The Community

American Health Information Community

September 18, 2007
8:30 a.m. - 12:45 p.m.

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

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September 18, 2007

8:30 a.m. – 12:45 p.m. (EDT)

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

8:30 a.m. **CALL TO ORDER** – *Secretary Leavitt*

8:35 a.m. **Introductory Comments** – *Secretary Leavitt*

8:40 a.m. **Comments** – *Robert M. Kolodner, National Coordinator for Health IT*

8:45 a.m. **NHIN Trial Implementation Update**
- *John Loonsk, Office of the National Coordinator*

9:00 a.m. **Report on Clinical Decision Support**
- *John Glaser, Partners HealthCare*
- *Carolyn Clancy, Agency for Healthcare Research and Quality*
- *Charles Friedman, Office of the National Coordinator*

9:30 a.m. **New Workgroup Recommendations for Discussion:**
Population Health/Clinical Care Connections Workgroup
- *John Lumpkin, Robert Wood Johnson Foundation, Co-Chair*

10:15 a.m. **BREAK**

10:30 a.m. **State Alliance for eHealth**
- *Governor Phil Bredesen, Tennessee*
- *Governor Jim Douglas, Vermont*

11:15 a.m. **AHIC Standing Committee of the Whole: Successor**
- *Secretary Leavitt and Rob Kolodner*

11:45 a.m. **Findings from the *Enhancing Data Quality in EHRs* Report**
- *Jodi Daniel, Office of the National Coordinator*
- *Reed D. Gelzer, Advocates for Documentation Integrity & Compliance*
- *Rebecca Busch, Medical Business Associates, Inc.*
- *Susan Turney, Wisconsin Medical Society*

12:30 p.m. **Public Comment**

12:45 p.m. **ADJOURN**

Meeting Report

American Health Information Community
July 31, 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 15th meeting on July 31, 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 assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting's discussions focused on: (1) a discussion of the AHIC successor entity, (2) recommendations from the Personalized Healthcare Workgroup, (3) a presentation on the Office of the National Coordinator's (ONC) use case/priority-setting process, (4) a report from the Health Information Security and Privacy Collaboration (HISPC), (5) a report from the Certification Commission for Health Information Technology (CCHIT), and (6) an update from the Consumer Empowerment Workgroup.

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

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

Call to Order

Joining Secretary Leavitt around the table were:

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

Craig Barrett, PhD, Chairman of the Board, Intel (Dr. Barrett was represented by Mr. Colin Evans, Director of Policy Standards, Intel for part of the meeting)

Linda Fischetti, RN, MS, Health Informatics Architect, Veterans Health Administration (Ms. Fischetti represented Gail Graham, Director of Health Data at the Department of Veterans Affairs, Veterans Health Administration)

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

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

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

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention (Dr. Gerberding was represented by Steven Solomon, MD, Director of the Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention, for part of the meeting)

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

John Menzer, Vice Chairman, Wal-Mart

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

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

Robert Cresanti, Under Secretary of Commerce for Technology, U.S. Department of Commerce (Mr. Cresanti was represented by Bettijoyce Lide, Scientific Advisor for Health Information Technology, National Institute of Standards and Technology's Information Technology Laboratory, for part of the meeting)

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

Kevin Hutchinson, CEO of SureScripts

S. Ward Casscells, MD, Assistant Secretary for Health Affairs, Department of Defense (Dr. Casscells was represented by Robert Foster, Acting Chief Information Officer and Program Executive Officer for the Military Health System, for part of the meeting)

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

Introductory Comments

Secretary Leavitt welcomed Community members to the meeting and opened his remarks by commenting that progress is being made towards the goal of achieving interoperable health information technology (HIT). He reminded Community members that the need for standards is at the heart of these efforts, and that the President's established goal of implementing interoperable health records by 2014 represents an important step. Additional important components include the development of the ONC and the development of AHIC. Secretary Leavitt emphasized that although the government must play a role in this work, that role is to organize, not to own the process and products that result. It is expected that 30 harmonized interoperability standards will be recognized this year. In addition, more than 80 ambulatory EHR products have been certified, representing more than 40 percent of the market. The next phase of certification is already underway at the CCHIT. Trial implementation of the Nationwide Health Information Network (NHIN) to demonstrate the possible configurations for secure interoperability is ongoing.

Secretary Leavitt suggested that there are three major components of the work to be accomplished under the current administration. These components are: (1) finish the agenda that has been laid out for AHIC as it currently is configured (referred to as AHIC 1.0); (2) successfully create and transition to the perpetual successor organization (referred to as AHIC 2.0); and (3) more securely connect AHIC 2.0 and the standards process to the ongoing flow of how health care is financed, practiced, and organized. He also noted that during the next few months, the means of being able to secure this work in the federal government will become more evident. For example, a four-state pilot to test ways of compensating physicians and hospitals that report quality data using AHIC systems and standards has been announced. The Secretary hinted that an expanded and even more aggressive effort in this regard would be announced soon. As the development of AHIC 2.0 progresses, Secretary Leavitt emphasized that AHIC and its successor organization represent the vehicle of standards creation and the adoption that the federal government is going to use to achieve interoperability.

Approval of June 12, 2007, Meeting Minutes

Minutes from the June 12, 2007, AHIC meeting were distributed, reviewed by Community members, and approved unanimously with no changes.

AHIC Long-Term Succession Update

Before discussing the formation of AHIC 2.0, Dr. Kolodner welcomed Community members and reminded them that the November AHIC meeting will be held in Chicago in conjunction with a meeting of the American Medical Informatics Association. Dr. Kolodner noted that to achieve the better, safer, lower cost health care that Americans desire and deserve, it is essential that the widespread adoption of interoperable HIT solutions (i.e., EHRs, personal health records [PHRs], and a robust public information system) as well as a practical implementation of a secure, interoperable health information network to connect those solutions are achieved. Included in these efforts is the need to empower individuals to play a more active role in their health and in their health care. Dr. Kolodner commented that interoperability of health information is not a technical problem. Rather, it is a "people problem," or a "people issue." It is a matter of being able to work together to not just implement the technology, but to have the proper training, workflows, and trust that the information that flows is reliable and is protected. He emphasized that this issue cannot be solved by a small group of technical people or small group of stakeholders joining together to devise the solution—all health care stakeholders must participate to achieve success.

Dr. Kolodner stated that a traditional organization will not solve these problems. Traditional organizations do not address issues of trust and typically do not include the necessary checks and balances to prevent inequities from occurring. In developing AHIC 2.0, a strategy is being put in place to create an organization that is structured in such a way that this trust can begin to develop as progress is made. The core challenge is establishing that trust so that all parties can work together as partners without a dominant entity controlling the activities. AHIC 2.0's organizers are attempting to learn from other unique successes to launch an organization that has the opportunity for broad participation while being guided by a few simple, yet powerful principles. The organization will incorporate several key attributes to become an entity that can be trusted by all of its participants to be equitable and to be fair in making the complex decisions that have to be made. In addition to building trust, AHIC 2.0 faces the challenge of making progress quickly and reliably enough to establish credibility and a formula for action and achieving its goals.

Dr. Kolodner reminded the Community that the AHIC charter does recommend moving forward with a successor entity. Following discussions at the previous AHIC meeting, ONC staff have developed a succession plan and created a draft white paper that was distributed to Community members (the white paper also is available online). The white paper will be changed based on discussions at this AHIC meeting and based on input received from a subsequent public comment period.

The AHIC successor will address the need for interoperability in a secure, trusted environment as an inclusive, participatory entity that is efficient and results oriented. Dr. Kolodner presented the following principles for successful governance (which also were discussed at the June 12 AHIC meeting):

- 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 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.

Dr. Kolodner explained that the current trajectory is set to have an operational AHIC successor in place by the end of 2008. Concepts from three contractors have been synthesized, as has input from expert consultants, to generate a successor prototype model. Dee Hock, founder and first CEO of Visa International, is providing expertise in guiding these efforts as well. Key attributes and success factors for the AHIC successor have been identified, and an implementation strategy has been developed. Dr. Kolodner discussed six AHIC successor attributes:

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. The successor entity's 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. Included in this successor vision are various functions believed to constitute interoperability. These include:

- Accelerate and coordinate current AHIC interoperability initiatives including standards harmonization and certification of HIT.
- Prioritize stakeholder requirements for nationwide HIT interoperability.
- Advance the harmonization of technology standards and policies, including those to protect confidentiality, privacy, and security.
- Oversee and facilitate the NHIN, including necessary governance and/or accreditation of participant organizations.
- Advance the certification of products, network participants, and/or operations.

Dr. Kolodner summarized that the focus of the AHIC successor will be on achieving interoperability by working through the development of standards, certification, and networking. Initiatives undertaken by AHIC 2.0 will be designed to identify and remove obstacles for the exchange of health information nationwide. These obstacles can be technology based, such as a lack of harmonized technology data exchange standards, or business based, such as a lack of shared business rules and agreements that enable confidential and secure health information exchange.

Discussion Highlights

"There is a need for the continuity of leadership that comes with an executive and group of executives that will ultimately be hired by this entity that will go perpetually, as opposed to from place-to-place. They will need to be appointed on the basis of the confidence that the community has in them, not necessarily a political appointment. In other words, this needs to begin to approximate a corporate democracy more than it does a political democracy. And as such, it needs to have, as one of its primary patrons, members and participants, the federal government in its role as a payer." – Secretary Leavitt

"Any organization that's going to look at this as being a convener or the future entity would have to take into consideration the requirements or the requests of HHS, as it would any other member of the organization. But obviously, as the largest payer for healthcare services in the United States, those desires and requests for focus of the organization is going to sway heavy inside the organization." – Mr. Hutchinson

"We also endorse going forward, that it be as broad and as apolitical as possible, and to that end…if NIST has not been involved, in terms of their expertise with nonpartisan government private standard setting, that's one thing they just love to do. And they've had a lot of experience in standard setting." – Dr. Casscells

"Once you create the United Nations of health IT, does it behave like the United Nations or does it behave like it has a priority directive? And one of the concerns I have is that once you open this, as the document suggests, to all comers, and you use the words 'democratic decision making,' this is precisely how the United Nations works. Although one entity may contribute the majority of the resources to it, the other 191 nations get to make the decision. And how do you foresee this diverse group having the directional characteristics you want?" – Mr. Barrett

"I see this being different in that I see this needing to have a means of reaching conclusions that have the effect of binding the participants to act as a condition of their participation...This isn't about us being the technicians and figuring out exactly how to make this work. I think we have to use our collective wisdom to find ways to create a vehicle…Our task is to organize this in a way that it will generate the right outcomes." – Secretary Leavitt

"The recognition is that you need to make the technical decision to move forward to enlarge the pie for all, and to bring the technology into the marketplace. In an entity as large as this, which is a two trillion dollar business, not everyone is aligned in terms of 'I need to make this decision to enlarge the market. I'm relatively happy with the situation as it stands'…We don't have alignment of all…members. They all have their own different agendas. And getting them aligned to move forward can be extremely difficult." – Mr. Barrett

"The importance of this we all recognize and the importance of getting it right we all recognize. And I'm just concerned that this creation of this democratically represented body, without a CEO who controls the bank account, will be totally ineffective." – Mr. Barrett

"If HHS is perpetually connected, as perhaps largest and most influential member, and if HHS is connecting our activities in the way that we pay, the way that we organize, and other ways conduct ourselves to this organization, it does seem to me that that 'paycheck' is still very much there." – Secretary Leavitt

"That is a leap of faith, in the business world, to assume that the different parties around this table, in the spirited discussions we have, will just lay down and say 'I recognize the goodness, the value to the whole, and will behave in an entirely different fashion than they have in the past.' So there needs to be a stronger mechanism than this inherent belief that we will all do the right thing for the body as a whole." – Mr. Barrett

"I think we've got some models out there, though, where this could work, where at the end of the day, the mechanism is prodded along by HHS. And if you look at the Hospital Quality Alliance…I sort of see the same thing here, that HHS is going to say to the AHIC 2.0, 'we need X, Y and Z. We want you to set the policies. If you don't set the policies, you know, we're going to do it. But we want you to do it.' And they give AHIC 2.0 the opportunity to do it." – Mr. Kahn

"If it ever comes to the point that a majority of the marketplace views this process not to be in its best interests, they'll begin to peel off, and it won't work and it will break down. But if you've got the anchor tenant, which will be government there, and AHIC becomes the place, you referred it to as the UN, but it is, in fact, a place where these things can be collaboratively developed." – Secretary Leavitt

"I think this is the right path to go down. I'm not concerned about it becoming the United Nations. That's not been our experience. We've dealt with very difficult competitive environment in our state, and dealt with it in an environment where we chose to keep the information open. So I would endorse this proposal, because it has worked…I've seen it work effectively." – Mr. Roob

"A picture of what the health care system of the future ought to look like has come to my mind…It is a system of competition based on value, and to get there, you have to have four cornerstones. And the first one is health IT. The second is quality measures. The third is the ability to compare price, and the fourth is to have the incentives lined up correctly. This body, AHIC and the successor, is about the first cornerstone, which is health IT standards." – Secretary Leavitt

"When you take a complete industry and you try to take what works in a local community and take it nationwide, it becomes a lot more complex and a lot more complicated, and a lot more political. But we [SureScripts] have various levels of membership; equity members, charter members, foundation members, affiliate members. And each one of those memberships has different rights and voting rights and governance of the organization. And I think it works, if implemented effectively. But it does go back to those that can influence the market the most, that have the largest buying power, that have the largest ability to implement those changes." – Mr. Hutchinson

"I believe that whoever the convener is, can create an atmosphere and a structure that is sufficiently strong that it overcomes those imperfections, but it does, in fact, depend on the self interest of the majority being met. And if it ever gets to the point that the majority of the interests at the table are no longer being met, one way or another, they will begin to bolt and the coalition and the collaboration will fail." – Secretary Leavitt

"We're going to create this 2.0, and then simultaneous to that, I, as Secretary, am going to be proposing a whole series of things that will secure the way we view payment, organization and finance to be linked to what we do here. Now, if that's not sufficient, ultimately it will break down. But I believe it will be [sufficient]." – Secretary Leavitt

"I would first like to say that I'm in full agreement that we need to have AHIC 2.0. I am concerned, as we listen to the discussion today, as we talk about the fact that there may be those that will operate in their own best interest, that there may be those that follow the money. I'm in complete agreement, when Lillee talks about the fact that we really need to look at the issue of social capital." – Ms. Davenport-Ennis

"The process that you're proposing through 2.0 gives us the opportunity to expand the work of AHIC, and to engage the consuming community of America, and the adoption and utilization of health information technology that is interoperable. But it will only do that in direct proportion, I think, to our ability to have a patient-centric process. So that as we're looking at technology, the technology is only there to support a patient-centric model." – Ms. Davenport-Ennis

"It's important for us all to recognize that sometimes HHS could get it wrong. And without a mechanism for the rest of the market to modify it in the context of all this collaboration, we could lead the entire system astray. And I think that's the virtue of this. It does link the paycheck, if you will, the checkbook of the largest payer to it; but it also provides the protection of a lot of different consultive interests that are driven by their self-interest, that does begin to create a market action." – Secretary Leavitt

"I would ask that we…continue to focus [on it being] driven by the users…I think it's important it's always user driven…Where we've seen some really big success is where we've had co-industry chairmen, for instance, a major retailer CEO working with a major supplier CEO, [who] have used their leadership, have utilized their companies to really move the industry. It's taken that type of leadership to get everyone aligned. And I understand that it's hard to get people aligned. But that really helps the process." – Mr. Menzer

Membership

Dr. Kolodner explained that the successor entity should be open to membership (direct or participating) by all organizations and individuals in all parts of the health community. The health community would likely be organized into sectors, such that all relevant and affected parties are included. These sectors might include: (1) ancillary health services, (2) clinicians, (3) consumers, (4) employers/purchasers, (5) government, (6) health information exchange, (7) institutional providers, (8) payers/health plans, and (9) pharmaceuticals and devices. Dr. Kolodner explained that the sectors included in AHIC's successor would be used to support the creation of the organization's governance body (sectors may be added or modified as appropriate as the successor entity evolves). Also in terms of membership, the successor should define differing classes of membership with differing rights and obligations. There likely will be different classes of membership. For example, organizations tightly coupled to the successor entity may be termed "direct" members and may be affiliated with multiple participating members. These participating members would agree to participate and abide by AHIC successor standards through the direct members. Only direct members would have voting rights in the AHIC successor. Dr. Kolodner provided the following example to illustrate these points:

- Main Street Physicians is a direct member in the Clinician Sector. Elm Street University is a direct member in the Institutional Providers Sector. Main Street Physicians is a part of Elm Street University and so they are also a participating member of the Institutional Provider Sector.

Dr. Kolodner noted that membership classes will encourage self-organization of the members into various health exchange entities or other types of suborganizations at any time, and at any scale, for any reason, without losing the member rights and obligations that they originally had.

