clinical purposes. Tests that are used primarily for other purposes, but may contribute to diagnosing a genetic/genomic disease (e.g., blood smear, certain serum chemistries), would not be covered by this definition.[FN2]

The process of performing a genetic/genomic test can be segmented into three distinct phases with each having different information collection requirements. The three phases include: (1) the pre-analytic phase, which encompasses such events as determining which genetic/genomic test, if any, is appropriate to answer the clinical question being asked, collecting clinical information that is necessary to interpret the test, and collecting an appropriate sample and transporting it to the test site; (2) the analytic phase, which involves steps taken to perform the analysis and analyze the results; and (3) the post-analytic phase, which includes reporting and interpretation of the results.[FN2]

As the area of genetic/genomic tests is relatively new to the medical community, and there are a growing number of different types of tests that are captured by the broad definition of a genetic/genomic test, standards development in some areas of this diverse category may be immature. Therefore, an iterative process should be pursued where use case development is performed in parallel with standards identification/creation. Gaps in available standard reference materials, protocols, metrics, IT standards (terminology, coding, messaging, instrument integration, and implementation guides) will therefore be highlighted early in the process and brought to the attention of the appropriate standards development organizations. Standards that address communication between EHRs and Laboratory Information Systems (LIS) are crucial to ensure comprehensive bidirectional transfer of information between the EHR and LIS in the pre- and post-analytic phases.

The many different information requirements for incorporation of genetic/genomic test information in the EHR is an issue of immediate concern to the PHC Workgroup. Longer term goals of this Workgroup include supporting the development of accompanying information about benefits, risks, analytical validity, clinical validity, and clinical utility to ensure the development of robust clinical decision support concerning genetic/genomic test results. Additionally, incentives to develop new genetic/genomic tests that provide new or added value to clinical care and the corresponding reimbursement strategies to ensure their widespread use need to be addressed. These longer term goals would be facilitated by the development of means and standard materials and processes for capturing laboratory data and test results identified as the immediate concerns for Healthcare Information Technology Standards Panel (HITSP) use case development. Future recommendations by the PHC Workgroup may address these longer term issues.

> **Recommendation 2.0**: An extension to the Harmonized Use Case for EHRs (Laboratory Results Reporting) should be developed to address the specific information needs in the pre-analytic, analytic, and post-analytic phases of genetic/genomic tests. This extension to the use case should additionally address the need for integrated data flow across the pre-analytic, analytic, and post-analytic phases of genetic/genomic testing and address both the EHR and Laboratory Information Systems.
>
> **Recommendation 2.1**: A multi-stakeholder workgroup, including the private sector, federal health care providers, and federal Public Health Service agencies, should be formed to identify what types of data and information are generated when performing genetic/genomic tests, and to identify standard metrics, terminology, language, and processes. This work should inform the extension to the Harmonized Use Case for EHRs (Laboratory Results Reporting) developed for genetic/genomic tests.
>
> **Recommendation 2.2:** Research activities that increase the knowledge base regarding genetic/genomic test results need to be supported. The National Institutes of Health (NIH) should continue to work with public and private partners to support, develop, and enhance public reference databases that enable more effective and efficient genetic/genomic testing and incorporation of test results that can be aggregated in electronic health records.[FN3]

III. Family Health History

Health care professionals and the general public have widely accepted the importance of family health history for predicting increased risk for a number of common diseases, including cancer, heart disease, and diabetes. As our scientific understanding of the molecular and genetic/genomic basis for health and disease improves, the importance of family health history as a valuable predictive tool has only increased. This has been highlighted throughout HHS by the Surgeon General's online web portal for collecting family health history information, the 'My Family Health Portrait', developed in conjunction with the NIH and the Centers for Disease Control and Prevention. The Family Health History priority area for the PHC Workgroup includes activities of immediate concern related to use case development by HITSP. The use case should represent the continuum of information collection, from consumer entry of family health history in the PHR to clinician entry of family health history in the EHR, with the longer term goal of interoperability between the PHR and EHR. Health care providers involved in any pilots of this use case should examine the merits of developing a modular family history tool, where collection of family health history is performed within the EHR, followed by messaging of this information to a variety of richer family history tools that perform risk analyses. In these tools, family history data can continue to be extended with new family history information as well as analyzed using the latest risk assessment algorithms. The enhanced family history and results of these algorithmic calculations could then be returned to the EHR, allowing for the ongoing curation of novel risk assessment algorithms and use of these tools in concert with well established family health history collection tools.

Additionally, the longer term goals of the Family Health History priority include: infrastructure and incentives to use PHRs to improve consumer-clinician communication; and characterization of the validity and utility of use of family health history in making clinical decisions. An overarching theme across the Family Health History priority area is how the clinician can use the family health history information, and this should be considered in short and long term activities. These longer term goals are contingent on the development of means and standards to capture the family health history information identified as the immediate concerns for HITSP use case development. Future recommendations by the PHC Workgroup may address these longer term issues.

> **Recommendation 3.0**: A multi-stakeholder workgroup, including the private sector, federal health care providers, and federal Public Health Service agencies, should be formed to develop a core minimum data set and common data definition available for primary care collection of family health history information.
>
> **Recommendation 3.1:** Additionally, studies should be performed as part of this collaboration as an evidence-base to determine the validity and utility of family health history risk assessment and management tools, clinical decision support tools, and how clinicians view this information as helpful for informing their medical decisions.
>
> **Recommendation 3.2**: Federal agencies in conjunction with private health care organizations with similar interests and expertise sponsoring pilots in the area of family health history should be used to evaluate the core minimum data set and evidence-base developed through Recommendations 3.0 and 3.1. Health care providers involved in these pilots should also examine the feasibility of consumer-clinician exchange of family health history information between PHR and EHR systems. When possible, the pilots

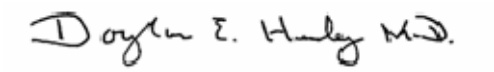
should test and implement the standards and architecture identified in the HITSP developed use case.

These recommendations are supported by information obtained through research and testimony to the Personalized Health Care 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,

John Glaser
Co-chair, PHC Workgroup



Douglas E. Henley
Co-chair, PHC Workgroup

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1 www.genetests.org

2 CDC definition, Federal Register, Vol 65, No 87, 5/4/2000, 25928.

3 Specifically, NIH, and the National Library of Medicine (NLM) in particular, should continue to: (1) enhance its collection of mutation data; (2) expand a National Center for Biotechnology Information (NCBI) clinical reference sequence database (RefSeqGene); (3) expand coverage of genetic/genomic tests in Logical Observations Identifiers Names Codes (LOINC) in collaboration with other HHS agencies, state public health laboratories, and the American Society of Human Genetics; and (4) provide more integrated access to genetic/genomic information for the public through NCBI portal developments, the Genetics Home Reference, Online Mendelian Inheritance in Man (OMIM), and MedlinePlus in cooperation with other HHS agencies, the Genetic Alliance, the American College of Medical Genetics, and other professional and disease advocacy groups.

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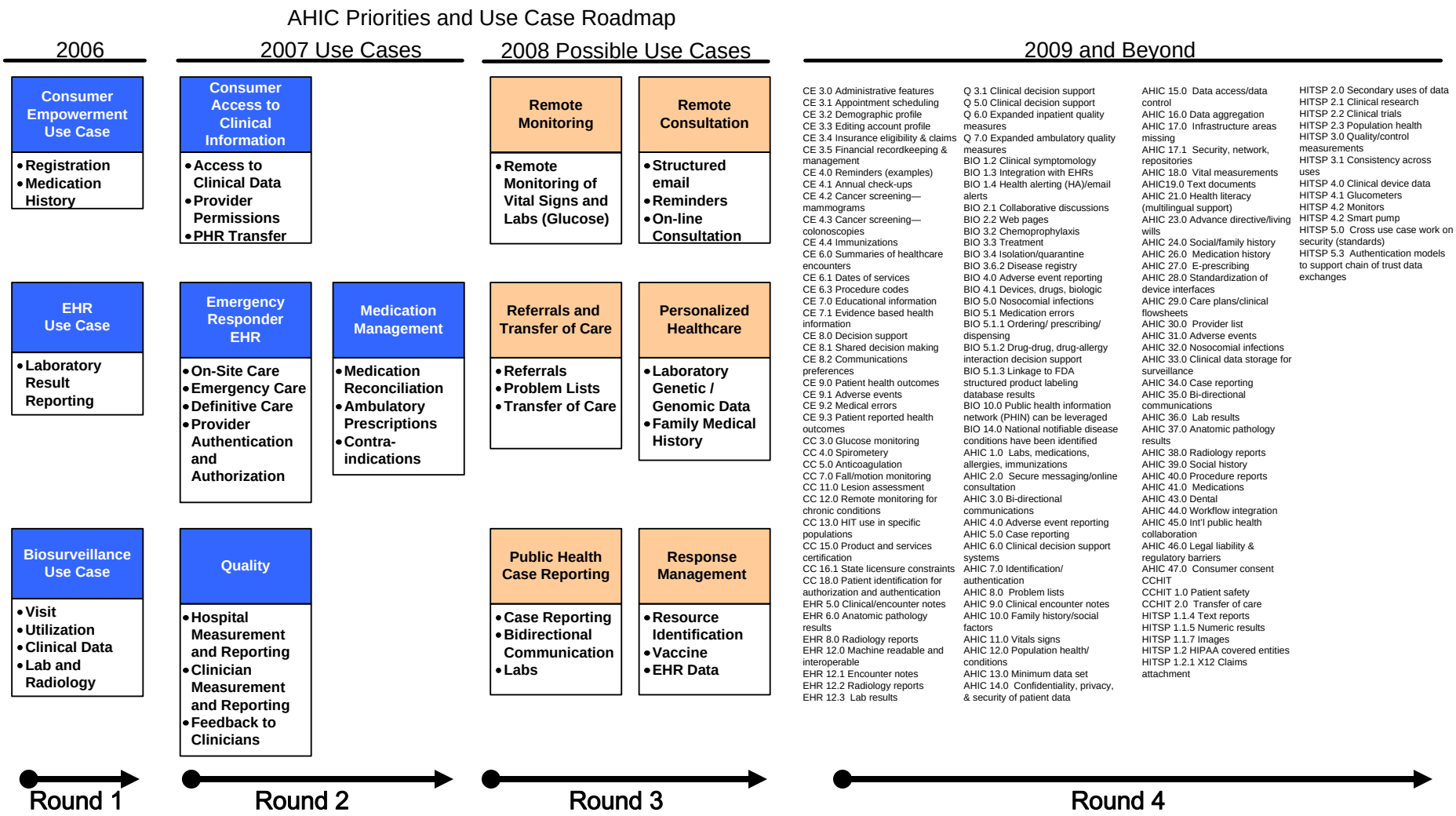
Priorities / Use Case Development Update

John Loonsk
Office of the National Coordinator

Ken Gebhart
BearingPoint

July 31, 2007

AHIC Priorities and Use Case Roadmap



Need for "Roadmap Standards"

- CCHIT, the NHIN, and possibly others need to understand HITSP "directions" in certain standards areas, even if those directions are not yet specified with enough detail to achieve interoperability
- ONC is working with CCHIT and HITSP leadership to advance a process where priorities for "roadmap standards" can be worked in parallel to the AHIC priorities
- Anticipate that these "roadmap standards" would represent a minor portion of the HITSP work

AHIC Concurrent Use Case Activities

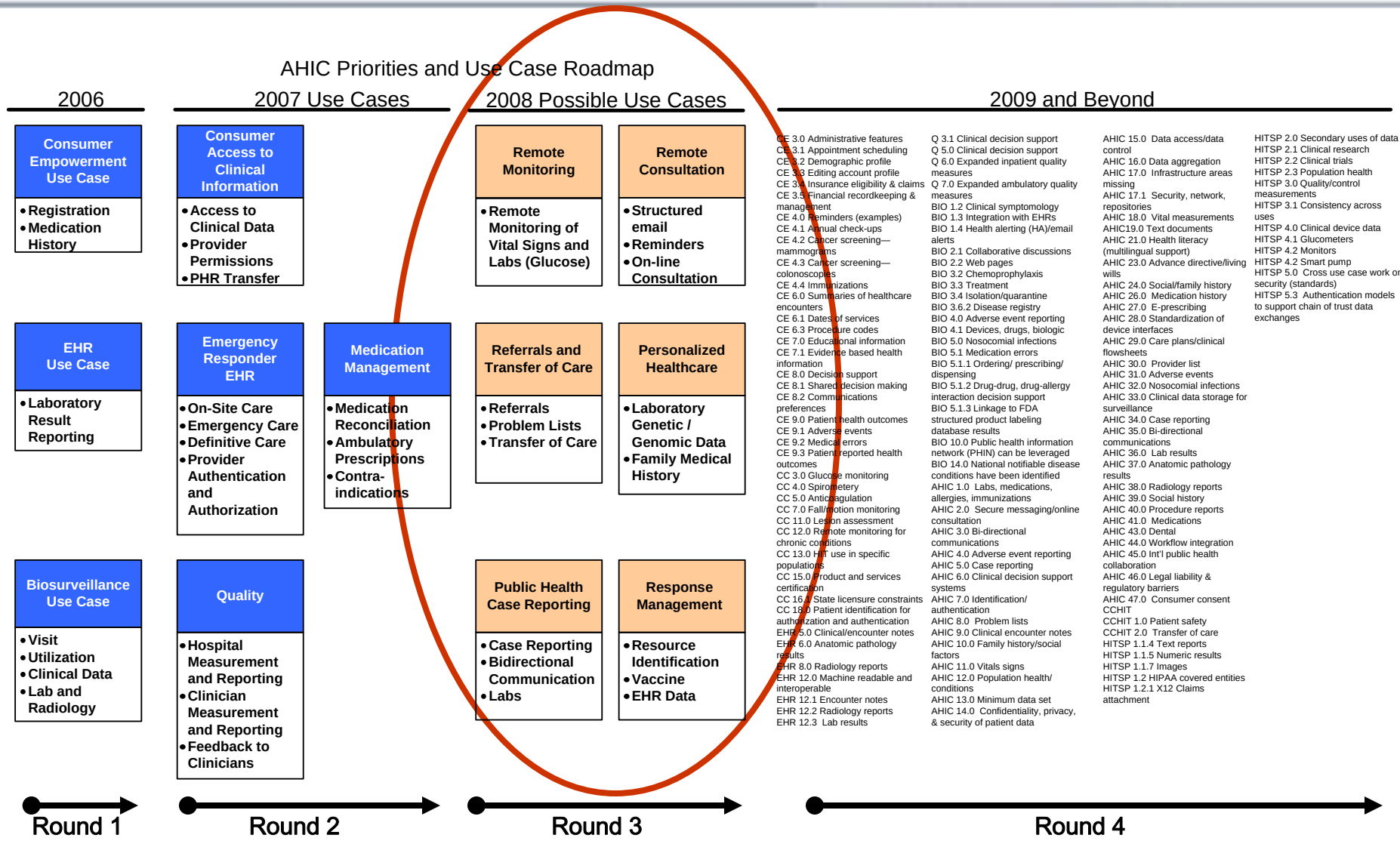
Develop 2008 Use Cases (Round #3)

- Remote Monitoring, Remote Consultation, Referrals and Transfer of Care, Personalized Healthcare, Public Health Case Reporting, Response Management
- Publish Use Cases in December 2007
- Advance Use Cases into the National Agenda Activities (Standards Harmonization, Certification, Policy Development and NHIN) in 2008

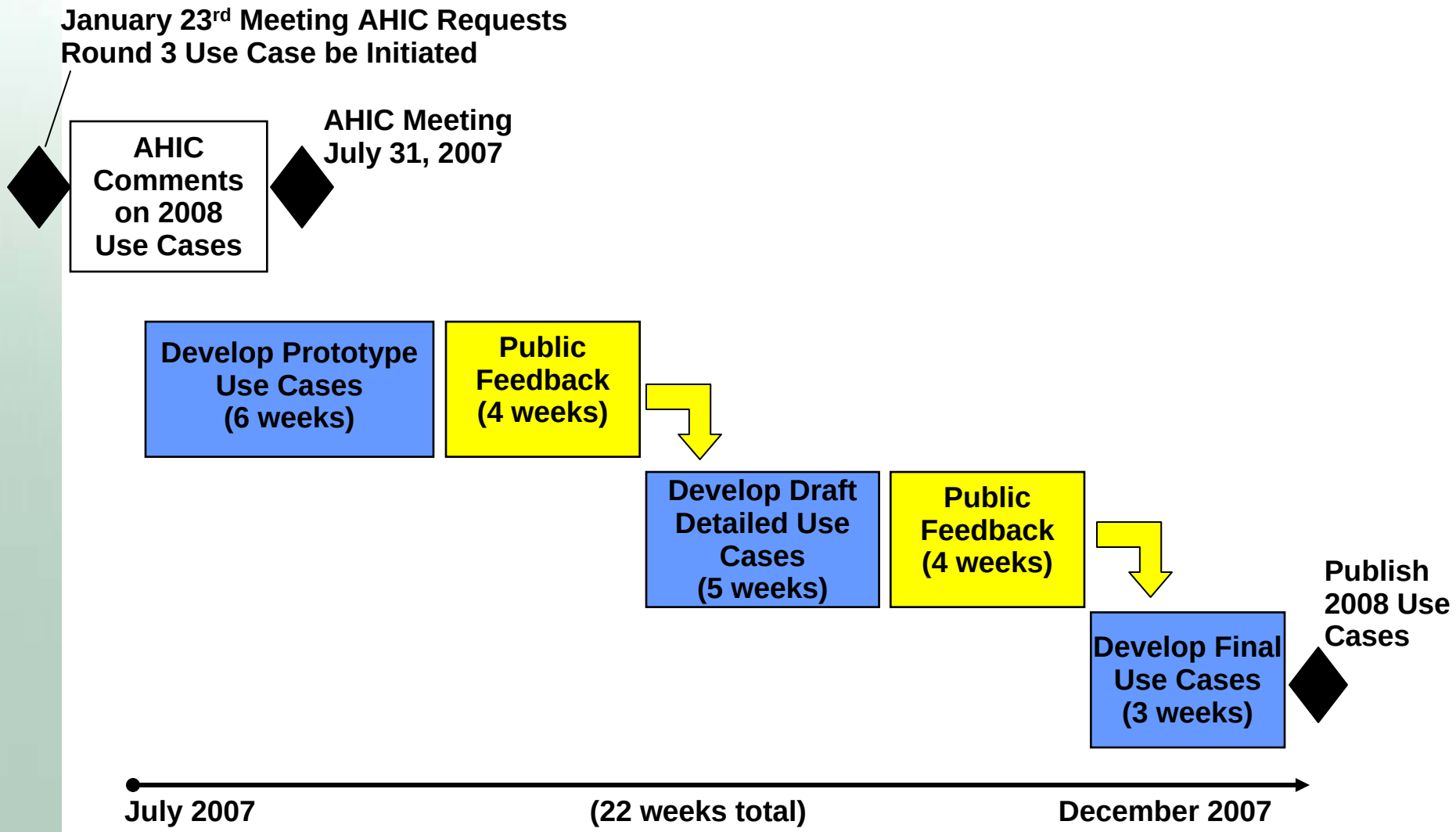
Prioritize Needs for 2009 Use Cases (Round #4)

- Refresh and Prioritize Work Group Needs for 2009 Use Cases
- Prioritize Use Cases to be Developed in 2008 for 2009 National Agenda Activities

AHIC Priorities and Use Case Roadmap



Development Timeline for 2008 Use Cases



Comments on Round Three Use Cases

- 255 comments from AHIC and AHIC working group members
- Policy and obstacles -> include / share with relevant working groups
- Detailed comments -> prototype use case development
- Scope and focus -> disposition today

2008 Use Case Draft Description
Remote Monitoring

The ability for a clinician to remotely monitor a patient's at-home vital signs, other physiologic measurements, and tests is a key enabler for the management of chronic health problems.

This use case will focus on the ability to communicate a subset of vital signs, physiological measurements, and tests from the home care setting to a clinician's EHR with appropriate privacy and security considerations.

Possible Scenarios for the Use Case:

- Record and communicate measurements from home care setting to EHR and/or PHR (weight; blood pressure; heart rate and rhythm; pulse oximetry; and glucose measurements, "smart" pumps, spirometers, etc.)
- Access transmitted measurements using the EHR
- Configure measurement devices for at-home measurement and communication to EHR

Remote Monitoring Feedback

- Enhance care-coordination roles to monitor data and provide appropriate information to clinicians

  and

- Data supplied by devices may not (all) go into an EHR
  - Will further emphasize the role of case managers, and other roles who may perform these functions
  - Will include the role of other entities who may collect data directly from the devices
  - Will include the information exchange needs outside of monitoring location

Remote Monitoring Feedback (continued)

- Incorporate decision support capabilities for consumers, care coordinators and other clinicians
  - Will enhance decision support roles
- Measurements from non-connected devices (both sides)
  - Will include some manual record measurement capabilities in some role
- Support for devices in other settings (work, assisted living, etc.)
  - Will incorporate additional examples of possible locations
- Business case is not apparent for remote monitoring

2008 Use Case Draft Description
Remote Consultation

The ability for a clinician and patient to communicate on health needs using remote technologies such as structured electronic messages and online interactive communication tools.

This use case will focus on the ability to send and receive structured communications such as electronic messages and the use of interactive communication tools to support chronic and other care, remote monitoring, and healthcare reminders.

Possible Scenarios for the Use Case:

- Use structured, secured messaging and synchronous tools to support patient and clinician initiated communications
- Support clinical reminders from clinicians to patients
- Configure communication tools to support at-home patient consultation with a remote clinician

Remote Consultation Feedback

- Include provider-to-provider remote consultation capabilities
  - Will incorporate capabilities for provider-to-provider remote consultation, including access to relevant patient clinical information
  - Will incorporate the provider's needs related to documenting the consultation
- Need to narrow the scope to specific capabilities
  - Will focus the use case on secure, structured messaging, static imaging and interactive video capabilities while including a framework for other interactive technologies

2008 Use Case Draft Description
Personalized Healthcare

Personalized healthcare enables providers to customize treatment and management plans for individuals based on their unique genetic makeup.

The personalized healthcare use case will focus on the exchange of genomic/genetic test information, family medical history and the use of analytical tools in the EHR to support clinical decision-making.

Possible Scenarios for the Use Case:

- Family medical history information is gathered from the consumer in an interoperable form
- Genomic/genetic laboratory test results are exchanged among laboratories and providers with appropriate privacy and security considerations
- Family medical information and other information including genetic/genomic test results are accessed by providers. The provider may also use additional capabilities that link large datasets to generate large-scale, individual-level genomic data with appropriate privacy and security considerations

Personalized Healthcare Feedback

- Include environmental, lifestyle and health risk assessment information
  - Will incorporate these factors into the information needs
- Patient's ability to control access to their data needs to be prominent
  - Will incorporate capabilities for patient to control access to their information as described in the Consumer Access to Clinical Information Use Case
- May be too early for this use case
  - Will acknowledge that this area is evolving quickly and be representative of needs, but not prescriptive of approaches where not necessary

2008 Use Case Draft Description
Referrals and Transfers in Care

Clinicians need the ability to communicate information during referrals and transfers of care to other clinicians and patients related to referrals for consultation and discharges from one setting to another.

This use case will focus on the ability to exchange a core set of clinical information to support referrals for care such as specialty services, second opinions or emergency referrals. Additionally, this use case will focus on the sharing of a summary discharge report from one setting to another during a transfer of care between care settings.

Possible Scenarios for the Use Case:

- Electronic referrals and exchange of information between clinicians, including feedback to referring clinicians and patients
- Electronic transfer of discharge information between health care settings

Referrals and Transfers of Care Feedback

- Include eligibility verification and related HIPAA information exchanges
  - Will incorporate interactions between providers and payors to confirm eligibility in the context of a referral or transfer of care
- Include decision support capabilities
  - Will incorporate decision support needs of the referring provider and/or patient
- Include the needs of the patient
  - Will incorporate information needs of the patient related to a referral or transfer of care
- Consider additional types of transfers of care

2008 Use Case Draft Description
Public Health Case Reporting

Public health effectiveness could be enhanced through electronic case reporting and the electronic exchange of information regarding population health and adverse events.

This use case will focus on the capabilities needed within information systems and EHR systems to gather, augment and communicate case-specific health information to appropriate organizations. In addition, the communication of other population health information and notifications through these systems may support electronic epidemiology.

Possible Scenarios for the Use Case

- Electronic case reporting, as well as the transmission of information and/or notifications between healthcare clinicians and governmental/public health entities
- Communication to clinicians about relevant community or population health information

Public Health Case Reporting Feedback

- Include adverse event reporting capabilities
  - Will include framework for adverse event reporting capabilities
- Include feedback to clinicians from public health entities
  - Will include clinician needs to receive relevant population health information
- Include identification of "possible" cases
  - Will include mechanisms to identify and report "possible" cases utilizing feedback to clinicians coupled with decision support tools
- Incorporate claims data to augment EHR data
  - Will incorporate administrative data where relevant

2008 Use Case Draft Description
Response Management

Response management includes the exchange of information which supports daily prevention and treatment operations as well as emergency situations.

This use case will focus on the ability to communicate a subset of relevant information such as immunization status, availability of medication stockpiles and other resources needed during routine and emergency situations.

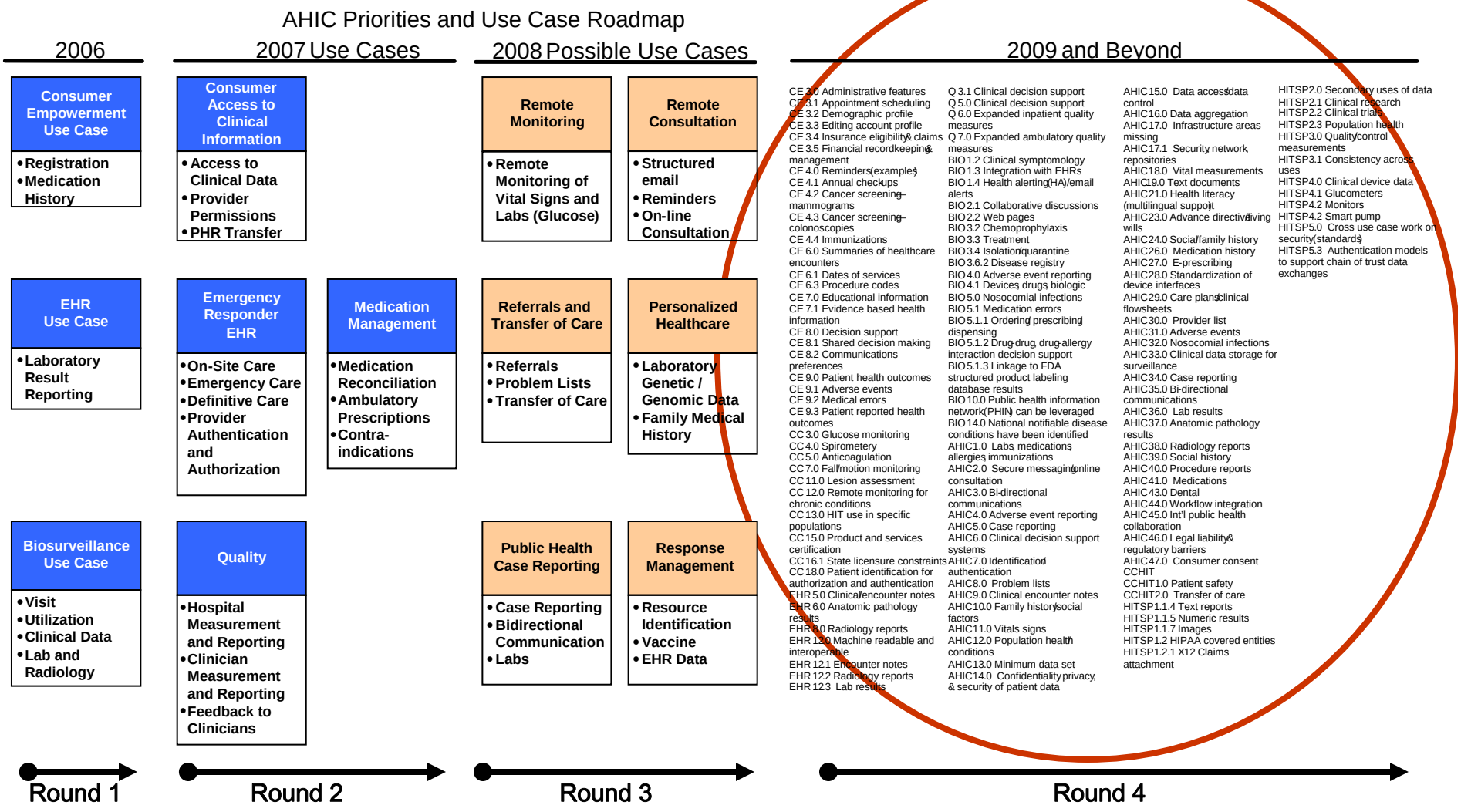
Possible Scenarios for the Use Case

- Recording and exchange of immunization information during routine care activities as well as during emergency situations
- Integration of supply chain information from public and private sectors to support treatment activities
- Integration with registries to support case management activities

Response Management Feedback

- Refine the scope of the use case
  - Will incorporate needs related to outbreak investigation (in keeping with same need identified in public health case reporting)
  - Will emphasize the role of routine clinical care treatment delivery (vaccinations etc.) in addition to emergency needs
- Include decision support capabilities
  - Will include decision support capabilities to assist in diagnosis, selection of therapeutic actions, and follow-up activities

AHIC Priorities and Use Case Roadmap



Refresh and Prioritize Workgroup Needs for 2009 Use Cases

Criteria for Prioritizing Needs

Workgroups Refresh and Prioritize Needs

11/30/2007

Cluster Prioritized Needs into Possible Use Cases

12/31/2007

AHIC Feedback on Possible Use Cases

AHIC Prioritizes 2009 Use Cases

Use Case Development

2009 and Beyond

CE 3.0 Administrative features
CE 3.1 Appointment scheduling
CE 3.2 Demographic profile
CE 3.3 Editing account profile
CE 3.4 Insurance eligibility & claims
CE 3.5 Financial recordkeeping & management
CE 4.0 Reminders (examples)
CE 4.1 Annual checkups
CE 4.2 Cancer screening—mammograms
CE 4.3 Cancer screening—colonoscopies
CE 4.4 Immunizations
CE 6.0 Summaries of healthcare encounters
CE 6.1 Dates of services
CE 6.3 Procedure codes
CE 7.0 Educational information
CE 7.1 Evidence based health information
CE 8.0 Decision support
CE 8.1 Shared decision making
CE 8.2 Communications preferences
CE 9.0 Patient health outcomes
CE 9.1 Adverse events
CE 9.2 Medical errors
CE 9.3 Patient reported health outcomes
CC 3.0 Glucose monitoring
CC 4.0 Spirometery
CC 5.0 Anticoagulation
CC 7.0 Fall/motion monitoring
CC 11.0 Lesion assessment
CC 12.0 Remote monitoring for chronic conditions
CC 13.0 HIT use in specific populations
CC 15.0 Product and services certification
CC 16.1 State licensure constraints
CC 18.0 Patient identification for authorization and authentication
EHR 5.0 Clinical/encounter notes
EHR 6.0 Anatomic pathology results
EHR 8.0 Radiology reports
EHR 12.0 Machine readable and interoperable
EHR 12.1 Encounter notes
EHR 12.2 Radiology reports
EHR 12.3 Lab results

Q 3.1 Clinical decision support
Q 5.0 Clinical decision support
Q 6.0 Expanded inpatient quality measures
Q 7.0 Expanded ambulatory quality measures
BIO 1.2 Clinical symptomology
BIO 1.3 Integration with EHRs
BIO 1.4 Health alerting (HA)/email alerts
BIO 2.1 Collaborative discussions
BIO 2.2 Web pages
BIO 3.2 Chemoprophylaxis
BIO 3.3 Treatment
BIO 3.4 Isolation/quarantine
BIO 3/6.2 Disease registry
BIO 4.0 Adverse event reporting
BIO 4.1 Devices, drugs, biologic
BIO 5.0 Nosocomial infections
BIO 5.1 Medication errors
BIO 5.1.1 Ordering/ prescribing/ dispensing
BIO 5.1.2 Drug-drug, drug-allergy interaction decision support
BIO 5.1.3 Linkage to FDA structured product labeling database results
BIO 10.0 Public health information network (PHIN) can be leveraged
BIO 14.0 National notifiable disease conditions have been identified
AHIC 1.0 Labs, medications, allergies, immunizations
AHIC 2.0 Secure messaging/online consultation
AHIC 3.0 Bi-directional communications
AHIC 4.0 Adverse event reporting
AHIC 5.0 Case reporting
AHIC 6.0 Clinical decision support systems
AHIC 7.0 Identification/ authentication
AHIC 8.0 Problem lists
AHIC 9.0 Clinical encounter notes
AHIC 10.0 Family history/social factors
AHIC 11.0 Vitals signs
AHIC 12.0 Population health/ conditions
AHIC 13.0 Minimum data set
AHIC 14.0 Confidentiality, privacy, & security of patient data

AHIC 15.0 Data access/data control
AHIC 16.0 Data aggregation
AHIC 17.0 Infrastructure areas missing
AHIC 17.1 Security, network, repositories
AHIC 18.0 Vital measurements
AHIC 19.0 Text documents
AHIC 21.0 Health literacy (multilingual support)
AHIC 23.0 Advance directive/living wills
AHIC 24.0 Social/family history
AHIC 25.0 Medication history
AHIC 27.0 E-prescribing
AHIC 28.0 Standardization of device interfaces
AHIC 29.0 Care plans/clinical flowsheets
AHIC 30.0 Provider list
AHIC 31.0 Adverse events
AHIC 32.0 Nosocomial infections
AHIC 33.0 Clinical data storage for surveillance
AHIC 34.0 Case reporting
AHIC 35.0 Bi-directional communications
AHIC 36.0 Lab results
AHIC 37.0 Anatomic pathology results
AHIC 38.0 Radiology reports
AHIC 39.0 Social history
AHIC 40.0 Procedure reports
AHIC 41.0 Medications
AHIC 43.0 Dental
AHIC 44.0 Workflow integration
AHIC 45.0 Int'l public health collaboration
AHIC 46.0 Legal liability & regulatory barriers
AHIC 47.0 Consumer consent
CCHIT
CCHIT 1.0 Patient safety
CCHIT 2.0 Transfer of care
HITSP 1.1.4 Text reports
HITSP 1.1.5 Numeric results
HITSP 1.1.7 Images
HITSP 1.2 HIPAA covered entities
HITSP 1.2.1 X12 Claims attachment

HITSP 2.0 Secondary uses of data
HITSP 2.1 Clinical research
HITSP 2.2 Clinical trials
HITSP 2.3 Population health
HITSP 3.0 Quality/control measurements
HITSP 3.1 Consistency across uses
HITSP 4.0 Clinical device data
HITSP 4.1 Glucometers
HITSP 4.2 Monitors
HITSP 4.2.5 Smart pump
HITSP 5.0 Cross use case work on security (standards)
HITSP 5.3 Authentication models to support chain of trust data exchanges

AHIC Meeting 7/31/2007 — 2007

AHIC Meeting January 2008 — 2008

2009 Use Case Draft Prioritizing Criteria

For each need, determine if it:

1. Advances the adoption of interoperable health information technology (HIT)
2. Realizes the window of opportunity for near-term societal benefits
3. Leverages existing HIT efforts
4. Demonstrates the tangible benefits of HIT adoption
5. Accelerates the vision articulated in the Federal HIT strategic framework
6. Necessary to meet or advance other top health policy goals

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Privacy and Security Solutions for Interoperable Health Information Exchange Nationwide Summary

Linda Dimitropoulos
RTI International

July 31, 2007

Overview of Progress

- September 2005 – Prime Contract Awarded
- June 2006 – Awarded 34 Subcontracts
- June 2006 – April 2007
  - Conducted the assessment of variation
  - Developed feasible solutions
  - Drafted plans to implement solutions
  - Final 34 individual state reports received
- July 2007 – Final summary reports released
  - www.rti.org/hispc
  - http://healthit.ahrq.gov

Methodology

- Community-based research model where state teams identify and “own” the issues and outcomes
- Engaged broad range of stakeholders to identify challenges to privacy and security, and develop solutions
- Followed a “core” methodology that framed discussions in terms of purposes for the exchange, type of health information being exchanged within 9 domains of privacy and security

Stakeholder Participation in Assessment of Variation

Total Participants	**3,811**	**112**
Stakeholder Group	N	AVG
Providers	1,630	48
Technology and Health Information Experts	582	17
Consumers	458	13
Other Government	243	7
Public Health Agencies/Departments	213	6
Employers	198	6
Legal Counsel/Attorneys	181	5
Medical & Public Health Schools/Research	140	4
Payers	122	4
Law Enforcement and Correctional Facilities	37	1
Foundations/Other Policy Consultants	4	<1

Challenges/Solutions

Challenge: Lack of awareness among stakeholders

Stakeholders lack sufficient knowledge of HIT/HIE to understand implications for privacy and security; Consumers are unaware of legal protections under state law; Providers frequently do not understand state law requirements

Solution: 14 states are developing model outreach and education programs

- Consumer and provider outreach and education
- State and multistate privacy and security summits
- Consumer advisory councils/committees
- Toolkits for educating stakeholders

Challenges/Solutions (continued)

Challenge: Variation created by state privacy and security laws

State law governing privacy and security is scattered, fragmented, sometimes inconsistent or contradictory within a state, and frequently does not apply sensibly to electronic exchange.

Solution: 9 states implementing solutions related to state law

- Producing a catalog of existing relevant statutes and administrative regulations
- Developing a road map of current P&S laws/statutes
- Developing model legislation to harmonize on multistate issues such as consent
- Completing a legal analysis to determine what changes need to be made to ensure privacy and security
- Reforming state privacy laws to address electronic HIE
- Drafting legislation for 2008 session

Challenges/Solutions (continued)

Challenge: Obtaining and Managing Patient Consent

Broad variation in the requirements for obtaining and managing patient consent and authorization for information disclosures

Solution: 8 states are working on reducing variation related to consent management

- Standardize patient consent process
- Harmonize consent language that addresses opt-in/opt-out issues across the state
- Implement consent management process; develop use cases that drive HIE transactions
- Create guiding principles for consent that can be used to update state law
- Model consent forms

Challenges/Solutions (continued)

Challenge: Variation in Methods of Implementing the 4 "A's"

Need for consensus on standards for authentication, authorization, access controls and information audits to reduce mistrust between entities

Solution: 4 states are working on issues related to the 4 "A's"

- Defining minimum standards for authentication acceptable to individuals or entities participating in an HIE
- Defining P&S requirements for providers' role-based access and authentication
- Developing "solutions building block," i.e., trusted digital identities for authentication, authorization, access control, data integrity, and digital signatures

Challenges/Solutions (continued)

Challenge: Privacy and Security Oversight

Lack of state-level authoritative governing bodies to oversee the development, adoption and enforcement of common privacy policies and security practices for HIE

Solution: 6 states working on governance and oversight

- Establish Governor's eHealth taskforce on Privacy and Security
- Create a Privacy and Security Advisory Board
- Establish formal work group to formulate and review P&S policy
- Create an umbrella organization to operationalize P&S strategies and interact with Governor's HIE Commission and the state Health Policy Authority.

Moving Forward

- State team subcontracts extended through December 2007 to implement a foundational component of their plan
- Moving toward multistate and regional coordination and collaboration
  - HISPC state project leaders have met with the State Alliance for eHealth Health Information Protection Taskforce
  - Forming multistate and regional collaborative work groups that will continue the work beyond the end of this contract
  - Representatives from all 56 states and territories have been invited to participate in the work groups
- The state teams will come together for a National Meeting in November 2007

Department of Health & Human Services
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Health Information Technology

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New York State Health Information Security and Privacy Collaboration

Lori M. Evans
Deputy Commissioner
Office of Health Information Technology Transformation
New York State Department of Health

July 31, 2007

NY HISPC Phase I: Priority Solutions

- Leadership
- Consent
- Patient Engagement
- Security/Access/Use
- Accreditation

Leadership

- Challenge: New York lacked the infrastructure to guide policy development, investment and implementation in the state in a coordinated and coherent manner
- Solution:
  - Office of Health Information Technology Transformation (OHITT)
  - New York e-Health Collaborative (NYeC)
  - Health Information Technology Evaluation Collaborative (HITEC)
  - Health Care Efficiency and Affordability Law for New Yorkers (HEAL NY) and Federal State Health Reform Partnership (FSHRP)

Consent

- Challenge:
  - Current laws governing health information exchange (HIE) were developed in paper-based world
  - NYS's current legal framework on HIE is not organized into one regulatory scheme
  - New York State law requires one-time patient consent
- HISPC Phase II Goal: Advance a patient consent solution through the development of a public policy and legal framework
  - Phase I: Assessment and Consensus Building
  - Phase II: Recommendation and Legislative Proposal
  - Phase III: Standardized Consent Form

Additional Activities

- Patient Engagement
  - Office of Consumers and Personalized Medicine, NYSDOH OHITT
  - Programs and Policies to:
    - Support the right of New Yorker's to have greater control over and access to their health information
    - Focus on building capacity of consumer and health advocacy organizations across State to educate and support New Yorkers
    - Educate New Yorker's through public education campaigns
- Security/Access/Use
  - State-Level Health Information Service Providers Consortium
- Accreditation
  - State-Level RHIO Committee

Department of Health & Human Services
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Washington State Health Information Security and Privacy Collaboration (HISPC) Solutions for Health Information Exchange

Jonathan Sugarman
Qualis Health, State of Washington

July 31, 2007

HISPC in Washington State

- Substantial health information technology momentum in Washington State; primary focus of most collaborative enterprises on applications in contrast to privacy and security
- Washington HISPC contract awarded to Qualis Health, a Seattle-based not-for-profit Quality Improvement Organization; close and effective collaboration with state Health Care Authority and many other private and public sector organizations
- Health Information Infrastructure Advisory Board (HIIAB) convened by the Washington State Legislature to develop statewide approaches to health information exchange
- Significant (and intentional) overlap of HIIAB and HISPC stakeholder participation

Barriers & Proposed Solutions to Privacy and Security Issues in Washington State

Barriers:

1. Lack of a defined set of minimum requirements for HIE privacy and security
2. Lack of stakeholder incentives to encourage adoption of HIE privacy and security standards
3. Lack of authoritative state-level governing body to oversee privacy and security standards for HIE

Solutions:

1. Establish the policies, procedures and standards for the Privacy and Security Core Solutions Set
2. Work with state regulatory entities to create stakeholder incentives to adopt the minimum requirements
3. Establish the Privacy and Security Administrative Body

Implementation Plans and Future Steps

- Health Information Infrastructure Advisory Board (HIIAB) funded by the Washington State Legislature in December, 2006 to develop a health record banking model
- Incorporation of HISPC work under the umbrella of HIIAB, wherein HIIAB becomes the HIE Privacy and Security “Administrative Body” as envisioned by stakeholders
- HISPC funding through December, 2007 to support creation of Privacy and Security Technical Advisory Council (PSTAC) to advise HIIAB
  - Consumer Engagement and Participation Subgroup
  - Authentication Subgroup

Objectives for HISPC Phase 2

- Develop roadmap for consumer engagement in health banking model (issues such as opt-in/opt-out procedures)
- Identify user and entity authentication approaches to support health banking pilots
- Explore incentive approaches related to the above and recommend to HIIAB for consideration

Contact Information

All Washington State HISPC reports are available at:

http://www.qualishealth.org/HISPC

All HIIAB reports are available at:

http://www.hca.wa.gov/hit/

For more information:

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

American Health Information Community

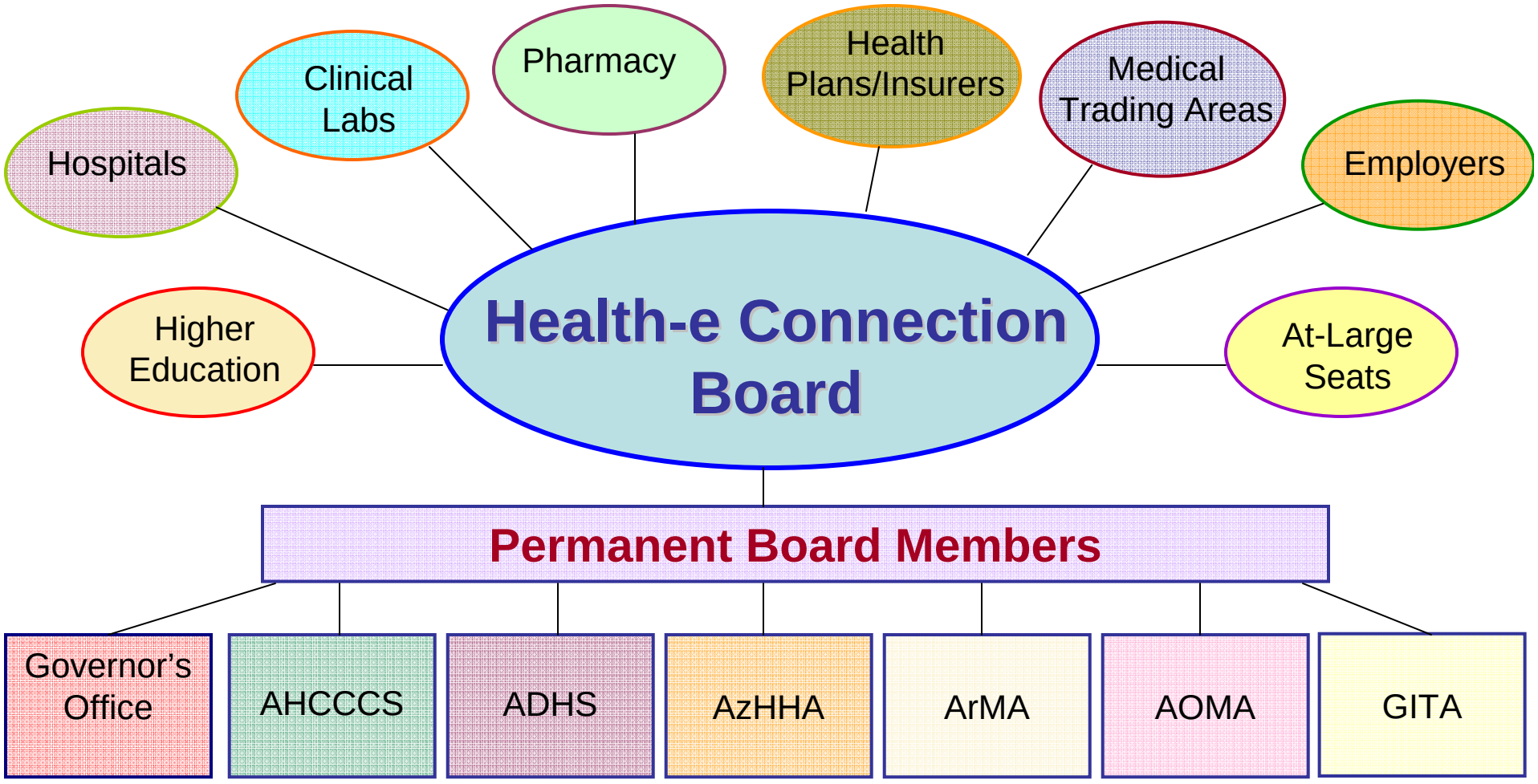
Establishing a Statewide Health Information Exchange: Privacy and Security Challenges and Solutions

Kristen B. Rosati
Coppersmith Gordon Schermer & Brockelman PLC
State of Arizona

July 31, 2007

Arizona's Statewide Public-Private Collaborative

Arizona Health-e Connection Governance Structure



Arizona's Developing RHIOs/ HIEs

Privacy and Security Challenges

- Challenge: Lack of “policy interoperability”
  - Inconsistent rules regarding how to protect individual privacy and secure electronic health information will interfere with electronic exchange of health information
- Solution: Standards development, with broad stakeholder involvement
  - Role-based access and authentication for a master provider index
  - Model privacy and security policies
  - Model participation agreement

Privacy and Security Challenges

- Challenge: Uncertainty regarding legal requirements
  - Uncertainty regarding present legal requirements will delay participation in health information exchanges
  - Uncertainty regarding future legal requirements will delay creation of health information exchanges
- Solutions:
  - Education
  - Federal and state restraint in changing fundamental privacy legal requirements, such as consent
  - Careful attention to national priorities to encourage the use of EHR/HIE

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

American Health Information Community

Update on Health IT Certification

Mark Leavitt, Chair
Certification Commission for Healthcare Information Technology

July 31, 2007

Overview of CCHIT

- Mission:
  Accelerate the adoption of robust, interoperable health IT by creating an efficient, credible certification process

- Goals of Certification:
  - Reduce the risks of investing in health IT
  - Facilitate interoperability of health IT products
  - Enhance availability of adoption incentives and regulatory relief
  - Ensure that the privacy of personal health information is protected

Scope of Work for CCHIT

- 2006: Develop, pilot test, and launch certification of ambulatory (office-based) EHRs
- 2007: Develop, pilot test, and launch certification of inpatient (hospital) EHRs
- 2008: Develop, pilot test, and launch certification of networks through which EHRs interoperate
- Update certification criteria for each domain annually
- Expand certification to address more specialized needs
- Transition to become an independent, self-sustaining organization by the end of the contract period

Ambulatory EHR Certification 2006

- 18 months in development, >100 volunteers, >2000 public comments
- Consensus achieved, criteria finalized, and accepted by the Community at its May 2006 meeting
- 89 products (>40% of ambulatory EHR vendor market) were certified under the 2006 criteria
- Broad diversity of products and companies represented

Ambulatory EHR Certification 2007

- All criteria on the published roadmap were reviewed, as well as newly emerging requirements
- Refinement through multiple cycles of public comment
- Consensus achieved, pilot test completed, updated criteria finalized and published in March 2007
- Certification against 2007 Ambulatory EHR criteria now in progress

Ambulatory EHR Certification 2007

- Comparison of 2007 vs. 2006:
  - 2006: 151 criteria inspected through 200 test steps
  - 2007: 247 criteria inspected through 315 test steps
- New or enhanced criteria for 2007 include:
  - Standards-compliant electronic prescribing
  - Interoperability testing of receiving laboratory results
  - Stronger legal compliance and audit requirements
  - Advance directives
  - Electronic ordering capabilities
  - Improved drug interaction and allergy checking
  - Disease management features
  - Improved population reporting

Evidence of Certification's Positive Impact

- Endorsements by provider organizations
- Vendors enhancing security features
- Payer IT incentives keyed to certification
- Health information networks and state eHealth initiatives
  - Using certification to qualify health IT for funding
  - Relying on certification to satisfy security requirements
- Hospitals providing certified EHRs for physicians in response to Stark/AKA safe harbor ruling
- Data indicating accelerating EHR adoption

Inpatient EHR Certification 2007

- Criteria development started in May 2006
- Four rounds of public comment; reviewed and responded to ~1000 comments
- Alpha Test and Pilot Tests completed May 2007
- Criteria finalized and published June 2007
- Applications for certification will be accepted starting August 1, 2007

Certification Development Activities for 2008

- New certification areas being developed for 2008 launch:
  - Networks / Health Information Exchanges
  - Emergency Department systems
  - Cardiovascular Medicine EHR requirements
  - Child health care EHR requirements
- Areas being updated for 2008:
  - Ambulatory EHR
  - Inpatient EHR
- Organizational growth to support development work:
  - Expert panels in Security, Interoperability, Privacy & Compliance
  - >160 volunteers now engaged; >120 attended our development kickoff meeting in person July 10
  - Additional staff with specialized expertise

Summary

- Updated Ambulatory EHR criteria, and new Inpatient EHR criteria, for 2007 are now submitted to the Community for acceptance
- Ambulatory EHR certification has become established and is having multiple positive impacts
- Inpatient EHR certification will be launched August 1
- Four new areas of certification are being developed for 2008
- CCHIT's plans to become independent and self-sustaining by the end of its Federal contract are on track

Thank you!
Q & A

For more information, please visit:

www.cchit.org

Certification Commission
for Healthcare
Information Technology

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Chicago, Illinois 60601-5800
Tel 312.233.1582 Fax 312.896.1466
www.cchit.org

July 23, 2007

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Dear Mr. Secretary:

Thank you for inviting me, in your capacity as Chair of the American Health Information Community, to appear at the Community's upcoming July 31 meeting to report on the progress of the Certification Commission for Healthcare Information Technology (CCHIT).

I am pleased to report that CCHIT, a public/private initiative working under contract HHS-P23320054102EC, recently completed two more major milestones: the development and publication of consensus-based criteria for the certification of inpatient electronic health records, and our first annual update to the criteria for ambulatory electronic health records (EHR).

For the inpatient (hospital) setting, CCHIT's volunteer workgroups drafted the requirements and test scripts, then refined and validated the work with an 'alpha test' at a major medical center as well as a pilot test involving inpatient EHR vendors. The one year development period included four cycles of public comment during which we reviewed and responded to over 1000 comments. The 2007 inpatient EHR criteria, including a roadmap of additional requirements expected in 2008 and 2009, were finalized by the Commission and published on June 28, 2007. Applications for certification will open on August 1. The 2007 inpatient EHR certification criteria and roadmap for functionality, interoperability, and security have been provided as attachments to this letter.

For the ambulatory (physician office and clinic) setting, the existing criteria were reviewed in light of newly emerging standards and use cases, and 96 criteria were added to the original set of 151 from 2006. Highlights of the new requirements include: standards-compliant electronic prescribing, more rigorous interoperability standards testing for receiving laboratory results, stronger compliance and privacy protection capabilities, disease management features, and improved population-based reporting. The 2007 ambulatory EHR criteria were published on March 16 and certification applications opened May 1. Five products have been certified so far and several more are in process. The 2007 ambulatory EHR certification criteria and roadmap for functionality, interoperability, and security have also been provided as attachments to this letter.

I look forward to attending the July 31 meeting to present this information, as well as to report to the Community on our plans for the year ahead.

Respectfully yours,

Mark Leavitt, MD, PhD
Chair, CCHIT

FUNCTIONALITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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						Providers	Vendors	Payers or Purchasers	Public Health	Patient	Quality Organization	2007	2008	2009 and beyond	Roadmap 2007	Roadmap 2008	Roadmap 2009 and Beyond			
1.01	New	IF	1. Patient Demographics and Administrative Information Provide patient demographics (i.e., name, age, date of birth, and gender) and administrative information (i.e., bed assignment) needed for CPOE and eMAR.	The system shall provide the ability to access demographic information needed for clinician ordering, verification and medication administration.	CCHIT Amb Criteria										N			For example, name, age, date of birth, and gender.	X	
1.02	1.3.3	IF	1. Patient Demographics and Administrative Information	The system shall provide the ability to query a patient by alternate forms of identification.	S.1.4.2										N			The choice of alternate forms of identification is flexible, and there can be more than one. For example, first name, date of birth, social security number, or medical record number.	X	
1.03	1.2.1	IF	1. Patient Demographics and Administrative Information	The system shall provide the ability to access bed assignment information including temporary bed assignment.	S 1.4.4										N			For example, holding area, triage, etc.	X	
1.04	1.3.1	IF	1. Patient Demographics and Administrative Information	The system shall provide the ability to identify the patient's current location within the hospital.	S.1.4.2												N	For example, the patient is in Radiology or Physical Therapy.	X	
1.05	New		1. Patient Demographics and Administrative Information	The system shall have the ability to record the time of birth.													N		X	
2.01	1.7.1	IF	2. Provider Information Manage information about providers and care teams / groups for the provision of care	The system shall provide the ability to uniquely identify clinicians for the provision of care.	S.1.3.7										N			The intent of the criterion is to access the directory of users and review user attributes required to determine the system security level to be granted to each user.	X	
2.02	1.8.3 2.7.5	IF	2. Provider Information	The system shall provide the ability to identify all clinicians who have been associated with care for a specific patient.	S.1.3.5 S.3.4	H	H	H	H	H	M	X				N			X	
2.03	1.8.1	IF	2. Provider Information	The system shall provide the ability to assign clinicians to appropriate teams, where teams are defined as groups of clinicians who share responsibility for covering the same group of patients.	S.1.3.5	H	M	H	H	M	M			X		N			X	
3.01	2.7.1	IF	3. Patient List Management Provide clinicians access to lists of their patients.	The system shall provide the ability to view a clinician's inpatient list information and sort by various criteria.	S.1.3.6										N			For 2007, criterion 3.01, clinicians refer to a physician in this criterion. In future years, the criteria will be expanded to include other clinicians.	X	
3.02	New	IF	3. Patient List Management	The system shall provide the ability to add, update, and remove patients from a clinician's patient list.												N			X	
3.03	New	IF	3. Patient List Management	The system shall provide the ability for the clinician to create a custom list of patients.													N		X	
3.04	2.7.3	IF	3. Patient List Management	The system shall provide the ability to identify all clinicians by name associated with a specific patient stay and to correct erroneous assignments of clinicians.	S.3.4												N		X	
3.05	2.7.8	IF	3. Patient List Management	The system shall provide the ability to specify the principal caregivers responsible for the care of a patient within the hospital.	S.3.4										N			Principal caregivers, for example, refer to the attending physician and / or nurse.	X	

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4.01	New	IF	4. Problem Lists Create and maintain during the inpatient stay an up-to-date list of patient-specific problems / diagnoses that are documented by a clinician	The system shall provide the ability to document a problem / diagnosis associated with a patient.													**N**	The intent is that an up-to-date problem list is maintained by clinicians during the hospital stay. The problem list refers only to patient-specific medical problems / diagnoses that are documented by a clinician.	X	
4.02	2.4.1	IF	4. Problem Lists	The system shall provide the ability to display different views of the problem / diagnosis list.	DC 1.4.3									X			**N**	For example, active, all, or resolved.	X	
4.03	2.4.2	IF	4. Problem Lists	The system shall provide the ability to document the status of a problem / diagnosis.	DC 1.4.3									X			**N**	For example, inactive, active, resolved, or by date.	X	
4.04	2.4.3	IF	4. Problem Lists	The system shall provide the ability to display the history of changes made to a specific problem / diagnosis, including clinician, date, and time.	DC 1.4.3									X			**N**		X	
4.05	New	IF	4. Problem Lists	The system shall provide the ability for the clinician to create, associate and display free text comments with the problem / diagnosis.													**N**		X	
4.06	New	IF	4. Problem Lists	The system shall provide the ability to print a problem / diagnosis list.													**N**	A screen print is not the intent in this criterion.	X	
4.07	New	IF	4. Problem Lists	The system shall provide the ability to search patient records for specific problems / diagnoses.													**N**		X	
5.01	2.9.1	IF	5. Allergy Information Create and maintain patient specific allergy information (i.e., allergens, reaction, level of severity).	The system shall provide the ability to document medications to which the patient has had an allergic reaction.	DC 1.4.1	H	H	L	L	H	M	X			**N**				X	
5.02	2.9.2	IF	5. Allergy Information	The system shall provide the ability to capture non-drug agents to which the patient has had an allergic reaction.	DC 1.4.1	H	H	L	L	H	M	X			**N**			For example, tape, latex, and peanuts.	X	
5.03	2.9.8	IF	5. Allergy Information	The system shall provide the ability to capture the source of the allergy information.	DC 1.4.1	H	H	L	L	H	M	X				**N**		For example, patient, mother, or medic alert bracelet.	X	
5.04	2.9.4	IF	5. Allergy Information	The system shall provide the ability to specify the type of allergic reaction.	DC 1.4.1	H	H	L	L	H	M	X			**N**			For example, anaphylaxis, allergic asthma, or itching.	X	
5.05	2.9.5	IF	5. Allergy Information	The system shall provide the ability to capture the severity of a reaction.	DC 1.4.1	H	M	L	L	H	L		X		**N**				X	
5.06	2.9.6	IF	5. Allergy Information	The system shall provide the ability to explicitly indicate that a patient has “No Known Drug Allergies" or "No Known Allergies."	DC 1.4.1	H	H	L	L	H	M	X			**N**				X	
5.07	2.9.7	IF	5. Allergy Information	The system shall provide the ability to indicate that the allergies are “Unknown” or “Unable to Assess Allergies.”		H	H	L	L	H	M	X			**N**				X	
5.08	2.9.7	IF	5. Allergy Information	If allergies are “Unknown” or “Unable to Assess Allergies,” the system shall provide the ability to require a reason to be documented.		H	H	L	L	H	M	X				**N**		For example, patient unconscious, patient does not know.	X	
5.09	New	IF	5. Allergy Information	When allergies are “Unknown” or “Unable to Assess Allergies,” the system shall provide the ability to inform the clinician for the need of an update.		H	H	L	L	H	M	X					**N**		X	
5.10	New	IF	5. Allergy Information	The system shall provide the ability to capture clinician name or logon identification, date, and time when allergy information is re-verified.											**N**				X	
5.11	2.9.9	IF	5. Allergy Information	The system shall provide the ability to modify an item from the allergy list.	DC 1.4.1	H	H	L	L	H	M	X			**N**			For example, inactivate an allergy.	X	