Discussion Highlights

"I think this is exactly in tune with what you would expect to see. And I'm comfortable with it." – Mr. Cresanti

"At the end of the day, this is about the consuming public moving this effort forward. It has to be about that. So the more inclusive we are at the end of the day, we can make this work. The Ambulatory Quality Alliance is a very similar analogy that has brought disparate stakeholders to the table." – Dr. Henley

"For each organization, assigning a spot, if that's how it's done, will be more challenging, I think, than deciding which sectors [should be included in the successor entity]." – Mr. Green

"The organizers may ultimately say, 'Office of Personnel Management, you ought to be a member of all of those [sectors], and if you're prepared to pay the dues to participate in each of them, then you deserve to have a voice.' And in some of them, you may not want to pay dues, but just be there to voice your concern. And you can play at a different level in each different subdivision." – Secretary Leavitt

"We have to consider building in an economic mechanism here to get this organization moving…that may be something that we want to consider with regard to the support that the government will ultimately provide in the form of grants or other support along this way. And I think that may help put pressure on the standard-setting process that maybe generates some of the momentum that we want to continue to see in that second-stage boost." – Mr. Cresanti

"If this is to be a consumer benefit, long term, then the membership has to have an adequate balance of the consumer or the individual, as opposed to the system. If you just look at some of the very obvious issues, which is effectively who owns the individual's health records, and does everyone have immediate access to that, et cetera, there is not one individual who would say 'the system owns my record, I don't own it.' However, the system, for its own reasons, basically guards that as a valued piece of property. So whatever the distribution of voting rights here, it has to be an adequate balance of balancing the individual consumer's benefit, as opposed to the system or business benefit." – Mr. Barrett

"When we choose the organization to create the proposal, they're ultimately going to have to bring it back to this group. And I'm going to look to your advice as to whether or not they've achieved that, before I accept a recommendation to appoint one group or another as the organizer of this." – Secretary Leavitt

"The individual doesn't have the bank account. So as soon as you start to put the financial hurdles in membership and representation, et cetera, you're immediately going to bias it towards the system…So it's going to be a tremendously difficult issue to balance representation, voting and benefit, and to separate that from the muscle power of the bank account." – Mr. Barrett

"This is about the development of technical standards. This will not be the place where lots of decisions are made, for example…about who owns the record. We have elected democratic processes that make a lot of those decisions…I do see this being the venue where technical issues are worked out related to standards." – Secretary Leavitt

"The intention is there would be a binding agreement for the direct members…ultimately, that's something that the coalition that comes together to write the final bylaws, and put the governance structure in place, will need to wrestle with and come up with. But the intention is that there would be a binding agreement for the direct members." – Dr. Kolodner

"To really achieve, then, the consumer balance, you would probably have to overweight the board for consumers?" – Dr. Gerberding

"You could certainly do that. That would be one of the things to be looked at." – Dr. Kolodner

"What we're talking about is that the hard process of taking an economic sector, that has not succeeded in moving itself forward as a system, and beginning to organize a governance process that will involve compromises and commitments, and will always be governed with the principle that if a majority of the governed don't feel like they are advantaged by being there, they always have the capacity to leave. And if they leave, the coalition begins to break down and the system no longer exists." – Secretary Leavitt

"Most problems that most people have in health care most of the time occur in the ambulatory environment in small- and medium-sized facilities or offices. And it would be very easy, with an entity like this, to get consumed by large entities…and that's not where most of the care occurs most of the time. So it's important that we keep that in mind, and make sure that, again, in this governance structure, that where care occurs, and the settings where it occurs most frequently is adequately represented." – Dr. Henley

"Even in a top-down organization like the DoD, we recognize the importance of this, and if we say 'charge' and no one goes up the hill, why, we're embarrassed by that. So I think it's a very important thing, for this organization to have a fair amount of autonomy. And you always have the opportunity, Mr. Secretary, to reel it in later. But if the members can set their ground rules…and then pick their members going forward, they have a near-term incentive to get on board early because they can begin to drive it early on." – Dr. Casscells

"The one thing, though…I'm not confident about, is this area…of confidentiality and privacy; which on the one hand we can argue should be the area of policy makers, and on the state level, legislators have not been shy about this. But we know from our experience with HIPAA that actually the federal legislators have been unable to come to the table and actually settle something. So ultimately HHS had to do it….I'm not sure that the Congress can handle it. They couldn't handle it before. And I'm not sure they'll handle it in the future." – Mr. Kahn

"To be completely accurate on that point, we'd all have to acknowledge that Congress did handle it. They just said 'we're incapable of doing it among 535 people, and therefore, we'll empower the Secretary to do it.' And that may, in fact, be what happens again. Because I think the Congress was smart to say 'it's impossible for 535 people to agree upon something this complex. Let's just agree on that and turn it to somebody else to do it'." – Secretary Leavitt

"It has to be alignment of interest that drives, or else you're not going to have that forward push. And so while this is such a huge project, and it's just going to be gigantic, and sweaty and expensive, the need is all the more there to keep it focused, and not try to have the group take on more than it's capable of doing. Focused on standards, focused on interoperability, and the policy issues, to the greatest extent possible." – Mr. Green

Governance Body

Dr. Kolodner noted that the successor's 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. Dr. Kolodner explained that there is a tie-in between the board members and the groups that they represent, so that instead of it being a board

operating in isolation, when a board decision is made, it is done so starting from all of the members, and then rolls up towards the board representatives. In addition, eligibility to be elected or appointed to the board should be clearly defined.

Rights and Obligation

Dr. Kolodner noted that the AHIC successor bylaws should have clear a delineation of voting rights, if any, of members and a clear delineation between voting rights of members and the board. The 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. He explained that the authority of the AHIC successor board and rights and obligations of members should be clearly delineated. The successor entity's decisionmaking process should specify the use of quorums, and identify decisions requiring double majorities or super majorities of the board for adoption.

Discussion Highlights

"These are intended to be, as I understand it, guidance for individuals or organizations that may choose to participate in becoming a convener or coming to set up the entity. So how much of this is…hard stone, the organization will do the following, versus guidance, and this is the intent of what we would like to see as we get responses back from conveners that may want to create this entity?" – Mr. Hutchinson

"Whoever becomes the convening organization and develops a proposal, I think what this creates is an agenda of topics for them to deal with. They're ultimately going to have to bring back a coherent vessel that is tight enough that it will hold water…They may come up with different ideas than what we have. They may have a good argument as to why one idea is better than another. Ultimately, they're going to have to persuade this body, who will give advice to the Secretary, that they have accomplished that." – Secretary Leavitt

"And I think that what I'm also hearing, that will help us as we to move forward, is to figure out what's the communication, and how frequent is the communication, between the group that gets the award and their activities, so that they may need to bring successive ideas as to how to proceed before they put the flesh on it and lock it in." – Dr. Kolodner

"Clearly AHIC 1.0 and AHIC 2.0 are going to have to coexist for a certain period of time. And as we look at what the authority is, or as that's being defined, how will we ensure that the ongoing work…as this transition continues, that we complement each other and AHIC 2.0 builds upon what's going on, that that transition happens, and there isn't overlap or deviation or confusion as to what the world of AHIC 1.0 and AHIC 2.0 is as we coexist for that period of time?" – Ms. Handelman

Protections and Incorporation

In describing this attribute of the AHIC successor, Dr. Kolodner explained that the entity should operate under a certificate if incorporation, detailed bylaws, and initial operating regulations and membership agreement(s) that reflect the most appropriate type of legal entity for the successor organization. Furthermore, 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.

Discussion Highlights

"I don't think this is the intent, but it has in here to prevent changes that would radically alter the structure. I don't think it's intended to prevent changes. It's a process by which changes would go through the process. Because to keep it current with the times, ten years from now, there may be a need to alter its structure." – Mr. Hutchinson

"That's an excellent point. The intention, in fact, [is that] it has to be adaptable and has to be able to change. The idea is that there may be some key features that are considered ones that need to be protected, without which it wouldn't be AHIC 2.0. And that those particular, very few attributes need to protected. But that, in fact, it has to be built for change and for adaptation, because the environment it will be operating in, as we know, will undergo incredible change." – Dr. Kolodner

Management Structure

Dr. Kolodner indicated that the successor entity likely will include the following:

- A Chief Executive Officer who has national recognition, is trusted, has wide constituency in the health community, and has a reputation of being an honest broker.

- A Chief Financial Officer, Counsel, Secretariat, and Operations Officer.

- A Senior Membership Officer whose responsibilities will include membership and recruitment, publicity, advertising, marketing, and public relations.

- A Senior Technology Officer who is responsible for driving forward issues related to standards harmonization, certification, NHIN services, and technology-related services.

- A Senior Data Uses Officer whose responsibilities include data stewardship, privacy policy, accreditation, and uses of data for purposes such as public health, quality, research, and all other related activities.

Discussion Highlights

"We have spent a good bit of time looking at the intricacies of adoption, because we really don't have a failure of ideas or the evidence. It's just a failure of execution, in many ways, at least in the private sector. Not in the government sector, but in the private sector. So where do you see this whole adoption piece falling in the new entity, or is that not a function of the new entity? It would be much more technical." – Ms. Gelinas

"I think once we get the standards, where there is a clear track for interoperability, where you've clearly hooked it to the payment system and people know that this is going to be a characteristic of payment, that we'll see adoption begin to spike even faster than it is now." – Secretary Leavitt

"AHIC's only role in adoption is to make certain that the standards pieces are there, and that they are connected to the payment structure. And then I'm sure Congress and others will have ideas on how they can stimulate adoption. But I believe the most powerful thing we can do to fuel adoption will be to have a reliable, consistent vision of standards, and have it hooked to the payment structure. Once that combination exists, we'll start to see adoption grow at a faster rate." – Secretary Leavitt

"You can't have someone who wants to come in and start with a white piece of paper and blow up what's been done. It's got to have someone with passion, who has been a patient or had a patient in the family. It's got to have someone with a record of integrity, working with industry on this very complex issue of getting standards set; and yet has some tolerance for government. Because so often, industry titans don't fully appreciate how complicated government is." – Dr. Casscells

"I think the opportunity for that conversation will occur when a proposal is returned to this body including a criteria, and we ought to, at that moment, critique, and add, and provide what guidance we can, as they go off to organize." – Secretary Leavitt

"The sooner we get this done, the more latitude we have, and the more exacting we can be in making the transition. But no matter how we make the transition between [AHIC] 1.0 and 2.0, the Workgroups, I hope you're listening to me out there, need to continue. Because whether it's 1.0 or 2.0, standing at the top of this, the mission is the same. And there will be a point in time where we do complete it. But the work needs to keep going forward." – Secretary Leavitt

Strategy, Milestones, and Next Steps

Dr. Kolodner explained that the strategy for moving AHIC 2.0 forward was designed to ensure continuity of progress towards interoperability—there cannot be gaps between AHIC 1.0's current work, the efforts of the AHIC Workgroups, and the work of AHIC 2.0. The grant mechanism that being proposed is a cooperative grant that allows the awards to be made that provide value to the public and also allows for substantial involvement of the federal government in the process. Dr. Kolodner noted that two awards will be made. The first award will be for soliciting interest and awarding a grant to a convener entity or a coalition that is broad based. That group will design and build, incorporate, and establish the AHIC successor. Their charge will be in a period of time between about November 2007 to March/April 2008. The second award will be to the entity itself and will help to ensure that linkage how the transition is made from AHIC 1.0 to AHIC 2.0. It will be important to design this mechanism in a way that the government organizations can serve as direct members with board representation.

Dr. Kolodner noted that some questions have been raised about the standards, such as how does the government take those standards in, or how do they become recognized as they do now in the current process so that they trigger off the various Executive Orders that affect STARK and anti-kickback kinds of donations. A number of mechanisms have been explored in this regard. For example, it could be passed to another Federal Advisory Committee. Alternatively, the AHIC successor or an arm of it as a voluntary consensus body may allow the federal government to identify those standards that have been established and to accept them without having to go through a long process. The convening coalition may identify alternative mechanisms, but at least two mechanisms are available that will allow these activities to occur.

The Notice of Funding Availability for the first grant will be made shortly. The white paper referenced earlier, and any changes that result from the discussion at this meeting, will be posted for public comment. That public comment then will be brought back through the federal government to the convening coalition for their consideration as they go about designing and establishing the AHIC successor.

Secretary Leavitt noted that a similar process was used in creating other entities, such as the CCHIT and HITSP. He explained that there are restrictions in the federal law as to how the federal government could go about directly organizing such an entity; therefore, the most effective approach is to empower another group while giving that group the appropriate guidance. Dr. Kolodner added that an information session

is planned for August 17, 2007, at which Secretary Leavitt will lead discussions on identifying interested parties and ideas for moving forward.

Discussion Highlights

"The key is to stimulate the activity, for people to start forming those coalitions. We are also considering having a technical session, kind of to drive down a little deeper for those who are involved and be able, for example, to be able to review those attributes more in depth, and things that might help them. But the first [step] is to stimulate the interest, and the question is how to maximally do that." – Dr. Kolodner

"We're talking about not necessarily an existing organization in a normal bidding process. We're talking about getting, as you said, a coalition of organizations together, and in fact, you would be creating a new entity from this coalition, that would be the convener, and then there would be the entity, itself, is probably a nonexisting entity today, but would be a new entity created through the coalition. Correct?" – Mr. Hutchinson

"A coalition isn't an entity, and we can't give them a grant, and they'd have to go through creating themselves. What they might do is identify, among the coalition members, one existing entity that raises its hand that can receive the grant on behalf of the coalition. And that's the one that's the convener of the activity. And obviously, the greater integrity that that convener organization has, the more trust, even, without a structure that the coalition can then have, and others can have about that coalition." – Dr. Kolodner

"The first requirement of a good collaboration is you have to have common pain. There have to be enough people who have an interest, whether it's the same interest or not, of seeing a solution. The second is this concept of a convener of stature…And I think what we need here will be either an institution, or a group of institutions who collectively have sufficient stature that people will know the gravitas is present to make this function. And they will not be, nor will any one of those individual organizations or institutions be the entity, but they will add the collective capacity or stature to form the new entity that will, then, begin to function. It may be an institution, it may be a collection of institutions that create the convener of stature." – Secretary Leavitt

"You want to make sure that the group that forms has enough members that are respected, and that have resources, because whatever the federal government puts up for the award, there is going to be, as we have with the AHIC, a tremendous amount of additional resource, activity, participation, that's going to be needed that won't be covered by any size of award that we have." – Dr. Kolodner

Early Success Factors

Dr. Kolodner discussed the factors that will determine how successful the new entity will be, and highlighted the following:

- Continued strong federal government participation.
  - The Secretary, HHS, will recognize harmonized standards and agencies must adopt them.

- A nationally recognized leader seen as an honest broker by a wide constituency of the health community.
  - This will attract other outstanding leadership and staff, and will engender trust needed to build a membership base.

- A 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.

Discussion Highlights

"There is going to be a period when both groups are operating, people are going to be asking questions like 'what happens to Workgroup recommendations that are now going to this AHIC,' and 'we have a new AHIC. What happens to HITSP work that comes to this AHIC and will come to the new AHIC?' So there are a lot of questions that are going to happen over that nine month period where there is overlap." – Mr. Trenkle

"Most of the standards bodies out there are run by volunteers, very committed people, very passionate people. I think it's very important that the ground rules and the way you're going to work with these different groups is established up front. You mentioned like NCVHS for bringing it into the federal government. I think it's important to get that established up front, because the more amorphous that is, the harder it's going to be to bring this group off the ground." – Mr. Trenkle

"There are a lot of groups out there that are establishing frameworks that don't go anywhere, because there is nowhere to go after they establish a framework. So I think it's very important to show an implementation path, not only in the federal government for how we're going to accept the standards and the interoperability work being done, but also in the private sector, as well. Otherwise, it just becomes a body that makes a lot of recommendations that don't go anywhere." – Mr. Trenkle

"Because we'll have the standards, the turns of the crank at different phases, [it] will be an opportunity to begin looking at how do we show that there is the continuity, and there isn't a drop of the baton, as we move from AHIC 1.0, to 2.0, but there is a continuity driving that forward; including, ultimately, that the acceptance and recognition of those standards as federal standards, as well as any that might be binding on the members of that organization." – Dr. Kolodner

"Could I make a request that through the course of today, and over the ensuing week, that you think about organizations you believe might be logical conveners? And that you pass them on to Rob? I intend to place phone calls and initiate contact with those that I believe could be logical conveners. I'd like to see a robust array of different types of organizations. I think there will be foundations that clearly ought to have an interest in this. I think there will be universities that clearly ought to have an interest in this." – Secretary Leavitt

"One of the things that we have, among ourselves, worried about, is that the coalitions that come together would be clustered in interests. And that one interest would compete against another, by virtue of the aggregation of their interest. I'd like to make clear that if that happens, we will not move forward. The successor of AHIC needs to be well balanced, a representation of all interests, and a thoughtful approach. We don't have to do this if we don't get the right successor." – Secretary Leavitt

"No one has ever done this before in healthcare, so we're pioneering. And when you pioneer, you sometimes get surprised. Sometimes happily, sometimes not. I have every optimism that this will come together. But we also ought to acknowledge that we have enough flexibility that if it doesn't, we don't have to act. We can continue until we get it right." – Secretary Leavitt

Personalized Health Care Workgroup Recommendations

AHIC member Dr. Douglas Henley, Co-Chair of the Personalized Health Care Workgroup, reminded Community members that in April 2007, the broad and specific charges of the Workgroup were approved by AHIC. Those charges are as follows:

- **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.