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5.12	2.9.10	IF	5. Allergy Information	The system shall provide the ability to specify the reason for inactivating or modifying an item from the allergy list and capture clinician, date, and time.	DC 1.4.1	H	H	L	L	H	M		X			**N**			X	
5.13	2.9.12	IF	5. Allergy Information	The system shall provide the ability to display the allergy history, including date and time of entry.												**N**			X	
6.01	4.1.1	IF	6. Medication List Create and maintain patient specific medication lists.	The system shall provide the ability to display patient-specific medication list based on medication orders.	DC 1.4.2	H	M	M	M	H	H	X			**N**				X	
6.02	New	IF	6. Medication List	When the display of the medication list exceeds the current screen or printed page, the system shall indicate that the list continues via scrolling, or on following pages or screens.												**N**		For example, Page one of two, End of report.	X	
6.03	4.1.3	IF	6. Medication List	The system shall provide the ability to view the name of the ordering clinician, medication order (name, dose, route, and frequency), a start date and time, and a stop date and time for entries on the medication list.	DC 1.4.2	H	H	H	H	H	H	X			**N**				X	
6.04	4.1.5	IF	6. Medication List	The system shall provide the ability to add start date and dose information for non-prescription medications on a patient-specific medication list, including over the counter medications such as vitamins, herbs and supplements.	DC 1.4.2											**N**			X	
6.05	4.1.6	IF	6. Medication List	The system shall provide the ability to display different views of the patient's medication list.	DC 1.4.2	H	H	H	L	H	H	X			**N**			For example, current, all, PRN, scheduled, and one time.	X	
6.06		IF	6. Medication List	The system shall provide the ability to discontinue a medication from the current medication list.											**N**				X	
6.07	4.1.2 4.1.9	IF	6. Medication List	The system shall provide the ability to print a current medication list.		L	L	L	L	L	L			X	**N**				X	
6.08	4.1.11	IF	6. Medication List	The system shall provide the ability to display that the patient takes no medications on the preadmission medication list.												**N**			X	
6.09	New	IF	6. Medication List	The system shall provide the ability to display on the medication list the medications that the patient brings from home which the Pharmacy would not dispense.	JCAHO Pt Safety Standard	H	L	M	M	H	M		X			**N**		For example, the patient brings in their medication from home.	X	
6.10	3.7.6	IF	6. Medication List	The system shall provide the ability to update the medication list with new medication orders, start and end date and time, and pharmacy verification status.	DC.1.7.1	H	H	H	H	H	H	X			**N**			For coding standards refer to Inpatient Interoperability Criteria and Roadmap.	X	
6.11	New	IF	6. Medication List	The system shall provide the ability to update the medication list with changes from pharmacist verification including pharmacist date and time.												**N**			X	
7.01	2.8	IF	7. Results Access and View Present current and historical test results to appropriate clinical personnel for review during the provision of care	The system shall provide the ability to view test results during the ordering process.	DC.1.8.3	H	M	M	M	H	H		X		**N**			The intent is to view any test results while ordering any order type and not interrupt the ordering process (e.g., do not have to close down the ordering screen).	X	
7.02	2.8	IF	7. Results Access and View	The system shall provide the ability to view test results during medication administration.	DC.1.8.3	H	M	M	M	H	H		X		**N**				X	

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8.01a	**New**	IF	8. General Ordering Requirements Create and communicate orders that are complete and actionable	The system shall provide the ability to display patient name, identification number, and age or date of birth on all order screens.											**N**				X	
8.01b	**New**	IF	8. General Ordering Requirements	The system shall provide the ability to have viewable the patient's weight or an indicator that the patient has a weight recorded on medication dosing screens.											**N**				X	
8.02	**New**	IF	8. General Ordering Requirements	The system shall provide the ability to have viewable an indicator that the patient has allergies (allergies exist) or no known allergies on all order screens.												**N**			X	
8.03	**2.11.1**	IF	8. General Ordering Requirements	The system shall provide the ability to document a verbal order, including the clinician taking the verbal order and the ordering physician in the patient record.	DC.3.2.1										**N**				X	
8.04	**New**	IF	8. General Ordering Requirements	The system shall provide the ability to document a telephone order, including the clinician taking the telephone order and the ordering physician in the patient record.											**N**				X	
8.05	**New**	IF	8. General Ordering Requirements	The system shall provide the ability to document a verification "read-back" of the complete order by the person receiving the telephone or verbal order.	JCAHO 2003 National Patient Safety Goal - Goal 2: Improve the effectiveness of communication among caregivers										**N**			JCAHO 2003 National Patient Safety Goal - Goal 2: Improve the effectiveness of communication among caregivers	X	
8.06	**New**	IF	8. General Ordering Requirements	The system shall provide the ability to include urgency status in orders.											**N**			For example, routine, Now, or STAT.	X	
8.07	**3.4.1 3.5.1**	IF	8. General Ordering Requirements	The system shall provide the ability for clinicians to write all patient care orders electronically, including, but not limited to nursing care, medications / immunizations, diagnostic testing, nutrition and food service, consultation, and blood products.	DC 1.7.2.1 DC 1.7.2.2										**N**				X	
8.08	**3.5.15**	IF	8. General Ordering Requirements	The system shall provide the ability to renew, modify, and discontinue orders.											**N**				X	
8.09	**New**	IF	8. General Ordering Requirements	The system shall provide the ability to capture the clinician, order date and time when an order is signed, co signed, renewed, modified, or discontinued.											**N**				X	
8.10	**New**	IF	8. General Ordering Requirements	The system shall provide the ability to permit display of order history for any order including clinician order, date, and time.											**N**				X	
8.11	**3.4.2 3.7.2**	IF	8. General Ordering Requirements	For each type of order, the system shall provide the ability to capture elements required by the receiving discipline or department to deliver the ordered service.	DC 1.7.2.1 CCHIT Amb Criteria										**N**			For example, a medication order that is actionable in Pharmacy.	X	
8.12	**3.7.2**	IF	8. General Ordering Requirements	The system shall provide the ability to set required fields for a complete order for any order type.	DC 1.7.2.1										**N**				X	
8.13	**3.7.9 3.7.2 3.5.10**	IF	8. General Ordering Requirements	The system shall provide the ability to default orders to typical order details.	DC.1.7.1	H	H	H	H	H	H	X			**N**				X	

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8.14	3.7.32	IF	8. General Ordering Requirements	The system shall provide the ability for the hospital to provide links to reference information / knowledge resources for any order.		M	L	L	H	L	H		X				**N**		X	
8.15	3.7.9	IF	8. General Ordering Requirements	The system shall provide the ability for the ordering clinician to add free text comments or instructions to the order.	DC.1.7.1	H	H	H	H	H	H	X			**N**				X	
8.16	3.1.8 3.2.5 3.7.31	IF	8. General Ordering Requirements	The system shall provide the ability for the clinician to associate an order with a clinical problem / diagnosis.	DC 1.7.3 DC 2.4.1 CCHIT Amb Criteria	H	H	H	H	H	H		X				**N**	Assumed standard coding for problem list.	X	
8.17	New	IF	8. General Ordering Requirements	The system shall provide the ability for the hospital to require problem / diagnosis as an order component.												**N**		For example, JCAHO requirement for pain medications.	X	
8.18	3.7.29 3.7.35	IF	8. General Ordering Requirements	The system shall provide the ability to allow the entry of orders to be activated at a future time including admission orders, discharge orders, and post-op orders.	CCHIT Amb Criteria	H	M	M	M	M	L			X		**N**			X	
8.19	New	IF	8. General Ordering Requirements	The system shall provide the ability to print orders.											**N**				X	
8.20	New	IF	8. General Ordering Requirements	The system shall provide the ability to enter “conditional” orders.												**N**		Conditional orders: A conditional order is an order that can be executed when certain criteria and conditions are met.	X	
8.21	3.7.11 3.7.17	IF	8. General Ordering Requirements	The system shall provide the ability for a clinician to save frequently used and approved orderables (“favorites” or "preferences") to facilitate retrieval and ordering.	DC.1.7.1	H	M	L	L	L	L		X			**N**			X	
8.22	3.5.16	IF	8. General Ordering Requirements	The system shall provide the ability to access orders for a patient by different views.											**N**			For example, Active, Discontinued, All, Date, Ordering Clinician, and Type.	X	
8.23	3.7.4	IF	8. General Ordering Requirements	The system shall have the ability to allow the hospital to specify orders that require co-signatures.	CCHIT Amb Criteria	H	M	L	L	L	L		X				**N**	For example, medical students.	X	
8.24	3.7.4	IF	8. General Ordering Requirements	The system shall provide the ability for cosigned orders to retain the identities of both clinicians in the order history.	CCHIT Amb Criteria	H	M	L	L	L	L		X			**N**			X	
8.25	2.11.3 3.4.6	IF	8. General Ordering Requirements	The system shall provide the ability to electronically communicate the order to the receiving departmental system.	DC.3.2.1 DC 1.7.2.1										**N**			2007 – Codified; tested for Pharmacy interface. For coding standards refer to Inpatient Interoperability Criteria and Roadmap.	X	
8.26	3.4.3 3.5.6	IF	8. General Ordering Requirements	The system shall provide the ability to view status information for ordered services.	DC 1.7.2.1 DC 1.7.2.2										**N**				X	
8.27	New	IF	8. General Ordering Requirements	The system shall allow the hospital to designate access to individual orders by user role and department.												**N**			X	
9.01	3.1.4	IF	9. Order Sets Create, use and maintain order sets	The system shall provide the ability to define a set of related orders to be ordered as a group.	DC 1.7.3										**N**				X	
9.02	3.1.5 3.2.2	IF	9. Order Sets	The system shall provide the ability to create and modify order sets.	DC 1.7.3 DC 2.4.1	M	M	M	L	M	L		X		**N**				X	

FUNCTIONALITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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9.03	3.2.1 3.2.3 3.2.4	IF	9. Order Sets	The system shall provide the ability for the hospital to define user roles with access to order set management.	DC 2.4.1	H	H	M	M	H	H	X			**N**			Usually only administrative access, and not a user function.	X	
9.04	3.2.2	IF	9. Order Sets	The system shall provide the ability to support the management of order sets to track history of updates including date and time.	DC 2.4.1	M	M	M	L	M	L		X			**N**			X	
9.05	New	IF	9. Order Sets	The system shall provide the option to include date last modified in the display of order sets.												**N**		The order set was modified on x date.	X	
9.06	3.1.6	IF	9. Order Sets	The system shall provide the ability to include in an order set any order type, including, but not limited to orders for nursing care, diagnostics, complex medication orders, consultation, blood products, and dietary.	DC 1.7.3	H	H	H	H	H	H				**N**			The intent is that clinicians can electronically write all of their orders.	X	
9.07	3.1.2	IF	9. Order Sets	The system shall provide the ability to set up individual orders in an order set to be selected or deselected by the clinician.	DC 1.7.3										**N**				X	
9.08	New	IF	9. Order Sets	The system shall provide the ability for the hospital to pre select recommended orders in an order set.											**N**				X	
9.09	3.1.12	IF	9. Order Sets	The system shall provide the ability to incorporate multiple choices of medications or other interventions for orders within an order set for clinician selection.	MH CPOE Initiative	H	M	M	L	H	H	X			**N**			For example, two possible pain medications.	X	
9.10	3.1.14	IF	9. Order Sets	The system shall provide the ability to incorporate text instructions or recommendations within order sets.	MH CPOE Initiative	H	L	L	L	H	H	X			**N**				X	
9.11	3.1.9	IF	9. Order Sets	The system shall allow the hospital to display individual orders in order sets with defaults for order details for clinician review.	DC 1.7.3										**N**				X	
9.12				DELETED															X	
9.13	New	IF	9. Order Sets	The system shall allow the hospital to designate access to individual order sets by user role and department.												**N**			X	
9.14	3.2.7	IF	9. Order Sets	The system shall provide the ability to link an order set to applicable clinical standards and reference materials.	DC 2.4.1	M	M	M	M	M	H		X			**N**			X	
9.15	3.1.8	IF	9. Order Sets	The system shall provide the ability to allow clinicians to search for order sets by hospital-designated selectable name.	DC 1.7.3										**N**			For example, search by diagnosis, CHF admission (order set name), or surgical procedure.	X	
9.16				DELETED																
9.17	New	IF	9. Order Sets	The system shall record and display orders in an order set to the clinician in the same manner as when the order is written individually.											**N**			For example, when the medication order of Vancomycin 1.5 gm IV every 12 hours is displayed in an order set, it should also be displayed in a similar manner when individually ordered outside of an order set (for example, through the order catalog).	X	
9.18				DELETED																
9.19	3.1.10	IF	9. Order Sets	The system shall provide the ability to repeat the entire order set for the same patient.	DC 1.7.3								X				**N**		X	
9.20	3.1.15	IF	9. Order Sets	The system shall apply the same order checking decision support to orders placed through an order set as orders written individually.	MH CPOE Initiative	H	H	M	L	H	H	X			**N**				X	

FUNCTIONALITY Criteria
For 2007 Certification of Inpatient EHRs
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9.21	3.1.11 3.2.1	IF	9. Order Sets	The system shall provide the ability for a clinician to save frequently used hospital order sets ("favorites") to facilitate retrieval and ordering.	DC 1.7.3											N		Comment: This is simply saving a "pointer" to a hospital order set in a clinician's favorites - not to modify and save an order set. For example, the ordering clinician is an orthopedic surgeon and uses the post-op ORIF order set on a large majority of his admissions, so if he has this order set on his "favorite list" then he has easy access and retrieval of this order set.	X	
9.22	3.1.7	IF	9. Order Sets	The system shall provide the ability to display orders placed through an order set individually or as a group.	DC 1.7.3											N		For example, when discontinuing orders.	X	
9.23	New	IF	9. Order Sets	The system shall provide the ability to obtain reports regarding the use of order sets.												N		For example, the use of CHF order sets and can go down to the department and / or the physician level. This criterion requires that the system can report on a specific order set (for example, usage, defined patient population with a specific diagnosis, or the ability to set specific search conditions).	X	
10.01	3.7.24	IF	10. Ordering: Medication Orders Create and use medication orders that are complete and actionable.	The system shall allow the hospital to permit ordering of uncoded or nonformulary medications.	CCHIT Amb Criteria	H	L	L	L	M	L	X			N			Non-formulary order can be entered as free-text.	X	
10.02	3.7.43	IF	10. Ordering: Medication Orders	The system shall provide the ability to spell out UNITS, use Thousands and Millions as part of expressing large doses and allow the use of commas in doses expressed in thousands in dosage fields in medication orders.	JCAHO Patient Safety Standards	H	L	L	M	M	H			X		N			X	
10.03a	New	IF	10. Ordering: Medication Orders	The system shall provide the ability to allow the clinician to order medication doses in mg/kg and mL/kg.											N				X	
10.03b	New	IF	10. Ordering: Medication Orders	The system shall provide the ability to allow the clinician to order medication doses in mg/kg/min, microgram/kg, and microgram/kg/min.												N			X	
10.04	3.7.8	IF	10. Ordering: Medication Orders	The system shall provide the ability to maintain a coded list of medications including a unique identifier for each medication.	CCHIT Amb Criteria	L	H	H	L	L	L	X			N				X	
10.05	3.7.7	IF	10. Ordering: Medication Orders	The system shall provide clinicians with the ability to search for medications by either generic or brand name or alternate names.	DC.1.7.1	H	L	L	L	M	M		X		N				X	
10.06	3.7.12	IF	10. Ordering: Medication Orders	The system shall provide clinicians with the ability to select a drug by therapeutic class.	DC.1.7.1	H	L	H	M	M	M			X		N			X	
10.07	3.5.16 3.7.13 3.7.16	IF	10. Ordering: Medication Orders	The system shall provide the ability to ~~sort for~~ select order details including strength, route, frequency and comments by the ordering clinician.													N		X	
10.08	3.7.15	IF	10. Ordering: Medication Orders	The system shall provide the ability to renew an existing medication order without requiring re-entry of order information.	DC.1.7.1	H	M	M	M	M	M	X			N				X	

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10.09	**3.7.34**	IF	10. Ordering: Medication Orders	The system shall provide the ability for order entry of medications that are brought in from home that the Pharmacy is not dispensing.												**N**			X	
10.10	**New**	IF	10. Ordering: Medication Orders	The system shall provide the ability to document complex medication orders that include dosing based on either physical status or laboratory values.												**N**		For example, antihypertensive dosing based on blood pressure and heparin dosing based on PTT. Another example of a complex medication order can be a taper order changing the dose over so many days.	X	
10.11	**New**	IF	10. Ordering: Medication Orders	The system shall provide the ability for entry of all order components and details for complex medication orders that include dosing adjustments and limits.												**N**		For example, taper dosing and titrating dose, patient-controlled analgesics.	X	
10.12	**4.2.24**	IF	10. Ordering: Medication Orders	The system shall provide the ability to view the electronic medication administration record without interrupting the ordering process.												**N**			X	
10.13	**4.2.23**	IF	10. Ordering: Medication Orders	The system shall provide the ability to view medication administration response at time of ordering.													**N**	For example, medication administration response can include documentation that views temperatures associated with the administration of Tylenol, or finger sticks and insulin administered.	X	
10.14	**4.3.10**	IF	10. Ordering: Medication Orders	The system shall provide the ability for the clinician to indicate the reason for discontinuing a medication.												**N**		For example, ineffective medication.	X	
10.15	**3.7.37**	IF	10. Ordering: Medication Orders	The system shall provide the ability to modify medication orders including dosing information without having to discontinue the order.		H	L	L	L	L	L			X		**N**			X	
10.16	**New**	IF	10. Ordering: Medication Orders	The system shall have the ability to allow clinician (or hospital by policy) to designate orders that require co-signature before activation.												**N**		For example, chemotherapy orders require two signatures.	X	
10.17	**New**	IF	10. Ordering: Medication Orders	The system shall provide the ability to enter medication orders utilizing a sliding scale as determined by hospital policy.											**N**				X	
11.01	**2.12.1 2.12.2 3.7.36**	IF	11. Medication Reconciliation Medication reconciliation is a process that requires the clinician to review a patient's prior medications when considering new orders at admission and each change in level of care (i.e., to surgery, to ICU, to step-down unit, at discharge). At discharge, medication reconciliation includes reviewing the "home medications" documented at admission, as the clinician considers the discharge medications and communicating the complete list of discharge medications to the next provider of care (i.e., PCP, nursing home).	The system shall provide the ability to enter a list of home medications including over-the-counter, vitamin, herbal, and other non-prescription medications.	JCAHO 2005 Hospitals' National Patient Safety Goals & Requirements; Goal: Accurately and completely reconcile medications across the continuum of care. Whittington J, Cohen H. OSF Healthcare's journey in patient safety. Quality Management in Health Care. 2004;13(1):53-59.										**N**			For coding standards refer to Inpatient Interoperability Criteria and Roadmap. This is not a structured list in 2007.	X	

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11.02	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	The system shall provide the ability to allow the designation of the source of information on home medications.											N			For example, patient, family, pharmacy, physician.	X	
11.03	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	The system shall provide the ability to accept information on patient home medications from an external source.												N		For coding standards refer to Inpatient Interoperability Criteria and Roadmap.	X	
11.04	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	The system shall provide the ability to accept information on patient allergies from an external source.												N		External source can be EHR, RHIO, or NHIN.	X	
11.05	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	The system shall provide the ability to accept information on patient home medications from prescription network intermediary.												N		For coding standards refer to Inpatient Interoperability Criteria and Roadmap.	X	
11.06	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	The system shall provide the ability to display home medications for provider review for medication reconciliation during writing of admission orders.												N			X	
11.07	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	At admission and discharge from the hospital, the system shall provide the ability to permit the clinician to designate which home medications are being continued / discontinued.												N			X	
11.08	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	At admission, the system shall proivde the ability to display corresponding inpatient orders for home medications the provider designates as being continued.													N		X	
11.09	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	At each change in level of care (to ICU, to surgery, discharge), the system shall display prior medication orders for provider review during writing of admission/transfer orders.												N			X	
11.10	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	At discharge and each change in level of care, the system shall provide the ability to designate which current medications are being continued / discontinued.												N			X	
11.11	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	At each change in level of care, the system shall provide the ability to display corresponding inpatient orders for medications the provider designates as being continued.													N		X	
11.12	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	At admission, discharge, and each change in level of care during the hospital stay, the system shall capture provider signature that medication reconciliation has been completed.												N			X	
11.13	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	At admission, discharge, and each change in level of care, the system shall provide the ability to retain the history of medication reconciliation for subsequent review.												N		Comment: prior medications reviewed, medications continued/discontinued, new medication orders, provider signature	X	
11.14	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	At discharge, the system shall provide the ability to communicate discharge medications and allergies to the next provider of care.												N			X	

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11.15	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	At discharge, the system shall provide the ability to communicate current weight to the next provider of care.												N		Weight is critical for pediatric patients.	X	
11.16	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	The system shall provide the ability to communicate the new medication list to appropriate providers (to the next provider of care).												N		This can pertain to a patient being transferred to another facility of care.	X	
11.17	2.12.1 2.12.2 3.7.36	IF	11. Medication Reconciliation	The system shall provide the ability to provide and print a complete list of current medications at the time of patient discharge.												N			X	
12.01	5.3.1	IF	12. Decision Support for Medication and Immunization Orders Provide knowledge-based assistance during medication ordering to improve medication safety and appropriateness (i.e., drug:drug interaction checking, dosing recommendations, allergy interactions, etc.)	The system shall provide the ability to detect a drug dose that exceeds the min-max range for a single dose for the medication and to inform the clinician during ordering.	DC.2.3.1.2	M	M	M	M	M	M		X		N			During testing, it is assumed that vendors will be employing a drug reference knowledge base. Patient age group (adult, pediatrics).	X	
12.02	3.7.10	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to detect a daily dose that exceeds the recommended range and inform the clinician during ordering.												N		Patient age group (adult, pediatrics)	X	
12.03a	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to detect a cumulative dose that exceeds the recommended daily dose and inform the clinician during ordering.											N				X	
12.03b	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to detect a cumulative dose (across inpatient stays and lifetime) that exceeds the recommended dose and inform the clinician during ordering.													N		X	
12.04	3.7.19 3.7.22	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide guidance during ordering for medications requiring age and weight-based dosing.													N	Suggested dose or dose calculator	X	
12.05	3.7.20	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide guidance during ordering for medications that require consideration of laboratory test results for dosing.													N	Suggested dose or dose calculator	X	
12.06	New	IF	12. Decision Support for Medication and Immunization Orders	For medications requiring age and weight-based dosing, the system shall provide the ability to check for inappropriate dosing and inform the clinician during ordering.													N	For example, renal dosing	X	
12.07	3.7.19	IF	12. Decision Support for Medication and Immunization Orders	For medications requiring dosing based on body surface area, the system shall provide the ability to check for inappropriate dosing and inform the clinician during ordering.													N		X	
12.08	4.3.9	IF	12. Decision Support for Medication and Immunization Orders	For medications that require consideration of laboratory test results in dosing, the system shall check for inappropriate dosing and inform the clinician during ordering.													N	Suggested dose or dose calculator	X	

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12.09	4.3.9	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability for informing the clinician that the medication selected for ordering will impact laboratory results.													N		X	
12.10	3.7.44	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to search from medication lists which use “Tall Man” letters.											N			For example, DOBUTamine and DOPamine.	X	
12.11	5.3.2	IF	12. Decision Support for Medication and Immunization Orders	For medications requiring consideration of laboratory test results in dosing, the system shall provide the ability to notify the clinician responsible for the patient’s care when changes in test results require that the dose be reconsidered.													N		X	
12.12	3.7.21	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to check for drug-drug interactions and inform the clinician during ordering.											N				X	
12.13	3.7.21	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to check for therapeutic ~~overlap~~ duplicate and inform the clinician during ordering.											N				X	
12.14	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability for the hospital to exclude therapeutic categories and drug pairs from drug-drug interaction and therapeutic overlap checking.													N	To reduce “alert fatigue”	X	
12.15	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the hospital with the ability to assign the level of medication checking based upon user role or user department or specialty.													N	For example, Anesthesia does not get alerts for combining analgesics but a hospitalist would.	X	
12.16	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to suppress repeat alerting for the same patient, same ordering clinician, and same medication.													N	To reduce “alert fatigue”	X	
12.17	3.7.21 3.15 4.3.64	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to check for coded drug allergies and inform the clinician during ordering.											N				X	
12.18	4.3.15	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to check all current medication orders for contraindications when a new allergy is documented for the patient.													N		X	
12.19	3.7.40	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability for the hospital to require the documentation of allergy information inclusive of using such terms as Unknown, before entering medication orders.											N				X	
12.20	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to check immunization orders against documented patient allergies (medication and non-medication) and inform the clinician during ordering.												N			X	
12.21	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability for the hospital to require documentation of information regarding patient weight inclusive of using such terms as Unknown before entering medication orders.												N			X	
12.22	4.3.8	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to inform the clinician about drug-food advisories.												N		For example, Lipitor ® (atorvastatin calcium)and grapefruit.	X	

FUNCTIONALITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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12.23	4.3.12	IF	12. Decision Support for Medication and Immunization Orders	This system shall provide the ability to check for drug-diagnosis contraindications and inform the clinician during ordering													N	Clinical problem / diagnosis from inpatient problem list.	X	
12.24	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to check for contraindications based on patient age and inform the clinician during ordering.													N		X	
12.25	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to check for contraindications based on laboratory test results and inform the clinician during ordering.													N	For example, creatinine, potassium	X	
12.26	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to check for inappropriate route of administration.													N	Will require codified script.	X	
12.27	5.2.2	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to display recommended medication for substitution (based on cost or clinical policy).												N			X	
12.28	4.3.13	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to allow a clinician to request that all available medication screening for allergies, drug:drug interactions, and other contraindications, be performed on medications being considered for ordering.													N		X	
12.29	4.3.14	IF	12. Decision Support for Medication and Immunization Orders	The system shall allow the hospital to provide the rationale for alerts or messages generated during medication ordering.											N				X	
12.30	4.3.7	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to require a clinician to enter a structured response to override a drug-interaction alert and include as part of the legal medical record.											N			Acknowledgement or coded explanation.	X	
12.31	5.3.6	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to transmit to Pharmacy the order override justification with the order and clinician, date, and time.													N		X	
12.32	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability for report generation capabilities to easily review override data.												N			X	
12.33	4.3.3	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to capture information concerning clinician notifications following screening of medication orders and the response (place, modify or cancel order).												N		User, time and date stamp, specific notification, response	X	
12.34	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to obtain reports concerning medication alerting and provider response, including date and time.												N		Needed for CDS management. The intent of this criterion is for all provider responses be captured and reported. For example, no change to order, order changed, and order cancelled.	X	
12.35	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to prevent the completion of medication orders with specific screening rules.													N	For example, hard stops.	X	
12.36	3.7.26	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability to update drug knowledge databases.											N			This criterion means incorporating updates to drug knowledge databases into the system.	X	
12.37	New	IF	12. Decision Support for Medication and Immunization Orders	The system shall provide the ability for the system to inform the clinician when immunizations are recommended according to the CDC schedule.													N		X	

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13.01	3.5.11	IF	13. General Clinical Decision Support Clinical decision support to provide care in accordance with standards established by the hospital	The system shall provide the ability to display relevant, patient-specific laboratory test results when entering an order.												N		For example, creatinine clearance while ordering an Intravenous Pyelogram.	X	
13.02	3.5.12 3.7.33	IF	13. General Clinical Decision Support	The system shall provide the ability to display for selection a secondary order that is recommended in conjunction with the primary order.												N		For example, NPO for an endoscopy procedure or blood level for medication that requires monitoring to adjust dosing.	X	
13.03	New	IF	13. General Clinical Decision Support	The system shall provide the ability to establish rules for identifying patients with potential gaps in standards-based care.												N		For example, demographics, problem, laboratory test result, presence or absence of medication order.	X	
13.04	New	IF	13. General Clinical Decision Support	The system shall provide the ability to update rules for identifying patients with potential gaps in standards-based care.												N			X	
13.05	New	IF	13. General Clinical Decision Support	The system shall provide the ability to generate clinical messages/reminders to clinicians responsible for the patient's care based on rules.												N		Mechanism (e-mail, pop-up) is not specified (e.g., patient with AMI has no order for Beta blocker; patient on IV antibiotics now on regular diet; suggestion to consider clinical indications or alternate treatment)	X	
13.06	CCHIT Amb Criteria	IF	13. General Clinical Decision Support	The system shall provide the hospital the ability to allow clinicians who trigger rule-based clinical messages to document reason deviation from standard of care.												N		Needed for quality management and external reporting	X	
13.07	New	IF	13. General Clinical Decision Support	The system shall provide the ability to set elapsed time parameters for purposes of duplicate checking.												N		For example, Cannot order CBC within *X* hours of prior CBC order.	X	
13.08	New	IF	13. General Clinical Decision Support	The system shall provide the ability to generate clinical messages/reminders concerning duplicate orders to the clinicians responsible for a patient's care.												N			X	
14.01	4.2.1	IF	14. Medication, Immunization, and Blood Products Administration Administer and document ordered medications, immunizations, and blood products	The system shall provide the ability to present medications to be administered over a selectable date/time range.	DC 1.8.1	H	H	H	H	H	H	X			N			A selectable date / time range in this criterion refers to during a current hospital stay.	X	
14.02	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to view the medication administration history including clinician, date and time.											N				X	
14.03	4.2.2	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display the date and time, route of administration, and dose of all medications.	DC 1.8.1	H	H	H	H	H	H	X			N				X	
14.04	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display the date and time of the last dose administered.											N				X	
14.05	4.2.4 4.2.12a	IF	14. Medication, Immunization, and Blood Products Administration	The system shall allow the clinician to identify and display due and overdue medications.											N			Can use various methods to identify and display the overdue medications. For example, the nurse receives an alert when logging into the system, or on the eMAR the overdue medications are in a different color.	X	

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For 2007 Certification of Inpatient EHRs
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14.06	**4.2.13**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display continuous infusions in a distinguishable manner from other medications that is complete, and visible in one place on the eMAR.											**N**			Method not specified, but for example, highlighting or section breaks.	X	
14.07	**4.2.14**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display PRN medications in a manner that distinguishes them from other medications.											**N**				X	
14.08	**New**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to present a PRN effectiveness list that alerts the clinician to record the effectiveness of PRN or "as needed" doses after they have been administered.												**N**			X	
14.09	**New**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display medications as dispensed.												**N**		For example, dose is 20 mg, and the Pharmacy sends two 10 mg tablets. The intent is that the clinician sees the total dosage and the quantity of dispensed units.	X	
14.10	**4.2.11**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to indicate any tasks/assessments associated with medication administration.											**N**			For example, assess blood pressure, pain.	X	
14.11	**New**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to attach a comment to an individual scheduled dose and include as part of the legal medical record.												**N**		For example, "Draw blood level with the 4th dose."	X	
14.12	**4.2.3**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to access and review general medication information (such as patient education material or drug monograph) from the eMAR.											**N**				X	
14.13	**4.2.5 5.1.1 5.1.4**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document medication administration including medication name, strength, dose, route, date and time of administration and administrator of the medication.											**N**				X	
14.14	**New**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to view the medication order as written during administration.													**N**	Using industry standard coding in the future.	X	
14.15	**4.2.8**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document clinical assessment pertinent to medication administration.												**N**		Capture pain scale, heart rate, temperature, etc., This may be a free text / comment field. Will consider this criteria to be structured entry in the future.	X	
14.16	**New**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to indicate on the eMAR where the clinician can locate the medication on the unit.													**N**	For example, refrigerator, dispensing machine, or cart.	X	
14.17	**4.2.15**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide ability for a second provider to witness and co-document administration.											**N**			Two signatures	X	
14.18	**New**	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to receive pump settings and start time and end time from an IV Smart Pump for incorporation into documentation.													**N**	For coding standards refer to Inpatient Interoperability Criteria and Roadmap	X	