In March 2007, the Workgroup participated in a visioning exercise during which they defined personalized health care as "a consumer-centric system in which clinicians customize diagnostic, treatment, and management plans." Dr. Henley commented that personalized health care represents an important opportunity for improved health care, from the standpoint of prevention, early intervention, and early diagnosis and treatment. The Workgroup identified four important perspectives: (1) Consumer, (2) Clinician, (3) Researcher, and (4) Health Plan/Payer. In addition, four priority areas across each perspective were identified (genetic/genomic tests; family health history; confidentiality, privacy, and security; and clinical decision support.

Personalized Healthcare Workgroup Co-Chair Dr. John Glaser, of Partners HealthCare, presented the Community with the following recommendations:

- **Recommendation 1.0 (Overarching):** The Community should advance the area of personalized health care as a priority for use case development.

- **Recommendation 1.1 (Overarching):** 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.

- **Recommendation 2.0 (Genetic/Genomic Tests):** 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.

As there was no discussion following presentation of these recommendations, Dr. Kolodner declared that the Community had reached consensus and accepted Recommendations 1.0, 1.1, and 2.0.

- **Recommendation 2.1 (Genetic/Genomic Tests):** 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.

Discussion Highlights

"So your Workgroup will essentially take this task on?" – Secretary Leavitt

"We would be delighted to do that, yes." – Dr. Glaser

"We think this is an area that is going to explode in terms of medical innovation and breakthrough in the years ahead. So our expectation is that the variety, range, and importance of genetic/genomic testing and family history will climb dramatically in the years to come…One of the best times to get standards is before it's too entrenched at a level, and so to provide guidance to those of us who are. And it's not just the Partners HealthCares of the world, it's community hospitals of the world, and physician offices of the world that are beginning to do this." – Dr. Glaser

"That's precisely the reason it was teed up at this point, was recognizing that there is data being gathered in virtually every university setting, and it's not just within the United States. It's literally across the world. And undoing that at a future date will be extraordinarily difficult. I don't think we're any too soon to take this on, personally." – Secretary Leavitt

"The standard that you're talking about or standards that you're talking about is for the storage of the information, but it's also for the exchange of the information as well, which obviously are two very different things. But you're not suggesting that there would be a new standards body that would work on this topic. You would look at existing ANSI accredited standards organizations and ensure that these elements are included?" – Mr. Hutchinson

"Correct. We have taken the recommendations up to the point, and assuming you all are comfortable with where we're going…we would not propose to create a new organization or body, but rather to work with those who are already looking at, or in early stages, or reasonably far enough stages in some cases on this, and help drive them to the right place." – Dr. Glaser

"This is the appropriate time for this to come forward…and so I would like to support this as it goes forward at this time." – Ms. Fischetti

During these discussions, Secretary Leavitt indicated that AHIC did not need to take action on this recommendation. He asked that the Workgroup continue to drive these efforts forward.

- **Recommendation 2.2 (Genetic/Genomic Tests):** 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.

Discussion Highlights

"I don't know if you've had the opportunity to work with them, but NTIS [National Technical Information Service], which is one of the elements that reports up through the technology administration, just like NIST, is charged with the responsibility of distributing government research or government funded research throughout, and they collect as many papers and products that they can get their hands on, either electronically or physically…[it] might be worthwhile reaching out to…start a special project that could be linked up to help facilitate what might be the sort of government presence of mind on some of these issues." – Mr. Cresanti

"I would like to suggest that where we, in the last line talk about test results that can be aggregated in electronic health records, that perhaps we could…show test results that can be de-identified and aggregated in electronic health records. Consumers are extremely concerned about that matter, and I think if we have it in public record that they will be de-identified, it is a step in assuring privacy and security." – Ms. Davenport-Ennis

"I think it's a reasonable suggestion…Clearly there are privacy issues that are exceptional here and need to be understood, and we are quite mindful, and have engaged the Confidentiality, Privacy and Security Workgroup in discussions about to make sure that the resulting legal, regulatory, and cultural environment, that protects that, is in place." – Dr. Glaser

Following these discussions, Dr. Kolodner declared that the Community had reached consensus and accepted Recommendation 2.2.

Dr. Henley then presented the following additional recommendations put forward by the Personalized Health Care Workgroup:

- **Recommendation 3.0 (Family Health History):** 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 (Family Health History):** 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 (Family Health History):** Federal agencies in conjunction with private health care organizations with similar interests and expertise sponsoring pilots in the area of gamily 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-clinicians 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.

Discussion Highlights

"Just to clarify, those recommendations would be coming back not to the Workgroup, but to HHS for HHS and a multi-agency approach to take action, is that correct?" – Dr. Kolodner

"That's correct, yes." – Dr. Henley

"Would that be part of 3.0, not only the data that was collected, but the methodology and the way it was collected, the way the questions were asked so that it could be gathered in some sort of coherent fashion?" – Mr. Green

"Indeed it would." – Dr. Henley

"Did you, as a Workgroup, find issues with either a common data set that did not exist, or are you really looking at how to expand data set items for family history that are not being captured today? Is there too much of a variety or is there too basic of a core set that needs to be expanded on?" – Mr. Hutchinson

"I think the answer would be likely too much of a variety. It's all across the board, in terms of what you get with one link that you go to, and again, we feel very strongly that there needs to be a group coming together to determine what is the common baseline that all should have, so that we can move forward in that way in terms of how that data gets stored electronically." – Dr. Henley

"Did you talk about how fast you could make this happen, or make it simple? The Electronic Health Records Workgroup struggled with the common data elements and definitions, when Secretary Leavitt gave us the first responder task many, many months ago. And we did come up very quickly with a short list of what first responder data points needed to be. And that work may inform what you need to do, because we had consensus of our Workgroup around what these data elements needed to be." – Ms. Gelinas

"I'm just wondering if the definitions of family history and the forms, or the information that's used to capture that in veterans and active duty personnel, that would seem to me to be a large body of knowledge that we already have, that has some standardization around it. So I'm just wondering if you were able to take a look at that. Or maybe that will come soon." – Ms. Gelinas

"There was certainly a commonality of interests within the federal groups that had been working on this issue and saw the immediate, not only opportunity, but the need to avoid groups continuing to work on developing their own subsets of terminologies. And the Workgroup has continued, in the face of these recommendations coming forward, to meet." – Dr. Downing

"[In terms of] the timelines for the development, we would like to have by the time this group convenes back in September, the core data set ready for, obviously, the HITSP standards to come forward. We think probably, as is pointed out here, this is an iterative fashion, and that the evaluation elements for that are going to be quite important." – Dr. Downing

"We see the value and that there are many emerging private-sector organizations that are quite interested in this activity moving forward that we think we can stimulate by engaging them a great deal, early adoption interests by many of the vendors that are potentially looking at augmenting their existing systems through these kinds of tools. So again, the core data set is really the starting point, and that augmenting this, and learning process as we go forward. So I think it's certainly doable within the next year, to have at least the beta one version of this that augments some of the work that's already been done with some of the existing public health service tools." – Dr. Downing

"The Department of Defense has 4.6 million DNA samples, with varying amounts of medical history attached to them, which could be used to pilot test something. Those data have to be anonymized and so forth, and go through our 20 layers of IRBs within the Department. But there is a lot of information there, and it's accelerating." – Dr. Casscells

"This is, I think, one of the big missing pieces in the whole personalized health record area. And one of the problems we have in the Defense Department is getting the doctors and nurses to embrace electronic records. And we're not the only ones with this problem, but if the patient comes in with enthusiasm, and has filled out a form either electronically or in a scannable document, with their history, this is a big incentive for providers to go ahead and stick with that approach." – Dr. Casscells

"I'm very, very enthusiastic about this. Anything we can do in DoD to be a test bed for you, anything that needs a little command authority, why please let me know." – Dr. Casscells

"I think it's evident that personal health records will be unsatisfying, so long as the consumer has to populate them. But once they have the capacity to get information that they have a right to, and have it populate, then I think this really begin." – Secretary Leavitt

"I'm really intrigued by the idea of DoD partnering with a couple of other people around this table to create an anonymized test bed. That in and of itself is a powerful outcome of an AHIC-like collaboration." – Secretary Leavitt

Following these discussions, Dr. Kolodner declared that the Community had reached consensus and accepted Recommendations 3.0, 3.1, and 3.2.

Dr. Henley then described the next steps for the Personalized Health Care Workgroup. In terms of issues related to confidentiality, privacy, and security, the Workgroup plans to consider whether aspects of genomic/genetic test results and family health history information may raise different concerns relative to other types of medical data. The Workgroup also intends to discuss the Genetic Information Nondiscrimination Act. With regard to clinical decision support (CDS), the Workgroup is planning to survey commercial CDS tools, examine evidence development, and survey user perspectives.

Priorities/Use Case Development Update

Dr. John Loonsk, Director of ONC's Office of Interoperability and Standards, explained that the AHIC use cases have been clustered together in a "use case roadmap" that has been and will continue to be helpful in accelerating the work of AHIC and its successor. He noted that the next round of use cases should be available in December so that they can feed into the HITSP and to the other aspects of the national agenda earlier in this coming year than they did in this past year. He also stated that at this AHIC meeting, his comments would focus specifically on the next two rounds of the use case process. A total of 255 comments on the use cases in question have been received from AHIC workgroup members and AHIC members themselves. These comments fall into a number of different categories, such as policies and obstacles. Mr. Ken Gebhart of Bearing Point has been leading the last round of use case development from the use case team perspective. He and Dr. Loonsk summarized comments and feedback received on the six uses cases for the next round.

Remote Monitoring

Mr. Gebhart explained that in terms of the remote monitoring draft use case, AHIC members provided comments on a number of working assumptions. Members suggested that there be a focus on devices that would be used in a home-care setting and produce interoperable data. It also was suggested that there should be a focus on patient-to-clinician communication of those measurements, and that there should be inclusion of measurements gathered by the patient using non-connected devices. AHIC members also indicated that provider-to-provider communication, including telemedicine, would be out of scope for this

use case. Dr. Loonsk added that the following common themes emerged through feedback to this draft use case:

- 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. As a result of this feedback, ONC will: (1) further emphasize the role of case managers and others who may perform these functions, (2) include the role of other entities that may collect data directly from the devices, and (3) include the information exchange needs outside of monitoring location.

- Incorporate decision support capabilities for consumers, care coordinators, and other clinicians. In response, ONC will enhance decision support roles.

- Measurements from non-connected devices should be considered. ONC will include some manual record measurement capabilities in some role.

- Support for devices in other settings (e.g., work, assisted living, etc.) is needed. ONC will incorporate additional examples of possible locations.

- The business case is not apparent for remote monitoring.

Discussion Highlights

"If we're going to drive remote monitoring as a practice, we've not only got to have standards, we've got to, then, have reimbursement practices that will drive a business case that will make it practical." –Secretary Leavitt

"There is a 'chicken and egg aspect of this.' From our interpretation of the status of the industry, it's an appropriate time to be working on the standards for data exchange, and that can help feed into some of these other considerations as well." – Dr. Loonsk

"It's not just the reimbursement, but it is handling emergency room overcrowding and some of those aspects of business case…And in some instances, in private providers, when you actually move care to remote, their inpatient volume goes down. So there is an inpatient revenue impact…Business case is not just one piece, it's all of those things that pretty easily could be made and tied together…that remote monitoring that's done in the VA that's keeping the veterans out of the acute care setting is something that could really help inform the private sector." – Ms. Gelinas

Remote Consultation

Mr. Gebhart indicated that this use case will focus on the ability to send and receive structured communications, such as electronic messages, as well as the use of interactive communication tools that would support chronic and other care remote monitoring and health reminders. Working assumptions associated with this use case include: (1) the focus of this is use case is patient-to-provider communication and vice versa; and (2) provider-to-provider communication, including telemedicine, would be out of scope for this use case. Recording and storing these communications will be a priority as part of the use case. Both the asynchronous secure structured Web-based communication (some of it e-mail) as well synchronous types of communication will be included. Dr. Loonsk discussed the following common themes that emerged in the feedback to this draft use case:

- Include provider-to-provider remote consultation capabilities. In response to this feedback, ONC will incorporate: (1) capabilities for provider-to-provider remote consultation, including access to relevant patient clinical information; and (2) the provider's needs related to documenting the consultation.

- There is a need to narrow the scope to specific capabilities. As a result of this input, ONC will focus the use case on secure, structured messaging, static imaging, and interactive video capabilities while including a framework for other interactive technologies.

Discussion Highlights

"What's an example of one of the technologies that you would be considering? What did you refer to?" – Secretary Leavitt

"Things like chat, where one would presume that the provider was online and actively typing at the same time as the patient, which may be functional in some circumstances, but is broadening of the scope." – Dr. Loonsk

Personalized Health Care

Mr. Gebhart explained that this use case focuses on the exchange of genomic/genetic test information and family medical history as well as the use of analytical tools in the EHR to support clinical decisionmaking. Working assumptions tied to this use case are: (1) including provisions for recording consumer-provided family medical history into a PHR or EHR, (2) receiving and utilizing discreet genetic/genomic test results in EHRs, (3) support for aspects of decision support for the consumer and the provider, and (4) capabilities to provide information for secondary use with protections for the use on limits on the use and the access to information. Dr. Loonsk discussed the following points identified in the feedback related to this use case:

- Include environmental, lifestyle, and health risk assessment information. ONC will respond to this feedback by incorporating these factors into the information needs.

- The patient's ability to control access to their data needs to be prominent. ONC will address this by incorporating capabilities for patients to control access to their information as described in the Consumer Access to Clinical Information use case.

- It may be too early for this use case. ONC acknowledges that this area is evolving quickly and will be representative of its needs, but not prescriptive of approaches where not necessary.

Discussion Highlights

"I understand the patient's ability to control access to their data, but essentially…people can see health information about members of the family that aren't actually the patient, and HIPAA doesn't exactly apply to them, so how will this protect your mother who has a certain family history, when she's not actually participating in the transaction between this patient and this provider?" – Dr. Gerberding

"One aspect of the use case that has been suggested is the ability for the exchange of family information between family members, and patient surrogates and others. Having a secure manner for allowing that access, but facilitating that exchange. And that that's part of the equation here, the strong suggestion for consumer controls, does not mean that they will prevent information from being shared. In fact, a lot of

evidence is to the contrary of that, but that they do want the opportunity to control some of that information, and that given that opportunity, they actually choose frequently to share it. And so I think it's supportive of the concept you have described." – Dr. Loonsk

Referrals and Transfers in Care

Mr. Gebhart explained that this draft use case focuses on the ability exchange a core set of clinical information and supportive referrals for care, such as specialty services, second opinions, or emergency referrals. It also includes sharing a summary discharge report from one care setting to another during a transfer of care between care settings. The working assumptions associated with the Referrals and Transfers in Care use case include: (1) a focus on provider-to-provider referrals in the ambulatory settings, not referrals within the acute care world; (2) it includes both clinical and nonclinical aspects of the referral process; and (3) for transfer of care, there is a focus on clinical and nonclinical information needed by clinicians to accomplish a transition between emergent, acute, and long-term care settings.

Dr. Loonsk described the following common themes that emerged related to this use case:

- Include eligibility verification and related HIPAA information exchanges. In light of this feedback, ONC will incorporate interactions between providers and payers to confirm eligibility in the context of a referral or transfer of care.

- Include decision support capabilities. ONC will incorporate decision support needs of the referring provider and/or patient.

- Include the needs of the patient. In response, ONC will incorporate the information needs of the patient related to a referral or transfer of care.

- Consider additional types of transfers of care.

Public Health Case Reporting

Mr. Gebhart noted that this use case focuses on the capabilities needed within EHRs and other information systems to gather, augment, and communicate case-specific health information to appropriate organizations. The working assumptions associated with this use case include: (1) the ability to report specific occurrences as in individual case reports, as well as support the ability to respond to queries for population data when requested by authorized public health agencies; (2) the ability for a clinician to receive relevant community or population health information from public health entities is also within scope; and (3) whether the capabilities related to adverse event reporting should be included within the scope has yet to be determined.

Dr. Loonsk described the following common themes that emerged:

- Include adverse event reporting capabilities. Dr. Loonsk indicated that ONC will include a framework for adverse event reporting capabilities.

- Include feedback to clinicians from public health entities. In response to this feedback, ONC will include clinician needs to receive relevant population health information.

- Include identification of "possible" cases. ONC 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. In response to this input, ONC will incorporate administrative data where relevant.

Discussion Highlights

"In the past, we've then gone out to do demonstration projects on each of these use cases. But I see so much of these use cases that are very much related to exchange of information between provider-to-provider, provider-to-patient. Do you envision, as we go forward with these use cases, that this isn't necessarily viewed as individual projects as much as it's viewed as a project that has individual elements to it?" – Mr. Hutchinson

"What we're pursuing now is a path of both. It's very helpful for the groups that work on these to have specific focus on which debates there were, but it's also critically important that we don't duplicate those activities. What you don't see, necessarily, in this presentation in the ways in which each of the steps along the way tends to re-aggregate and reuse and componentize these activities." – Dr. Loonsk

"In the use case process, we're actually structuring these according to the three high-level priorities we expressed before, which are consumer facing, provider facing and population facing." – Dr. Loonsk

Response Management

Mr. Gebhart explained that this draft use case includes the exchange of information to support daily prevention and treatment options, as well as emergency situations, including a subset of relevant information such as immunization status, ability of medication stockpiles, and other resources needed during routine and emergency situations. Mr. Gebhart added that the working assumption tied to this use case is that the systems will support clinicians, but the data could also be used for incident command.