FUNCTIONALITY Criteria
For 2007 Certification of Inpatient EHRs
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14.19a	6.6.1	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to accurately exchange discrete electronic data with hemodynamic monitoring devices for incorporation into the medication administration record.													N	The intent here is primarily documentation associated with medication administration that can be captured from monitoring devices (e.g., pulse oximeters, physiologic monitors). Different device classes are not included, such as diagnostic devices (e.g., laboratory machines, EKG, diagnostic radiology), treatment devices (ventilators), and product-producing devices (e.g., pharmacy compounding devices). For coding standards refer to Inpatient Interoperability Criteria and Roadmap.	X	
14.19b	4.2.21	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to accurately exchange discrete electronic data with automated dispensing machines for incorporation into the medication administration record.													N		X	
14.20	4.2.12b	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to modify medication administration schedules on the medication administration record.											N			For example, first dose	X	
14.21	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to notify the Pharmacy of changes in schedules on the medication administration record.													N		X	
14.22	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the clinician to acknowledge medication orders prior to administration including date and time.											N			Includes nursing verification of medication orders.	X	
14.23	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the hospital with the ability to allow documentation of medication administration prior to pharmacy review.											N				X	
14.24	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document the actual time and date for STAT medication administration.												N			X	
14.25	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document on the eMAR the clinician administering a respiratory medication and the following items: respiratory medication name, dose, route, and method of delivery.												N			X	
14.26	4.2.16	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide ability for second provider to witness administration and record date/time/dose given by another provider (Chart on behalf of) and include as part of the legal medical record.												N		For example, during a patient emergency	X	
14.27	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the hospital to provide links to reference information / knowledge resources for any medication on the MAR.													N		X	
14.28	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to chart medication not given with reason.											N			For example, patient refused, patient off floor, No IV access.	X	

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14.29	4.2.20	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to amend medication administration documentation and include as part of the legal medical record.											N			For example, wrong patient	X	
14.30a	4.2.22	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide ability to indicate a reaction / response to medication administration.											N				X	
14.30b	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide ability to indicate a reaction / response to vaccination administration.												N			X	
14.31	5.1.5	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to capture discrete immunization administration details, including (1) date of administration; (2) type; (3) manufacturer; (4) lot number; (5) clinician administering the vaccine, and 6) site of injection.												N			X	
14.32	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to produce a Vaccine Information Statement (VIS) to the parent or guardian.													N	Vaccines for Children program and the National Childhood Vaccine Injury Act of 1986.	X	
14.33	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the clinician to document that a Vaccine Information Statement (VIS) was given including the version.													N		X	
14.34	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the documentation of blood and blood component administration on the medication administration record.												N		This does not include the documentation of the transfusion record.	X	
14.35	4.1.4	IF	14. Medication, Immunization, and Blood Products Administration	The system shall maintain and display as part of the medication administration profile the dates and times associated with the medication orders such as start, modify, and stop dates.											N				X	
14.36	New	IF	14. Medication, Immunization, and Blood Products Administration	The medication administration section of the system shall provide the ability to automatically default the date, time, and volume of IV medication and blood products into the Intake / Output portion of the EHR.													N		X	
14.37	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the medication administration record to be printed.											N				X	
15.01a	4.2.6	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration Provide knowledge-based assistance during medication administration to improve medication safety and appropriateness (i.e., "Five Rights" - patient, time and frequency of administration, dose, route of administration, and drug)	The system shall provide the hospital the option to set for re-alerting via the eMAR for allergies at the time of administration.												N		Available types of checking become available in different years, see Medication-Related Clinical Decision Support.	X	
15.01b	New	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the hospital the option to set for re-alerting via the eMAR for potential medication interactions at the time of administration.												N				

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15.02	New	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the ability to indicate medication orders with acknowledged and unacknowledged medication screening alerts during medication administration.													N		X	
15.03	New	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the ability to provide the option to view the medication screening alert history during administration.													N		X	
15.04	5.1.2 5.1.3	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the hospital with the ability to capture medication identification for five rights checking, at a minimum, from linear bar code labels encoding the NDC number.												N			X	
15.05	4.2.9	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document medication administration using a positive ID technology to confirm right patient, right medication, right dose, right time, and right dose.												N			X	
15.06	New	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall have the ability to document "manual" methods verifying Five Rights information (e.g., Bar code does not work; the bar code reader is not working).												N			X	
15.07	New	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the ability to record the medication NDC number or other ID of the drug actually administered to the patient.												N		For example, a subsequent medication recall. This assumes that bar code scanning is being used for medication administration.	X	
16.01	2.6.2	IF	16. Clinical Task Management Assignment, delegation, and escalation of ordering and administration tasks to the appropriate parties or their designees (i.e., orders expiring, orders that need a co-signature, overdue medications, etc.)	The system shall provide the ability to permit an ordering clinician to forward expiring order notifications to another clinician.													N	Sign-out for order management tasks	X	
16.02	New	IF	16. Clinical Task Management	The system shall provide the ability to establish time periods for designating medication administration tasks overdue.												N			X	
16.03	New	IF	16. Clinical Task Management	The system shall provide the ability to establish time periods and recipients for escalation of overdue medication administration tasks.												N			X	
16.04	2.6.3 4.2.19	IF	16. Clinical Task Management	The system shall provide the ability to notify the designated clinician of overdue medication administration tasks.											N				X	
16.05	New	IF	16. Clinical Task Management	The system shall provide the ability to establish time periods for order expiration for types of orders.												N			X	
16.06	2.6.4	IF	16. Clinical Task Management	The system shall provide the ability to notify the ordering clinician concerning orders due to expire.												N			X	
16.07	2.6.4	IF	16. Clinical Task Management	The system shall provide the ability to notify the ordering clinician concerning orders requiring signature (verbal and telephone orders, cosignature).												N		For example, verbal and telephone orders, cosignature.	X	

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17.01	**2.12.1**	IF	17. Capture Patient-Originated Data Capture and explicitly label patient originated data, link the data source with the data, and support provider authentication for inclusion in patient health record.	The system shall provide the ability to capture and explicitly label patient-originated data.	DC.1.1.3.2	M	L	L	L	H	H			X			**N**		X	
17.02	**2.12.2**	IF	17. Capture Patient-Originated Data	The system shall provide the ability to label the data as patient entered when data is entered by the patient.	DC.1.1.3.2	H	L	L	L	H	H			X			**N**		X	
17.03	**2.12.3**	IF	17. Capture Patient-Originated Data	The system shall provide the ability to capture and label the source of clinical data provided on behalf of the patient.	DC.1.1.3.2	H	L	L	L	H	H			X			**N**		X	
17.04	**2.12.4**	IF	17. Capture Patient-Originated Data	The system shall provide the ability to present patient-originated data for use by care providers.	DC.1.1.3.2	H	L	L	L	H	H			X			**N**		X	
17.05	**2.12.5**	IF	17. Capture Patient-Originated Data	The system shall provide the ability for a provider to verify the accuracy of patient-originated data for inclusion in the patient record.	DC.1.1.3.2	H	M	L	L	H	H			X			**N**		X	
17.06	**2.12.6**	IF	17. Capture Patient-Originated Data	The system shall provide the ability to view or comment, but not alter patient-originated data.	DC.1.1.3.2	H	M	L	L	H	H			X			**N**		X	
18.01	**2.15.1**	IF	18. Health Record Management Support the creation of legal documentation needed for the inpatient electronic medical record	The system shall provide the ability to view patient data from previous admissions.	S.3.1.5	H	H	H	H	H	H	X			**N**			For eMAR only, the intent is to view medication administration record from previous admissions. The intent of this criterion is within the same setting, within the scope of the applications/system.	X	
18.02	**1.4.2**	IF	18. Health Record Management	The system shall provide the ability to include patient identifying information as well as time and date report printed, on each page of individual patient-specific reports generated.	S.2.2.1							X			**N**				X	
18.03	**1.6.1 2.2.1 2.2.2 2.3.1 2.16.1**	IF	18. Health Record Management	The system shall provide the ability to create paper copies of order- and medication-administration-related medical record elements.								X			**N**			Comprehensive order list and medication administration record	X	
18.04	**1.5.1 2.2.3 2.3.5**	IF	18. Health Record Management	The system shall provide the ability to view the complete order and medication administration history.								X			**N**				X	

FUNCTIONALITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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Test Configuration 2 is designed to make certification available for vendors whose product suite addresses electronic medication administration, but not clinician electronic order writing and medication reconciliation. The criteria below will be included in the certification process for addressing Test Configuration 2.																				
1.01	New	IF	1. Patient Demographics and Administrative Information Provide patient demographics (i.e., name, age, date of birth, and gender) and administrative information (i.e., bed assignment) needed for CPOE and eMAR.	The system shall provide the ability to access demographic information needed for clinician ordering, verification and medication administration.	CCHIT Amb Criteria										**N**			For example, name, age, date of birth, and gender.		X
1.02	1.3.3	IF	1. Patient Demographics and Administrative Information	The system shall provide the ability to query a patient by alternate forms of identification.	S.1.4.2										**N**			The choice of alternate forms of identification is flexible, and there can be more than one. For example, first name, date of birth, social security number, or medical record number.		
1.03	1.2.1	IF	1. Patient Demographics and Administrative Information	The system shall provide the ability to access bed assignment information including temporary bed assignment.	S 1.4.4										**N**			For example, holding area, triage, etc.		X
1.04	1.3.1	IF	1. Patient Demographics and Administrative Information	The system shall provide the ability to identify the patient's current location within the hospital.	S.1.4.2												**N**	For example, the patient is in Radiology or Physical Therapy.		X
1.05	New		1. Patient Demographics and Administrative Information	The system shall have the ability to record the time of birth.													**N**			X
2.01	1.7.1	IF	2. Provider Information Manage information about providers and care teams / groups for the provision of care	The system shall provide the ability to uniquely identify clinicians for the provision of care.	S.1.3.7										**N**			The intent of the criterion is to access the directory of users and review user attributes required to determine the system security level to be granted to each user.		X
2.02	1.8.3 2.7.5	IF	2. Provider Information	The system shall provide the ability to identify all clinicians who have been associated with care for a specific patient.	S.1.3.5 S.3.4	H	H	H	H	H	M	X				**N**				X
2.03	1.8.1	IF	2. Provider Information	The system shall provide the ability to assign clinicians to appropriate teams, where teams are defined as groups of clinicians who share responsibility for covering the same group of patients.	S.1.3.5	H	M	H	H	M	M			X		**N**				X
3.01	2.7.1	IF	3. Patient List Management Provide clinicians access to lists of their patients.	The system shall provide the ability to view a clinician's inpatient list information and sort by various criteria.	S.1.3.6										**N**			For 2007, criterion 3.01, clinicians refer to a physician in this criterion. In future years, the criteria will be expanded to include other clinicians.		X
3.02	New	IF	3. Patient List Management	The system shall provide the ability to add, update, and remove patients from a clinician's patient list.												**N**				X
3.03	New	IF	3. Patient List Management	The system shall provide the ability for the clinician to create a custom list of patients.													**N**			X
3.04	2.7.3	IF	3. Patient List Management	The system shall provide the ability to identify all clinicians by name associated with a specific patient stay and to correct erroneous assignments of clinicians.	S.3.4												**N**			X
3.05	2.7.8	IF	3. Patient List Management	The system shall provide the ability to specify the principle caregivers responsible for the care of a patient within the hospital.	S.3.4										**N**			Principle caregivers, for example, refer to the attending physician and / or nurse.		X

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4.02	2.4.1	IF	4. Problem Lists	The system shall provide the ability to display different views of the problem / diagnosis list.	DC 1.4.3									X			**N**	For example, active, all, or resolved.		X
5.01	2.9.1	IF	5. Allergy Information Create and maintain patient specific allergy information (i.e., allergens, reaction, level of severity).	The system shall provide the ability to document medications which the patient has had an allergic reaction.	DC 1.4.1	H	H	L	L	H	M	X			**N**					X
5.02	2.9.2	IF	5. Allergy Information	The system shall provide the ability to capture non-drug agents to which the patient has had an allergic reaction.	DC 1.4.1	H	H	L	L	H	M	X			**N**			For example, tape, latex, and peanuts.		X
5.03	2.9.8	IF	5. Allergy Information	The system shall provide the ability to capture the source of the allergy information.	DC 1.4.1	H	H	L	L	H	M	X				**N**		For example, patient, mother, or medic alert bracelet.		X
5.04	2.9.4	IF	5. Allergy Information	The system shall provide the ability to specify the type of allergic reaction.	DC 1.4.1	H	H	L	L	H	M	X			**N**			For example, anaphylaxis, allergic asthma, or itching.		X
5.05	2.9.5	IF	5. Allergy Information	The system shall provide the ability to capture the severity of a reaction.	DC 1.4.1	H	M	L	L	H	L		X		**N**					X
5.06	2.9.6	IF	5. Allergy Information	The system shall provide the ability to explicitly indicate that a patient has "No Known Drug Allergies" or "No Known Allergies."	DC 1.4.1	H	H	L	L	H	M	X			**N**					X
5.07	2.9.7	IF	5. Allergy Information	The system shall provide the ability to indicate that the allergies are "Unknown" or "Unable to Assess Allergies."		H	H	L	L	H	M	X			**N**					X
5.08	2.9.7	IF	5. Allergy Information	If allergies are "Unknown" or "Unable to Assess Allergies," the system shall provide the ability to require a reason to be documented.		H	H	L	L	H	M	X				**N**		For example, patient unconscious, patient does not know.		X
5.09	New	IF	5. Allergy Information	When allergies are "Unknown" or "Unable to Assess Allergies," the system shall provide the ability to inform the clinician for the need of an update.		H	H	L	L	H	M	X					**N**			X
5.10	New	IF	5. Allergy Information	The system shall provide the ability to capture clinician name or logon identification, date, and time when allergy information is re-verified.											**N**					X
5.11	2.9.9	IF	5. Allergy Information	The system shall provide the ability to modify an item from the allergy list.	DC 1.4.1	H	H	L	L	H	M	X			**N**			For example, inactivate an allergy.		X
5.12	2.9.10	IF	5. Allergy Information	The system shall provide the ability to specify the reason for inactivating or modifying an item from the allergy list and capture clinician, date, and time.	DC 1.4.1	H	H	L	L	H	M		X			**N**				
5.13	2.9.12	IF	5. Allergy Information	The system shall provide the ability to display the allergy history, including date and time of entry.												**N**				X
6.01	4.1.1	IF	6. Medication List Create and maintain patient specific medication lists.	The system shall provide the ability to display patient-specific medication list based on medication orders.	DC 1.4.2	H	M	M	M	H	H	X			**N**					X
6.02	New	IF	6. Medication List	When the display of the medication list exceeds the current screen or printed page, the system shall indicate that the list continues via scrolling, or on following pages or screens.												**N**		For example, Page one of two, End of report.		X
6.03	4.1.3	IF	6. Medication List	The system shall provide the ability to view the name of the ordering clinician, medication order (name, dose, route, and frequency), a start date and time, and a stop date and time for entries on the medication list.	DC 1.4.2	H	H	H	H	H	H	X			**N**					X

FUNCTIONALITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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6.04	4.1.5	IF	6. Medication List	The system shall provide the ability to add start date and dose information for non-prescription medications on a patient-specific medication list, including over the counter medications such as vitamins, herbs and supplements.	DC 1.4.2											N				X
6.05	4.1.6	IF	6. Medication List	The system shall provide the ability to display different views of the patient's medication list.	DC 1.4.2	H	H	H	L	H	H	X			N			For example, current, all, PRN, scheduled, and one time.		X
6.06		IF	6. Medication List	The system shall provide the ability to discontinue a medication from the current medication list.											N					X
6.07	4.1.2 4.1.9	IF	6. Medication List	The system shall provide the ability to print a current medication list.		L	L	L	L	L	L			X	N					X
6.08	4.1.11	IF	6. Medication List	The system shall provide the ability to display that the patient takes no medications on the preadmission medication list.												N				X
6.09	New	IF	6. Medication List	The system shall provide the ability to display on the medication list the medications that the patient brings from home which the Pharmacy would not dispense.	JCAHO Pt Safety Standard	H	L	M	M	H	M		X			N		For example, the patient brings in their medication from home.		X
6.10	3.7.6	IF	6. Medication List	The system shall provide the ability to update the medication list with new medication orders, start and end date and time, and pharmacy verification status.	DC.1.7.1	H	H	H	H	H	H	X			N			For coding standards refer to Inpatient Interoperability Criteria and Roadmap.		X
6.11	New	IF	6. Medication List	The system shall provide the ability to update the medication list with changes from pharmacist verification including pharmacist date and time.												N				X
7.02	2.8	IF	7. Results Access and View	The system shall provide the ability to view test results during medication administration.	DC.1.8.3	H	M	M	M	H	H		X		N					X
13.03	New	IF	13. General Clinical Decision Support	The system shall provide the ability to establish rules for identifying patients with potential gaps in standards-based care.												N		For example, demographics, problem, laboratory test result, presence or absence of medication order.		X
13.04	New	IF	13. General Clinical Decision Support	The system shall provide the ability to update rules for identifying patients with potential gaps in standards-based care.												N				X
13.05	New	IF	13. General Clinical Decision Support	The system shall provide the ability to generate clinical messages/reminders to clinicians responsible for the patient's care based on rules.												N		Mechanism (e-mail, pop-up) is not specified (e.g., patient with AMI has no order for Beta blocker; patient on IV antibiotics now on regular diet; suggestion to consider clinical indications or alternate treatment)		X
13.06	CCHIT Amb Criteria	IF	13. General Clinical Decision Support	The system shall provide the hospital the ability to allow clinicians who trigger rule-based clinical messages to document reason deviation from standard of care.												N		Needed for quality management and external reporting		X
14.01	4.2.1	IF	14. Medication, Immunization, and Blood Products Administration Administer and document ordered medications, immunizations, and blood products	The system shall provide the ability to present medications to be administered over a selectable date/time range.	DC 1.8.1	H	H	H	H	H	H	X			N			A selectable date / time range in this criterion refers to during a current hospital stay.		X
14.02	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to view the medication administration history including clinician, date and time.											N					X

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14.03	4.2.2	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display the date and time, route of administration, and dose of all medications.	DC 1.8.1	H	H	H	H	H	H	X			N					X
14.04	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display the date and time of the last dose administered.											N					X
14.05	4.2.4 4.2.12a	IF	14. Medication, Immunization, and Blood Products Administration	The system shall allow the clinician to identify and display due and overdue medications.											N			Can use various methods to identify and display the overdue medications. For example, the nurse receives an alert when logging into the system, or on the eMAR the overdue medications are in a different color.		X
14.06	4.2.13	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display continuous infusions in a distinguishable manner from other medications that is complete, and visible in one place on the eMAR.											N			Method not specified, but for example, highlighting or section breaks.		X
14.07	4.2.14	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display PRN medications in a manner that distinguishes them from other medications.											N					X
14.08	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to present a PRN effectiveness list that alerts the clinician to record the effectiveness of PRN or "as needed" doses after they have been administered.												N				X
14.09	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to display medications as dispensed.												N		For example, dose is 20 mg, and the Pharmacy sends two 10 mg tablets. The intent is that the clinician sees the total dosage and the quantity of dispensed units.		X
14.10	4.2.11	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to indicate any tasks/assessments associated with medication administration.											N			For example, assess blood pressure, pain.		X
14.11	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to attach a comment to an individual scheduled dose and include as part of the legal medical record.												N		For example, "Draw blood level with the 4th dose."		X
14.12	4.2.3	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to access and review general medication information (such as patient education material or drug monograph) from the eMAR.											N					X
14.13	4.2.5 5.1.1 5.1.4	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document medication administration including medication name, strength, dose, route, date and time of administration and administrator of the medication.											N					X
14.14	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to view the medication order as written during administration.													N	Using industry standard coding in the future.		X
14.15	4.2.8	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document clinical assessment pertinent to medication administration.												N		Capture pain scale, heart rate, temperature, etc., This may be a free text / comment field. Will consider this criteria to be structured entry in the future.		X
14.16	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to indicate on the eMAR where the clinician can locate the medication on the unit.													N	For example, refrigerator, dispensing machine, or cart.		X

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14.17	4.2.15	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide ability for a second provider to witness and co-document administration.											N			Two signatures		X
14.18	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to receive pump settings and start time and end time from an IV Smart Pump for incorporation into documentation.													N	For coding standards refer to Inpatient Interoperability Criteria and Roadmap		X
14.19a	6.6.1	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to accurately exchange discrete electronic data with hemodynamic monitoring devices for incorporation into the medication administration record.													N	The intent here is primarily documentation associated with medication administration that can be captured from monitoring devices (e.g., pulse oximeters, physiologic monitors). Different device classes are not included, such as diagnostic devices (e.g., laboratory machines, EKG, diagnostic radiology), treatment devices (ventilators), and product-producing devices (e.g., pharmacy compounding devices). For coding standards refer to Inpatient Interoperability Criteria and Roadmap.		X
14.19b	4.2.21	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to accurately exchange discrete electronic data with automated dispensing machines for incorporation into the medication administration record.													N			X
14.20	4.2.12b	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to modify medication administration schedules on the medication administration record.											N			For example, first dose		X
14.21	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to notify the Pharmacy of changes in schedules on the medication administration record.													N			X
14.22	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the clinician to acknowledge medication orders prior to administration including date and time.											N			Includes nursing verification of medication orders.		X
14.23	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the hospital with the ability to allow documentation of medication administration prior to pharmacy review.											N					X
14.24	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document the actual time and date for STAT medication administration.												N				X
14.25	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document on the eMAR the clinician administering a respiratory medication and the following items: respiratory medication name, dose, route, and method of delivery.												N				X
14.26	4.2.16	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide ability for second provider to witness administration and record date/time/dose given by another provider (Chart on behalf of) and include as part of the legal medical record.												N		For example, during a patient emergency		X

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14.27	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the hospital to provide links to reference information / knowledge resources for any medication on the MAR.													N			X
14.28	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to chart medication not given with reason.											N			For example, patient refused, patient off floor, No IV access.		X
14.29	4.2.20	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to amend medication administration documentation and include as part of the legal medical record.											N			For example, wrong patient		X
14.30a	4.2.22	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide ability to indicate a reaction / response to medication administration.											N					X
14.30b	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide ability to indicate a reaction / response to vaccination administration.												N				X
14.31	5.1.5	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to capture discrete immunization administration details, including (1) date of administration; (2) type; (3) manufacturer; (4) lot number; (5) clinician administering the vaccine, and 6) site of injection.												N				X
14.32	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability to produce a Vaccine Information Statement (VIS) to the parent or guardian.													N	Vaccines for Children program and the National Childhood Vaccine Injury Act of 1986.		X
14.33	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the clinician to document that a Vaccine Information Statement (VIS) was given including the version.													N			X
14.34	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the documentation of blood and blood component administration on the medication administration record.												N		This does not include the documentation of the transfusion record.		X
14.35	4.1.4	IF	14. Medication, Immunization, and Blood Products Administration	The system shall maintain and display as part of the medication administration profile the dates and times associated with the medication orders such as start, modify, and stop dates.											N					X
14.36	New	IF	14. Medication, Immunization, and Blood Products Administration	The medication administration section of the system shall provide the ability to automatically default the date, time, and volume of IV medication and blood products into the Intake / Output portion of the EHR.													N			X
14.37	New	IF	14. Medication, Immunization, and Blood Products Administration	The system shall provide the ability for the medication administration record to be printed.											N					X
15.03	New	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the ability to provide the option to view the medication screening alert history during administration.													N			X
15.04	5.1.2 5.1.3	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the hospital with the option to capture medication identification for five rights checking, at a minimum, from linear bar code labels encoding the NDC number.												N				X
15.05	4.2.9	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the ability to document medication administration using a positive ID technology to confirm right patient, right medication, right dose, right time, and right dose.												N				X

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15.06	**New**	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall have the ability to document "manual" methods verifying Five Rights information (e.g., Bar code does not work; the bar code reader is not working).												**N**				X
15.07	**New**	IF	15. Decision Support for Medication, Immunization, and Blood Products Administration	The system shall provide the ability to record the medication NDC number or other ID of the drug actually administered to the patient.												**N**		For example, a subsequent medication recall. This assumes that bar code scanning is being used for medication administration.		X
16.02	**New**	IF	16. Clinical Task Management	The system shall provide the ability to establish time periods for designating medication administration tasks overdue.												**N**				X
16.03	**New**	IF	16. Clinical Task Management	The system shall provide the ability to establish time periods and recipients for escalation of overdue medication administration tasks.												**N**				X
16.04	**2.6.3** **4.2.19**	IF	16. Clinical Task Management	The system shall provide the ability to notify the designated clinician of overdue medication administration tasks.											**N**					X
18.01	**2.15.1**	IF	18. Health Record Management Support the creation of legal documentation needed for the inpatient electronic medical record	The system shall provide the ability to view patient data from previous admissions.	S.3.1.5	H	H	H	H	H	H	X			**N**			For eMAR only, the intent is to view medication administration record from previous admissions. The intent of this criterion is within the same setting, within the scope of the applications/system.		X
18.02	**1.4.2**	IF	18. Health Record Management	The system shall provide the ability to include patient identifying information as well as time and date report printed, on each page of individual patient-specific reports generated.	S.2.2.1							X			**N**					X
18.03	**1.6.1** **2.2.1** **2.2.2** **2.3.1** **2.16.1**	IF	18. Health Record Management	The system shall provide the ability to create paper copies of order- and medication-administration-related medical record elements.								X			**N**			Comprehensive order list and medication administration record		X
18.04	**1.5.1** **2.2.3** **2.3.5**	IF	18. Health Record Management	The system shall provide the ability to view the complete order and medication administration history.								X			**N**					X

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II-01	**Admission into Inpatient Care Setting - Medication History**	Receive Current Medication List ("patient home medications") from Pharmacy (directly), PBM (directly) or via intermediary network (e.g. SureScripts, RxHub, etc.)	NCPDP Script 8.1 (RXHREQ, RXHRES) for Current Medication List (2008) Use of RxNorm for clinical drug terminology (2009)		N	M	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.05 The system shall provide the ability to accept information on patient home medications from prescription network intermediary. (2008 - display; 2009 codified)
II-02		Receive Current Medication List ("patient home medications") from outpatient documentation sources (e.g., Physicians office EMR) or RHIO/network	HL7/ASTM CCD for Current Medication List (2008) Use of RxNorm for clinical drug terminology (2009)		N	M	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.03 The system shall provide the ability to accept information on patient home medications from an external source. (2008 - display; 2009 codified)
II-03		Receive Current Medication List ("patient home medications") from Health Plans	TBD			N	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.03 The system shall provide the ability to accept information on patient home medications from an external source. (2008 - display; 2009 codified)
II-04		Receive / import Current Medication List and Medication History from a PHR	HITSP IS-03 Consumer Empowerment			pilot	HITSP IS-03 CE includes HL7/ASTM CCD and terminology standards in HITSP/ISC-32 Registration and Medication History Document Content Component	X		IF-11.03 The system shall provide the ability to accept information on patient home medications from an external source. (2008 - display; 2009 codified)
II-05		Receive Home Meds, Current Active Medications, and Discharge Medications from other inpatient institution (e.g., Hospital, Nursing home, Rehabilitation center)	TBD for message format Use of RxNorm for clinical drug terminology			N	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.13 At admission, discharge, and each change in level of care, the system shall retain the history of medication reconciliation for subsequent review. (2008 - display; 2009 codified)
II-06		Receive Current Medication List ("patient home medications") and Medication History from other sources (State Medicaid, home health/nursing agencies, public health, etc.) via direct feed or intermediary	TBD for message format Use of RxNorm for clinical drug terminology			N	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.03 The system shall provide the ability to accept information on patient home medications from an external source. (2008 - display; 2009 codified)

INTEROPERABILITY Criteria
For 2007 Certification of Inpatient EHRs
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II-07	**Admission into Inpatient Care Setting - Allergy Information**	Receive Allergy History from Pharmacy (directly), PBM (directly) or via intermediary network (e.g. SureScripts, RxHub, etc.)	NCPDP Script 8.1 with text-based allergy data (2008) Use of allergy vocabulary standards (2009)		N		CCHIT will align with the AHIC Medication Management Use Case development and monitor allergy vocabulary standards such as those specified by HITSP-and the CHI Approved Standards Standards Allergy 2009 certification.	X		IF-11.04 The system shall provide the ability to accept information on patient allergies from an external source. (2008 - display; 2009 codified)
II-08		Receive Allergy History from outpatient documentation sources (e.g., Physician office EMR) or RHIO/network	HL7/ASTM CCD (2008) Use of allergy vocabulary standards (2009)		N		CCHIT will align with the AHIC Medication Management Use Case development and monitor allergy vocabulary standards such as those specified by HITSP-and the CHI Approved Standards Standards for Allergy 2009 certification.	X		IF-11.04 The system shall provide the ability to accept information on patient allergies from an external source. (2008 - display; 2009 codified)
II-09		Receive Allergy History from Health Plans	TBD			N	CCHIT will track allergy coding standards development for migrating towards use of codified allergy data in 2009 and beyond.	X		IF-11.04 The system shall provide the ability to accept information on patient allergies from an external source. (2008 - display; 2009 codified)
II-10		Receive / import Allergy History from a PHR	HITSP IS-03 Consumer Empowerment			pilot		X		IF-11.04 The system shall provide the ability to accept information on patient allergies from an external source. (2008 - display; 2009 codified)

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II-11		Receive Allergy History from other inpatient institution (e.g., Hospital, Nursing home, Rehab Center)	TBD			N	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.04 The system shall provide the ability to accept information on patient allergies from an external source. (2008 - display; 2009 codified)
II-12		Receive Allergy History from other sources (State Medicaid, home health/nursing agencies, public health, etc.) via direct feed or intermediary	TBD			N	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.04 The system shall provide the ability to accept information on patient allergies from an external source. (2008 - display; 2009 codified)
II-13	**Within Inpatient Care Setting - Orders and Medication Administration**	Receive Patient Demographics and Administrative Information from inpatient IT systems (e.g., name, age, dob, gender)	Functional Integration	FI				X	X	IF-1.01The system shall provide the ability to access demographic information (i.e., name, date of birth, gender) needed for clinician ordering and medication administration. (Test Config 1 and 2) IF-8.01 The system shall provide the ability to display patient name, gender and age/date of birth on all order screens. (Test Config 1 only)
II-14		Receive Patient Bed Assignment information from inpatient IT systems (e.g. registration, bed tracking)	Functional Integration	FI				X	X	IF-1.03 The system shall provide the ability to access bed assignment information.
II-15		Receive Patient Location information from inpatient IT systems or patient tracking technologies	Functional Integration			FI		X	X	IF-1.04 The system shall provide the ability to identify the patient's current location within the hospital.
II-16		Utilize a standard nomenclature and coding system for clinician-generated problem lists	Functional Integration			FI	CCHIT will continue to evaluate standards development in this area and use of SNOMED-CT, ICD-9, and ICD-10CM	X	X	IF-4.02 The system shall provide the ability to display different views of the problem/diagnosis list.

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II-17		Receive clinical data pertinent for medication administration (e.g., weight, vital signs, from inpatient IT systems if captured in other systems (e.g., nursing documentation system)	Functional Integration		FI			X	X	IF-14.15 The system shall provide the ability to document clinical assessment pertinent to medication administration. IF-5.13 The system shall provide the ability to display the allergy history, including date and time of entry.
II-18		Send Non-Medication Orders and Updates to receiving system (e.g., LIS, RIS, Dietary)	Functional Integration	FI				X		IF-8.07 The system shall provide the ability for clinicians to write all patient care orders electronically IF-8.08 The system shall provide the ability to renew, activate, suspend, modify, and discontinue orders. IF-8.11 For each type of order, the system shall provide the ability to capture elements required by the receiving discipline or department to deliver the ordered service. IF-8.25 The system shall provide the ability to electronically communicate the order to the receiving departmental system.
II-19		Send Medication Orders and Updates to Pharmacy IT system utilizing a coding system for medications	Functional Integration	FI			CCHIT will align with the AHIC Medication Management Use Case development and monitor clinical drug terminology standards such as RxNorm for future consideration.	X		IF-8.07, IF-8.09, IF-8.11, IF-8.25 IF-10.1 The system shall allow the hospital to permit ordering of uncoded or nonformulary medications. IF-10.3 The system shall provide the ability to maintain a coded list of medications including a unique identifier for each medication.

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II-20		Receive Status Updates from Pharmacy	Functional Integration	FI				X		IF-8.26 The system shall provide the ability to view status information for ordered services.
II-21		Provide access and view capabilities for relevant lab results for medication ordering or administration	Functional Integration	FI			CCHIT will monitor standards for lab data to be used for decision support.	X	X	IF-7.01 The system shall provide the ability to view test results during the ordering process. (Test Config 1 only) IF-7.02 The system shall provide the ability to view test results during medication administration. (Test Config 1 and 2)
II-22		Send medication administration schedule updates to Pharmacy	Functional Integration			FI		X	X	IF-14.21 The system shall provide the ability to notify the Pharmacy of changes in schedules on the medication administration record.
II-23		Integrate with devices such as IV Smart Pumps and hemodynamic monitoring	Functional Integration			FI		X	X	IF-14.18 The system shall provide the ability to receive pump settings and start time from an IV Smart Pump for incorporation into documentation. IF-14-19 The system shall provide the ability to accurately exchange discrete electronic data with hemodynamic monitoring devices for incorporation into the medication administration record.
II-24		Integrate with bar-code technology to capture information from linear bar code labels and wristbands	Functional Integration		FI			X	X	IF-15.04 The system shall provide the hospital with the option to capture medication identification for five rights checking, at a minimum, from linear bar code labels encoding the NDC number.

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II-25		Integrate with other positive ID technology (e.g., RFID) to capture information	Functional Integration			FI		X	X	IF-15.05 The system shall provide the ability to document medication administration using a positive ID technology to confirm right patient, right medication, right dose, right time, and right dose.
II-26	**Discharge from Inpatient Care Setting or Transfer to Other Health Care Facility - Medications and Allergies**	Send an electronic prescription of discharge medications and allergies to Pharmacy (directly), PBM (directly), or via intermediary network (e.g., SureScripts, RxHub)	NCPDP Script 8.1 (NEWRX) Use of allergy vocabulary standards			N	CCHIT will align with AHIC Medication Management Use Case development and monitor allergy vocabulary standards such as those specified by HITSP for CE and the CHI Approved Standards Standards for Allergy for 2009 certification.	X		No current corresponding inpatient functionality criteria -- will coordinate with IFWG.
II-27		Send Current Medication List and Discharge Medications ("patient home medications" and "medications prescribed upon discharge") and Allergies to outpatient documentation sources (e.g., Physicians office EMR), or RHIO/network	HL7/ASTM CCD (2008) Use of RxNorm for clinical drug terminology (2009) Use of allergy vocabulary standards (2009)		N	M	CCHIT will align with AHIC Medication Management Use Case development and monitor allergy vocabulary standards such as those specified by HITSP for CE and the CHI Approved Standards Standards for Allergy for 2009 certification.	X		IF-11.14 At discharge, the system shall provide the ability to communicate discharge medications and allergies to the next provider of care. IF-11.17 The system shall provide the ability to provide a complete list of current medications at the time of patient discharge.
II-28		Send outpatient Current Medication List (active home medications upon discharge) and allergies to Health Plans	TBD			N	CCHIT will align with AHIC Medication Management Use Case development.	X		No current corresponding inpatient functionality criteria -- will coordinate with IFWG.
II-29		Send Current Medication List and Discharge Medications ("patient home medications" and "medications prescribed upon discharge") and Allergies to patient PHR in response to a query from a PHR	HITSP IS-03 Consumer Empowerment			pilot	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.17 The system shall provide the ability to provide a complete list of current medications at the time of patient discharge.

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II-30		Send Active Medications,-Inpatient Medication History, and Allergies to other inpatient institution (e.g., Hospital, Nursing home, Rehabilitation center)	TBD for message format Use of RxNorm for clinical drug terminology Use of allergy vocabulary standards			N	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.16 The system shall provide the ability to communicate the current inpatient medication list to the next provider of care.
II-31		Send Current Medication List and Discharge Medications ("patient home medications" and "medications prescribed upon discharge") and Allergies to other sources (State Medicaid, home health/nursing care agencies, public health, etc.) directly or via intermediary	TBD for message format Use of RxNorm for clinical drug terminology Use of allergy vocabulary standards			N	CCHIT will align with AHIC Medication Management Use Case development.	X		IF-11.17 The system shall provide the ability to provide a complete list of current medications at the time of patient discharge.

SECURITY Criteria
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S1	Sec	Security: Access Control	The system shall enforce the most restrictive set of rights/privileges or accesses needed by users/groups (e.g. System Administration, Clerical, Nurse, Doctor, etc.), or processes acting on behalf of users, for the performance of specified tasks.	ISO 17799: 9.1.1.2.b; HIPAA: 164.312(a)(1)	P			
S2			The system shall provide the ability for authorized administrators to assign restrictions or privileges to users/groups.	Canadian: Alberta 4.1.3 (EMR); CC SFR: FMT_MSA; SP800-53: AC-5 LEAST PRIVILEGE; HIPAA: 164.312(a)(1)	P			
S3			The system must be able to associate permissions with a user using one or more of the following access controls: 1) user-based (access rights assigned to each user); 2) role-based (users are grouped and access rights assigned to these groups); or 3) context-based (role-based with additional access rights assigned or restricted based on the context of the transaction such as time-of-day, workstation-location, emergency-mode, etc.)	Canadian: Ontario 5.3.12.e (System Access Management); CC SFR: FDP_ACC, FMT_MSA; ASTM: E1985-98; SP800-53: AC-3 ACCESS AND INFORMATION FLOW CONTROL; HIPAA: 164.312(a)(1)	P			
S4			The system shall support removal of a user's privileges without deleting the user from the system. The purpose of the criteria is to provide the ability to remove a user's privileges, but maintain a history of the user in the system.		M			
S5.1	Sec	Security: Audit	**Removed**		M			
S5.2			The system shall be able to detect security-relevant events that it mediates and generate audit records for them. At a minimum the events shall include: start/stop, user login/logout, session timeout, account lockout, patient record created/viewed/updated/deleted, scheduling, query, order, node-authentication failure, signature created/validated, PHI export (e.g. print), PHI import, and security administration events. Note: The system is only responsible for auditing security events that it mediates. A mediated event is an event that the system has some active role in allowing or causing to happen or has opportunity to detect. The system is not expected to create audit logs entries for security events that it does not mediate.	CC SFR: FAU_GEN; SP800-53: AU-2 AUDITABLE EVENTS; HIPAA: 164.312(b)	M			

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S6			The system shall record within each audit record the following information when it is available: (1) date and time of the event; (2) the component of the system (e.g. software component, hardware component) where the event occurred; (3) type of event (including: data description and patient identifier when relevant); (4) subject identity (e.g. user identity); and (5) the outcome (success or failure) of the event.	CC SFR: FAU_GEN; SP800-53: AU-3 CONTENT OF AUDIT RECORDS, AU-10 NON-REPUDIATION; HIPAA: 164.312(b)	P			
S7			The system shall provide authorized administrators with the capability to read all audit information from the audit records in one of the following two ways: 1) The system shall provide the audit records in a manner suitable for the user to interpret the information. The system shall provide the capability to generate reports based on ranges of system date and time that audit records were collected. 2) The system shall be able to export logs into text format in such a manner as to allow correlation based on time (e.g. UTC synchronization).	CC SFR: FAU_SAR; SP800-53: AU-7 AUDIT REDUCTION AND REPORT GENERATION; HIPAA: 164.312(b)	M			
S8.1			The system shall be able to support time synchronization using NTP/SNTP, and use this synchronized time in all security records of time.	CC SFR: FPT_STM; SP800-53: AU-8 TIME STAMPS	P			
S8.2			The system shall have the ability to format for export recorded time stamps using UTC based on ISO 8601. Example: "1994-11-05T08:15:30-05:00" corresponds to November 5, 1994, 8:15:30 am, US Eastern Standard Time.	CC SFR: FPT_STM; SP800-53: AU-8 TIME STAMPS	M			
S9			The system shall prohibit all users read access to the audit records, except those users that have been granted explicit read-access. The system shall protect the stored audit records from unauthorized deletion. The system shall prevent modifications to the audit records.	CC SFR: FAU_SAR, FAU_STG; SP800-53: AU-9 PROTECTION OF AUDIT INFORMATION; HIPAA: 164.312(a)(1)	P			
S10			**Removed**		M			

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S11			The system shall allow an authorized administrator to enable or disable auditing for groups of related events to properly collect evidence of compliance with implementation-specific policies. Note: In response to a HIPAA-mandated risk analysis and management, there will be a variety of implementation-specific organizational policies and operational limits.	CC SFR: FAU_SEL; HIPAA 164.312(b)	M			
S12	Sec	Security: Authentication	The system shall authenticate the user before any access to Protected Resources (e.g. PHI) is allowed, including when not connected to a network e.g. mobile devices.	Canadian: Alberta 1.1; CC SFR: FIA_UAU, FIA_UID; SP800-53: IA-2 USER IDENTIFICATION AND AUTHENTICATION; HIPAA: 164.312(d)	P			
S13			When passwords are used, the system shall support password strength rules that allow for minimum number of characters, and inclusion of alpha-numeric complexity.	Canadian: Alberta 7.3.12 (Security) Canadian Ontario 5.3.12.b (System Access Management); CC SFR: FIA_SOS, FIA_UAU, FIA_UID; ASTM: E1987-98; SP800-53: IA-2 USER IDENTIFICATION AND AUTHENTICATION (no strength of password); ISO 17799: 9.3.1.d; HIPAA: 164.	P			
S14			The system upon detection of inactivity of an interactive session shall prevent further viewing and access to the system by that session by terminating the session, or by initiating a session lock that remains in effect until the user reestablishes access using appropriate identification and authentication procedures. The inactivity timeout shall be configurable.	Canadian: Alberta 7.3.14 (Security) Canadian Ontario 5.6.12.a (Workstation Security); CC SFR: FTA_SSL, FMT_SAE; SP800-53: AC-11 SESSION LOCK; HIPAA: 164.312(a)(1)	M			
S15			The system shall enforce a limit of (configurable) consecutive invalid access attempts by a user. The system shall protect against further, possibly malicious, user authentication attempts using an appropriate mechanism (e.g. locks the account/node until released by an administrator, locks the account/node for a configurable time period, or delays the next login prompt according to a configurable delay algorithm).	Canadian: Ontario 5.3.12.c (System Access Management); CC SFR: FIA_AFL, FMT_SAE; SP800-53: AC-6 UNSUCCESSFUL LOGIN ATTEMPTS, AC-11 SESSION LOCK ; ISO 17799: 9.3.1.e, 9.5.2.e; HIPAA: 164.312(a)(1)	M			
S16.1			When passwords are used, the system shall provide an administrative function that resets passwords.	CC SFR: FMT_MTD; ISO 17799: 9.2.3.b, (9.3.1.f); HIPAA: 164.312(d)	P			

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S16.2			When passwords are used, user accounts that have been reset by an administrator shall require the user to change the password at next successful logon.	CC SFR: FMT_MTD; ISO 17799: 9.2.3.b, (9.3.1.f); HIPAA: 164.312(d)	P			
S17			The system shall provide only limited feedback information to the user during the authentication.	CC SFR: FIA_UAU; SP800-53: IA-6 AUTHENTICATOR FEEDBACK; HIPAA: 164.312(d)	P			
S18			The system shall support case-insensitive usernames that contain typeable alpha-numeric characters in support of ISO-646/ECMA-6 (aka US ASCII).	CC SFR: FMT_MTD	P			
S19			When passwords are used, the system shall allow an authenticated user to change their password consistent with password strength rules (S13).	CC SFR: FMT_MTD	P			
S20			When passwords are used, the system shall support case-sensitive passwords that contain typeable alpha-numeric characters in support of ISO-646/ECMA-6 (aka US ASCII).	Canadian: Ontario 5.3.12 (b); SP 800-63	P			
S21			When passwords are used, the system shall not store passwords in plain text.		P			
S22			When passwords are used, the system shall prevent the reuse of passwords previously used within a specific (configurable) timeframe (i.e., within the last X days, etc. - e.g. "last 180 days"), or shall prevent the reuse of a certain (configurable) number of the most recently used passwords (e.g. "last 5 passwords").	CC SFR: FMT_MTD; ISO 17799 9.5.4.f; HIPAA 164.312(d)	M			
S23	Sec	Security: Documentation	The system shall include documentation available to the customer that provides guidelines for configuration and use of the EHR security controls necessary to support secure and reliable operation of the system, including but not limited to: creation, modification, and deactivation of user accounts, management of roles, reset of passwords, configuration of password constraints, and audit logs.	CC SFR: AGD_ADM	M			
S24	Sec	Security: Technical Services	The system shall support protection of confidentiality of all Protected Health Information (PHI) delivered over the Internet or other known open networks via encryption using triple-DES (3DES) or the Advanced Encryption Standard (AES) and an open protocol such as TLS, SSL, IPSec, XML encryptions, or S/MIME or their successors.	Canadian: Alberta 7.4.6.2 & 8.4.6.2 (Technical); CC SFR: FCS_COP; SP800-53: SC-13 CRYPTOGRAPHIC OPERATIONS; HIPAA: 164.312(e)(1)	P			

SECURITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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S25			When passwords are used, the system shall not transport passwords in plain text.	Canadian: Ontario 5.3.12.a (System Access Management); CC SFR: FCS_CKM; SP800-53: SC-12 CRYPTOGRAPHIC KEY ESTABLISHMENT AND MANAGEMENT; HIPAA: 164.312(e)(1)	P			
S26			When passwords are used, the system shall not display passwords while being entered.	CC SFR: FPT_ITC; ISO 17799 9.2.3; HIPAA 164.312(a)(1)	P			
S27			For systems that provide access to PHI through a web browser interface (i.e. HTML over HTTP) shall include the capability to encrypt the data communicated over the network via SSL (HTML over HTTPS). Note: Web browser interfaces are often used beyond the perimeter of the protected enterprise network	CC SFR: AGD_ADM	P			
S28			The system shall support protection of integrity of all Protected Health Information (PHI) delivered over the Internet or other known open networks via SHA1 hashing and an open protocol such as TLS, SSL, IPSec, XML digital signature, or S/MIME or their successors.	CC SFR: FPT_RCV	P			
S29			The system shall support ensuring the authenticity of remote nodes (mutual node authentication) when communicating Protected Health Information (PHI) over the Internet or other known open networks using an open protocol (e.g. TLS, SSL, IPSec, XML sig, S/MIME).	CC SFR: FPT_RCV	P			
S30	Sec		The system, when storing PHI on any physical media intended to be portable/removable (e.g. thumb-drives, CD-ROM, PDA), shall support use of a standards based encrypted format using triple-DES (3DES), and the Advanced Encryption Standard (AES).	FIPS 140-2, CC SFR: FCS_COP, OMB M-06-16			N	
S31	Sec	Security: Authentication	The system shall support two-factor authentication in alignment with NIST 800-63 Level 3 Authentication. Note: The standards in this area are still evolving.	CC SFR: FIA_UAU; SP800-53: IA-2/AC-19, OMB M-06-16			N	
S32	Sec	Security: Technical Services	The system shall support the storage of any Protected Health Information (PHI) data on any associated mobile device(s) such as PDAs, smartphones, etc. in an encrypted format, using triple-DES (3DES), the Advanced Encryption Standard (AES), or their successors.	FIPS 140-2, CC SFR: FCS_COP, OMB M-06-16, SP800-53: AC-19			N	

SECURITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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S33	Sec		The system, prior to a user login, shall display a (configurable) notice warning (e.g. "The system should only be accessed by authorized users").	CC 2.1 L.4 TOE access banners (FTA_TAB); CC 3.0 FIA_TIN.1 Advisory warning message			N	
S34	Sec	Security: Access Control	The system shall allow certain role clinicians to mark a patient's specific information as blinded, prohibiting access to all other users. Note: The standards in this area are still evolving.	§164.312(a)(2)(ii)		N		
S35	Sec		The system shall support access to blinded information to a treating clinician, when the blinded information is necessary for managing an emergency condition. Note: This is commonly known as a "break the glass" function. This does not provide increased access rights for the user.	§164.312(a)(2)(ii)		N		
S36	Sec		The "break the glass" function must be capable of requiring the clinician requesting access to blinded information to document and record the reason(s) for requesting access.	§164.312(a)(2)(ii)		N		
S37	Sec	Security: Audit	The system shall support logging to a common audit engine using the schema and transports specified in the Audit Log specification of IHE Audit Trails and Node Authentication (ATNA) Profile	NIST 800-92/SP 800-92			N	
R1	Sec	Reliability: Backup / Recovery	The system shall be able to generate a backup copy of the application data, security credentials, and log/audit files.	Canadian: Alberta 7.3.16 (Security); CC SFR: FDP_ROL, FPT_RCV; HIPAA: 164.310(d)(1)	**P**			
R2			The system restore functionality shall result in a fully operational and secure state. This state shall include the restoration of the application data, security credentials, and log/audit files to their previous state.	Canadian: Alberta 7.3.18.9 (Security); CC SFR: FAU_GEN; SP800-53: AU-2 AUDITABLE EVENTS; HIPAA: 164.310(d)(1)	**P**			
R3			If the system claims to be available 24x7 then the system shall have ability to run a backup concurrently with the operation of the application.	Canadian: Alberta 7.4.2.5 (Technica+D1l); CC SFR: FDP_ROL; HIPAA: 164.310(d)(1)	**P**			
R4	Sec	Reliability: Documentation	The system shall include documentation available to the customer stating whether or not there are known issues or conflicts with security services in at least the following serivce areas: antivirus, intrusion detection, malware eradication, host-based firewall and the resolution of that conflict (e.g. most systems should note that full virus scanning should be done outside of peak usage times and should exclude the databases.).	Canadian: Alberta 7.3.17 (Security); CC SFR: FPT_TST CC SFR: AGD_ADM; SP800-53 SI-3 MALICIOUS CODE PROTECTION	**M**			

SECURITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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R5			If the system includes hardware, the system shall include documentation that covers the expected physical environment necessary for proper secure and reliable operation of the system including: electrical, HVAC, sterilization, and work area.	CC SFR: AGD_ADM	M			
R6			**Removed**					
R7			The system shall include documentation that itemizes the services (e.g. PHP, web services) and network protocols/ports (e.g. HL-7, HTTP, FTP) that are necessary for proper operation and servicing of the system, including justification of the need for that service and protocol. This information may be used by the healthcare facility to properly configure their network defenses (firewalls and routers).	CC SFR: AGD_ADM; SP 800-53 AC-5 CM-6; SP 800-70; HIPAA 164.312(a)(1)	M			
R8			**Removed (Merged with R4)**					
R9			The system shall include documentation that describes the steps needed to confirm that the system installation was properly completed and that the system is operational.	CC SFR: AGD_ADM	M			
R10			The system shall include documentation that describes the patch (hot-fix) handling process the vendor will use for EHR, operating system and underlying tools (e.g. a specific web site for notification of new patches, an approved patch list, special instructions for installation, and post-installation test).	CC SFR: AGD_ADM	M			
R11			The system shall include documentation that explains system error or performance messages to users and administrators, with the actions required.	CC SFR: AGD_ADM	P			
R12			The system shall include documentation of product capacities (e.g. number of users, number of transactions per second, number of records, network load, etc.) and the baseline representative configurations assumed for these capacities (e.g. number or type of processors, server/workstation configuration and network capacity, etc).	CC SFR: AGD_ADM; SP800-53 CM-2	M			
R13			The system shall include documented procedures for product installation, start-up and/or connection.	CC SFR: ADO_IGS	P			

SECURITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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R14	Sec	Reliability: Technical Services	The software used to install and update the system, independent of the mode or method of conveyance, shall be certified free of malevolent software ("malware"). Vendor may self-certify compliance with this standard through procedures that make use of commercial malware scanning software.	CC SFR: ADO_DEL	M			
R15			**Removed**					
R16	Sec	Reliability: Documentation	The system shall include documentation of the minimal privileges necessary for each service and protocol necessary to provide EHR functionality and/or serviceability.	SP800-53 AC-5	P			
R17	Sec	Reliability: Technical Services	The system shall be configurable to prevent corruption or loss of data already accepted into the system in the event of a system failure (e.g. integrating with a UPS, etc.).	CC SFR: FPT_RCV	P			
R18	Sec		**Removed (Merged with S23)**					
R19			**Removed**					

References:
1) ISO 17799: ISO/IEC 17799:2005 Information technology - Security techniques - Code of practice for information security management. http://www.iso.org/iso/en/prods-services/popstds/informationsecurity.html

2) HIPAA: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996. 45 CFR Parts 160, 162, and 164 Health Insurance Reform: Security Standards; Final Rule. http://www.cms.hhs.gov/SecurityStandard/Downloads/securityfinalrule.pdf

3) Alberta VCUR Standards: Alberta Medical Association, Vendor Conformance and Usability Requirements (VCUR), April 18, 2006. http://www.posp.ab.ca/vendors/VCURv2.asp

4) CC SFR: (Common Criteria for Information Technology Security Evaluations - Part 2: Security functional requirements) - ISO/IEC 15408:2005-2 Security Techniques—Evaluation Criteria for IT Security is based on Common Criteria for Information Technology Security Evaluation 2.3 (referred to as Common Criteria or CC).
http://isotc.iso.org/livelink/livelink/fetch/2000/2489/lttf_Home/PubliclyAvailableStandards.htm

5) NIST 800-53 - Recommended Security Controls for Federal Information Systems ;800-63 - Electronic Authentication Guideline;800-70 - Security
Configuration Checklists Program for IT Products: Guidance for Checklists Users and Developers;800-92 - Guide to Computer Security Log Management. http://csrc.nist.gov/publications/nistpubs/

*Assignable Functions:
Applicants may assign certain functionality to a third party (e.g. when security and operating functions are handled by the operating system, a third party component, tool or service, etc.). Where a function is indicated as "assignable", applicants can indicate they are delegating and provide related materials for self attestation. For example – for backup and restore: applicants that use a third party database backup utility could assign backup functionality and provide related documentation for self-attestation.

SECURITY Criteria
For 2007 Certification of Inpatient EHRs
FINAL

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Provisional Criteria (2007) are highlighted in yellow
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				6) Ontario specification references are from: Ontario Medical Association, CMS Local Solution Specification V1.3. Copy located at: http://www.ontariomd.ca/cms/infoForVendors.shtml				

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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1	F	**Identify and maintain a patient record:** Key identifying information is stored and linked to the patient record. Both static and dynamic data elements will be maintained. A look up function uses this information to uniquely identify the patient.	1. The system shall create a single patient record for each patient.	DC.1.1.1	P			
2			2. The system shall associate (store and link) key identifier information (e.g., system ID, medical record number) with each patient record.	DC.1.1.1	P			Key identifier information must be unique to the patient record but may take any system defined internal or external form.
3			3. The system shall provide the ability to store more than one identifier for each patient record.	DC.1.1.1	P			For interoperability, practices need to be able to store additional patient identifiers. Examples include an ID generated by an Enterprise Master Patient Index, a health plan or insurance subscriber ID, regional and/or national patient identifiers if/when such become available.
4			4. The system shall use key identifying information to identify (look up) the unique patient record.	DC.1.1.1	P			
5			5. The system shall provide more than one means of identifying (looking up) a patient.	DC.1.1.1	P			Examples of identifiers for looking up a patient include date of birth, phone number.
6			6. The system shall provide a field which will identify patients as being exempt from reporting functions.	DC.1.1.1	N			Examples include patients who are deceased, transferred, moved, seen as consults only. Being exempt from reporting is not the same as de-identifying a patient who will be included in reports. De-identifying patients for reporting is addressed in the "Health record output" functionality.
7			7. The system shall provide the ability to merge patient information from two patient records into a single patient record.	DC.1.1.1		N		If a duplicate chart is created, information could be merged into one chart.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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8	F	**Manage patient demographics:** Contact information including addresses and phone numbers, as well as key demographic information such as date of birth, gender, and other information is stored and maintained for reporting purposes and for the provision of care.	1. The system shall capture and maintain demographic information as part of the patient record.	DC.1.1.2	P			Examples of a minimum set of demographic data elements include: name, address, phone number and date of birth. It is assumed that all demographic fields necessary to meet legislative and regulatory (e.g., HIPAA), research, and public health requirements will be included. A desirable feature would be a method of identifying how patients would like to be contacted (e.g., alternate addresses). De-identifiying demographic information is addressed in the "Health record output" functionality.
9			2. The system shall provide the ability to include demographic information in reports.	DC.1.1.2	P			This includes using demographics to generate reports and also allows demographics to be gathered into a report. See also "Report generation" functionality.
10			3. The system shall provide the ability to maintain and make available historic information for demographic data including prior names, addresses, phone numbers and email addresses.	DC.1.1.2	N			Providers need this for look up and contact purposes, e.g., when attempting to locate a patient or family member for clinical communications.
11			4. The system shall provide the ability to modify demographic information about the patient.	DC.1.1.2	P			
12			5. The system shall store demographic information in the patient medical record in separate discrete data fields, such that data extraction tools can retrieve these data.	DC.1.1.2	N			

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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13	F	**Manage problem list:** Create and maintain patient specific problem lists.	1. The system shall provide the ability to display all current problems associated with a patient.	DC.1.4.3	P			We assume current and active to mean the same thing.
14			2. The system shall provide the ability to maintain a history of all problems associated with a patient.	DC.1.4.3	P			This means both current and inactive and/or resolved problems.These may be viewed on separate screens or the same screen. Ideally each discrete problem would be listed once.
15			3. The system shall provide the ability to maintain the onset date of the problem.	DC.1.4.3	P			It is a vendor design decision whether to require complete date or free text of approximate date.
16			4. The system shall provide the ability to record the chronicity (chronic, acute/self-limiting, etc.) of a problem.	DC.1.4.3	P			
17			5. The system shall provide the ability to record the user ID and date of all updates to the problem list.	DC.1.4.3	P			
18			6. The system shall provide the ability to associate orders, medications, and notes with one or more problems.	DC.1.4.3	N			One should be able to identify all visits for a particular diagnosis/problem. Association can be made in structured data or in non-structured data.
18a			7. The system shall provide the ability to associate orders, medications and notes with one or more problems; association to be structured, codified data.				2009	
19			8. The system shall provide the ability to maintain a coded list of problems.	DC.1.4.3	P			For example: ICD-9 CM, ICD-10 CM, SNOMED-CT, DSM-IV. The Functionality WG will not specify which code set(s) are to be employed.
20			9. The system shall provide the ability to display inactive and/or resolved problems.		P			
21a			10. The system shall provide the ability to separately display active problems from inactive/resolved problems.		N			

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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21b			11. The system shall provide the ability to manually order the problem list.				2009	
22	F	**Manage medication list:** Create and maintain patient specific medication lists- Please see DC.1.7.1 for medication ordering as there is some overlap.	1. The system shall provide the ability to create and maintain medication lists.	DC.1.4.2	P			The medication list should be "patient-centric" and may include medications prescribed by any provider.
22a			2. The system shall provide the ability for the user to experssly indicate that the medication list has been reviewed; this must be a structured field.				2009	
23			3. The system shall provide the ability to record the prescribing of medications including the identity of the prescriber.	DC.1.4.2	P			
24			4. The system shall provide the ability to maintain medication ordering dates.	DC.1.4.2	P			
25			5. The system shall provide the ability to maintain other dates associated with medications including start, modify, renewal and end dates as applicable.	DC.1.4.2	P			
26			6. The system shall provide the ability to display medication history for the patient.	DC.1.4.2	P			For clarification, medication history includes all medications prescribed since the EMR was established.
27			7. The system shall provide the ability to capture medications entered by authorized users other than the prescriber.	DC.1.4.2	P			It is important to have all current medications in the system for drug interaction checking. This in the future would include the incorporation of medication history obtained from outside electronic interfaces from insurers, PBMs, etc. "User" means medical and non-medical staff who are authorized by policy to enter prescriptions or other documentation.
27a			8. The system shall provide the ability to capture, store and display medication history received electronically.			N		

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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28			9. The system shall provide the ability to enter non-prescription medications, including over the counter and complementary medications such as vitamins, herbs and supplements.	DC.1.4.2	P			This is important for interaction checking, associating symptoms with supplements e.g. the L-trytophan related eosinophila-myalgia syndrome
29			10. The system shall provide the ability to exclude a medication from the current medication list (e.g., marked inactive, erroneous, completed, discontinued) and document reason for such action.	DC.1.4.2	P			Reason for removal or discontinuation may be captured as a discrete data element or as free text. In future this should be structured.
30			11. The system shall store medication information in discrete data fields such as dose, route, sig, dispense amount, refills, associated diagnoses, etc.	DC.1.4.2		N		Only approved abbreviations should be included.
31			12. The system shall provide the ability to print a current medication list.	DC.1.4.2	P			
32			13. The system shall provide the ability to display current medications only.	DC.1.4.2	P			Excluding prior medications to make current medications easier to identify. Any given medication should display only once in the list.
33			14. The system shall include standard medication codes associated with each medication in the list.	DC.1.4.2		N		It is anticipated that upcoming eRx regulation and the work of AHIC will define these in the near future. This requires publication by HITSP of an implementation guide by 3/07. This requirement will be postponed for a year after the publication of such a guide if one is not available by 3/07.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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34			15. The system shall provide the ability to enter uncoded or free text medications when medications are not on the vendor-provided medication database or information is insufficient to completely identify the medication.		M			Medications that are not on the vendor-provided medication database or not enough information is available to completely identify the medication. This could be either uncoded (Synthroid unknown dose) or free text (blue hypertension pill).
35			16. The system shall provide the ability to alert the user at the time a new medication is prescribed that drug interaction and allergy checking will not be performed against the uncoded or free text medication.		N			
36			17. The system shall provide the ability to enter or further specify in a discrete field that the patient takes no medications.		N			
37			18. The system shall provide the ability to record the date of changes made to a patient's medication list and the identity of the user who made the changes.		M			This information may appear as an optional view rather than a required view on the main screen. Need to capture the identity of the user and the date of changes made. Changes are to be recorded at the level of the individual medication.
38	F	**Manage allergy and adverse reaction list:** Create and maintain patient specific allergy and adverse reaction lists.	1.The system shall provide the ability to capture and store lists of medications and other agents to which the patient has had an allergic or other adverse reaction.	DC.1.4.1	P			The user determines what defines an allergy or adverse reaction.
39			2. The system shall provide the ability to specify the type of allergic or adverse reaction.	DC.1.4.1	N			Allergy type may be specified as a discrete data element and/or as a free text description. This should be a modifiable field.
39a			3. The system shall provide the ability to specify the type of allergic or adverse reaction in a discrete data field.				2009	Data does not need to be codified.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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40			4. The system shall provide the ability to deactivate an item from the allergy and adverse reaction list.	DC.1.4.1	P			This could include removal, marking as erroneous, or marking as inactive. "Remove" in this context implies specifying that an allergy or allergen specification is no longer valid or active as opposed to deleting the information from the database entirely.
41			5. The system shall provide the ability to specify the reason for deactivating an allergy/allergen from the allergy list.	DC.1.4.1		N		Reason for deactivating an allergy type may be specified as a discrete data element or in non-structured data. This could include removal, marking as erroneous, or marking as inactive. "Remove" in this context implies specifying that an allergy or allergen specification is no longer valid or active as opposed to deleting the information from the database entirely.
42a			6. The system shall provide the ability to record the deactivation of items from the allergy list.	DC.1.4.1	N			Necessary for medico-legal purposes. This could include removal, marking as erroneous, or marking as inactive. "Remove" in this context implies specifying that an allergy or allergen specification is no longer valid or active as opposed to deleting the information from the database entirely.
42b			7. The system shall provide the ability to record the identity of the user who added, modified, inactivated or removed items from the allergy list, including attributes of the changed items.		N			Attributes include the name of the allergen, the date of the change, and the action (added, modified, inactivated or removed).