Dr. Loonsk described the following common themes that emerged based on feedback on this draft use case:

- Refine the scope of the use case. In response to this suggestion, ONC will: (1) incorporate needs related to outbreak investigation (in keeping with the same need identified in public health case reporting); and (2) emphasize the role of routine clinical care treatment delivery (vaccinations, etc.) in addition to emergency needs.

- Include decision support capabilities. Based on this feedback, ONC will include decision support capabilities to assist in the diagnosis, selection of therapeutic actions, and followup activities.

Discussion Highlights

At the onset of this discussion session, AHIC members agreed that ONC should continue to pursue these six use cases.

"Are there enough resources at hand to be able to pull these off? Because they are right on. But there is also the reality of resources, people, time, consultants, to make them happen. And I know that underpinning or foundational issues don't come before this body, but we're all accountable for assuring AHIC's success…In order for these to go forward as rapidly as we probably need them to, are there enough resources in place to make that happen?" – Ms. Gelinas

"We do think we can help with some of the resources, the staff resources for the HITSP process, for example, in the next round, and can help bring that even further up to support the volunteer resources, but it will still take an ongoing contribution of volunteer support to make this happen. And we think we have a timetable that lays out the accomplishment of this. We're going to give them more time than we gave them this year." – Dr. Loonsk

"We don't want volunteer fatigue, but at the same time we want to meet goals." – Ms. Gelinas

"Absolutely, and we're doing what we can to try to optimize the use of volunteers where we can, just for the critical decisions and to try to staff support wherever else we can to meet those needs. But it is a huge amount of work that's being carried out." – Dr. Loonsk

"Are we seeing the capacity to use components of what was done in round one and round three? And I presume that as we build a base and foundation, and it continues to grow, we'll see more of that. And that would create, I think, some optimism that the further out we go, the faster we can move, because we're building on components that were manufactured in the early part of the process." – Secretary Leavitt

"That's been part of the design. So in the first round that was worked through, some of it was designing that modular nature, designing the process, and working the first round. And that took, as we've said before, over 12,000 hours of volunteer effort to do that. Now we're starting to get into a rhythm. The design of the process, the design of the components for reusability has been largely laid out, so I think reuse will increasingly be the order of the day and the opportunity to move with that." – Dr. Loonsk

"Thank you for your sensitivity to the consumers and I think, John, that you know Consumer Empowerment Working Group will still be working with you as you move forward on the use cases." – Ms. Davenport-Ennis

"Are we on track with the 2007 use cases? You know, we're bringing in now the 2008 use cases that we're going to do, but are there any particular use cases that are not on track?" – Mr. Hutchinson

"2006 [use cases] have gone almost completely through the process, the standards from them are going to be recognized in the coming months. [For] 2007, the use cases are completed. They have been handed over to the different aspects. They're being looked at by the Certification Commission. They are part of the scope of the next round of trial implementations for the NHIN, and it's also something that HITSP is now actively engaged in and working on. The timeline for that delivery will be probably the first quarter of next year. And we want to have this next round, round three, available to them so they can immediately pick up with that and move forward. And that's part of what we're driving toward here." – Dr. Loonsk

2009 Use Cases

Dr. Loonsk noted that the AHIC as whole and the AHIC workgroups will be asked to work on the next round of use cases based on the following use case draft prioritizing criteria, determining for each need whether it:

- Advances the adoption of interoperable HIT.
- Realizes the window of opportunity for near-term societal benefits.
- Leverages existing HIT efforts.

- Demonstrates the tangible benefits of HIT adoption.

- Accelerates the vision articulated in the federal HIT strategic framework.

- Is necessary to meet or advance other top health policy goals.

The Workgroups will be asked to revisit and refresh the list of proposed use cases for 2009 keeping these criteria in mind. Dr. Kolodner added that the ONC will be issuing a contract to the Institute of Medicine and to the National Academies of Science to examine the process and determine if it can be optimized in any way.

Health Information Security and Privacy Collaborative (HISPC) Report Workgroup Recommendations and Updates

Privacy and Security Solutions for Interoperable Health Information Exchange Nationwide Summary

In introducing this session, Dr. Kolodner recognized Lori Evans, one of the founders of the ONC for all of her efforts (Ms. Evans is now with the State of New York). Linda Dimitropoulos of RTI International then provided the Community with a brief overview of HISPC's work in the last year related to the variation in privacy and security practices, policies, and state laws, as they exist in practice today. Since this contract was awarded in September of 2005, a tremendous amount of work has been accomplished. In June of 2006, all 34 of the state teams were onboard, and in the span of 10 months, by April of 2007, they had assembled their steering committees and workgroups, conducted the assessment of variation among stakeholder organizations, developed an array of potential solutions, and drafted implementation plans. Also during that period, the teams shared their findings through attendance at regional meetings and at a national meeting. Each state team drafted five reports (three interim reports and two final reports). Summary reports are available online through the Agency for Healthcare Research and Quality.

Ms. Dimitropoulos explained that one of the core assumptions driving this work is the concept that all health care is local, and that decisions about health care should be made at the local level. Her group was charged with developing a method for the states to assess the variation in their business practices, policies, and state laws that govern the privacy and security of health information, develop feasible solutions to reduce the variation, and develop a plan to implement solutions. A modified Community-based participatory research model was used wherein the members of the state teams worked to identify and "own" their issues and outcomes. A broad range of stakeholders was engaged in the process to identify challenges to privacy and security, and to develop solutions. The RTI project team and the Technical Advisory Panel, along with the National Governors Association, provided central coordination and support by providing the core methodology that framed discussions that the state teams that had with their stakeholders.

A total of 18 scenarios were developed in collaboration with the American Health Information Management Association; these scenarios were based on 11 purposes for exchange; the discussions were further framed by the nine domains of privacy and security. All of the materials developed for the state teams also are available through the National Resource Center's Web site. Ms. Dimitropoulos commented that stakeholder engagement is a key element in this process. Ultimately, the solutions have to be adopted by the stakeholders if variation is to be reduced. In the assessment of variation process, the state teams engaged 3,811 stakeholders in the first phase of the project (an average of 112 stakeholders per state).

Ms. Dimitropoulos discussed a number of challenges faced by the state teams as well as solutions that have been implemented. For example, state teams faced a lack of awareness among stakeholders. In response, 14 states are developing model outreach and education programs. Another challenge facing the state teams was the variation created by state privacy and security laws. To address this challenge, nine states are implementing solutions related to state law. Another challenge was obtaining and managing patient consent—eight states are now working on reducing variation related to consent management.

In terms of moving forward, state team subcontracts have been extended through December 2007 to implement a foundational component to their plan. There also is movement toward multistate and regional coordination and collaboration. For example, HISPC state project leaders have met with the State Alliance for eHealth Health Information Protection Task Force. Multistate and regional collaborative workgroups are being formed that will continue the work beyond the end of this contract, and representatives from all 56 states and territories have been invited to participate in the work groups. In addition, the state teams will convene for a national meeting in November 2007.

New York State Health Information Security and Privacy Collaboration

Lori Evans, Deputy Commissioner of the Office of Health Information Technology Transformation within the New York State Department of Health, explained that in the first phase of the work done by the New York State team, five priority solutions were identified in conjunction with stakeholders: (1) leadership, (2) consent, (3) patient engagement, (4) security/access/use, and (5) accreditation.

In terms of leadership the challenge that was identified in the first year of work was that New York lacked the infrastructure to guide policy development, investment, and implementation across the state in a coordinated and coherent manner. A multifaceted solution was developed and included the creation of the Office of Health Information Technology Transformation, an executive-level office in the Department of Health in New York that is charged with addressing HIT issues across the public and private health care sectors. The New York e-Health collaborative also is addressing this challenge—this not-for-profit organization will be facilitating a state-level governance and collaboration process and has evolved to pull together the regions and implement a regional health information organization (RHIO) or health information exchange committee, as well as a health information service provider. Ms. Evans noted that careful consideration has to be given to the role of the state efforts within the context of national/federal activities. Secretary Leavitt commented that from the anecdotal exposure he has had, in most cases the state is focused on adoption, and in some cases, focused on the development of RHIOs. However, there typically is little conversation among states on the implementation of the standards. He added that states also are beginning to examine quality through somewhat independent approaches; somehow, these efforts need to be linked. Ms. Evans agreed, adding that New York's Health Care Efficiency and Affordability Law for New Yorkers and the Federal State Health Reform Partnership will provide a significant investment in HIT. Finally, in terms of the leadership priority solution, New York has established the Health Information and Technology and Evaluation Collaborative, a collaboration of academic institutions and researchers that will be assessing adoption progress in New York.

With regard to consent, Ms. Evans identified three specific challenges: (1) current laws governing health information exchange (HIE) were developed in a paper-based world, (2) New York State's current legal framework on HIE is not organized into one regulatory scheme, and (3) New York State law requires one-time patient consent. The goal in overcoming these challenges is to advance a patient consent solution through the development of a public policy and legal framework through three phases. Phase I involves assessment and consensus building, Phase II focuses on recommendations and a legislative proposal, and Phase III deals with a standardized consent form.

Additional activities underway in the State of New York include patient engagement activities through the Office of Consumers and Personalized Medicine as well as programs and policies to: (1) support the right of New Yorkers to have greater control over and access to their health information, (2) focus on building capacity of consumer and health advocacy organizations across the state to educate and support New Yorkers, and (3) educate New Yorkers through public education campaigns. Activities focused on security, access, and use are ongoing through a state-level Health Information Service Providers Consortium. Finally, a state-level RHIO committee is addressing issues related to accreditation.

Before the next presentation, Secretary Leavitt announced that he had to leave the meeting (Dr. Kolodner took over as Chair). Before departing, the Secretary Leavitt commented that a cultural bias against sharing information, based mostly on fear, exists. As issues of HIT and its relationship to privacy are addressed, it should be acknowledged that there is a significant educational effort that is needed in terms of privacy and what information can and should be shared.

Washington State Health Information Security and Privacy Collaboration Solutions for Health Information Exchange

Jonathan Sugarman, of Qualis Health, explained that there is substantial momentum in the areas of HIT and the interoperable exchange of information in Washington State; the primary focus of most collaborative enterprises is on applications in contrast to privacy and security. The Washington HISPC contract was awarded to Qualis Health, a Seattle-based not-for-profit quality improvement organization, in close consultation and effective collaboration with the state health care authority and many other private and public-sector organizations.

In 2005, before initiation of the HISPC project, the Washington State legislature directed the state health care authority to establish an advisory board "To develop a strategy for the adoption and use of electronic medical records and health information technologies that are consistent with emerging standards and that promote interoperability of health information systems." Mr. Sugarman explained that this, in many ways, is similar to what AHIC is doing at the national level. As a result of this mandate from the Washington State legislature, the Health Information Infrastructure Advisory Board (HIIAB) was convened to develop statewide approaches to HIE. Mr. Sugarman noted that there is significant and intentional overlap of HIIAB and HISPC stakeholder participation.

A series of barriers and proposed solutions to privacy and security issues in Washington State were identified. The barriers include lack of: (1) a defined set of minimum requirements for HIE privacy and security, (2) stakeholder incentives to encourage adoption of HIE privacy and security standards, and (3) an authoritative state-level governing body to oversee the privacy and security standards for HIE. The corresponding proposed solutions are to: (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; and (3) establish a privacy and security "administrative body."

Mr. Sugarman noted that in terms of implementation plans and future steps, HISPC work will be incorporated under the umbrella of the HIIAB, wherein the Board becomes the HIE privacy and security "administrative body" envisioned by stakeholders. HISPC funding will continue through December 2007 to support the creation of the Privacy and Security Technical Advisory Council (PSTAC) to advice the HIIAB. The PSTAC will include a Consumer Engagement and Participation Subgroup as well as an Authentication Subgroup. It is hoped that over the next 6 months that the PSTAC will help create a foundation for future activities in the areas related to consumer consent, opt-in/opt-out procedures, and provide recommendations to the HIIAB (which in turn makes recommendations to the legislature). It also is planned to identify user and entity authentication approaches to support health banking pilots.

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

Kristen B. Rosati, a Partner at Coppersmith Gordon Schermer and Brockelman PLC, described Arizona's statewide public-private collaborative, Arizona Health-e Connection (Ms. Rosati Chairs the legal workgroup for this health exchange initiative and also serves on the National Governors Association State Alliance for e-Health Health Information Protection Task Force). She explained that Arizona has been fairly unique because it is one of few states tackling HIE initiatives at the statewide level. Arizona Health-e Connection was created with the goal of creating an HIE connectivity system in Arizona in 5 years. One of the organization's most important roles is that of a convener of stakeholders, with the goal of getting every interested individual, health care organization, and government agency at the table to make the decisions. In terms of Arizona Health-e Connection's governance structure, a broad range of stakeholders serve as permanent members of the organization's board.

In addition to this statewide public-private collaborative, there are a number of RHIOs and HIEs developing in Arizona. The state's Medicaid program, known as the Arizona Healthcare Cost Containment System, received one of the Medicaid Transformation Grants in the amount of $12 million to create an HIE system for all of the Medicaid providers throughout the state. One of the developing regional efforts is the Southern Arizona Health Information Exchange, which is well down the path to creating electronic exchange systems for the providers and plans. Ms. Rosati explained that Arizona Health-e Connection will serve as a central resource to support these various regional and HIE initiatives by establishing standards and procedures for e-health data exchange.

The first area being tackled at a statewide level in Arizona is privacy and security standards for e-health data exchange. Closely tied to this activity is the challenge of a lack of "policy interoperability." Ms. Rosati emphasized that inconsistent rules regarding how to protect individual privacy and secure electronic health information will interfere with the electronic exchange of health information. To address this challenge, Arizona is using the second phase of HISPC funding to foster standards development with broad stakeholder involvement through three resources: (1) role-based access and authentication for a master provider index, (2) model privacy and security policies for HIE, and (3) a model participation agreement. It is hoped that these resources will have benefits that extend outside the State of Arizona.

Another privacy challenge in Arizona (and in states across the country) is uncertainty regarding legal requirements. Ms. Rosati explained that uncertainty regarding present legal requirements will delay participation in HIEs. Similarly, uncertainty regarding future legal requirements will delay the creation of HIEs. She added that the evolution of law is inevitable, and very necessary, especially within the context of developing technology. In Arizona, for example, many laws on the books are fairly archaic and were written for the paper medical record world. It has been proposed to update all of the Arizona State health information laws to reflect the electronic environment, and to make sure that there are no artificial barriers to electronic HIE. Care must be taken, however, at the state and federal levels, about changing some of the fundamental privacy requirements that are applicable to the exchange of health information. For example, the newly introduced Health Information Privacy and Security Act of 2007 proposes to prohibit the use or disclosure of health information without the explicit authorization of an individual, even for treatment purposes. If a law like this were to pass, it would fundamentally change the requirements in a number of states, especially states such as Arizona that do not have a consent requirement at this point. Ms. Rosati added that it also may threaten the use of electronic health information to develop quality information and to use health information to improve the quality and efficiency of health care.

Discussion Highlights

"What are you seeing from outside of your own states…either through your work at the National Governors Association or through collaborative work with your peers, that is potentially the largest roadblock in having consistent regulations and laws across the states? Is this something that each individual state takes on, and we have consistency? Or is this something that is taken at a federal level like the bills and laws that we're seeing proposed currently, today?" – Mr. Hutchinson

"Through the work of the National Governors Association Health Information Protection Task Force, it looks to me that there are really two primary areas where the differences in state laws will make a big difference in our ability to exchange e-health data interstate. That's the consent requirements, whether states require affirmative consent to exchange health information for treatment or don't…the second large area is where states have legislated very different rules about protecting sensitive health information." – Ms. Rosati

"When you think about how electronic health records are put together, there is not really a technically feasible way to segregate that information that has that special protection under state law. And from a clinical standpoint, it's usually not a very good idea to do that anyway, because care providers want to see all of the information that is relevant to the health care. So when you start talking about wholesale exchange of the electronic health record across state lines, you will deal with very, very tricky issues about how to handle those differing state laws." –Ms. Rosati

"I think that at the federal level, a lot more work could really help us. I think consumer protection laws are really needed for the nation. And I think a lot of things are making it more difficult for us at the state level because of the complexity that we're facing at the federal level." – Ms. Evans

Certification Commission for Health Information Technology – Inpatient and Ambulatory Care Certification Criteria

Dr. Mark Leavitt, Chair of the CCHIT, provided a brief overview of the Commission, noting that its mission is to accelerate the adoption of robust, interoperable HIT by creating an efficient, credible certification process. He reminded Community members that the goals of certification are to: (1) reduce the risks of investing in HIT; (2) facilitate interoperability if HIT products; (3) enhance the availability of adoption incentives and regulatory relief, and (4) ensure that the privacy of personal health information is protected. The Commission is working under a 3-year federal contract that has/had the following three phases: (1) develop, pilot test, and launch certification of ambulatory (office-based) EHRs (2006); (2) develop, pilot test, and launch certification of inpatient (hospital) EHRs (2007); and (3) develop, pilot test, and launch certification of networks through which EHRs interoperate (2008). The contract also requires the Commission to become independent and self-sustaining by the end of the period of performance. The CCHIT also updates certification criteria for each domain annually and expands certification to address more specialized needs.