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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43			8. The system shall provide the ability for a user to explicitly document that the allergy list was reviewed. The user ID and date stamp shall be recorded when the allergies reviewed option is selected.	DC.1.4.1	M			Medico-legal and regulatory compliance. This requires the user to explicitly select this option documenting that they have reviewed the allergies with the patient. Ideally this would be a structured field.
43a			9. The system shall provide the ability for a user to explicitly document, in a structured field, that the allergy list was reviewed. The user ID and date stamp shall be recorded when the allergies reviewed option is selected.				2009	Medico-legal and regulatory compliance.
44			10. The system shall provide the ability to explicitly indicate that a patient has no known drug allergies.	DC.1.4.1	P			Medico-legal and regulatory compliance. This is meant to be specific to drug allergies.
44a			11. The system shall provide the ability to explicitly indicate in a discrete field that a patient has no known drug allergies.				2009	
45			12. The system shall provide the ability to display information which has been inactivated or removed from the list as well as details of information that has been modified.	DC.1.4.1		N		Could include changing the type of reaction for a particular allergy
46			13. The system shall provide the ability to capture non-drug agents to which the patient has had an allergic or other adverse reaction.	DC.1.4.1	P			These could include items such as foods or environmental agents. This need not be accomplished within the same portion of the chart where medication allergies are noted.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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47	F	**Manage patient history:** Capture, review, and manage medical, procedural/surgical, social and family history including the capture of pertinent positive and negative histories, patient reported or externally available patient clinical history.	1. The system shall provide the ability to capture, store, display, and manage patient history.	DC.1.2	P			Examples include past medical/surgical problems, diagnoses, procedures, family history and social history.
48			2. The system shall provide the ability to capture structured data in the patient history.	DC.1.2	N			This function demonstrates the ability of a system to capture structured data but does not define the required elements of the patient history that shall be structured. Discrete data elements allow for searching and/or reporting by the EHR, and for this criterion the data could be free text or codified. Future functions would define the required patient history elements that shall be captured discretely as structured data, and where appropriate codified terminologies will be used.
49			3. The system shall provide the ability to update a patient history by modifying, adding, removing, or inactivating items from the patient history as appropriate.	DC.1.2	P			Requirement not predicated on the capture of structured data.
50			4. The system shall provide the ability to capture patient history as both a presence and absence of conditions, i.e., the specification of the absence of a personal or family history of a specific diagnosis, procedure or health risk behavior.	DC.1.2	N			Requirement not predicated on the capture of structured data.
51			5. The system shall provide the ability to capture history collected from outside sources.	DC.1.2	P			This could include data from a personal health record, online patient histories, and information from pharmacy benefit management organizations. This criterion will accept any method of entry for year one, but electronic entry of information will be required thereafter.

AMBULATORY FUNCTIONALITY

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For 2007 Certification of Ambulatory EHRs

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52			6. The system shall provide the ability to capture patient history in a standard coded form.	DC.1.2		N		Not all data elements may currently be represented in existing standard coding schemes.
53	F	**Summarize health record**	1. The system shall provide the ability to create and display a summary list for each patient that includes, at a minimum, the active problem list, current medication list, medication allergies and adverse reactions	DC.1.1.4	P			Health record summary is at the patient level as opposed to at the level of an individual visit or episode of care.
54	F	**Manage clinical documents and notes:** Create, correct, authenticate, and close, as needed, transcribed or directly entered clinical documentation.	1. The system shall provide the ability to create clinical documentation or notes (henceforth "documentation").	DC.1.9.1	P			
55			2. The system shall provide the ability to display documentation.	DC.1.9.1	P			
56			3. The system shall provide the ability to save a note in progress prior to finalizing the note.	DC.1.9.1	P			
56a			4. The system shall provide the ability to insert date/time stamp at the initial creation of an encounter and when the note is completed.				2009	

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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57			5. The system shall provide the ability to finalize a note, i.e., change the status of the note from in progress to complete so that any subsequent changes are recorded as such.	DC.1.9.1	P			Medico-Legal. User rights are determined by role-based access defined in security. Only authorized users can complete, change or finalize a clinical note. The words, "sign," "signature," "cosign," and "cosignature" are intended here to convey actions, rather than referring to digital signature standards. It is recognized that an electronic signature is useful here. However, a widely accepted standard for electronic signatures does not exist. Thus, the criteria calls for documenting the actions of authenticated users at a minimum. In the future, when appropriate digital signature standards are available, certification criteria may be introduced using such standards.
58			6. The system shall provide the ability to record the identity of the user finalizing each note and the date and time of finalization.	DC.1.9.1	P			Medico-Legal. User rights are determined by role-based access defined in security. Only authorized users can complete, change or finalize a clinical note. The words, "sign," "signature," "cosign," and "cosignature" are intended here to convey actions, rather than referring to digital signature standards. It is recognized that an electronic signature is useful here. However, a widely accepted standard for electronic signatures does not exist. Thus, the criteria calls for documenting the actions of authenticated users at a minimum. In the future, when appropriate digital signature standards are available, certification criteria may be introduced using such standards.

AMBULATORY FUNCTIONALITY
2007 Final Criteria - March 16, 2007
For 2007 Certification of Ambulatory EHRs

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59			7. The system shall provide the ability to cosign a note and record the date and time of signature.		N			The words, "sign," "signature," "cosign," and "cosignature" are intended here to convey actions, rather than referring to digital signature standards. It is recognized that an electronic signature is useful here. However, a widely accepted standard for electronic signatures does not exist. Thus, the criteria calls for documenting the actions of authenticated users at a minimum. In the future, when appropriate digital signature standards are available, certification criteria may be introduced using such standards. ASTM has developed "2003 Updated ASTM Standard Guide for Electronic Authentication of Health Care Information" to address some of these issues.
60			8. The system shall provide the ability to addend and/or correct notes that have been finalized.	DC.1.9.1	P			The words, "sign," "signature," "cosign," and "cosignature" are intended here to convey actions, rather than referring to digital signature standards. It is recognized that an electronic signature is useful here. However, a widely accepted standard for electronic signatures does not exist. Thus, the criteria calls for documenting the actions of authenticated users at a minimum. In the future, when appropriate digital signature standards are available, certification criteria may be introduced using such standards.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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60a			9. The system shall provide the ability to identify the full content of a modified note, both the original content and the content resulting after any changes, corrections, clarifications, addenda, etc. to a finalized note.				2009	This may be in the GUI or in the audit trail.
61			10. The system shall provide the ability to record and display the identity of the user who addended or corrected a note, as well as other attributes of the addenda or correction, such as the date and time of the change.	DC.1.9.1	P			Necessary for medico-legal purposes. The words, "sign," "signature," "cosign," and "cosignature" are intended here to convey actions, rather than referring to digital signature standards. It is recognized that an electronic signature is useful here. However, a widely accepted standard for electronic signatures does not exist. Thus, the criteria calls for documenting the actions of authenticated users at a minimum. In the future, when appropriate digital signature standards are available, certification criteria may be introduced using such standards.
62			11. The system shall provide the ability to enter free text notes.	DC.1.9.1	P			
63			12. The system shall provide the ability to filter, search or order notes by the provider who finalized the note.	DC.1.9.1	N			
64			13. The system shall provide the ability to filter, search or order notes by associated diagnosis within a patient record.	DC.1.9.1	N			This is intended to be the coded diagnosis and not free text in the body of a note.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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65			14. The system shall provide the ability to capture patient vital signs, including blood pressure, heart rate, respiratory rate, height, and weight, as discrete data.	DC.1.9.1	P			It is understood that vendors should support conversion to numeric values that can be graphed. Coding in ICD-9 CM, ICD-10 CM, SNOMED, UMLS, etc., would enhance interoperability and for public health surveillance or clinical research.
65a			15. The system shall be capable of indicating to the user when a vital sign measurement falls outside a preset normal range. Authorized users should set the normal ranges.				2009	
66			16. The system shall provide the ability to capture other clinical data elements, such as peak expiratory flow rate, size of lesions, severity of pain, as discrete data.	DC.1.9.1		N		
66a			17. The system shall provide the ability to display other discrete numeric clinical data elements, such as peak expiratory flow rate or pain scores, in tabluar and graphical form.				2009	Listed items are examples only.
67			18. The system shall provide the ability to associate standard codes with discrete data elements in a note.	DC.1.9.1		N		Examples include but are not limited to SNOMED-CT, ICD-9 CM, ICD-10 CM, DSM-IV, CPT-4, MEDCIN, and LOINC. This would allow symptoms to be associated with SNOMED terms, labs with LOINC codes, etc. The code associated with a note would remain static even if the code is updated in the future.
68			19. The system shall provide templates for inputting data in a structured format as part of clinical documentation.	DC.1.9.1	P			Codified data are data that is structured AND codified according to some 'external' industry accepted standard such as ICD-9 CM, ICD-10 CM, SNOMED-CT, and CPT-4.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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69			20. The system shall provide the ability to customize clinical templates.	DC.1.9.1	P			Customizations may be site specific.
70			21. The system shall provide templates for displaying medical summary data in a structured format.	DC.1.9.1		N		Examples might include the continuity of care record or the CDA. This requirement does not specify a particular format although many vendors will choose to use the harmonized CCR/CDA/CRS once available.
71a			22. The system shall be capable of recording comments by the patient or the patient's representative regarding the accuracy or veracity of information in the patient record (henceforth 'patient annotations').		N			For 2007 it is sufficient for these to be recorded as either free-text notes (see item F54) or scanned paper documents (see item F78). It is not required that the system facilitate direct entry into the system by the patient or patient's representative.
71b			23. The system shall display patient annotations in a manner which distinguishes them from other content in the system.			N		Examples include but are not limited to use of a different font or text color, a text label on the screen indicating that the comments are from a patient or patient's representative, etc. "Distinguishable" refers specifically to comments made by the patient or patient's representative, but does not refer to the individual components of that chart that they may disagree with.
~~72~~			Deleted.					

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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73			24. The system shall provide the ability to identify and maintain patient or patient proxy completed clinical information.			N		Once verified by a physician and shared with other parts of the chart, the shared data does not need to be identified as patient completed in all sections where data may be shared, but the original patient completed information shall be maintained.
74			25. The system shall provide the ability to graph height and weight over time.		P			
74a			The system shall provide the ability to calculate and graph body mass index (BMI) over time.				2009	
74b			The system shall provide the ability to compare body mass index (BMI) to standard norms for age and sex over time.				2009	
~~75~~			Deleted.					
76	F	**Capture external clinical documents:** Incorporate clinical documentation from external sources.	1. The system shall provide the ability to capture and store external documents.	DC.1.1.3.1	P			Scanned documents are sufficient in 2005, granular data will be expected in the future. This covers all types of documents received by the practice that would typically be incorporated into a medical record, including but not limited to faxes, referral authorizations, consultant reports, and patient correspondence of a clinical nature.
77			2. The system shall provide the ability to receive, store in the patient's record, and display discrete lab results received through an electronic interface.	DC.1.1.3.1	P			This may be an external source such as a commercial lab or through an interface with on site lab equipment.
78			3. The system shall provide the ability to save scanned documents as images.	DC.1.1.3.1	P			

AMBULATORY FUNCTIONALITY
2007 Final Criteria - March 16, 2007
For 2007 Certification of Ambulatory EHRs

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79			4. The system shall provide the ability to receive, store in the patient's record, and display text-based outside reports.	DC.1.1.3.1	P			This could be either from an outside system or from scanning with optical character recognition. Integration here means the ability to find and display the documents within the system.
79a			5. The system shall provide the ability to index and retrieve scanned documents based on the document type, the date of the original document, and the date of scanning.				2009	
80			6. The system shall provide access to clinical images. They must be accessible from within the patient's chart and labeled and date-time stamped or included in a patient encounter document. These images may be stored within the system or be provided through direct linkage to external sources.	DC.1.1.3.1		N		These images may include but are not limited to radiographic, digital or graphical images. Eventually the goal would be to allow linkage to outside systems such as a hospital PAC system.
81			7. The system shall provide the ability to accept, store in the patient's record, and display clinical results received through an interface with an external source.	DC.1.1.3.1		N		In addition to lab and radiology reports, this might include interfaces with case/disease management programs and others.
82			8. The system shall provide the ability to accept, store in the patient's record, and display medication details from an external source.	DC.1.1.3.1			2009	External source may include a retail pharmacy, the patient, or another provider. Medication details include strength and sig. Does not imply that this date will populate the medication module; that functionality will be required in future. Year to be determined based on applicability of available standards.
83			9. The system shall provide the ability to accept, store in the patient's record, and display structured text-based reports received from an external source.	DC.1.1.3.1		N		This allows for more granular integration of data.

AMBULATORY FUNCTIONALITY

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84			10. The system shall provide the ability to accept, store in the patient's record, and display~~,~~ codified data received from an external source.	DC.1.1.3.1			2009	Such as those sent from another physician using a standardized format. Coding schema will be determined by HITSP and will be included in test scenarios in appropriate years.
85	F	**Generate and record patient specific instructions:** Generate and record patient specific instructions as clinically indicated.	1. The system shall provide access to patient instructions and patient educational materials, which may reside within the system or be provided through links to external sources.	DC.1.10	N			An example would be a vaccine information statement.
86			2. The system shall have the ability to provide access to medication instructions, which may reside within the system or be provided through links to external sources.	DC.1.10	P			
87			3. The system shall have the ability to provide access to test and procedure instructions that can be customized by the physician or health organization. These instructions may reside within the system or be provided through links to external sources.	DC.1.10	M			This item relates to customization of instructions, not to recording in patient record that instructions have been provided.
88			4. The system shall provide the ability to record that patient specific instructions or educational material were provided to the patient.	DC.1.10	P			This does not require automatic documentation.
89			5. The system shall provide the ability to create patient specific instructions.	DC.1.10	P			
90	F	**Order medication:** Create prescriptions or other medication orders with detail adequate for correct filling and administration.	1. The system shall provide the ability to create prescription or other medication orders with sufficient information for correct filling and administration by a pharmacy.	DC.1.7.1	P			The term pharmacy here refers to all entities which fill prescriptions and dispense medications including but not limited to retail pharmacies, specialty, and mail order pharmacies.
91			Deleted					

AMBULATORY FUNCTIONALITY
2007 Final Criteria - March 16, 2007
For 2007 Certification of Ambulatory EHRs

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92			2. The system shall provide the ability to record user and date stamp for prescription related events, such as initial creation, renewal, refills, discontinuation, and cancellation of a prescription.	DC.1.7.1	P			Security to limit prescription writing is included in I.1.2 below.
93			3. The system shall provide the ability to capture the identity of the prescribing provider for all medication orders	DC.1.7.1	P			The words, "sign," "signature," "cosign," and "cosignature" are intended here to convey actions, rather than referring to digital signature standards. It is recognized that an electronic signature is useful here. However, a widely accepted standard for electronic signatures does not exist. Thus, the criteria calls for documenting the actions of authenticated users at a minimum. In the future, when appropriate digital signature standards are available, certification criteria may be introduced using such standards.
94			4. The system shall provide the ability to cosign medication orders	DC.1.7.1		N		The words, "sign," "signature," "cosign," and "cosignature" are intended here to convey actions, rather than referring to digital signature standards. It is recognized that an electronic signature is useful here. However, a widely accepted standard for electronic signatures does not exist. Thus, the criteria calls for documenting the actions of authenticated users at a minimum. In the future, when appropriate digital signature standards are available, certification criteria may be introduced using such standards.

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95			5. The system shall provide the ability to update the medication history with the newly prescribed medications.	DC.1.7.1	P			The words, "sign," "signature," "cosign," and "cosignature" are intended here to convey actions, rather than referring to digital signature standards. It is recognized that an electronic signature is useful here. However, a widely accepted standard for electronic signatures does not exist. Thus, the criteria calls for documenting the actions of authenticated users at a minimum. In the future, when appropriate digital signature standards are available, certification criteria may be introduced using such standards.
96			6. The system shall have the ability to provide a list of medications to search from, including both generic and brand name.	DC.1.7.1	N			
97			7. The system shall provide the ability to maintain a coded list of medications.	DC.1.7.1	P			For clarification - Coding means a unique identifier for each medication. This functional requirement does not intend to require a national system of coding for medications.
98			8. The system shall provide the ability to capture common content for prescription details including strength, sig, quantity, and refills to be selected by the ordering clinician.	DC.1.7.1	P			We encourage the development of standard national abbreviations and that only approved abbreviations should be supported.
99			9. The system shall provide the ability to check for daily dose outside of recommended range for patient age (e.g., off-label dosing).			N		Year to be determined once e-prescribing sig requirements have been defined.
99a			10. The system shall provide the ability to check for dose ranges based on patient age and weight.				2009	Depends on availability of **F108** in the system.

AMBULATORY FUNCTIONALITY

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For 2007 Certification of Ambulatory EHRs

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100			11. The system shall provide the ability to select a drug by therapeutic class.	DC.1.7.1		N		As available through 3rd-party drug databases.
101			12. The system shall provide the ability to receive, display and store information received through electronic prescription eligibility checking.			N		Will be required by e-prescribing. This criterion should maintain a record of whether the patient was eligible for coverage in the system.
102			13. The system shall provide the ability to display and store information received through health plan/payer formulary checking.	DC.1.7.1		N		If this included medications already on the medication list, a duplicate should not be created (same date, medication, strength, and prescriber). Formulary checking refers to whether a particular drug is covered.
103			14. The system shall provide the ability to reorder a prior prescription without re-entering previous data (e.g. administration schedule, quantity).	DC.1.7.1	P			
104			15. The system shall provide the ability to print and electronically fax prescriptions.	DC.1.7.1	P			Appropriate audits and security should be in place.
105			16. The system shall provide the ability to re-print and re-fax prescriptions.		P			This allows a prescription that did not come out of the printer, or a fax that did not go through, to be resent/reprinted without entering another prescription. Appropriate audits and security should be in place.
106			17. The system shall provide the ability to submit prescriptions electronically.	DC.1.7.1	N			See also line 166 (DC 3.2.2). Faxing for 2006, tentative electronic 2007 once standards are promulgated. This presupposes that the pharmacy is capable of receiving electronic prescriptions. This function relates to computer e-prescribing and not faxing. Appropriate audits and security should be in place.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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107			18. The system shall provide the ability to display a dose calculator for patient-specific dosing based on weight and age.	DC.1.7.1		N		This allows the user to enter pertinent information to calculate doses. This would be an interim step until databases are available to calculate doses automatically.
108			19. The system shall provide the ability to display patient specific dosing recommendations based on age and weight.	DC.1.7.1			2009	This would calculate automatically from pertinent information in the chart (age and weight) and should be in standard units and based on a standard periodicity. This is contingent upon availability of databases. We encourage their rapid development.
108a			20. The system shall provide the ability to display patient specific dosing recommendations based on renal function.				2010	On roadmap for 2010
109			21. The system shall have the ability to receive and display information about the patient's financial responsibility for the prescription.	DC.1.7.1		N		This could include co-payments or tier level of the drug obtained through an interface with a pharmacy benefits manager (PBM).
110			22. The system shall provide the ability to identify medication samples dispensed, including lot number and expiration date.	DC.1.7.1	N			Lot numbers and expiration date could be entered in free text or encoded.
111			23. The system shall provide the ability to prescribe fractional amounts of medication (e.g. 1/2 tsp, 1/2 tablet).	DC.1.7.1	P			Very important to prescribing for pediatric and geriatric patients.
112			24. The system shall provide the ability to prescribe uncoded medications.		N			See DC.1.4.2

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

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113			25. The system shall provide the ability to alert the user at the time a new medication is prescribed that drug interaction, allergy, and formulary checking will not be performed against the uncoded medication.		N			
114			26. The system shall provide the ability to update drug interaction databases.		P			This includes updating or replacing the database with a current version.
115			27. The system shall provide the ability to alert the user if the drug interaction information is outdated.			N		The drug database should have an "expiration date" based on the frequency of their updates such that when that date has passed, the user is alerted.
116			28. System shall provide the ability to allow the user to configure prescriptions to incorporate fixed text according to the user's specifications and to customize the printed output of the prescription.		P			This refers to the "written" output and language on the prescription such as specific language, dispense as written. For instance, users should be able to modify the format/content of printed prescriptions to comply with state Board of Pharmacy requirements.
117			29. The system shall provide the ability to associate a diagnosis with a prescription.		P			
118			30. The system shall provide the ability to display the associated problem or diagnosis (indication) on the printed prescription.		M			At least one diagnosis shall be able to be displayed but the ability to display more than one is desirable. Associated problem or diagnosis can be non-structured data or structured data.
119			31. The system shall have the ability to provide links to general prescribing information at the point of prescribing.			N		
120			32. The system shall provide the ability to create provider specific medication lists of the most commonly prescribed drugs with a default dose, frequency, and quantity.		N			

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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121			33. The system shall provide the ability to add reminders for necessary follow up tests based on medication prescribed.			N		Does not imply that this must be an automated process.
121a			34. The system shall provide the ability to automatically add reminders for necessary follow up tests based on medication prescribed.				2009	As available through 3rd-party drug databases.
122	F	**Order diagnostic tests:** Submit diagnostic test orders based on input from specific care providers.	1. The system shall provide the ability to order diagnostic tests, including labs and imaging studies.	DC.1.7.2.2	P			This includes physicians and authorized non-physicians.
123			2. The system shall provide the ability to associate a problem or diagnosis with the order.			N		May associate more than one problem or diagnosis with the order.
124			3. The system shall provide the ability to capture the identity of the ordering provider for all test orders.		P			
125			4. The system shall provide the ability to capture applicable co-signatures for all test orders.			N		The words, "sign," "signature," "cosign," and "cosignature" are intended here to convey actions, rather than referring to digital signature standards. It is recognized that an electronic signature is useful here. However, a widely accepted standard for electronic signatures does not exist. Thus, the criteria calls for documenting the actions of authenticated users at a minimum. In the future, when appropriate digital signature standards are available, certification criteria may be introduced using such standards.
126			5. The system shall provide the ability to capture appropriate order entry detail, including associated diagnosis.	DC.1.7.2.2	P			Including associated diagnoses. It is desirable that all information for medical necessity checking be captured.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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127			6. The system shall provide the ability to display user created instructions and/or prompts when ordering diagnostic tests or procedures.	DC.1.7.2.2	N			Refers to diagnostic test or procedure specific instructions and/or prompts; not patient specific instructions and/or prompts. Instructions and/or prompts may be created by the system adminstrator. A 3rd party product may be used, providing that the instructions and/or prompts appear at the point of care.
128			7. The system shall provide the ability to relay orders for a diagnostic test to the correct destination for completion.	DC.1.7.2.2	P			Mechanisms for relaying orders may include providing a view of the order, sending it electronically, or printing a copy of the order or order requisition.
129			8. The system shall have the ability to provide a view of active orders for an individual patient.	DC.1.7.2.2	N			Additional sorts and filters may be provided by the vendors but not required.
130			9. The system shall have the ability to provide a view of orders by like or comparable type, e.g., all radiology or all lab orders.	DC.1.7.2.2	N			May include filters or sorts.
131	F	**Manage order sets:** Provide order sets based on provider input or system prompt, medication suggestions, drug recall updates.	1. The system shall provide the ability to define a set of related orders to be subsequently ordered as a group on multiple occasions.	DC.1.7.3	N			Does not imply that the system needs the ability to create an order set on the fly.
132			2. The system shall provide the ability to modify order sets.	DC.1.7.3	N			
133			3. The system shall provide the ability to include in an order set orders for medications, laboratory tests, imaging studies, procedures and referrals.	DC.1.7.3	N			
134			4. The system shall provide the ability to display orders placed through an order set either individually or as a group.	DC.1.7.3	N			Need to be able to see the individual components of the order set, rather than just the name of the order set. Does not mean to break down a lab panel into individual components.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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135			5. The system shall provide the ability for individual items in an order set to be selected or deselected.	DC.1.7.3		N		
136	F	**Manage results:** Route, manage, and present current and historical test results to appropriate clinical personnel for review, with the ability to filter and compare results.	1. The system shall provide the ability to indicate normal and abnormal results based on data provided from the original data source.	DC.1.8.3	P			As each lab has it's own normal values, these should be reflected in the indication as to whether a lab is normal or abnormal.
137			2. The system shall provide the ability to display numerical results in flow sheets and graphical form in order to compare results, and shall provide the ability to display values graphed over time.	DC.1.8.3	N			It is desirable for the system indicate if abnormal results are high or low.
138			3. The system shall provide the ability to display non-numeric current and historical test results as textual data.	DC.1.8.3	P			
139			4. The system shall provide the ability to notify the relevant providers (ordering, copy to) that new results have been received.	DC.1.8.3	N			Examples of notifying the provider include but are not limited to a reference to the new result in a provider "to do" list or inbox.
140a			5. The system shall provide the ability to filter or sort results by type of test and test date.		N			
140b			6. In areas where results from multiple patients are displayed, the system shall provide the ability to filter or sort results by patient.			N		
141			7. The system shall provide the ability to forward a result to other users.	DC.1.8.3	N			
~~142~~			Deleted.					

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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143			8. The system shall provide the ability to link the results to the original order.	DC.1.8.3	N			In 2007 this link can be effected manually by changing the status of the order from pending to complete. Future requirements could automate this link for certain electronically received labs although the requirement should not require that all types of orders be electronically linked to the results since the variety of result formats can be quite large (PT consult, Diabetes education...) and even the variety of lab result formats can be wide.
144			9. The system shall provide the ability for a user to attach a free text comment to a result that can be seen by another user who might subsequently view that result.	DC.1.8.3	N			
145			10. The system shall provide the ability to associate one or more images with a result.	DC.1.8.3		N		Through direct storage or links to the data.
146			11. The system shall provide the ability for a user to whom a result is presented to acknowledge the result.	DC.1.8.3	P			This is separate from audit trail.
147	F	**Manage consents and authorizations:** Create, maintain, and verify patient treatment decisions in the form of consents and authorizations when required.	1. The system shall provide the ability to capture scanned paper consent documents (covered in DC.1.1.3.1).	DC.1.3.3	P			
148			2. The system shall provide the ability to store, display and print patient consent forms.	DC.1.3.3	M			Example: Consent forms stored in the computer which are capable of being signed by the patient with either an electronic pen or a digital signature once widely available.