Dr. Leavitt explained that the CCHIT has been certifying ambulatory EHRs for 1 year. That development took 18 months, more than 100 volunteers, and about 2,000 comments. The criteria were released in March 2006 and the Commission started certifying in May last year. Surprisingly, the Commission has certified 89 products within the last year, representing about 40 percent of the EHR vendor market. Dr. Leavitt commented that the bulk of these vendors are small businesses, refuting some of the dire predictions that certification might shut out innovation in favor of large vendors.

While the CCHIT was certifying those EHRs during the past year, it also was developing the update to the ambulatory EHR criteria for 2007. All criteria on the CCHIT's published roadmap were reviewed, as well as newly emerging requirements. The criteria were refined through multiple cycles of public comment. Consensus was achieved, a pilot test was completed, and updated criteria were finalized and published in March 2007. Certification against 2007 ambulatory EHR criteria is now in progress (six have been announced to date). By way of comparison, in 2006 a total of 151 criteria were inspected through 200 test steps; in 2007, 247 criteria were 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, and improved population reporting. Dr. Leavitt commented that evidence of certification's positive impact includes endorsements by provider organizations, vendors enhancing security features, payer IT incentives keyed to certification, health information networks and state e-health initiatives (using certification to qualify HIT for funding and 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.

Dr. Leavitt then presented the EHR certification criteria to the Community for the first time. Criteria development started in May 2006. There were four rounds of public comment; the Commission reviewed and responded to approximately 1,000 comments. An alpha test and pilot tests were completed in May 2007; the criteria were finalized and published in June. The Commission will accept applications for certification starting on August 1, 2007. Dr. Leavitt commented that these criteria were significantly more complex to develop than the ambulatory EHR criteria, because the systems are more complex and the organizations are more complex. He added that it is the medication ordering and administration chain where the Commission's biggest opportunity for safety and quality improvement in the hospital may rest. Applications will be accepted for 14 days, and then the Commission will have 3 months to certify the first batch of applications.

The CCHIT is developing four new areas to launch in 2008: (1) networks/HIEs, (2) emergency department systems, (3) cardiovascular medicine EHR requirements, and (4) child health care EHR requirements. In addition, the ambulatory and inpatient EHRs will be updated in 2008.

Discussion Highlights

"For the ambulatory EHR as well as inpatient, what does it cost these vendors to get certified?" – Ms. Gelinas

"We've actually set the price. Ambulatory certification was $28,000, for the initial fee and the first year's license. And the inpatient I believe is $34,000. So we've held it in the same range. And in the inpatient EHR, we not only require a practicing physician, but a practicing nurse on the jury. So our costs were a little higher. And also the development costs were higher. We don't have a clue what the network costs would be yet." – Dr. Leavitt

"Thinking of the ambulatory environment now only, as you said, there are 200 vendors and about 90 have gone through the certification process. So what do you see happening with the other 110? Do you see the 110 becoming 40, because some people go out of business because they just don't want to compete in a certification market? Or do you see those other 110 finally coming up to the plate and paying the $28,000 and getting certified?" – Dr. Henley

"I believe that two-thirds of those aren't EHRs, in our definition. There is a class of products that's just a note generator, lets you create a more complex note. And they're low in cost. And they're popular

because it increases your reimbursement. And yet they advertise, and they end up being categorized as an EHR…I think that we're making the market more transparent. And we've actually sharpened the definition of an electronic health record." – Dr. Leavitt

"In terms of that marketplace that's covered by the 89 products…what percent of the marketplace do you think they cover?" – Dr. Kolodner

"The vendors have different market shares. So it's over 40 percent of the vendors, but when you look at the market shares of those vendors, I would hazard that the percentage is twice as high. Probably 80 percent of the marketplace is represented by those vendors." – Dr. Leavitt

"Are there internal, proprietary EHRs that aren't marketed but used internally by organizations? And if so, is there any incentive for those organizations to get certified?" – Mr. Green

"Yes, there are internally developed systems, the Department of Defense is an example. And also, large health centers sometimes develop them. And we opened the doors to them about six months through the program. They came to us and said, 'We want to do this because it could help us with pay-per-performance programs.' So we'll certify an internally developed system. We modified the test so it wouldn't interfere with a live system." – Dr. Leavitt

"Have you had providers that are coming to you and want to have EHRs certified, but perhaps financially they simply are in a setting or serving a population where there are not the resources available to underwrite a certification fee that's being charged? Is there any charity, care charity provision for people that are trying to get certification and just don't have the resources?" – Ms. Davenport-Ennis

"We haven't had a provider come with an internally developed system, saying, 'I'd like this to be tested and I can't afford it.' If we recognized a market like that, I think we'd look for some grants for them, or scholarships…it hasn't really come up yet. But if you're referring to the safety net clinics, we have a good connection with them. And I have a number of friends that are involved in that sector. And we haven't been hearing that too much. They tend to be adopting actually the commercial systems, from what I've seen. And in fact, the certified commercial systems." – Dr. Leavitt

"As long as we're meeting the need of those special populations, then I think that we're doing what we need to do, as a nation, in certification." – Ms. Davenport-Ennis

"I think HRSA this year was able to put $20 million into the safety net communities towards EHRs. So they're continuing to make investments, and help that community." – Dr. Kolodner

"As you look to the next wave of EHRs…behavioral health would be extraordinarily helpful for states. States fund, through their IMDs and community mental health centers, the care for much of the SMI population. It moves between a public and a not-for-profit system. There is no certification. I tried to go buy a certified system for our five state mental health hospitals. They don't exist. So we won't buy one until you certify one." – Mr. Roob

"It's on the roadmap. It was one of the groups that popped up and was prioritized." – Dr. Leavitt

"When we start to solve interoperability and systems are certified, everybody gets them, but then do they use them to full advantage and use all the features? It's going to be a big job for everybody to solve." – Dr. Leavitt

"What would you say that the most common criticism that you're getting right now in the field as far as the process is? Enough resources? Is there a large backlog of certifications? Or what would you say is the number one thing that we need to work on?" – Mr. Hutchinson

"We don't have a backlog. We were able to ramp up to meet the scale. There's always tension between vendors wanting it to be inexpensive and simple, which is fair. And providers want it to be very rigorous. So we expect to always have that going on. But the loudest protest we heard was that it would shut out small vendors because the cost was excessive. And I think that still goes on. But I think it comes from the sector of vendors making, not comprehensive EHRs, but something else." – Dr. Leavitt

"As you're looking at the work you're beginning to undertake, particularly on the network certification criteria, have you focused in on exactly what you will be looking to certify in that area? It can be very complicated. And is it being looked at the applications, the connectivity, the organizations that may be the networks? Have you given thought to exactly what road that's going to take at this point?"
– Ms. Handelman

"We don't know the answer. We have to find what is effective, and what will move the marketplace. We have to kind of meet the marketplace where it is. And there's the issue of health information exchanges. Like personal health records, they are fledgling, and many of them are not richly funded. And we wouldn't want the costs of applying for certification to be a barrier, so we may need to seek a solution for that. So all we have now are questions, not answers. We have a year to develop those, and we hope everyone will participate in our finding the answers." – Dr. Leavitt

Consumer Empowerment Workgroup Recommendation Status Report

Nancy Davenport-Ennis, Co-Chair of the Consumer Empowerment Workgroup and a member of the Community, provided an update on four recommendations that were made to AHIC in May of 2006. Those recommendations, and an update on their status, are as follows:

- **Recommendation 1.0 (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 the first iteration of HITSP standards.

- **Recommendation 2.0 (In 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: – A CMS PHR pilot is in progress.
  – CMS is working with AHRQ on qualitative evaluation statement of work.
  – There is a proposed scope of work to demonstrate the value f 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.

- **Recommendation 2.1 (In Progress):** Recommended that federal agencies sponsoring pilots for 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: – A CMS PHR pilot was done in collaboration with AHIP and Blue Cross Blue Shield Association.
– A pilot began in June 2007.
– CMS is working with the Office of External Affairs to evaluate appropriate and effective outreach and messages.

- **Recommendation 3.0 (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: – The Confidentiality, Privacy, and Security Workgroup convened in August 2006.
  – An *ad hoc* subgroup of Consumer Empowerment and CPS Workgroups was established in January 2007 and completed is work in June 2007.

Discussion Highlights

"I think this group has done some great work. And I think it's a real good example of public/private cooperation. The pilot that you spoke of…my office has worked very closely with Justine and a number of other people to make this work. And I think it's been a very cooperative effort between CMS, the Office of the National Coordinator, AHRQ, and the private sector, to really make this work." – Mr. Trenkle

Public Input Session

No members of the public offered comments at this meeting.

Closing Remarks

Before adjourning the 15th AHIC meeting, Dr. Kolodner thanked the Community members and speakers for their efforts.

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

American Health Information Community

Advancing Clinical Decision Support

John Glaser
Partners HealthCare

Carolyn M. Clancy
Agency for Healthcare Research and Quality

Charles Friedman
Office of the National Coordinator

September 18, 2007

Framing Remarks

John Glaser, PhD

Vice President and Chief Information Officer
Partners HealthCare

Definition of Clinical Decision Support

- Provides clinicians, staff, patients and other individuals with knowledge and person-specific information, intelligently filtered at appropriate times, to enhance health and health care
- Encompasses computerized alerts and reminders, clinical guidelines, order sets, patient data reports and dashboards, documentation templates, diagnostic support, and clinical workflow tools

Clinical Decision Support Impact

- There are several studies that have documented the ability of CDS-enabled EHRs to reduce errors, improve care quality, and reduce costs
- However:
  - There are other studies that have illustrated limited or no impact or adverse impacts
  - CDS adoption is low due to limited EHR adoption, EHR technical limitations, lack of CDS adoption incentives, challenges of workflow integration, and difficulty of acquiring and managing CDS-based knowledge

A Roadmap for National Action on Clinical Decision Support

- Chronology
  - Commissioned by ONC in partnership with AHRQ in 2005
  - Conducted by the American Medical Informatics Association
  - Findings presented to AHIC on June 13, 2006
- Identified six strategic objectives for promoting CDS adoption with the broader framework of interoperable health IT:
  - Represent clinical knowledge and CDS interventions in standardized formats
  - Collect, organize, and distribute clinical knowledge and CDS interventions
  - Remove policy/legal/financial barriers and create additional support and enablers
  - Improve clinical adoption and usage of CDS interventions
  - Assess and refine the national experience with CDS
  - Advance care-guiding knowledge

Current Activities and Future Plans

Charles Friedman, PhD

Senior Advisor to National Coordinator
Office of the National Coordinator for Health Information Technology

Summer 2007 Follow-up to the Roadmap

- CDS is cross-cutting
  - Five AHIC Workgroups have expressed interest in CDS
  - Personalized Healthcare Workgroup had a meeting focused on CDS yesterday
- An ad hoc AHIC CDS planning group, with members from government and several workgroups, has met twice
- AHIC Workgroups asked for comments on CDS priorities
- ONC has commissioned a study of CDS by Gartner
- ONC is conducting a scan of CDS activities within government agencies

Gartner Report: Current State and Future Directions in Clinical Decision Support for Healthcare Providers

- Commissioned by ONC and completed in July 2007 to:
  - Provide an overview of the current use of CDS in vendor systems
  - Understand how the challenges and open questions are being addressed in selected vendor products and locally developed solutions
- Addressed specific questions in the following topic areas:
  - Knowledge Management
  - Decision Support Modes
  - Genetic/Genomic Knowledge
  - Advanced CDS Functions
  - Studies on Practice Behavior
  - Shareable CDS Content

Gartner Report: Summary Comments

- While the combination of deploying EHR solutions with CDS capabilities offers great potential, near-term reality of deploying CDS is much more limited
- Adoption of CDS is still in the early stages within hospital and integrated health care delivery systems
- Current challenges include limitations in:
  - Availability and acceptance of decision support content
  - How to effectively engage but not overwhelm the clinical user
  - Organizational readiness to support CDS

Federal Agency Scan

- Over 25 individuals who play varying roles across eight agencies have been targeted for phone interviews
  - HHS: AHRQ, CDC, CMS, HRSA, IHS, NIH
  - DoD, VA
  - To date, interviews have been completed with 11 individuals representing four agencies
- Interview agenda depends on agency's role as a funder, implementer, or facilitator of CDS
- Questions include but are not limited to:
  - Level of priority for funding, or importance in strategic plan
  - Examination of the usability and workflow
  - Interoperability of CDS tools
  - Future steps planned for CDS funding, deployment, or policy development

The Plan Going Forward

- Ad hoc CDS Planning Group (Public-Private) to continue
  - Coordinate deliberations and recommendations across workgroups
  - Identify problems that need to be addressed in a coordinated way
- Efforts internal to the government to be coordinated through a “collaboratory”
  - Co-sponsored by ONC, AHRQ, and Personalized Healthcare Initiative
  - Building on government agency scan
  - Focus on funding and implementation activities

Clinical Decision Support Activities at AHRQ

Carolyn M. Clancy, MD

Director
Agency for Healthcare Research and Quality

Relevant AHRQ Programs

- Core mission: improving quality and value
- Comparative Effectiveness
- Health IT
- Leadership on AHIC Quality Workgroup

AHRQ's Health IT Initiative

- Improving quality through health IT since 2004
- Broad grant portfolio
- Demonstration contracts
- National Resource Center for Health IT
- Many collaborations with public and private partners

Diffusion of Knowledge

Clinical Procedure	Landmark Trial*	NHQR 2005
Flu Vaccine	1968	63%
Pneumococcal Vaccine	1977	54%
Diabetic Eye Exam	1981	70%
Mammography	1982	70%
Cholesterol Screening	1984	67%

* Balas EA, Boren SA. Managing Clinical Knowledge for Health Care Improvement. Yearbook of Medical Informatics 2000.

Adapt Evidence to Clinical Situation
Patient-Centered Care

- What's right for one patient may not be right for the next
- Balance of benefits and harms influenced by:
  - Baseline risks
  - Preferences

Clinical Decision Making

- CDS is an important tool to improve quality
- Not a one size fits all strategy
- No systematic approach in the past
- Domain matters
- Guidelines developers are engaging
- Workflow is under addressed – but is a critical factor

Clinical Decision Support Demonstrations

- Advance understanding how to best incorporate CDS into health care delivery
- Address clinical practice guidelines for:
  - Preventative care
  - Multiple common chronic illness
- Ambulatory setting
- Implementation in certified health IT
- Two contracts
- $1.25M per year per contract
- Two base years and three option years

Deliverables of Note

- Regularly scheduled meetings to update stakeholders
- Steering committee with broad stakeholder participation
- Report documenting implementation and evaluation, describing barriers and risks to implementation encountered along with any solutions
- Guidance on suggested certification of health IT that provides CDS based on demonstration contractor work and other input
- Guidance to:
  - Guideline developers
  - Quality measure developers
  - IT vendors
  - Clinician professional organizations

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

American Health Information Community

Population Health and Clinical Care Connections Workgroup Recommendations

John Lumpkin
The Robert Wood Johnson Foundation

September 18, 2007

PH/CCC Workgroup Member List

- **Co-Chairs:**
  - John Lumpkin — The Robert Wood Johnson Foundation
  - Julie Gerberding — CDC
- **Members:**
  - Michael Barr — ACP
  - Scott Becker — APHL
  - Larry Biggio — State of WY
  - Theresa Cullen — IHS
  - Art Davidson — Denver Public Health Dept. (NACCHO)
  - Lisa Dwyer — CSTE
  - Jon Einbinder — Partners Healthcare
  - Thomas Frieden — NYC Dept. of Health and Mental Hygiene (NACCHO)
  - Angela Fix — ASTHO
  - Shawn Fultz — Dept. of VA
  - Shaun Grannis — Regenstrief
  - James Hadler — CT Dept of Health (CSTE)
  - Amy Helwig — AHRQ
  - Brian Keaton — ACEP
  - Martin LaVenture — MN Dept of Health (ASTHO)
  - John Loonsk — ONC
  - Bob Martin — CDC/CoCHIS
  - David Parramore — Dept of Defense
  - Dave Ross — PHII
  - Lisa Rovin — FDA
  - Edward Sondik — CDC
  - Paula Soper — NACCHO
- **Office of the National Coordinator:**
  - Kelly Cronin — ONC WG Director
  - Laura Conn — Senior Advisor
  - Shu McGarvey — Lead Staff, NG – Contractor to ONC

Population Health and Clinical Care Connections Workgroup Overview

Broad Charge:

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

Specific Charge:

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

Scope of Response Management Recommendations

- Outbreak Management
- Laboratory Response
- Countermeasure Allocation, Distribution and Administration
- Automated Integration with Registries

Recommendation 1.0: Overarching

CDC, in collaboration with AMIA and the PHDSC, and working with Schools of Public Health and other informatics fellowship programs should enhance and promote the public health domain of the AMIA 10X10 initiative, the Partnership for Workforce Public Health Informatics Training, and similar programs to advance public health informatics workforce development. The public health informatics competencies developed by the University of Washington and CDC, and other applicable work, should be used as a basis for this initiative.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 1.1: Overarching

HHS should work with CDC, HRSA, CMS and other federal agencies to include language in contracts, grants and cooperative agreements that ensures:

- Funds from a variety of programs can contribute to an informatics capacity and technical architecture that invests in advancing information systems and IT infrastructure required to support their implementation and interoperability. This language should explicitly include systems and infrastructure that support public health labs, registries, surveillance systems, outbreak management and response systems, as well as other systems that receive data used for population health purposes.