AMBULATORY FUNCTIONALITY
2007 Final Criteria - March 16, 2007
For 2007 Certification of Ambulatory EHRs

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148a			3. The system shall display and provide the ability for patients to electronically sign consent forms using currently available digital signature standards. Electronically signed consent forms shall be maintained within the patient medical record.				2009	
149			4. The system shall provide the ability to store and display administrative authorizations (e.g. privacy notices).	DC.1.3.3	N			Needed for HIPAA. Scanned copy is acceptable for 2007.
150			5. The system shall provide the ability to store and display patient consents associated with a specific clinical activity and provide the ability to link to that event in the patient's electronic chart.	DC.1.3.3		N		
151			6. The system shall provide the ability to chronologically display consents and authorizations.	DC.1.3.3		N		
152	F	**Manage patient advance directives:** Capture, maintain, and provide access to patient advance directives.	1. The system shall provide the ability to indicate that a patient has completed advanced directive(s).	DC.1.3.2	P			Important for appropriate use of resources at end of life and may just include a yes, no indication.
153			2.The system shall provide the ability to indicate the type of advanced directives, such as living will, durable power of attorney, or a "Do Not Resuscitate" order.	DC.1.3.2	N			This may be recorded in non-structured data or as discrete data.
154			3. The system shall provide the ability to indicate when advanced directives were last reviewed.	DC.1.3.2	N			This may be recorded in non-structured data or as discrete data.
155	F	**Support for standard care plans, guidelines, protocols:** Support the use of appropriate standard care plans, guidelines, and/or protocols for the management of specific conditions.	1. The system shall have the ability to provide access to standard care plan, protocol and guideline documents when requested at the time of the clinical encounter. These documents may reside within the system or be provided through links to external sources.	DC.2.2.1.1	P			This requirement could be met by simply including links or access to a text document. Road map would require more comprehensive decision support in the future. This includes the use of clinical trial protocols to ensure compliance.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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156			2. The system shall provide the ability to create site-specific care plan, protocol, and guideline documents.	DC.2.2.1.1	P			This includes the use of clinical trial protocols to ensure compliance. It is expected that in the future discrete data elements from other areas of the chart will populate matching fields.
157			3. The system shall provide the ability to modify site-specific standard care plan, protocol, and guideline documents obtained from outside sources.	DC.2.2.1.1	N			
~~158~~	F	**Capture variances from standard care plans, guidelines, protocols:** Identify variances from patient-specific and standard care plans, guidelines, and protocols.	Deleted.					
159			1. The system shall provide the ability to record the reason for variation from care plans, guidelines, and protocols as discrete data.				2009	
160	F	**Support for drug interaction:** Identify drug interaction warnings at the point of medication ordering	1. The system shall provide the ability to check for potential interactions between medications to be prescribed and current medications and alert the user at the time of medication ordering if potential interactions exist.	DC.2.3.1.1	P			This reduces risk of inappropriate prescribing, prevents pharmacy call backs, and can reduce malpractice liability.
161			2. The system shall provide the ability to check for potential interactions between medications to be prescribed and medication allergies and intolerances listed in the record and alert the user at the time of medication ordering if potential interactions exist.	DC.2.3.1.1	P			
162			3. The system shall provide the ability to prescribe a medication despite alerts for interactions and/or allergies being present.	DC.2.3.1.1	P			
163			4. The system shall provide the ability to set the severity level at which drug interaction warnings should be displayed.	DC.2.3.1.1	P			

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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164			Deleted.					
165			5. The system shall provide the ability to document at least one reason for overriding any drug-drug or drug-allergy interaction warning triggered at the time of medication ordering.	DC.2.3.1.1	N			Necessary for medico-legal purposes.
166			6. The system shall be capable of providing proactive alerts, for patients on a given medication when they are due for required laboratory or other diagnostic studies, to monitor for therapeutic or adverse effects of the medication.	DC.2.3.1.1			2009	Limited to availability of databases.
166a			7. The system shall be capable, at the time of medication ordering, of alerting the provider that based on the results of a laboratory test, the patient may be at increased risk for adverse effects of the medication.				2009	Limited to availability of databases.
167			8. The system shall provide the ability to check whether a medication being prescribed has been noted to be ineffective for the patient in the past, and alert the user at the time of medication ordering if noted ineffectiveness exists.	DC.2.3.1.1		N		This criterion assumes that at the time a medication was discontinued, it was marked "ineffective."
168			9. The system shall provide the ability to display, on demand, potential interactions on a patient's medication list, even if a medication is not being prescribed at the time.	DC.2.3.1.1	N			
169			10. The system shall provide drug-disease interaction alerts at the time of medication ordering.			N		Within the limitations of available databases.
169a			11. The system shall provide drug-disease interaction alerts at the time of entering a problem.				2009	

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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170			12. The system shall provide the ability to view the rationale for a drug interaction alert.			N		Drug reference information typically provided by drug database vendors is an example of the source to obtain the rationale.
171			13. The system shall provide the ability to check for potential interactions between a current medication and a newly entered allergy.			N		
172			14. The system shall provide the ability to generate alerts based on patient age.			N		This could be based on user defined medication lists or on standard lists such as the Beers lists.
173	F	**Support for medication or immunization administration or supply:** To reduce medication errors at the time of administration of a medication, the patient is positively identified; checks on the drug, the dose, the route and the time are facilitated. Documentation is a by-product of this checking; administration details and additional patient information, such as injection site, vital signs, and pain assessments, are captured. In addition, access to online drug monograph information allows providers to check details about a drug and enhances patient education.	1. The system shall provide the ability to document medication administration.	DC.2.3.2	P			
173a			2. The system shall provide the ability to document, for any medication, the medication type, dose, time of administration, route, site, lot number, expiration date, manufacturer, and user ID as structured documentation.				2009	
174			3. The system shall provide the ability to document immunization administration.	DC.2.3.2	P			
175			4. The system shall provide the ability to document, for any immunization, the immunization type, dose, time of administration, route, site, lot number, expiration date, manufacturer, and user ID as structured documentation.	DC.2.3.2	N			
176			5. The system shall provide the ability to record an adverse reaction to a specific immunization.			N		Immunization allergies may be indicated in the Allergy section.

AMBULATORY FUNCTIONALITY
2007 Final Criteria - March 16, 2007
For 2007 Certification of Ambulatory EHRs

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177			6. The system shall provide the ability to alert a user at the time of ordering that the patient had a prior adverse reaction to that immunization.				2009	
178	F	**Support for non-medication ordering (referrals, care management)**	1.The system shall provide the ability to create referral orders with detail adequate for correct routing.	DC.2.4.2	N			This could include referrals to sub-specialists, physical therapy, speech therapy, nutritionists, and other non-medication, non-clinical order. Adequate detail includes but is not limited to: • Date • Patient name and identifier • "Refer to" specialist name, address and telephone number • "Refer to" specialty • Reason for referral • Referring physician name
179			2. The system shall provide the ability to record user ID and date/time stamp for all referral related events.	DC.2.4.2	N			Necessary for medico-legal purposes.
180	F	**Present alerts for disease management, preventive services and wellness:** At the point of clinical decision making, identify patient specific suggestions /	1. The system shall provide the ability to establish criteria for disease management, wellness, and preventive services based on patient demographic data (minimally age and gender).	DC.2.5.1	P			This includes the use of clinical trial protocols to ensure compliance.

AMBULATORY FUNCTIONALITY
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181		reminders, screening tests / exams, and other preventive services in support of disease management, routine preventive and wellness patient care standards.	2. The system shall provide the ability to display alerts based on established guidelines.	DC.2.5.1	P			Guidelines may be from national organizations, payers, or internal protocols. It is expected that in the future discrete data elements from other areas of the chart will populate matching fields. It is assumed that when a service is completed, this change will be immediately reflected with removal of the prompt.
182			3. The system shall provide the ability to establish criteria for disease management, wellness, and preventive services based on clinical data (problem list, current medications).	DC.2.5.1	P			Lab results in future years
183			4. The system shall provide the ability to update disease management guidelines and associated reference material.	DC.2.5.1	N			This allows the system's decision support tools to support changes in best practice guidelines.
184			5. The system shall provide the ability to update preventive services/wellness guidelines and associated reference material.	DC.2.5.1	P			
185			6. The system shall provide the ability to override guidelines.	DC.2.5.1	P			
186			7. The system shall provide the ability to document reasons disease management or preventive services/wellness prompts were overridden.	DC.2.5.1	N			Needed for medico-legal reasons and clinical decision support.
187			8. The system shall provide the ability to modify the rules or parameters upon which guideline-related alerts are based.	DC.2.5.1	N			This is necessary for modifications as guidelines change or practices wish to adhere to more stringent levels for example, using a HbA1c target of 6.5% instead of 7%.

AMBULATORY FUNCTIONALITY
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For 2007 Certification of Ambulatory EHRs

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188			9. The system shall provide the ability to document that a preventive or disease management service has been performed based on activities documented in the record (e.g., vitals signs taken).	DC.2.5.1	N			
189			10. The system shall provide the ability to document that a disease management or preventive service has been performed with associated dates or other relevant details recorded.	DC.2.5.1	N			This could include services performed internally or external to the practice.
189a			11. The system shall provide the ability to individualize alerts to address a patient's specific clinical situation.		M			This is done at the patient level. Examples include but are not limited to: • Remove mammography for woman that has had a mastectomy • Remove annual pap smear alert for a woman who has had a complete hysterectomy. • Inactivate an alert for routine colon cancer screening in a patient who is terminally ill.
190	F	**Notifications and reminders for disease management, preventive services and wellness:** Between healthcare encounters, notify the patient and/or appropriate provider of those preventive services, tests, or behavioral actions that are due or overdue.	1. The system shall provide the ability to identify preventive services, tests, or counseling that are due on an individual patient.	DC.2.5.2	P			In the future, the system should perform this automatically and proactively "contact" patient(s) without physician intervention (e.g. automated reminder letter). These guidelines might come from national organizations, medical societies, etc.
191			2. The system shall provide the ability to display reminders for disease management, preventive, and wellness services in the patient record.	DC.2.5.2	P			It is expected that in the future discrete data elements from other areas of the chart will populate matching fields.
192			3. The system shall provide the ability to identify criteria for disease management, preventive, and wellness services based on patient demographic data (age, gender).	DC.2.5.2	P			

AMBULATORY FUNCTIONALITY

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193			4. The system shall provide the ability to identify criteria for disease management, preventive, and wellness services based on clinical data (problem list, current medications, lab values).	DC.2.5.2	N			
194			5. The system shall provide the ability to modify the guidelines that trigger the reminders.	DC.2.5.2	P			
195			6. The system shall provide the ability to notify the provider that patients are due or are overdue for disease management, preventive, or wellness services.	DC.2.5.2	P			
196			7. The system shall provide the ability to produce a list of patients who are due or are overdue for disease management, preventive, or wellness services.	DC.2.5.2	P			
197			8. The system shall provide the ability to automatically generate letters to remind the patient or the patient's guardian of services that are due.	DC.2.5.2		N		Reminders that include PHI must be delivered through HIPAA-compliant means.
197a			9. The system shall provide the ability to automatically generate an electronic reminder to the patient or the patient's guardian of services that are due.				2009	Reminders that include PHI must be delivered through HIPAA-compliant means.
198	F	**Clinical task assignment and routing:** Assignment, delegation and/or transmission of tasks to the appropriate parties.	1. The system shall provide the ability to create and assign tasks by user or user role.	DC.3.1.1	P			Examples of tasks are messages, notifications, inbox items, worklist to-do's. This task assignment refers to internal users. External tasks would be handled under ordering section.
199			2. The system shall provide the ability to present a list of tasks by user or user role.	DC.3.1.1	N			Examples of tasks are messages, notifications, inbox items, worklist to-do's. This task assignment refers to internal users. External tasks would be handled under ordering section.
200			3.The system shall provide the ability to re-assign and route tasks from one user to another user.	DC.3.1.1	N			

AMBULATORY FUNCTIONALITY
2007 Final Criteria - March 16, 2007
For 2007 Certification of Ambulatory EHRs

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201			4. The system shall provide the ability to designate a task as completed.	DC.3.1.1	P			
202			5. The system shall provide the ability to remove a task without completing the task.	DC.3.1.1	P			Removing a task eliminates it from an individual user's "to do" list, not from audit logs, etc.
203			6. The system shall provide the ability to automatically escalate incomplete tasks to the appropriate supervisor or authority.	DC.3.1.1			2009	Escalation can be based on elapsed time or time of day.
204	F	**Inter-provider communication:** Support secure electronic communication (inbound and outbound) between providers in the same practice to trigger or respond to pertinent actions in the care process (including referral), document non-electronic communication (such as phone calls, correspondence or other encounters) and generate paper message artifacts where appropriate.	1. The system shall provide the ability to document verbal/telephone communication into the patient record.	DC.3.2.1	P			
205			2. The system shall provide the ability to incorporate paper documents from external providers into the patient record.	DC.3.2.1	P			
206			3. The system shall support messaging between users.	DC.3.2.1	P			Results and other patient data could be included. As clarification, messaging is defined as any text string sent from one person to another in the office.
207	F	**Pharmacy communication:** Provide features to enable secure and reliable communication of information electronically between practitioners and pharmacies or between practitioner and intended recipient of pharmacy orders.	1. The system shall have the ability to provide electronic communication between prescribers and pharmacies or other intended recipients of the medication order.	DC.3.2.2	P			Until electronic standards are established, FAX is a suitable means of transmission.
208			2. The system shall provide the ability to electronically communicate from the prescriber to the pharmacy an initial medication order as well as renewals of an existing order.	DC.3.2.2	N			
208a			3. The system shall have the ability to electronically communicate cancellations from the prescriber to the pharmacy.			N		

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

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209			4. The system shall provide the ability to capture and display any renewal requests received electronically from or on behalf of any dispensing entity.	DC.3.2.2	N			This refers to e-prescribing.
209a			5. The system shall provide the ability to capture and display notification of prior authorizations received electronically from or on behalf of any dispensing entity.				2009	Dependent upon standards development and availability
210	F	**Provider demographics:** Provide a current directory of practitioners that, in addition to demographic information, contains data needed to determine levels of access required by the EHR security and to support the practice of medicine.	1. The system shall provide the ability to maintain a directory of all clinical personnel who currently use or access the system.	S.1.3.1	P			
211			2. The system shall provide the ability to maintain a directory which contains identifiers required for licensed clinicians to support the practice of medicine including at a minimum state medical license, DEA, NPI, and UPIN number.	S.1.3.1	N			This directory may be the same as that in criterion #1 for this functionality.
212			3. The system shall provide the ability to maintain a directory that stores user attributes required to determine the system security level to be granted to each user.	S.1.3.1	P			This directory may be the same as that in criterion #1 for this functionality.
213			4. The system shall allow authorized users to update the directory.	S.1.3.1	P			
214			5. The system shall provide the ability to create and maintain a directory of clinical personnel external to the organization who are not users of the system to facilitate communication and information exchange.	S.1.3.1	M			This directory may be the same as that in criterion #1 for this functionality.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

Compliance Key:

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Original line # Phase I	WG	Category and Description	Specific Criteria	Source or References* * See reference list at end of document	Compliance: Certify in May 2007	Compliance: Roadmap for May 2008	Compliance: Roadmap for May 2009 and beyond	Discussion / Comments
215	F	**Scheduling:** Support interactions with other systems, applications, and modules to provide the necessary data to a scheduling system for optimal efficiency in the scheduling of patient care, for either the patient or a resource/device.	1. The system shall provide the ability to display a schedule of patient appointments, populated either through data entry in the system itself or through an external application interoperating with the system.	S.1.6	P			
216	F	**Report Generation:** Provide report generation features for the generation of standard and ad hoc reports	1. The system shall provide the ability to generate reports of clinical and administrative data using either internal or external reporting tools.	S.2.2	N			Needed for pay for performance, quality improvement activities. All data that is entered in a structured format should be individually reportable.
217			2. The system shall provide the ability to generate reports consisting of all or part of an individual patient's medical record (e.g. patient summary).	S.2.2	P			Report format may be plain text.
218			3. The system shall provide the ability to generate reports regarding multiple patients (e.g. diabetes roster).	S.2.2	N			Any disease registry might be included.
219			4. The system shall provide the ability to specify report parameters (sort and filter criteria) based on patient demographic and clinical data (e.g., all male patients over 50 that are diabetic and have a HbA1c value of over 7.0 or that are on a certain medication).	S.2.2	N			Minimum demographic data are age and gender.
220			5. The system shall provide the ability to access reports outside the EHR application.	S.2.2	P			For example, printed output, export to a file, etc.
221			6. The system shall provide the ability to produce reports based on the absence of a clinical data element (e.g., a lab test has not been performed or a blood pressure has not been measured in the last year).	S.2.2		N		

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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Original line # Phase I	WG	Category and Description	Specific Criteria	Source or References* * See reference list at end of document	Compliance: Certify in May 2007	Compliance: Roadmap for May 2008	Compliance: Roadmap for May 2009 and beyond	Discussion / Comments
222			7. The system shall provide the ability to save report parameters for generating subsequent reports.	S.2.2	N			
223			8. The system shall provide the ability to modify one or more parameters of a saved report specification when generating a report using that specification.	S.2.2		N		
224	F	**Health record output:** Allow users to define the records and/or reports that are considered the formal health record for disclosure purposes, and provide a mechanism for both chronological and specified record element output.	1. The system shall provide the ability to define one or more reports as the formal health record for disclosure purposes.	S.2.2.1	N			This allows the practice to not print demographics, certain confidential sections, or other items. Report format may be plain text initially. In the future there will be a need for structured reports as interoperability standards evolve.
225			2. The system shall provide the ability to generate hardcopy or electronic output of part or all of the individual patient's medical record.	S.2.2.1	P			This could include but is not limited to the ability to generate standardized reports needed for work, school, or athletic participation.
226			3. The system shall provide the ability to generate hardcopy and electronic output by date and/or date range.	S.2.2.1	M			

AMBULATORY FUNCTIONALITY
2007 Final Criteria - March 16, 2007
For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow	
Compliance Key:	
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N = New for Year	
M = Modified for Year	

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227			4. The system shall provide the ability to export structured data which removes those identifiers listed in the HIPAA definition of a limited dataset. This export on hardcopy and electronic output leaves the actual PHI data unmodified in the original record.	S.2.2.1		N		De-identifying data on hardcopy or electronic output is necessary for research. However, it must be emphasized that this function is not intended to cleanse the text in the note or data in the original record. As per HIPAA Standards for Privacy of Individually Identifiable Health Information, 45 CFR Parts 160 and 164, identifiers that shall be removed are: 1. Names; 2. Postal address information, other than town or city, state and zip code; 3. Telephone numbers; 4. Fax numbers; 5. Electronic mail addresses; 6. Social security numbers; 7. Medical record numbers; 8. Health plan beneficiary numbers; 9. Account numbers; 10. Certificate/license numbers; 11. Vehicle identifiers and serial numbers, including license plate numbers; 12. Device identifiers and serial numbers; 13. Web Universal Resource Locators (URLs); 14. Internet Protocol (IP) address numbers; 15. Biometric identifiers, including finger and voice prints; and 16. Full face photographic images and any comparable images.

AMBULATORY FUNCTIONALITY
2007 Final Criteria - March 16, 2007
For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow
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228			5. The system shall provide the ability to create hardcopy and electronic report summary information (procedures, medications, labs, immunizations, allergies, and vital signs).	S.2.2.1	P			The report that's produced should be organized by section to make it easier to read.
229			6. The system shall have the ability to provide support for disclosure management in compliance with HIPAA and applicable law.		N			This criterion may be satisfied by providing the ability to create a note in the patient's record. More advanced functionality may be market differentiators or requirements in later years.
230	F	**Encounter management:** Manage and document the health care delivered during an encounter.	1. The system shall provide the ability to document a patient encounter.	S.3.1	P			
231			2. The system shall provide the ability to document encounters by one or more of the following means: direct keyboard entry of text; structured data entry utilizing templates, forms, pick lists or macro substitution; dictation with subsequent transcription of voice to text, either manually or via voice recognition system.	S.3.1	P			This does not preclude entry via new technologies.
232			3. The system shall provide the ability to associate individual encounters with diagnoses.	S.3.1	P			
233			4. The system shall have the ability to provide filtered displays of encounters based on encounter characteristics, including date of service, encounter provider and associated diagnosis.	S.3.1	N			
234	F	**Rules-driven financial and administrative coding assistance:** Provide financial and administrative coding assistance based on the structured data available in the encounter documentation.	1. The system shall have the ability to provide a list of financial and administrative codes.	S.3.2.2	P			For example, ICD-9 CM, ICD-10 CM, and CPT-4 codes.
235			2. The system shall provide the ability to select an appropriate CPT Evaluation and Management code based on data found in a clinical encounter.	S.3.2.2	P			May be accomplished via a link to another application.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

Compliance Key:

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N = New for Year

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236			3. The system shall have the ability to provide assistance in selecting appropriate billing codes based on codified clinical information in the encounter.	S.3.2.2		N		Criterion satisfaction will require that the system can automatically count elements in the history and examination documentation to accomplish this calculation. MDM complexity will still require specification by the provider/coder.
~~237~~			Deleted.					
238	F	**Eligibility verification and determination of coverage**	1. The system shall provide the ability to display medical eligibility obtained from patient's insurance carrier, populated either through data entry in the system itself or through an external application interoperating with the system.	S.3.3.2	M			The EHR need only provide information for the physician as to whether the patient is covered by that insurance plan. This can be accomplished by a text note following telephone verification.
239			2. The system shall be capable of receiving and displaying prescription benefits eligibility information.	DC.1.7.1		N		Will be required by e-prescribing
240	F	**Manage Practitioner/Patient relationships:** Identify relationships among providers treating a single patient, and provide the ability to manage patient lists assigned to a particular provider.	1. The system shall provide the ability to identify by name all providers associated with a specific patient encounter.	S.3.4	P			A provider is defined as anyone delivering clinical care such as physicians, PAs, CNPs and nurses; the provider is the person who completes the note.
241			2. The system shall provide the ability to specify the role of each provider associated with a patient, such as encounter provider, primary care provider, attending, resident, or consultant.			N		This is simply meant as a means to define the provider role. Display of that data is not addressed.
242			3. The system shall provide the ability to specify the primary or principal provider responsible for the care of a patient within a care setting.		N			
243			4. The system shall provide the ability to create a list of all patients who have had an encounter with a given provider.			N		

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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244	F	**Clinical decision support system guidelines updates:** Receive and validate formatted inbound communications to facilitate updating of clinical decision support system guidelines and associated reference material	1. The system shall provide the ability to update the clinical content or rules utilized to generate clinical decision support reminders and alerts.	S.3.7.1	P			Growth charts, CPT-4 codes, drug interactions would be an example. Any method of updating would be acceptable. Content could be third party or customer created.
245			2. The system shall provide the ability to update clinical decision support guidelines and associated reference material.	S.3.7.1	P			Any method of updating would be acceptable. Content could be third party or customer created.
~~246~~	F	**Entity Authorization:** Manage the sets of access control permissions granted to entities that use an EHR-S. Enable EHR-S security administrators to grant authorizations to users for roles, and within contexts. A combination of the authorization levels may be applied to control access to EHR-S functions or data within an EHR-S, including at the application or the OS level.	Deleted.					
247		**Enforcement of confidentiality:** Enforce the applicable jurisdiction's patient privacy rules as they apply to various parts of an EHR-S through the implementation of security mechanisms.	1. The system shall provide the ability to audit the date/time and user of each instance when a patient chart is printed by the system.	I.1.9	N			Does not include screen print and other functions that are outside the EHR system.
248			2. The system shall provide a means to document a patient's dispute with information currently in their chart.	I.1.9		N		This does not imply that the patient can document directly in their chart. Some methods include but are not limited to allowing the patient a view only access to their record, printing a copy of the record for a patient to review. Methods to include the information in the chart could be as a note, a scanned copy of patient comments, an addendum to the note or other method not described.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

Compliance Key:

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M = Modified for Year

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249			3. The system shall provide the ability to identify all users who have accessed an individual's chart over a given time period, including date and time of access.	I.1.9	N			Specific items/sections of information accessed shall be identified, with appropriate audit trail.
250			4. The system shall provide the ability to identify certain information as confidential and only make that accessible by appropriately authorized users.	I.1.9		N		This may be implemented by having a "confidential" section of the chart
251			5. The system shall provide the ability to prevent specified user(s) from accessing a designated patient's chart	I.1.9		N		An example would be preventing access to a VIP or staff member's chart. When access is restricted, the system shall provide a means for appropriately authorized users to "break the glass" for emergency situations. Such overrides should be audited.
252	**F**	**Data retention, availability, and destruction:** Retain, ensure availability, and destroy health record information according to organizational standards. This includes: Retaining all EHR-S data and clinical documents for the time period designated by policy or legal requirement; Retaining inbound documents as originally received (unaltered); Ensuring availability of information for the legally prescribed period of time; and Providing the ability to destroy EHR data/records in a systematic way according to policy and after the legally prescribed retention period.	1. The system shall provide the ability to retain data until otherwise purged, deleted, archived or otherwise deliberately removed.	I.2.1	P			
253			2. The system shall provide a method for archiving health record information.	I.2.1			2009	Archiving is used to mean information stored in a retrievable fashion without defining where or how it is stored.
253a			3. The system shall provide the ability to retrieve information that has been archived.				2009	Retrieval does not imply restoration to current version of the software.
~~254~~			Deleted.					

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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255	F	**Audit trail:** Provide audit trail capabilities for resource access and usage indicating the author, the modification (where pertinent), and the date and time at which a record was created, modified, viewed, extracted, or removed. Audit trails extend to information exchange and to audit of consent status management (to support DC.1.5.1) and to entity authentication attempts. Audit functionality includes the ability to generate audit reports and to interactively view change history for individual health records or for an EHR-system.	1. The system shall provide the ability to log outgoing information exchange in an auditable form.	I.2.2		N		In future, the work group will clarify details of what should be included in the log, and revise timing of this criterion based on those elements, if required.
256			2. The system shall provide the ability to log the receipt of documents in an auditable form.	I.2.2		N		
257	F	**Extraction of health record information:** Manage data extraction in accordance with analysis and reporting requirements. The extracted data may require use of more than one application and it may be pre-processed (for example, by being de-identified) before transmission. Data extractions may be used to exchange data and provide reports for primary and ancillary purposes.	1. The system shall provide the ability to export (extract) pre-defined set(s) of data out of the system	I.2.4	N			For example, export of performance measures, ability to query data base, chronic disease management tools.
258			2. The system shall provide the ability to import data into the system	I.2.4	N			Data import implies receiving discrete data into the EHR in an automated manner as opposed to manual data entry or document scanning. This could be accomplished via a real time or batch interface or a manual data load.
259			3. The system shall provide the ability remove discrete patient identifiers.	I.2.4	N			De-identification is necessary for research purposes, e.g., to identify patterns of disease. External applications can be used to meet this criteria.

AMBULATORY FUNCTIONALITY

2007 Final Criteria - March 16, 2007

For 2007 Certification of Ambulatory EHRs

Provisional Criteria (2007) are highlighted in yellow

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260			4. The system shall provide the ability to specify the intended destination of the extracted information.	I.2.4		N		The user may indicate to whom they are sending results. The lack of control of information once it leaves the practice is acknowledged.
261	F	**Concurrent Use:** EHR system supports multiple concurrent physicians through application, OS and database.	1. The system shall provide the ability for multiple users to interact concurrently with the EHR application.	Ontario 5.6.1.a	P			
262			2. The system shall provide the ability for concurrent users to simultaneously view the same record.	Ontario 5.6.1.a	P			
263			3. The system shall provide the ability for concurrent users to view the same clinical documentation or template.	Ontario 5.6.1.a	P			
264			4. The system shall provide protection to maintain the integrity of clinical data during concurrent access.	Ontario 5.6.1.a, I.1.9	P			To prevent users from simultaneously attempting to update a record with resultant loss of data

References:

1) DC, I and S prefixed references are from: HL7 EHR-S Functional Model, Release 1 - September 2006 from www.hl7.org.

2) Ontario specification refereneces are from: Ontario Medical Association, CMS Local Solution Specification V1.3. Copy located at: http://www.ontariomd.ca/cms/infoForVendors.shtml

Ambulatory Interoperability - 2007 Final Criteria - March 16, 2007

INTEROPERABILITY For 2007 Certification of Ambulatory EHRs

Compliance Key:	
N=New for 2007	
P=Previous Criteria	
M=Modified for 2007	

Line Number	WG	Category and Description	Specific Criteria	Source or References * See References at end of document	Compliance Certify in May 2007	Compliance Roadmap for May 2008	Compliance Roadmap for May 2009 and beyond	Discussion / Comments
IA-1.01	II	Laboratory	Receive general laboratory results (includes ability to replace preliminary results with final results and the ability to process a corrected result)	Either HL7 v2.4 or HL7 v2.5.1, LOINC	N			The test files are designed so that products implementing either the HL7 v2.4 or HL7 v2.5.1 standard will be found compliant. The test identifier will be encoded in LOINC, and will be drawn from among 52 common test codes. Refer to *2007 CCHIT Laboratory Interoperability Test Instructions and Applicant Form* for the list of these codes and more information on the interoperability test procedure.
IA-1.02			Receive microbiology laboratory results	HITSP IS-01 EHR-Lab, HL7 v2.5, ELINCS v2.1 LOINC, SNOMED		N		Organisms will be coded using SNOMED, Sensitivity testing will be coded using LOINC
IA-1.03			Respond to a query to share laboratory results	HITSP IS-01 EHR-Lab, HL7 CDA R2 IHE XDS-Lab		N		Part of ONC EHR-Lab Use Case Will work with Ambulatory Functionality WG to align functionality criteria and interoperability roadmap dates in preparation for next round of public comments.
IA-1.04			Send an order for a laboratory test	HL7 v2.5 / Implementation guide not available yet / improvements or alternatives to LOINC required for test ordering			N	Further work is need on defining the ordering messages and codes for ordering tests, should include an EHR generated order number for tracking
IA-1.05			Send a query to check status of a test order	Implementation guide not available			N	Part of a function for closing the orders loop as part of quality improvement. Also need to be able to detect orders not matched with results.
IA-2.01	II	Imaging	Receive imaging reports and view images, includes ECG and other images as well as radiology	IHE XDS-I Cross-Enterprise Image Information Sharing integration profile		N		
IA-2.02			Send a query to other providers to share imaging results	IHE XDS-I Cross-Enterprise Image Information Sharing integration profile		N		see also line IA 5.6 send a query to a registry for documents
IA-2.03			Respond to a query to share imaging results with other providers	IHE XDS-I Cross-Enterprise Image Information Sharing integration profile		N		
IA-2.04			Order radiology tests	HL7 v2.5			N	Final standards to be selected in 2008
IA-2.05			Schedule radiology tests	IHE XDS-I Procedure Scheduled			N	Final standards to be selected in 2008

Ambulatory Interoperability - 2007 Final Criteria - March 16, 2007

INTEROPERABILITY For 2007 Certification of Ambulatory EHRs

Compliance Key:	
N=New for 2007	
P=Previous Criteria	
M=Modified for 2007	

Line Number	WG	Category and Description	Specific Criteria	Source or References * See References at end of document	Compliance: Certify in May 2007	Compliance: Roadmap for May 2008	Compliance: Roadmap for May 2009 and beyond	Discussion / Comments
IA-3.01	II	Medications	Send an electronic prescription to pharmacy	NCPDP Script 8.1 (NEWRX)	N			Will be aligned with Medicare Part D final regulations
IA-3.02			Respond to a request for a refill sent from a pharmacy	NCPDP Script 8.1 (REFREQ, REFRES)	N			Transaction is now wide spread use so that systems that send new prescriptions need to be ready to respond to requests for refills.
IA-3.03			Send a cancel prescription message to a pharmacy	NCPDP Script 8.1 (CANRX, CANRES)		N		Sent by the prescriber to cancel a prescription that was sent previously
IA-3.04			Respond to a request for a prescription change from a pharmacy	NCPDP Script 8.1 (RXCHG, CHGRES)		N		Sent by the pharmacy to request that the prescriber make changes to a prescription before it is filled.
IA-3.05			Send electronic prescription to pharmacy including structured and coded SIG instructions	NCPDP Script 11.1 not available yet			N	Standard has been written but has not been finalized, balloted, or implemented. Will work with Ambulatory Functionality WG to align functionality criteria and interoperability roadmap dates in preparation for next round of public comments.
IA-3.06			Send a query to verify prescription drug insurance eligibility and coverage	X12 270/271/ CORE Phase I Rules		N		An essential first step prior to sending a query for medication history or formulary information directed at prescription drug coverage.
IA-3.07			Access and view formulary information from pharmacy or PBM	NCPDP Formulary and Benefit Standard Implementation Guide v1.0		N		Usually preceded by a query for insurance eligibility to verify potential source of data.
IA-3.08			Send a query for medication history to PBM or pharmacy to access and view medication list from EHR	NCPDP Script 8.1 (RXHREQ, RXHRES) / NDC codes		N		Part of ONC CE-PHR Use Case, used effectively during Medicare Part D pilots.
IA-3.09			Receive medication fulfillment history	NCPDP Script 8.12 (RXFILL)		N		Sent by pharmacy after medication has been dispensed to the patient, not currently in wide spread use but is a priority for providers
IA-3.10			Access and view a medication history from a PHR	HITSP IS-03 CE-PHR Interoperability Specification HL7-ASTM CCD, IHE XDS-XPHR, ASTM CCR		N		Part of ONC CE-PHR Use Case, may use PHR standards such as HL7/CCD and ASTM CCR instead of NCPDP standards. Will probably use RxNORM medication codes that are more appropriate for consumers and providers than the NDC codes used by pharmacies.