Recommendation 1.1: Overarching (cont.)

- In order to meet the requirements of the Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs, funds can be used for technical support, to cover the cost of on-going system maintenance, and for updates and enhancements to provide functionality and adhere with interoperability specifications.

Recommendation 1.1: Overarching (cont.)

- Metrics should be collaboratively developed with state and local public health partners to assess the ability of public health information systems to interoperate and support public health investigation and response. These metrics should measure and monitor interoperability, usability, flexibility, quality, completeness and timeliness of data, as well as system functionality to support:
  - Outbreak and event management.
  - Countermeasure allocation, tracking, distribution and administration.
  - Integration of laboratory information.
  - Bi-directional exchange of data across clinical care and public health.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 2.0: Outbreak and Event Management

By March 2008, CDC with ASTHO, NACCHO, CSTE, APHL and other appropriate groups, should update and refine criteria for functionality, security and interoperability of systems that support outbreak management at local, tribal, state and federal levels. The criteria should:

- Be minimal but sufficient to support the needs of managing complex outbreaks.
- Ensure interoperability with other systems (such as other outbreak systems, laboratory information systems (LIS), systems that manage countermeasures, fatality management tracking systems, monitoring tools for quarantine and isolation, electronic health records (EHRs), and surveillance databases).

Recommendation 2.0: Outbreak and Event Management (cont'd)

- Provide a starting point for a freely distributable software implementation and ongoing development and maintenance.
- Use as a starting point the AHIC Use Cases, the HITSP Interoperability Specifications, and the PHIN Functional Requirements for Outbreak Management.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 2.1: Outbreak and Event Management

CDC, with input and assistance from state and local public health should support the development and testing of software systems designed to manage public health investigations (e.g., CDC Outbreak Management System, state or commercially-developed systems), including identification of important exposures, laboratory diagnostics, contact tracing and indication for preventive countermeasures such as infection control, isolation, quarantine, prophylaxis or treatment.

Recommendation 2.1: Outbreak and Event Management (cont.)

- Facilitate the development of standards, shared architectural components and implementation guidance for possible and confirmed case exchange and make available to public health partners by October 2008.
- Develop, or commission the development or acquisition of, and support the maintenance of a freely distributable software implementation to support local, tribal, state and national agencies to manage outbreaks. The criteria for this software implementation would be based on the collaboratively defined criteria defined in recommendation 2.0 above. This software should be available no later that March 2009.
- Develop test sites to measure the level of interoperability between EMR, LIS, surveillance and software developed for outbreak management.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 3.0: Laboratory Response

By June 2008, CDC in collaboration with APHL, CSTE, ASTHO, NACCHO, and other appropriate organizations should identify any types of data, codes and relationships needed (beyond those specified in the HITSP EHR / Biosurveillance lab result message), necessary to support:

- Test orders to and result reporting from public health labs.
- The coding of public health conditions in the HITSP lab message.
- Result reporting of veterinary and environmental data.
- Unambiguous linkage of laboratory data to clinical and public health records.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 3.1: Laboratory Response

HHS, in conjunction with state and regional health information exchanges, public health and clinical laboratories, should develop the infrastructure and architecture for unambiguous unique identification of medical service providers in association with the NHIN initiative. This should include ensuring that registries of medical service providers exist and that registry lookup capability is developed and available to laboratories for routing laboratory data back to the originating requestor, and to other appropriate parties, to support national electronic laboratory data exchange.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 3.2: Laboratory Response

By October 2008, HHS, in collaboration with APHL, private laboratories, and other federal laboratories, should establish regional or national capabilities to receive and route laboratory results to all appropriate recipients simultaneously.

- Define the processes and approaches for consolidated receipt and routing of laboratory results.
- Support a proof-of-concept demonstrating an efficient regional or national mechanism for the acquisition of laboratory test order information as well as dissemination of test results to appropriate public health and clinical care providers.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 4.0: Countermeasure Allocation, Distribution, Admin.

By March 2008, CDC with ASTHO, NACCHO, CSTE, APHL, FDA, and other appropriate groups, should update and refine criteria for functionality, security and interoperability of systems that support countermeasure apportionment, tracking, distribution and administration at local, tribal, state and federal levels. The criteria should:

- Be minimal but sufficient to support the needs of managing countermeasures during a response.
- Ensure systems are interoperable with other systems (such as outbreak systems, vendor managed inventories, point of distribution software, fatality management tracking systems, monitoring tools for quarantine and isolation electronic medical record (EMR), and surveillance databases).

Recommendation 4.0: Countermeasure (cont.)

- Provide a starting point for a freely distributable software implementation and ongoing development and maintenance.
- Use as a starting point the AHIC Use Cases, the HITSP Interoperability Specifications, and the PHIN Functional Requirements for Countermeasure Response and Administration.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 4.1: Countermeasure

By April 2008, CDC should convene a meeting to include representation from clinical partners, manufacturers, and distributors to understand the resources that are available in the private sector and develop strategies to exchange information on the availability of and demand for resources at any given time.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 4.2: Countermeasure

CDC with HHS, and through the national agenda, should support the harmonization of standards and development of implementation guidance and shared architectural approaches for the exchange of countermeasure information. These products should be made available to public health partners by December 2008. Following the implementation of countermeasure response solutions, support the establishment of test sites to measure the level of interoperability with electronic health records, outbreak management systems, registries, surveillance systems.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 4.3: Countermeasure

By June, 2008, HHS should facilitate development of national administrative or legal approaches for routine and emergency inter-state data exchange of countermeasure and immunization information.

- Address business propriety data concerns of relevant commercial supply chain entities.
- Develop a blanket agreement to provide federal support for sharing of data and resources when it is necessary.
- Communicate with and educate hospital risk management staff and privacy and confidentiality officers in clinical care settings to alleviate concerns about public health access to clinical data.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 5.0: Automated Integration with Registries

By March 2008, CDC should convene a group of public health registry experts such as immunization, cancer, trauma, donor, chronic disease, and others to determine how the established capabilities and unique attributes of existing registries could be used in public health response.

☐ **Accept** ☐ **Table** ☐ **Reject**

Recommendation 5.1: Automated Integration with Registries

By October 2008, CDC should develop a communication plan based on discussion and recommendations from the March 2008 meeting referenced in 5.0 above. The overall goal of this plan is to communicate to public health officials the available registry resources for use during an emergency response.

☐ **Accept** ☐ **Table** ☐ **Reject**

September 18, 2007

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

Dear Secretary Leavitt:

The Population Health and Clinical Care Connections Workgroup (PH/CCC) encompasses a broad perspective of population health and is described using five interrelated domains: Public Health Surveillance and Response; Health Status and Disease Monitoring; Population Based Research; Population Based Clinical Care; and Health Communications/Education.

The recommendations in this document fall predominantly under the domain of Public Health Surveillance and Response. Future recommendations will be required to better address the remaining four domains. The Population Health and Clinical Care Connections Workgroup (PH/CCC) has the following broad charge:

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

The Workgroup's deliberations highlighted a number of key issues with respect to the broad charge:

- Public Health infrastructure at the local, state and federal levels needs to be modernized to meet current and emerging threats by increasing the flexibility, functionality, and interoperability of systems that support public health.

  While public health has made progress in the last several years toward developing information systems to support program specific needs, many of these systems have followed a pattern of program specific funding that constrained the scope of the solution (e.g., HIV surveillance systems cannot be easily adapted to serve other communicable disease surveillance needs). Resulting solutions are "siloed" and unable to be scaled to large complex outbreaks and events. As evidenced in the last decade alone – SARS, monkeypox, anthrax, and natural disasters such as hurricanes Katrina and Rita, public health emergencies are becoming more routine. Testimony has shown that point or targeted solutions built in response to an emergency, often relying on inexpensive and readily available technologies such as Microsoft Access and/or Microsoft Excel, scale poorly in large emergencies that require complex contact tracing, data or information sharing across jurisdictions, and cross source data linking. Robust, scalable solutions that integrate detection with investigation and response are largely unavailable to public health agencies; resulting vulnerabilities could be mitigated by thoughtful development of a strong public health infrastructure founded on interoperable systems that support

routine use but are designed to scale and adapt to all hazards. A strong public health infrastructure available across all jurisdictions and levels of public health, regardless of size, will go far toward reducing the wide variation in deployment of information technology that exists in public health today.

However, before interoperable systems are developed, functional, security, and interoperability criteria must be in place. The lack of criteria for public health systems is the next key issue.

- Functional, security and interoperability criteria will establish the basis for developing flexible, information systems that can be certified for functionality to support public health activities.

  Public health agencies at different jurisdictional levels have disparate business needs and different capacities. Across state and local health departments there are significant capacity disparities. Large municipal health departments may have substantially more resources than their smaller rural counterparts or than some of the smaller states, yet each are expected to provide similar services. Activities supported by information systems differ across public health jurisdictional levels. For instance, outbreak investigations are comprehensively carried out and conducted at the local or state setting, with federal assistance being requested when needed. Key functions at those levels (e.g., case triage and management, epidemiologic investigation, contact tracing and tracking of laboratory diagnostics) must be incorporated into information system solutions. All levels of public health should collaboratively define criteria for interoperable systems to effectively support public health functions.

  Variable organizational responsibilities across public health jurisdictional levels complicate efforts to standardize communications. While functional requirements may differ across jurisdictional levels, common data needs exist for all levels; a key difference is in how the data are used and analyzed by each level. Data standard requirements are necessary to ensure content and transmission uniformity across organizations involved in public health. Our goal is to limit the variation in capacity across similar jurisdictional levels while promoting interoperability across all levels.

- Public health has as a goal the consistent implementation of nationally recognized data standards, common vocabulary standards and definitions, and systems available to support response.

  Standards to support public health functions related to response should be prioritized for harmonization by the Health Information Technology Standards Panel (HITSP). Certification criteria should be established to evaluate software solutions for functionality that support public health. This reinforces recommendations 1.1 and 1.2 submitted to American Health Information Community (AHIC) by the PH/CCC Workgroup and accepted in March 2007[1]. These recommendations commit to the development of an approach, including development of additional and more detailed use cases to support standards identification and methods to measure certification criteria. There is

insufficient emphasis and resources within public health to support the HITSP and certification processes to ensure there is capacity to harmonize standards and develop certification criteria for AHIC population health use cases. Software developed for public health response would need to adhere to HITSP harmonized standards, and meet certification criteria. This would promote standardized, interoperable solutions suitable for broad use and should curtail current redundant development pathways.

- The value to clinical care for including public health as an integral partner in health information technology (HIT) should be clearly articulated and widely distributed.

  This issue reiterates the need for a public health business case as indicated in recommendation 1.0 of the PH/CCC March 2007 letter to AHIC[1]. Public health should be considered as more than just a recipient of clinical information but also as a source of information to clinical care. Clinical care provides case reports, adverse event reports and clinical data to appropriate public health entities, as well as providing updates to registries (such as immunization registries). Public health adds value to data derived from multiple sources (e.g., clinical care, veterinary, Food and Drug Administration, environmental sources), and makes this information available to clinicians to assist them in decision-making. Treatment recommendations, guidelines, assistance during vaccine shortages as well as updates to case definitions and the notifiable conditions list are examples of information provided back to clinical care.

  The business case should encompass integration with clinical decision support (CDS) tools in electronic health records. The integration would not only prompt for reports to be sent to public health, but also provide clinical reminders from public health such as treatment recommendations and guidelines or vaccinations that are due. The AHIC CDS Planning Group focuses on CDS integration, and the PH/CCC Workgroup supports these and the other national efforts that exist in this space.

This letter provides both context and recommendations for how these issues can be addressed to implement informational tools and business operations to support real-time nationwide public health event monitoring and rapid response management. The overarching recommendations strive to address the key issue of strengthening the public health infrastructure. The area specific recommendations are aimed at addressing the key issues of defining criteria and standards for information systems that support public health.

BACKGROUND AND DISCUSSION

The threat of significant naturally occurring or man-made health events is a critical issue for the nation. Once an event has been detected, the ability to manage the event, determine the appropriate response, quickly mobilize resources and administer countermeasures can save lives.

The real-time nationwide public health event monitoring and rapid response management is addressed through four underlying priority areas. These priority areas were defined and ranked by the Workgroup based on an iterative process in 2006. The prioritization was followed by a

visioning exercise to baseline the current state, and establish mid-state (by 2010) and end-state (2014 and beyond) visions for each priority area. After Biosurveillance, the PH/CCC Workgroup defined and recommended the implementation order for the following priority areas:

1. Case Reporting
2. Bi-directional Communications
3. Response Management
4. Adverse Events Reporting

Recommendations in the priority areas of Case Reporting and Bi-directional Communications were made to AHIC in March, 2007. The Workgroup then turned deliberations to the priority area of Response Management. The recommendations in this letter are based on Workgroup input, and informed by testimony given on March 29th and June 15th, 2007. Testimony and the resulting recommendations focus on four interrelated aspects of response management:

1. Outbreak and event management
2. Laboratory response
3. Countermeasure allocation, tracking, distribution and administration
4. Automated integration with registries

The overarching recommendations and the recommendations in the four aspects of response management are aimed at addressing the key issues described in this letter. As stated earlier, the key issue around a business case for data/information exchange between public health and clinical care has been covered in the March 2007 recommendation letter.

These current recommendations seek to increase the adoption and modernize public health information systems by making them fully functional (certified), and interoperable (standards compliant), in order to support the business processes required by local (~ 3000), state and territorial (~ 57) and federal (CDC and other) governmental public health authoritities.

RECOMMENDATIONS:

1. Overarching

The overarching recommendations are divided into two areas. The first targets improvements in infrastructure by developing informatics expertise in the public health workforce. The PH/CCC Workgroup endorses the effort to train 1,000 public health informaticians by 2010 and provide informatics leadership training to an additional 1,000 public health executives. The Workgroup endorses the concept of and placement of chief public health informatics officers in each state health department.

The second recommendation provides clarification for, and endorses use of, preparedness and other funds for building infrastructure in public health agencies and labs. This recommendation strives to move away from funding by program function, which has exacerbated the diversity seen in existing systems, and move toward an informatics capacity by building modular systems

that adhere to common interface specifications. Both recommendations seek to close the disconnect between information technology and public health program areas that has contributed to the inadequate infrastructure issue facing public health today.

Recommendation 1.0: The Centers for Disease Control and Prevention (CDC), in collaboration with the American Medical Informatics Association (AMIA) and the Public Health Data Standards Consortium (PHDSC), and working with Schools of Public Health and other informatics fellowship programs, should enhance and promote the public health domain of the AMIA 10X10 initiative, the Partnership for Workforce Public Health Informatics Training, and similar programs to advance public health informatics workforce development. The public health informatics competencies developed by the University of Washington and CDC, and other applicable work, should be used as a basis for this initiative.

Recommendation 1.1: HHS should work with the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Centers for Medicare and Medicaid Services (CMS) and other federal agencies to include language in contracts, grants and cooperative agreements that ensures:

- **Funds from a variety of programs can contribute to an informatics capacity and technical architecture that invests in advancing information systems and IT infrastructure required to support their implementation and interoperability. This language should explicitly include systems and infrastructure that support public health labs, registries, surveillance systems, outbreak management and response systems, as well as other systems that receive data used for population health purposes.**
- **In order to meet the requirements of the Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs[2], funds can be used for technical support, to cover the cost of on-going system maintenance, and for updates and enhancements to provide functionality and adhere with interoperability specifications.**
- **Metrics should be collaboratively developed with state and local public health partners to assess the ability of public health information systems to interoperate and support public health investigation and response. These metrics should measure and monitor interoperability, usability, flexibility, quality, completeness and timeliness of data, as well as system functionality to support:**
  - **Outbreak and event management.**
  - **Countermeasure allocation, tracking, distribution and administration.**
  - **Integration of laboratory information.**
  - **Bi-directional exchange of data across clinical care and public health.**

2. Outbreak and Event Management

Outbreaks vary in size and complexity, and can extend across local jurisdictions, state lines, and national borders. The SARS outbreak in Toronto[3] and the monkeypox[4] response in the U.S. illustrate the need to have systems with the ability to identify and triage suspected cases; collect initial clinical, demographic and laboratory data on suspected cases; support laboratory

diagnosis, both in the clinical and public health laboratory sectors; collect relevant epidemiologic data to identify important common exposures (such as places, persons, gatherings, conveyances, or vectors) and support contact tracing and infection control, including: tracing, monitoring and possible quarantine of individuals exposed to a person with a communicable disease. Systems must be in place to manage complex relationships between cases, contacts and potential exposures. Methods for real-time tracking of these linkages should provide public health authorities with the ability to know who to investigate, manage, offer prophylaxis, isolate, quarantine, and/or treat.

Testimony to the PH/CCC Workgroup expressed a common theme: systems to support outbreak and event management are needed for use by public health. Criteria for these systems should be defined collaboratively, and the solutions should be both flexible and scalable to be used routinely and during emergencies. A freely distributable version of outbreak and event management software that integrates well across jurisdictions should be made available for use by public health departments.

Recommendation 2.0: By March 2008, the Centers for Disease Control and Prevention (CDC) with the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), the Council of State and Territorial Epidemiologists (CSTE), the Association of Public Health Laboratories (APHL) and other appropriate groups, should update and refine criteria for functionality, security and interoperability of systems that support outbreak management at local, tribal, state and federal levels. The criteria should:

- **Be minimal but sufficient to support the needs of managing complex outbreaks.**
- **Ensure interoperability with other systems (such as other outbreak systems, laboratory information systems (LIS), systems that manage countermeasures, fatality management tracking systems, monitoring tools for quarantine and isolation, electronic health records (EHRs), and surveillance databases).**
- **Provide a starting point for a freely distributable software implementation and ongoing development and maintenance.**
- **Use as a starting point the AHIC Use Cases, the HITSP Interoperability Specifications, and the PHIN Functional Requirements for Outbreak Management.**

Recommendation 2.1: The Centers for Disease Control and Prevention (CDC), with input and assistance from state and local public health should support the development and testing of software systems designed to manage public health investigations (e.g., CDC Outbreak Management System, state or commercially-developed systems), including identification of important exposures, laboratory diagnostics, contact tracing and indication for preventive countermeasures such as infection control, isolation, quarantine, prophylaxis or treatment.

- **With HHS, and through the national agenda, support the harmonization of standards and the development of implementation guidance and shared architectural approaches for possible and confirmed case management and**

exchange. These products should be made available to public health partners by October 2008.

- **Develop, or commission the development or acquisition of, a freely distributable software; and support the maintenance and implementation to assist local, tribal, state and national agencies in the management of outbreaks. The criteria for this software implementation would be based on the collaboratively defined criteria defined in recommendation 2.0 above. This software should be available no later than March 2009.**
- **By December 2009, support the establishment of test sites to measure the level of interoperability between electronic health records, laboratory information systems, surveillance and software developed for outbreak management.**

3. Laboratory Response

Laboratory testing plays an important role in multiple domains related to this report including Public Health Surveillance and Response, Health Status and Disease Monitoring and Population Based Clinical Care. While much attention has been placed on electronic laboratory reporting for notifiable diseases (ELR), the full breadth of laboratory testing from which actionable information can be derived extends to other processes associated with laboratory testing, including requests for testing services and physician orders. The ability to electronically exchange test orders and test results facilitates multiple functions, including the rapid identification of outbreaks of disease, the monitoring of the health of a population and the generation of data essential for response to a public health event and ongoing situational awareness. Testimony illustrated that during an outbreak or event, laboratory test volume can dramatically escalate, requiring the test loads be balanced among laboratories in different jurisdictions. This was observed during the anthrax events of 2001 when the Laboratory Response Network (LRN)[5] laboratories tested over 125,000 samples representing over 1 million separate laboratory tests. The reporting, aggregation, and analysis of the results from the many labs performing the testing was complex and unsupported by electronic exchange between organizations involved in the response. Significant human effort was required to consolidate and reconcile data, activities that can be largely eliminated through adoption of standard approaches to electronic laboratory test ordering and reporting. The anthrax events, followed by SARS and more recently the numerous food borne outbreaks (E. coli in spinach, salmonella in peanut butter) illustrate the need to develop and broadly adopt common specifications and processes to enable specimen and results tracking and corroboration among public and private laboratories and public health partners. Infectious diseases are not the only challenges facing public health laboratories. Following the impact of Hurricane Katrina, laboratory services provided by the Louisiana Public Health Laboratory had to be shifted to other distant sites including the Iowa State Hygienic Laboratory. The testimony not only called attention to the need for collaboration among labs and public health partners, but also the need for federal agencies to coordinate and harmonize requirements across the entire United States.

Coordination of reporting requirements from clinical, veterinary, environmental and public health laboratories to state and federal agencies would reduce the current reporting burden on labs and clear the path to define standards and vocabulary for automated exchange of test results.

In June 2005, the Department of Homeland Security established the Integrated Consortium of Laboratory Networks (ICLN) with a Memorandum of Agreement to promote harmonization and coordination across multiple laboratory networks affiliated with federal agencies (LRN-B, LRN-C, NAHLN, FERN, eLRN, etc.). The ICLN includes 10 federal departments/agencies, including Agriculture, Commerce, Defense, Energy, Health and Human Services, Homeland Security, Interior, Justice, State, and the Environmental Protection Agency. The ICLN's mission is to create a U.S. homeland security infrastructure with a coordinated operational system of laboratory networks that provide timely, high quality, and interpretable results for early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response. The PH/CCC Workgroup recommends support of the interagency coordination efforts of the ICLN.

While federal agencies play an important role in confirmation and investigation of disease outbreaks or public heath events, the majority of sentinel data is generated either within the community laboratory or the local or state public health laboratory. The lack of uniform process and standards significantly hinders the ability of federal agencies to coordinate the response effort and limits efforts at the local and state levels to share information efficiently. Therefore, a significant need exists to harmonize data reporting standards and guidelines among local, state and federal agencies. Testimony addresses significant progress being accomplished by the CDC and APHL in pilot projects directed toward achieving a uniform approach to electronic exchange of laboratory test orders and results reporting. The PH/CCC Workgroup recommends the expansion of these efforts with the goal of achieving an integrated laboratory system focused on public health.

To achieve these collective goals, the Workgroup further recommends:

Recommendation 3.0: By June 2008, the Centers for Disease Control and Prevention (CDC), in collaboration with the Association of Public Health Laboratories (APHL), the Council of State and Territorial Epidemiologists (CSTE), the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and other appropriate organizations, should identify any types of data, codes and relationships needed (beyond those specified in the HITSP EHR / Biosurveillance lab result message) necessary to support:

- **Test orders to and result reporting from public health labs.**
- **The coding of public health conditions in the HITSP lab message.**
- **Result reporting of veterinary and environmental data.**
- **Unambiguous linkage of laboratory data to clinical and public health records.**

The scope of this effort should be inclusive of the additional public health laboratory response requirements not included in the AHIC EHR Laboratory and Biosurveillance Use Cases (e.g., orders and results for veterinary, environmental and food specimens). This effort should include, at a minimum, the AHIC Minimum Biosurveillance Data Set (MBDS) and the HITSP lab result message interoperability specification as well as the planned HITSP additions. An analysis

should be done to identify possible additional domain vocabularies to support the expanded scope for public health laboratory response. The CDC should identify new priorities from this work and advance them through the PH/CCC Workgroup for incorporation into the national agenda process.

Recommendation 3.1: HHS, in conjunction with state and regional health information exchanges, public health and clinical laboratories, should develop the infrastructure and architecture for unambiguous unique identification of medical service providers in association with the Nationwide Health Information Network (NHIN) initiative. This should include ensuring that registries of medical service providers exist and that registry lookup capability is developed and available to laboratories for routing laboratory data back to the originating requestor, and to other appropriate parties, to support national electronic laboratory data exchange.

Recommendation 3.2: By December 2008, HHS, in collaboration with the Association of Public Health Laboratories (APHL), private laboratories, and other federal laboratories, should establish regional or national capabilities to receive and route laboratory results to all appropriate recipients simultaneously.

- **Define the processes and approaches for consolidated receipt and routing of laboratory results.**
- **Support a proof-of-concept demonstrating an efficient regional or national mechanism for the acquisition of laboratory test order information as well as dissemination of test results to appropriate public health and clinical care providers.**

4. Countermeasure Allocation, Tracking, Distribution and Administration

Response Management includes interventions (i.e., isolation and quarantine) as well as acquisition and allocation of supportive countermeasures (e.g., treatments, prophylaxis, and provisions) during a public health response. Tracking activities include monitoring shortages and apportioning countermeasures during a shortage, administration management, distribution of resources, and coordination of potential assets through the commercial sector supply chain.

Some of the same issues exist in the area of countermeasures, as noted in other public health activities:

- Standards are currently incomplete or not available to support countermeasure needs across jurisdictional units. Standards should include a set of uniform minimum data elements, common vocabulary and defined relationships between the data elements; operational guidance to include system redundancy, security, and reliability; and should consider methods to handle materiel identification, such as bar coding standards.
- Information on the availability of countermeasures in the commercial supply chain is, at times, considered to be sensitive and proprietary information of commercial organizations; not readily sharable with public health.

- While countermeasure distribution systems are available for tracking and follow-up, they are not well-integrated. There are few commercial off-the-shelf (COTS) products available to support countermeasure administration and follow-up.
- Customization of a COTS product can be cost prohibitive and still not guarantee that the final product will meet the organization's requirements nor interoperate with other jurisdictions or vendor resources.
- Hospitals have developed and implemented electronic tracking systems that do not interoperate with public health resources or informational needs. During testimony, specific local health departments mentioned limited capacities to fund interfacing with community providers and partners as it would detract from capacity to provide ongoing public health services.
- Legal concerns persist regarding provision of clinical data (e.g., hospital system data) to public health officials for active surveillance.
- There is a need for obtaining as much information as possible during an outbreak or event so that you know what materials are available, who has them, and where the greatest need exists.
- Information gaps exist in the supply chain; for example, information doesn't come back from treatment centers to Point of Distribution (POD) sites.

Because outbreaks and events are not limit to jurisdictional boundaries, systems must interconnect both horizontally and vertically. During a response, secure exchange between the private sector and public health may be needed across jurisdictions and national borders. To be effective, this requires comparable growth toward integration and interoperability in both public health and the private sector -- a need which the AHIC process strives to fulfill. Although it is recognized that data needs to be exchanged across jurisdictions during an emergency, it is also important to recognize that data must be shared on a routine basis. In 2004, 14% of the population moved domiciles at least once. In addition, annually there is a significant portion of the population that changes domiciles on a temporal basis, such as college students and "snowbirds."

Recommendation 4.0: By March 2008, the Centers for Disease Control and Prevention (CDC) with the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), the Council of State and Territorial Epidemiologists (CSTE), the Association of Public Health Laboratories (APHL), the Food and Drug Administration (FDA), and other appropriate groups, should update and refine criteria for functionality, security and interoperability of systems that support countermeasure apportionment, tracking, distribution and administration at local, tribal, state and federal levels. The criteria should:

- **Be minimal, but sufficient to support the needs of managing countermeasures during a response.**
- **Ensure systems are interoperable with other systems (such as outbreak systems, vendor managed inventories, point of distribution software, fatality management tracking systems, monitoring tools for quarantine and isolation electronic health records, and surveillance databases).**

- **Provide a starting point for a freely distributable software implementation, and ongoing development and maintenance.**
- **Use as a starting point the AHIC Use Cases, the HITSP Interoperability Specifications, and the PHIN Functional Requirements for Countermeasure Response and Administration.**

Recommendation 4.1: By April 2008, the Centers for Disease Control and Prevention (CDC) should convene a meeting to include representation from clinical partners, manufacturers, and distributors to understand the resources that are available in the private sector and develop strategies to exchange information on the availability of and demand for resources at any given time.

Recommendation 4.2: The Centers for Disease Control and Prevention (CDC), with HHS, and through the national agenda, should support the harmonization of standards and development of implementation guidance and shared architectural approaches for the exchange of countermeasure information. These products should be made available to public health partners by December 2008. Following the implementation of countermeasure response solutions, support the establishment of test sites to measure the level of interoperability with electronic health records, outbreak management systems, registries, surveillance systems.

Recommendation 4.3: By June, 2008, HHS should facilitate development of national administrative or legal approaches for routine and emergency inter-state data exchange of countermeasure and immunization information.
- **Address business propriety data concerns of relevant commercial supply chain entities.**
- **Develop a blanket agreement to provide federal support for sharing of data and resources when it is necessary.**
- **Communicate with and educate hospital risk management staff and privacy and confidentiality officers in clinical care settings to alleviate concerns about public health access to clinical data.**

5. Automated Integration with Registries

During a response, registries may be used for multiple purposes, and the potential for additional uses should be explored. Registries of emergency response volunteers, credentialing, and those responders with appropriate immunization status may be used to identify personnel prepared to participate in a response. Similarly, during a response, registries may be used to track people given countermeasures, being monitored (e.g., quarantine) and those requiring long-term follow-up. Immunization registries played a key role after hurricanes Katrina and Rita in providing vaccination records for displaced children; saving an estimated $4.6 million dollars in potential revaccination costs[6]. During deliberations, the Workgroup recognized that health information exchanges (HIEs) may eventually assume some of the functions currently handled through integration with registries. The Workgroup identified that a powerful role may be possible for

HIEs in the future, and this may be an area to prioritize for future deliberations. However, this section is focused on recommendations for registries.

In the area of immunization registries, the infrastructure for these systems, known as Immunization Information Systems (IIS), is partially established. The IIS information infrastructure is in place in a number of states and includes characteristics that should be endorsed and extended. In general, registry systems should be population-based and adopt industry standards-based techniques for data communication.

Capabilities developed in more established registries, such as the infrastructure of IIS and the clinical data exchange of cancer registries, could be leveraged to improve integration with both clinical and public health registries during a response. The first step is to facilitate dialog to discover short-term and long-term benefits that could be realized from automating integration with registries. The second step is to prioritize potential advances, and communicate efficiencies that could be realized with the appropriate parties.

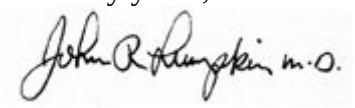
Recommendation 5.0: By March 2008, the Centers for Disease Control and Prevention (CDC) should convene a group of public health registry experts such as immunization, cancer, trauma, donor, chronic disease, and others to determine how the established capabilities and unique attributes of existing registries could be used in public health response.

Recommendation 5.1: By October 2008, the Centers for Disease Control and Prevention (CDC) should develop a communication plan based on discussion and recommendations from the March 2008 meeting referenced in recommendation 5.0 above. The overall goal of this plan is to communicate to public health officials the available registry resources for use during an emergency response.

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

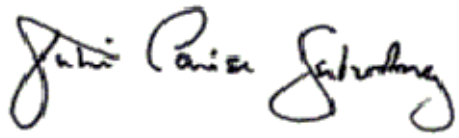
Thank you for giving us the opportunity to submit these recommendations. We look forward to discussing these recommendations with you and the members of the American Health Information Community.

Sincerely yours,



John R. Lumpkin, MD, MPH
Co-Chair, AHIC Population Health and Clinical Care Connections Workgroup

Sincerely yours,



Julie L. Gerberding, MD, MPH
Co-Chair, AHIC Population Health and Clinical Care Connections Workgroup

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[1] *Population Health Recommendation Letter. Available from URL: http://www.hhs.gov/healthit/documents/m20070313/pophealthletter.html [Accessed Sep 2007]*

[2] *Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs. Available from URL: http://www.whitehouse.gov/news/releases/2006/08/20060822-2.html [Accessed Sep 2007]*

[3] *Wallington T, MD, Berger L, MD, et al. Update: Severe Acute Respiratory Syndrome --- Toronto, Canada, 2003 Morbidity and Mortality Weekly Report. 2003: 52(23);547-550*

[4] *State and local health departments. Monkeypox investigation team, CDC. Update: Multistate Outbreak of Monkeypox --- Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003. Morbidity and Mortality Weekly Report. 52(25);589-590*

[5] *Centers for Disease Control and Prevention, Atlanta, Ga. The Laboratory Response Network Partners in Preparedness. Available from URL: http://www.bt.cdc.gov/lrn/examples.asp [Accessed Sep 2007]*

[6] *Urquhart, G, Williams, W, et al. Immunization Information Systems Use During a Public Health Emergency in the United States, J Public Health Management Practice, 2007, 13(5), 481–485*

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

American Health Information Community

Progress of the State Alliance for e-Health

Governor Phil Bredesen
Tennessee

Governor Jim Douglas
Vermont

September 18, 2007

The Alliance and its Taskforces

- The Alliance has met three times in 2007, and meets again in October. Three taskforces have met a number of times to provide input and perspectives to the Alliance.
  - The Health Information Protection (HIP) taskforce deals with issues of privacy and security of health data.
  - The Health Care Practice (HCP) taskforce is addressing primarily issues of health professional regulation related to information exchange.
  - The Health Information Communication and Data Exchange taskforce is addressing the ways publicly funded programs contribute to and interact with HIEs.

Recommendations to Date

- Two of the three taskforces have provided the Alliance with preliminary recommendations for state action.
- The Alliance accepted these recommendations at the August meeting.
- As additional recommendations are accepted, they will be consolidated with existing recommendations, as appropriate, and prioritized in terms of critical state actions.

HIP Taskforce Recommendations To Date

- **Recommendation 1.0:** The State Alliance should encourage states to recognize the certification of newly acquired electronic health record applications and network components by the Certification Commission for Health Information Technology (CCHIT) or other certification body designated by the Secretary of the U.S. Department of Health and Human Services.
- **Recommendation 1.1:** The State Alliance should encourage the President to call on the Secretary of the U.S. Department of Health and Human Services to designate a single, national certification body (such as CCHIT) for use by all relevant federal agencies and require product and network certification for participants in all federally funded programs, grants and contracts for newly acquired products or network components.
- **Recommendation 1.2:** The State Alliance should encourage states to become engaged and provide input into the certification process by supporting the participation of State Chief Information Officers (CIOs), public program CIOs and state health information technology coordinators (or equivalent-level personnel) in the CCHIT, Health Information Technology Standards Panel or similar federally endorsed activities in order to ensure that the state perspective is incorporated and to ensure applicability of the requirements in the state environment.