Ambulatory Interoperability - 2007 Final Criteria - March 16, 2007

INTEROPERABILITY For 2007 Certification of Ambulatory EHRs

Compliance Key:	
N=New for 2007	
P=Previous Criteria	
M=Modified for 2007	

Line Number	WG	Category and Description	Specific Criteria	Source or References * See References at end of document	Compliance			Discussion / Comments
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IA-3.11			Respond to a query for medication history send by a PHR	HITSP IS-03 CE-PHR Interoperability Specification		N		Part of ONC CE-PHR Use Case, may use PHR standards such as HL7/CCD and ASTM CCR instead of NCPDP standards, final standards to be specified by HITSP.
IA-4.01	II	Immunizations	Send a report of patient immunizations to an immunization registry	TBD			N	State immunization registries are not using uniform national standards at this time The cvx and mvx vocabularies constitute an option for representing immunizations, but have not been addressed by HITSP at this time. Working Group will evaluate standards and options for future versions of HL7.
IA-4.02			Send a query to retrieve immunization to an immunization registry and import immunization record into the EHR	TBD			N	State immunization registries are not using uniform national standards at this time The cvx and mvx vocabularies constitute an option for representing immunizations, but have not been addressed by HITSP at this time. Working Group will evaluate standards and options immunizations.
IA-4.03			Import immunization history from a PHR	HL7-ASTM CCD, IHE XDS-XPHR			N	May be part of ONC Use Cases for 2007, represents an alternative to obtaining this data from State immunization registries
IA-5.01	II	Clinical Documentation	Register documents with document registry	IHE Cross-Enterprise Document Sharing (XDS) integration profile			N	The ability to register documents in a registry or a repository will be part of the NHIN and final architecture has not been selected.
IA-5.02			Send a query a document registry for documents	IHE Cross-Enterprise Document Sharing (XDS) integration profile			N	This criteria is for the query request. This function deals only with the document registry and repository and the references to specific documents have been removed. When the criteria are finalized, any document constraints that are required by the network standards will be identified.

Ambulatory Interoperability - 2007 Final Criteria - March 16, 2007

INTEROPERABILITY For 2007 Certification of Ambulatory EHRs

Compliance Key:

N=New for 2007

P=Previous Criteria

M=Modified for 2007

Line Number	WG	Category and Description	Specific Criteria	Source or References * See References at end of document	Compliance: Certify in May 2007	Compliance: Roadmap for May 2008	Compliance: Roadmap for May 2009 and beyond	Discussion / Comments
IA-5.03			Send documents to repository	IHE Cross-Enterprise Document Sharing (XDS) integration profile			N	This criteria is for sending documents to the repository. The function of sending documents to a repository may be independent of the specific types of documents that will be identified by the network standards. Use of HITSP harmonized standards is expected and it is too early to set those standards at this time.
IA-5.04			Respond to a query to provide a document that was previously registered in a repository	IHE Cross-Enterprise Document Sharing (XDS) integration profile			N	This function refers only to the ability to provide a document that has been registered in response to a query. The ability to create documents and medical summaries are discussed in other lines below.
IA-5.05			Create and Send electronic documentation of a visit such as a consult letter to a referring physicians	HL7 CDA R2		N		Will include narrative data
IA-5.06			Import a clinical document such as a hospital discharge summary, a letter from a consultant, or an imaging report	HL7 CDA R2		N		Will include narrative data
IA-5.07			Send Medical Summary to refer or transfer clinical care of patient	HL7-ASTM CCD, ASTM CCR		N		Used for structured data. Use of CCR will require available translation to CCD.
IA-5.08			Receive Medical Summary and import into EHR for consult or transfer of clinical care	HL7-ASTM CCD, ASTM CCR		N		May use direct communication or a regional network
IA-5.09			Send data to PHR	HL7-ASTM CCD, IHE XDS-XPHR, ASTM CCR, HITSP IS-03 Consumer Empowerment		N		Use of CCR will require available translation to CCD, Use of XPHR is for interim use per HITSP IS-03
IA-5.10			Receive data from PHR and import into EHR	HL7-ASTM CCD, IHE XDS-XPHR, ASTM CCR, HITSP IS-03 Consumer Empowerment		N		Use of CCR will require available translation to CCD, Use of XPHR is for interim use per HITSP IS-03
IA-5.11			Receive registration summary from patient and import into EHR	HL7-ASTM CCD, IHE XDS-XPHR, ASTM CCR, HITSP IS-03 Consumer Empowerment		N		Use of CCR will require available translation to CCD, Use of XPHR is for interim use per HITSP IS-03
IA-6.01	II	**Chronic Disease Management / Patient Communication**	Secure electronic messaging with patients	Standards to be selected		N		Part of AHIC Chronic Care Breakthrough, standards and implementation guides have not been selected yet

Ambulatory Interoperability - 2007 Final Criteria - March 16, 2007

INTEROPERABILITY For 2007 Certification of Ambulatory EHRs

Compliance Key:

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IA-6.02			Import home physiologic monitoring data from patients	Standards to be selected			N	Part of AHIC Chronic Care Breakthrough, standards and implementation guides have not been selected yet
IA-7.01	II	Secondary Uses of Clinical Data	Send patient specific Public Health Disease Report for a reportable disease	CDC Disease registries, Public Health Information Network (PHIN)			N	Electronic replacement for traditional reportable disease notifications to health departments, may become part of bio-surveillance in the future.
IA-7.02			Send anonymous utilization and laboratory bio-surveillance data to public health agencies	HITSP IS-02 Biosurveillance Use Case Interoperability Specification; clinical content to be selected by the bio-surveillance data committee		N		ONC Bio-surveillance Use Case
IA-7.03			Quality Improvement reporting	TBD			N	Standards and implementation guides are not available yet and will be evaluated by the Work Group. An AHIC Quality Workgroup is being formed to address this.
IA-8.01	II	Administrative and Financial Data	Query and receive electronic medical insurance eligibility information	X12 270/271/ CORE Phase I Rules			N	Separated this requirement from IA-3.6 to avoid duplication of criteria.
IA-8.02			Send a query to coordinate patient identification	IHE PIX profile, IHE PDQ			N	Patient identification coordination will be part of network certification scheduled to begin in 2009 and is required as part of the document transport criteria.
IA-8.03			Practice Management System Communication, Revenue Cycle Related Transactions	X12, HL7, and related standards and codes			N	CCHIT requires more input on stakeholder priorities and feasibility of certifying a standard interface between all EHR systems and all practice management systems and billing systems
IA-8.04			Receive patient registration data from a practice management system	HL7 2.4 Patient Administration, X12N 4010		N		Transfer of registration and patient identification data between practice management systems and EHR is very desirable. Although earlier certification is desirable, without implementation guides, certification cannot happen.

Ambulatory Interoperability - 2007 Final Criteria - March 16, 2007

INTEROPERABILITY For 2007 Certification of Ambulatory EHRs

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IA-8.05			Receive scheduling information from a scheduling system	HL7 2.4 Scheduling		N		Transfer of data between a practice management scheduling system and an EHR is highly desirable and is essential for some EHR operations. Although earlier certification is desirable, without implementation guides, certification cannot happen.
IA-8.06			Send a query from the EHR to a scheduling system to schedule and appointment	Standards to be selected			N	The ability to schedule an appointment during a patient encounter will require new standards
IA-8.07			Receive electronic authorization for referral from payor	X12 278 - Health Care Services Review: Referral Certification and Authorization - Dental, Professional, Institutional;			N	Only a handful of insurers are supporting this today.
IA-9.01	II	Clinical Trials	Respond to query to Identify patients eligible for a clinical trial	NCI CABIG, CDISC			N	Clinical trial will send eligibility criteria, EHR will identify patients for review by practice and respond with a count of potentially eligible patients and an intent to participate or not participate in the trial
IA-9.02			Send data to register a patient in a clinical trial	NCI CABIG, CDISC			N	will include informed consent
IA-9.03			Receive clinical trial protocol and templates for data collection	NCI CABIG, CDISC			N	will include clinical trial protocol and data collection templates
IA-9.04			Send data report to a clinical trial	NCI CABIG, CDISC			N	will require digital signature to assure authentication, integrity, and non-repudiation

Ambulatory Interoperability - 2007 Final Criteria - March 16, 2007

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References:

HL7: (Health Level 7 - including v2.4; v3.5.1; CDA R2). http://www.hl7.org.

LOINC (Logical Observation Identifiers Names and Codes), Regenstrief Institute. http://www.regenstrief.org/medinformatics/loinc/

HITSP: (Health Information Technology Standards Panel – including IS-01 (EHR – Lab); IS-02 (Biosurveillence); IS-03 (CE-PHR).) http://www.ansi.org/hitsp/

IHE: (Integrated Health Enterprise - including XDS-Lab; XSD-I; XDS-XPHR; PDQ; PIX). http://www.ihe.net/

SNOMED (Systematized Nomenclature of Medicine –College of American Pathologists). http://www.snomed.org

ELINCS: (EHR-Lab Interoperability and Connectivity Specification - including v2.1), California HealthCare Foundation. http://www.chcf.org/topics/chronicdisease/index.cfm?itemID=108868

NCPDP: (National Council for Prescription Drug Programs - including Script v8.1, Formulary and Benefit Standard Implementation Guide v1.0). http://www.ncpdp.org/

NDC: (The National Drug Code Directory – US Federal Food and Drug Administration) http://www.fda.gov/cder/ndc/

HL7-ASTM CCD: (HL7/ASTM Implementation Guide for CDA Release 2 – Continuity of Care Document) - http://www.hl7.org/documentcenter/ballots/2007JAN/downloads/CDAR2_IMPL_CCD_I2_2007JAN.zip :

NCI CaBIG: (The National Cancer Institute - Cancer Biomedical Informatics Grid), https://cabig.nci.nih.gov/overview

CDISC: (Clinical Data Interchange Standards Consortium), http://www.cdisc.org/standards

Security - 2007 Final Criteria - Mar 16 2007

Final Secuirty Criteria For 2007 Certification of EHRs

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S1	Sec	Security: Access Control	The system shall enforce the most restrictive set of rights/privileges or accesses needed by users/groups (e.g. System Administration, Clerical, Nurse, Doctor, etc.), or processes acting on behalf of users, for the performance of specified tasks.	ISO 17799: 9.1.1.2.b; HIPAA: 164.312(a)(1)	P			
S2			The system shall provide the ability for authorized administrators to assign restrictions or privileges to users/groups.	Canadian: Alberta 4.1.3 (EMR); CC SFR: FMT_MSA; SP800-53: AC-5 LEAST PRIVILEGE; HIPAA: 164.312(a)(1)	P			
S3			The system must be able to associate permissions with a user using one or more of the following access controls: 1) user-based (access rights assigned to each user); 2) role-based (users are grouped and access rights assigned to these groups); or 3) context-based (role-based with additional access rights assigned or restricted based on the context of the transaction such as time-of-day, workstation-location, emergency-mode, etc.)	Canadian: Ontario 5.3.12.e (System Access Management); CC SFR: FDP_ACC, FMT_MSA; ASTM: E1985-98; SP800-53: AC-3 ACCESS AND INFORMATION FLOW CONTROL; HIPAA: 164.312(a)(1)	P			
S4			The system shall support removal of a user's privileges without deleting the user from the system. The purpose of the criteria is to provide the ability to remove a user's privileges, but maintain a history of the user in the system.		M			
S5.1	Sec	Security: Audit	**Removed**		M			
S5.2			The system shall be able to detect security-relevant events that it mediates and generate audit records for them. At a minimum the events shall include: start/stop, user login/logout, session timeout, account lockout, patient record created/viewed/updated/deleted, scheduling, query, order, node-authentication failure, signature created/validated, PHI export (e.g. print), PHI import, and security administration events. Note: The system is only responsible for auditing security events that it mediates. A mediated event is an event that the system has some active role in allowing or causing to happen or has opportunity to detect. The system is not expected to create audit logs entries for security events that it does not mediate.	CC SFR: FAU_GEN; SP800-53: AU-2 AUDITABLE EVENTS; HIPAA: 164.312(b)	M			

Security - 2007 Final Criteria - Mar 16 2007

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S6			The system shall record within each audit record the following information when it is available: (1) date and time of the event; (2) the component of the system (e.g. software component, hardware component) where the event occurred; (3) type of event (including: data description and patient identifier when relevant); (4) subject identity (e.g. user identity); and (5) the outcome (success or failure) of the event.	CC SFR: FAU_GEN; SP800-53: AU-3 CONTENT OF AUDIT RECORDS, AU-10 NON-REPUDIATION; HIPAA: 164.312(b)	P			
S7			The system shall provide authorized administrators with the capability to read all audit information from the audit records in one of the following two ways: 1) The system shall provide the audit records in a manner suitable for the user to interpret the information. The system shall provide the capability to generate reports based on ranges of system date and time that audit records were collected. 2) The system shall be able to export logs into text format in such a manner as to allow correlation based on time (e.g. UTC synchronization).	CC SFR: FAU_SAR; SP800-53: AU-7 AUDIT REDUCTION AND REPORT GENERATION; HIPAA: 164.312(b)	M			
S8.1			The system shall be able to support time synchronization using NTP/SNTP, and use this synchronized time in all security records of time.	CC SFR: FPT_STM; SP800-53: AU-8 TIME STAMPS	P			
S8.2			The system shall have the ability to format for export recorded time stamps using UTC based on ISO 8601. Example: "1994-11-05T08:15:30-05:00" corresponds to November 5, 1994, 8:15:30 am, US Eastern Standard Time.	CC SFR: FPT_STM; SP800-53: AU-8 TIME STAMPS	M			
S9			The system shall prohibit all users read access to the audit records, except those users that have been granted explicit read-access. The system shall protect the stored audit records from unauthorized deletion. The system shall prevent modifications to the audit records.	CC SFR: FAU_SAR, FAU_STG; SP800-53: AU-9 PROTECTION OF AUDIT INFORMATION; HIPAA: 164.312(a)(1)	P			
S10			**Removed**		M			

Security - 2007 Final Criteria - Mar 16 2007

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S11			The system shall allow an authorized administrator to enable or disable auditing for groups of related events to properly collect evidence of compliance with implementation-specific policies. Note: In response to a HIPAA-mandated risk analysis and management, there will be a variety of implementation-specific organizational policies and operational limits.	CC SFR: FAU_SEL; HIPAA 164.312(b)	**M**			
S12	Sec	Security: Authentication	The system shall authenticate the user before any access to Protected Resources (e.g. PHI) is allowed, including when not connected to a network e.g. mobile devices.	Canadian: Alberta 1.1; CC SFR: FIA_UAU, FIA_UID; SP800-53: IA-2 USER IDENTIFICATION AND AUTHENTICATION; HIPAA: 164.312(d)	**P**			
S13			When passwords are used, the system shall support password strength rules that allow for minimum number of characters, and inclusion of alpha-numeric complexity.	Canadian: Alberta 7.3.12 (Security) Canadian Ontario 5.3.12.b (System Access Management); CC SFR: FIA_SOS, FIA_UAU, FIA_UID; ASTM: E1987-98; SP800-53: IA-2 USER IDENTIFICATION AND AUTHENTICATION (no strength of password); ISO 17799: 9.3.1.d; HIPAA: 164.	**P**			
S14			The system upon detection of inactivity of an interactive session shall prevent further viewing and access to the system by that session by terminating the session, or by initiating a session lock that remains in effect until the user reestablishes access using appropriate identification and authentication procedures. The inactivity timeout shall be configurable.	Canadian: Alberta 7.3.14 (Security) Canadian Ontario 5.6.12.a (Workstation Security); CC SFR: FTA_SSL, FMT_SAE; SP800-53: AC-11 SESSION LOCK; HIPAA: 164.312(a)(1)	**M**			
S15			The system shall enforce a limit of (configurable) consecutive invalid access attempts by a user. The system shall protect against further, possibly malicious, user authentication attempts using an appropriate mechanism (e.g. locks the account/node until released by an administrator, locks the account/node for a configurable time period, or delays the next login prompt according to a configurable delay algorithm).	Canadian: Ontario 5.3.12.c (System Access Management); CC SFR: FIA_AFL, FMT_SAE; SP800-53: AC-6 UNSUCCESSFUL LOGIN ATTEMPTS, AC-11 SESSION LOCK ; ISO 17799: 9.3.1.e, 9.5.2.e; HIPAA: 164.312(a)(1)	**M**			
S16.1			When passwords are used, the system shall provide an administrative function that resets passwords.	CC SFR: FMT_MTD; ISO 17799: 9.2.3.b, (9.3.1.f); HIPAA: 164.312(d)	**P**			

Security - 2007 Final Criteria - Mar 16 2007

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S16.2			When passwords are used, user accounts that have been reset by an administrator shall require the user to change the password at next successful logon.	CC SFR: FMT_MTD; ISO 17799: 9.2.3.b, (9.3.1.f); HIPAA: 164.312(d)	P			
S17			The system shall provide only limited feedback information to the user during the authentication.	CC SFR: FIA_UAU; SP800-53: IA-6 AUTHENTICATOR FEEDBACK; HIPAA: 164.312(d)	P			
S18			The system shall support case-insensitive usernames that contain typeable alpha-numeric characters in support of ISO-646/ECMA-6 (aka US ASCII).	CC SFR: FMT_MTD	P			
S19			When passwords are used, the system shall allow an authenticated user to change their password consistent with password strength rules (S13).	CC SFR: FMT_MTD	P			
S20			When passwords are used, the system shall support case-sensitive passwords that contain typeable alpha-numeric characters in support of ISO-646/ECMA-6 (aka US ASCII).	Canadian: Ontario 5.3.12 (b); SP 800-63	P			
S21			When passwords are used, the system shall not store passwords in plain text.		P			
S22			When passwords are used, the system shall prevent the reuse of passwords previously used within a specific (configurable) timeframe (i.e., within the last X days, etc. - e.g. "last 180 days"), or shall prevent the reuse of a certain (configurable) number of the most recently used passwords (e.g. "last 5 passwords").	CC SFR: FMT_MTD; ISO 17799 9.5.4.f; HIPAA 164.312(d)	M			
S23	Sec	Security: Documentation	The system shall include documentation available to the customer that provides guidelines for configuration and use of the EHR security controls necessary to support secure and reliable operation of the system, including but not limited to: creation, modification, and deactivation of user accounts, management of roles, reset of passwords, configuration of password constraints, and audit logs.	CC SFR: AGD_ADM	M			
S24	Sec	Security: Technical Services	The system shall support protection of confidentiality of all Protected Health Information (PHI) delivered over the Internet or other known open networks via encryption using triple-DES (3DES) or the Advanced Encryption Standard (AES) and an open protocol such as TLS, SSL, IPSec, XML encryptions, or S/MIME or their successors.	Canadian: Alberta 7.4.6.2 & 8.4.6.2 (Technical); CC SFR: FCS_COP; SP800-53: SC-13 CRYPTOGRAPHIC OPERATIONS; HIPAA: 164.312(e)(1)	P			

Security - 2007 Final Criteria - Mar 16 2007

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S25			When passwords are used, the system shall not transport passwords in plain text.	Canadian: Ontario 5.3.12.a (System Access Management); CC SFR: FCS_CKM; SP800-53: SC-12 CRYPTOGRAPHIC KEY ESTABLISHMENT AND MANAGEMENT; HIPAA: 164.312(e)(1)	P			
S26			When passwords are used, the system shall not display passwords while being entered.	CC SFR: FPT_ITC; ISO 17799 9.2.3; HIPAA 164.312(a)(1)	P			
S27			For systems that provide access to PHI through a web browser interface (i.e. HTML over HTTP) shall include the capability to encrypt the data communicated over the network via SSL (HTML over HTTPS). Note: Web browser interfaces are often used beyond the perimeter of the protected enterprise network	CC SFR: AGD_ADM	P			
S28			The system shall support protection of integrity of all Protected Health Information (PHI) delivered over the Internet or other known open networks via SHA1 hashing and an open protocol such as TLS, SSL, IPSec, XML digital signature, or S/MIME or their successors.	CC SFR: FPT_RCV	P			
S29			The system shall support ensuring the authenticity of remote nodes (mutual node authentication) when communicating Protected Health Information (PHI) over the Internet or other known open networks using an open protocol (e.g. TLS, SSL, IPSec, XML sig, S/MIME).	CC SFR: FPT_RCV	P			
S30	Sec		The system, when storing PHI on any physical media intended to be portable/removable (e.g. thumb-drives, CD-ROM, PDA), shall support use of a standards based encrypted format using triple-DES (3DES), and the Advanced Encryption Standard (AES).	FIPS 140-2, CC SFR: FCS_COP, OMB M-06-16			N	
S31	Sec	Security: Authentication	The system shall support two-factor authentication in alignment with NIST 800-63 Level 3 Authentication. Note: The standards in this area are still evolving.	CC SFR: FIA_UAU; SP800-53: IA-2/AC-19, OMB M-06-16			N	
S32	Sec	Security: Technical Services	The system shall support the storage of any Protected Health Information (PHI) data on any associated mobile device(s) such as PDAs, smartphones, etc. in an encrypted format, using triple-DES (3DES), the Advanced Encryption Standard (AES), or their successors.	FIPS 140-2, CC SFR: FCS_COP, OMB M-06-16, SP800-53: AC-19			N	

Security - 2007 Final Criteria - Mar 16 2007

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S33	Sec		The system, prior to a user login, shall display a (configurable) notice warning (e.g. "The system should only be accessed by authorized users").	CC 2.1 L.4 TOE access banners (FTA_TAB); CC 3.0 FIA_TIN.1 Advisory warning message			N	
S34	Sec	Security: Access Control	The system shall allow certain role clinicians to mark a patient's specific information as blinded, prohibiting access to all other users. Note: The standards in this area are still evolving.	§164.312(a)(2)(ii)		N		
S35	Sec		The system shall support access to blinded information to a treating clinician, when the blinded information is necessary for managing an emergency condition. Note: This is commonly known as a "break the glass" function. This does not provide increased access rights for the user.	§164.312(a)(2)(ii)		N		
S36	Sec		The "break the glass" function must be capable of requiring the clinician requesting access to blinded information to document and record the reason(s) for requesting access.	§164.312(a)(2)(ii)		N		
S37	Sec	Security: Audit	The system shall support logging to a common audit engine using the schema and transports specified in the Audit Log specification of IHE Audit Trails and Node Authentication (ATNA) Profile	NIST 800-92/SP 800-92			N	
R1	Sec	Reliability: Backup / Recovery	The system shall be able to generate a backup copy of the application data, security credentials, and log/audit files.	Canadian: Alberta 7.3.16 (Security); CC SFR: FDP_ROL, FPT_RCV; HIPAA: 164.310(d)(1)	**P**			
R2			The system restore functionality shall result in a fully operational and secure state. This state shall include the restoration of the application data, security credentials, and log/audit files to their previous state.	Canadian: Alberta 7.3.18.9 (Security); CC SFR: FAU_GEN; SP800-53: AU-2 AUDITABLE EVENTS; HIPAA: 164.310(d)(1)	**P**			
R3			If the system claims to be available 24x7 then the system shall have ability to run a backup concurrently with the operation of the application.	Canadian: Alberta 7.4.2.5 (Technica+D1l); CC SFR: FDP_ROL; HIPAA: 164.310(d)(1)	**P**			
R4	Sec	Reliability: Documentation	The system shall include documentation available to the customer stating whether or not there are known issues or conflicts with security services in at least the following serivce areas: antivirus, intrusion detection, malware eradication, host-based firewall and the resolution of that conflict (e.g. most systems should note that full virus scanning should be done outside of peak usage times and should exclude the databases.).	Canadian: Alberta 7.3.17 (Security); CC SFR: FPT_TST CC SFR: AGD_ADM; SP800-53 SI-3 MALICIOUS CODE PROTECTION	**M**			

Security - 2007 Final Criteria - Mar 16 2007

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R5			If the system includes hardware, the system shall include documentation that covers the expected physical environment necessary for proper secure and reliable operation of the system including: electrical, HVAC, sterilization, and work area.	CC SFR: AGD_ADM	M			
R6			**Removed**					
R7			The system shall include documentation that itemizes the services (e.g. PHP, web services) and network protocols/ports (e.g. HL-7, HTTP, FTP) that are necessary for proper operation and servicing of the system, including justification of the need for that service and protocol. This information may be used by the healthcare facility to properly configure their network defenses (firewalls and routers).	CC SFR: AGD_ADM; SP 800-53 AC-5 CM-6; SP 800-70; HIPAA 164.312(a)(1)	M			
R8			**Removed (Merged with R4)**					
R9			The system shall include documentation that describes the steps needed to confirm that the system installation was properly completed and that the system is operational.	CC SFR: AGD_ADM	M			
R10			The system shall include documentation that describes the patch (hot-fix) handling process the vendor will use for EHR, operating system and underlying tools (e.g. a specific web site for notification of new patches, an approved patch list, special instructions for installation, and post-installation test).	CC SFR: AGD_ADM	M			
R11			The system shall include documentation that explains system error or performance messages to users and administrators, with the actions required.	CC SFR: AGD_ADM	P			
R12			The system shall include documentation of product capacities (e.g. number of users, number of transactions per second, number of records, network load, etc.) and the baseline representative configurations assumed for these capacities (e.g. number or type of processors, server/workstation configuration and network capacity, etc).	CC SFR: AGD_ADM; SP800-53 CM-2	M			
R13			The system shall include documented procedures for product installation, start-up and/or connection.	CC SFR: ADO_IGS	P			

Security - 2007 Final Criteria - Mar 16 2007
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R14	Sec	Reliability: Technical Services	The software used to install and update the system, independent of the mode or method of conveyance, shall be certified free of malevolent software ("malware"). Vendor may self-certify compliance with this standard through procedures that make use of commercial malware scanning software.	CC SFR: ADO_DEL	M			
R15			**Removed**					
R16	Sec	Reliability: Documentation	The system shall include documentation of the minimal privileges necessary for each service and protocol necessary to provide EHR functionality and/or serviceability.	SP800-53 AC-5	P			
R17	Sec	Reliability: Technical Services	The system shall be configurable to prevent corruption or loss of data already accepted into the system in the event of a system failure (e.g. integrating with a UPS, etc.).	CC SFR: FPT_RCV	P			
R18	Sec		**Removed (Merged with S23)**					
R19			**Removed**					

References:
1) ISO 17799: ISO/IEC 17799:2005 Information technology - Security techniques - Code of practice for information security management. http://www.iso.org/iso/en/prods-services/popstds/informationsecurity.html

2) HIPAA: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996. 45 CFR Parts 160, 162, and 164 Health Insurance Reform: Security Standards; Final Rule. http://www.cms.hhs.gov/SecurityStandard/Downloads/securityfinalrule.pdf

3) Alberta VCUR Standards: Alberta Medical Association, Vendor Conformance and Usability Requirements (VCUR), April 18, 2006. http://www.posp.ab.ca/vendors/VCURv2.asp

4) CC SFR: (Common Criteria for Information Technology Security Evaluations - Part 2: Security functional requirements) - ISO/IEC 15408:2005-2 Security Techniques—Evaluation Criteria for IT Security is based on Common Criteria for Information Technology Security Evaluation 2.3 (referred to as Common Criteria or CC).
http://isotc.iso.org/livelink/livelink/fetch/2000/2489/lttf_Home/PubliclyAvailableStandards.htm

5) NIST 800-53 - Recommended Security Controls for Federal Information Systems ;800-63 - Electronic Authentication Guideline;800-70 - Security
Configuration Checklists Program for IT Products: Guidance for Checklists Users and Developers;800-92 - Guide to Computer Security Log Management. http://csrc.nist.gov/publications/nistpubs/

*Assignable Functions:
Applicants may assign certain functionality to a third party (e.g. when security and operating functions are handled by the operating system, a third party component, tool or service, etc.). Where a function is indicated as "assignable", applicants can indicate they are delegating and provide related materials for self attestation. For example – for backup and restore: applicants that use a third party database backup utility could assign backup functionality and provide related documentation for self-attestation.

Security - 2007 Final Criteria - Mar 16 2007

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				6) Ontario specification references are from: Ontario Medical Association, CMS Local Solution Specification V1.3. Copy located at: http://www.ontariomd.ca/cms/infoForVendors.shtml				

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

American Health Information Community

AHIC Recommendations Implementation Progress Report - Consumer Empowerment

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ONC Director

July 31, 2007

Consumer Empowerment Workgroup Recommendations Summary

Recommendation	
• 1.0 (May 2006)	DONE
• 2.0 (May 2006)	Progress
• 2.1 (May 2006)	Progress
• 3.0 (May 2006)	DONE

CE Recommendation 1.0 May 2006

STATUS: DONE

Recommended that HITSP identify the technical and data standards to enable the availability of a core registration dataset and medication history.

Status:

- Interoperability of patient registration and medication summary data has been included in first iteration of HITSP standards

CE Recommendation 2.0 May 2006

STATUS: Progress

Recommended that HHS through CMS, AHRQ, other interested Federal agencies and private sector partners should pilot programs that measure and demonstrate the value of an electronic registration and medication history to patients with chronic disease and their clinicians.

Status:

- CMS PHR pilot is in progress
- CMS working with AHRQ on qualitative evaluation statement of work
- Proposed scope of work to demonstrate the value of electronic registration (ONC project)
- A pilot of this nature must be longitudinal in order to capture data of relevance; therefore, high level reporting will be quarterly, and the final report will be ready in November 2008

CE Recommendation 2.1 May 2006

STATUS: Progress

Recommended that Federal agencies sponsoring pilots for an electronic registration summary and medication history should work with appropriate private-sector health organizations to promote provider and consumer participation in a breakthrough project through a targeted outreach initiative.

Status:

- CMS PHR pilot was done in collaboration with AHIP and BlueCross BlueShield Association
- Pilot began in June 2007
- CMS working with the Office of External Affairs to evaluate appropriate and effective outreach and messages

CE Recommendation 3.0 May 2006

STATUS: DONE

Recommended creation of additional AHIC workgroup that would address the cross-cutting confidentiality, privacy and security issues related to all the Community charges.

Status:

- Confidentiality, Privacy, & Security Workgroup convened August 2006
- Ad hoc subgroup of Consumer Empowerment and Confidentiality, Privacy and Security Workgroups established in January 2007