Additional HIP Taskforce Recommendations

- **Recommendation 2.0:** The State Alliance should encourage states to continue to (1) educate leaders of the executive and legislative branches on the importance of interstate alignment of privacy protections and (2) sustain efforts through financial and political support or other means, to reduce the variability of state privacy requirements within and across states, in a manner that ensures appropriate consumer protections are in place.
- **Recommendation 2.1:** The State Alliance should call on the Executive Branch of the federal government to work with the Alliance to identify challenges in current federal statutory and regulatory requirements and create mutually acceptable solutions that would allow for alignment of these requirements as they relate to the privacy and security of health information and health information exchange, in a manner that ensures appropriate consumer protections are in place.

HCP Taskforce Recommendations To Date

- **Recommendation 1.1**: The State Alliance should recommend that state medical, nursing and pharmacy boards work to implement online licensure applications.
- **Recommendation 1.2**: The State Alliance should recommend that all state nursing and pharmacy boards develop common core licensure application forms, and state medical boards adopt the Federation of State Medical Board Common Licensure Application Form. Individual states may include state specific requirements.

Upcoming Recommendations

- In October and January, the Alliance expects to hear additional recommendations from its taskforces on some of the following topics:
  - Licensing of physicians, nurses and pharmacists
  - Clear objectives for efforts to reform state privacy laws
  - Priorities and methods for Medicaid/SCHIP, public health, and state employee programs to contribute to and participate in HIEs
  - Interstate information exchange challenges and opportunities for clearing obstacles, including professional accountability barriers
  - Analysis of trade-offs for the authorization (consent) process for sharing health information
- The Alliance will summarize these critical pathways for states in a report in early 2008.

Alliance Activities for 2007-2008

- In addition to recommendations and findings from the taskforces, the Alliance is addressing other priorities:
  - E-prescribing: The Alliance members believe this is a critical time for states to support, encourage, and drive the adoption of e-prescribing in the nation's health care system. The Alliance may consider supporting a compact among states or other mechanism to encourage concrete action in the promotion of e-prescribing.
  - HIE oversight and accountability: The Alliance will explore appropriate roles for states to support HIE while protecting the public. This may include regulatory structures on other requirements for ensuring the safety of health information and consumers.
  - Public Financing for HIE: The Alliance will receive input on potential business models and financing structures, and attempt to recommend funding and related priorities for states.

Encouraging State Adoption

- As recommendations flow from the Alliance, it is also essential for learning and input to continue. In 2008, the Alliance will turn some attention to tracking and supporting state implementation of these priorities.
  - The Alliance will provide a guide to state policy makers that will expand on the recommendations and include other resources and tools for states to take action.
  - The Alliance will oversee a process to drive reform in a select number of states. 5-7 states will participate in a rigorous process that the Alliance will use to refine guidance to all states based on emerging best practices in this implementation effort.
  - Working through the Alliance members and their relevant organizations, we will grow and build on state leaders' expertise and readiness for action.

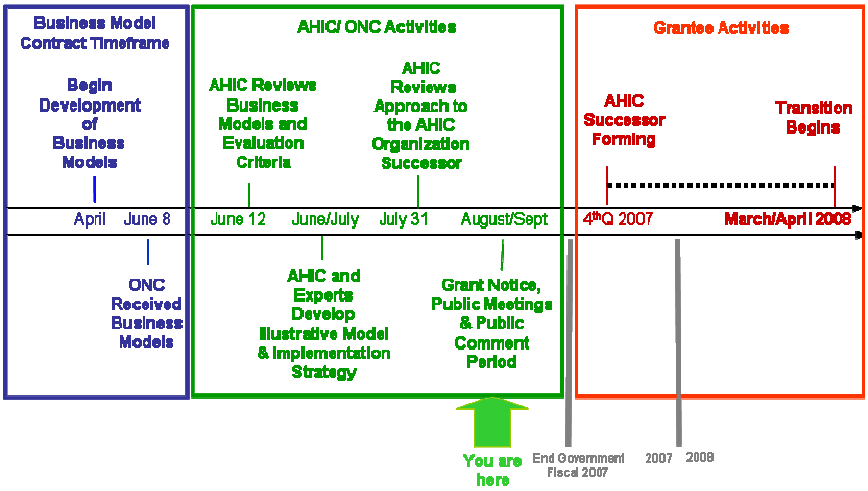
Department of Health & Human Services
Office of the National Coordinator for Health Information Technology

American Health Information Community

AHIC Successor Update

September 18, 2007

AHIC Successor - Timeline

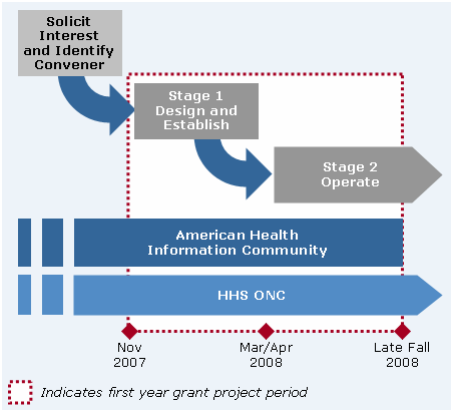


AHIC Successor - Recent Activity

August 6	• Published the AHIC Successor White Paper • Comment period through September 10
August 13	• Published the grant Notice of Funding Availability • Requested letters of intent by September 15
August 17	• Conducted a public meeting • Presented the succession strategy and introduced the grant
September 5	• Held the technical assistance session • Presented alternatives for key successor design aspects • Presented details regarding the grant process

AHIC Successor Implementation Strategy

- Two year grant project period
- First 12-month funding for
  - Stage 1 - Design and Establish
  - Stage 2 - Operation of new legal entity
- Substantive role for HHS across the grant period
  - Collaborate to design and build the successor organization
  - Participate as member of new legal entity

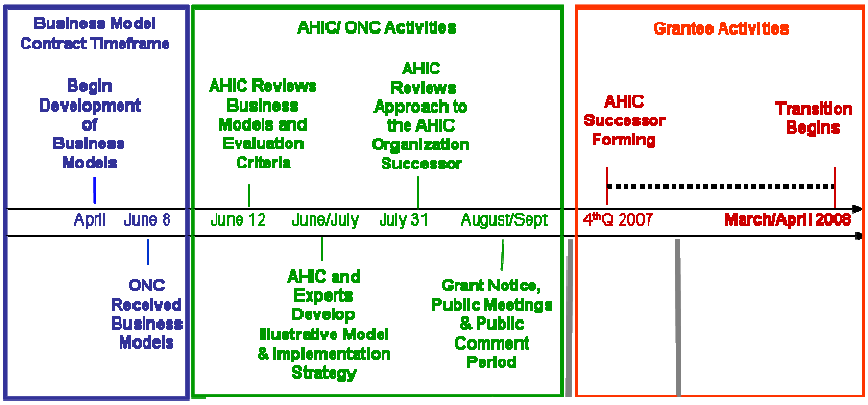


Grant Facts

Grantor	Department of Health and Human Services, the Office of the National Coordinator for Health IT
Grant Period	Two years from time of award; includes two budget periods (Anticipated Nov. 2007 – Oct. 2009)
Grant Type	Cooperative Agreement
Grant Value	Up to $13,000,000 over two years
Funding Number	HHS-ONC-07-001
Close Date	October 5, 2007
Eligible Applicants	Unrestricted
Purpose	Design, establish, and operate the American Health Information Community successor

http://www.grants.gov/search/search.do?oppId=15164&mode=VIEW

AHIC Successor - Timeline



- Applications will be reviewed beginning October 8, 2007
- Award expected on or before November 13, 2007

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

American Health Information Community

Recommended Requirements for Enhancing Data Quality in Electronic Health Records

Rebecca S. Busch
Medical Business Associates, Inc.

Reed D. Gelzer
Advocates for Documentation Integrity and Compliance

Susan Turney
Wisconsin Medical Society

September 18, 2007

Enhancing EHR Data Quality – Today's Presentation

1. Origin and overview of project
2. Project results: 14 recommendations
3. Why are the recommendations important?
4. How will the recommendations benefit providers and patients?
5. Questions & Answers and Discussion

The Costs of Health Care Fraud: Staggering and Growing

"Fraud has a significant impact on the U.S. health economy. The National Health Care Anti-Fraud Association (NHCAA) estimates that "...***of the nation's annual healthcare outlay at least 3% – or $51 billion in calendar year 2003*** was lost to outright fraud." Other estimates by government and law enforcement agencies place the loss as high as 10% of our annual expenditure, or $170 billion."*

***Excerpt from the Executive Summary of the** Report on the Use of Health Information Technology to Enhance and Expand Health Care Anti-Fraud Activities, **Prepared for: The Office of the National Coordinator, U.S. Department of Health and Human Services, September 30, 2005. Reports available through: http://www.hhs.gov/healthit/hithca.html**

Enhancing EHR Data Quality – Project Overview

- Project purpose: Enhance Data Quality in Electronic Health Records (EHRs) including the development of model anti-fraud requirements for EHRs.
- Project contractor: RTI International.
- Project led by a Model Requirements Executive Team (MRET): Industry experts in private and public sectors (see Slides 6 and 7).
- Validate the recommendations through public comment.

Enhancing EHR Data Quality – Project Overview (cont.)

- Work with the Health Information Technology Standards Panel (HITSP) to identify existing and new standards needed to meet model functionalities and requirements.
- Work with the Certification Commission for Health Information Technology (CCHIT) to map model functionalities and requirements for health care anti-fraud to CCHIT certification criteria.

Model Requirements Executive Team (MRET)

- Donald W. Simborg, MD, MRET Chairman
- Susan Hanson, MBA, RHIA, MRET Executive Coordinator

- A. John Blair, III, MD, Taconic IPA, Inc. (also Chair of the MRET Retrospective/Prospective Workgroup)
- Robert Burleigh, CHBME, Brandywine Healthcare Services
- Rebecca S. Busch, RN, MBA, Medical Business Associates, Inc.
- Bonnie Cassidy, MPA, RHIA, Cherry, Bekaert & Holland, LLP
- Christopher Dorn, United Health Group/Ingenix
- Jamie Ferguson, Kaiser Permanente
- Reed Gelzer, MD, MPH, Advocates for Documentation Integrity and Compliance (also Chair of the MRET Prevention Workgroup)
- Byron Hollis, Esq., Blue Cross/Blue Shield of America

Model Requirements Executive Team (MRET) (cont.)

- Lawrence Hughes, JD, American Hospital Association
- Richard Ingraham, SAS US Commercial
- Holly Louie, CHBME, BSN, Practice Management, Inc.
- Matthew McMullen, PhD, JD, Centers for Medicaid & Medicare Services
- Blackford Middleton, MD, MPH, Partner's HealthCare Systems, Inc.
- Wes Rishel, Gartner Group
- Louis Saccocio, National Health Care Anti-Fraud Association
- James Speros, JD, Veterans Health Administration
- Susan Turney, MD, MS, Wisconsin Medical Society
- Alan Yuspeh, JD, MBA, Hospital Corporation of America

Project Results – 14 Recommendations

1. Audit Functions and Features
2. Provider Identification
3. User Access Authorization
4. Documentation Process Issues
5. Evaluation and Management (E&M) Coding
6. Proxy Authorship
7. Record Modification after Signature

Project Results – 14 Recommendations (cont.)

8. Auditor Access to Patient Records
9. EHR Traceability
10. Patient Involvement in Anti-Fraud
11. Patient Identity-Proofing
12. Structured and Coded Data
13. Integrity of EHR Transmission
14. Accurate Linkage of Claims to Clinical Records

Why are the recommendations important?

- Why are the 14 recommendations important?
- Universal interest in valid, accurate, trustworthy health care information.
- Protects clinicians and patients by providing supportive functions to validate that correct procedures were used and identifying or highlighting outliers before they become serious issues.
- Raise the visibility of basic electronic documentation validity issues in the marketplace for buyers and sellers to take into account in evaluating currently available functions and capabilities.

How will recommendations help providers and patients?

How will the recommendations be beneficial for providers and patients?

Brief Examples:

Reed D. Gelzer, MD, MPH
Susan Turney, MD, MS
Rebecca S. Busch, RN, MBA

Discussion and Questions

Discussion And Questions

May 2007

Recommended Requirements for Enhancing Data Quality in Electronic Health Records

Final Report
Executive Summary

Prepared for

Kathleen H. Fyffe
Senior Advisor
The Office of the National Coordinator
for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, Room 4090
Switzer Building
Washington, DC 20201

Prepared by

RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709

RTI Project Number 0208490.035.005

Executive Summary

ES.1 Introduction

The rising cost of health care has become a major issue in the United States. In 2005, the United States spent $1.98 trillion, or 16% of its gross domestic product (GDP), on health care. By 2016, health care expenditures are projected to surpass $4.1 trillion, or 19.6% of GDP.[1,2] In 2006, the National Coalition on Health Care (NCHC) noted that "inappropriate care, waste and fraud" were major contributors to the cost of medical care and health insurance.[3]

Electronic health record systems (EHR-S) are the key to the transformation of health care. EHR-S can

- improve the quality of care through enhanced evidence-based clinical decision support, the timely communication of clinical information, and better documentation;
- increase operational efficiency and contain costs by automating routine tasks, streamlining clinical workflow, and avoiding duplication of procedures;
- help collect data for uses other than clinical care, such as billing, quality reporting, disease surveillance, public health reporting, and fraud detection and deterrence;[4] and
- protect the privacy of health information through secure mechanisms and authorized access and control procedures.

Thus, widespread use of EHR-S has the potential to improve the quality of care, increase patient safety, reduce medical errors, and control health care costs. The notion that EHR-S can be leveraged in such a wide variety of ways is central to this project.

ES.2 Purpose and Objectives

The primary purpose of this project is to identify requirements for EHR-S that can help enhance data protections, such as increased data validity, accuracy and integrity including appropriate fraud management[1] which would prevent fraud[2] from occurring, as well as detect fraud both prospectively and retrospectively. A key component of creating these recommended requirements is to overlap whenever possible with those requirements currently in use for EHR certification. For example, authentication is required for privacy and confidentiality, but it is just as useful for preventing and detecting fraud. All of the requirements identified through this project are framed as recommendations to the industry.

The deliverables for this project are as follows:

1. A set of recommended requirements for EHR-S that will help prevent fraud from occurring, as well as detect fraud prospectively and retrospectively, with each requirement having an accompanying rationale

2. The identification of technical standards that will need to be harmonized so that the recommended requirements can be implemented in an interoperable fashion

3. A map between the anti-fraud requirements and certification criteria so that the recommended requirements can be ultimately embedded in certified EHR-S

4. Recommended next steps for education and research, as well as for implementing the anti-fraud requirements

While the focus of this project is on enhancing data accuracy, including the detection and prevention of fraud, it is important to emphasize the following points:

- By and large, clinicians are not engaged in fraudulent activities. Not all improper payments are the result of fraud, and not all unusual billing patterns are fraudulent. However, certain documentation practices, such as data errors, mistakes in coding, and confusion regarding billing codes and procedures may result in improper payments.

- The recommended requirements are aimed equally at reducing such erroneous documentation practices, preventing improper payments, and improving supporting documentation for legitimate claims submissions.

The transforming nature of EHR-S can benefit clinicians, patients, and payers by reducing human error and improper payment. EHR-S can also help detect and deter health care

[1] Fraud management is defined as the prevention, detection, and prosecution of fraud.

[2] For the purposes of this report, fraud is defined generally as a deliberately false representation of fact or a failure to disclose a fact that is material to a health care transaction. This includes but is not limited to deliberate submittal of false claims to private health insurance plans and/or tax-funded public health insurance programs such as Medicare and Medicaid. A more complete definition for health care fraud is in Appendix C.

fraud, protecting both clinicians and patients by documenting that correct procedures were used, highlighting outliers before they become serious issues, and giving patients a clearer understanding and peace of mind that their health records are being disclosed only to appropriately authorized users.

Although requirements that enhance data accuracy might overlap with current EHR certification criteria, thought must be given specifically to the criteria that will help combat both large- and small-scale suspected fraud, as well as accentuate the potential benefits of these systems with regard to reducing improper payment and human error. While a component of combating fraud is the ability to trace and audit information that may be used in prosecution, these same functionalities can be used to ensure information validity over time, which can protect both clinicians and patients. The ability to definitively show that correct procedures were used, use audit functionality as an "early warning system" to locate outliers before they become serious issues, or to provide patients with a clearer understanding and peace of mind that their records are being disclosed only to appropriately authorized users are all factors that can benefit all major stakeholders, from clinicians to patients to payers.

The Office of the National Coordinator for Health Information Technology (ONC) is responsible for overseeing activities that will realize the vision set by President George W. Bush in April 2004 to develop and implement a strategic plan to guide the nationwide implementation of interoperable HIT in both the public and private health care sectors. Through a series of initiatives, ONC has advanced this goal considerably over the past 3 years and continues to pave the way for HIT adoption across the country. In addition to moving the current directives forward, ONC is charged with planning for the future, such as anticipating the potential benefits of such a system. Designing enhanced data protections into EHR-S and the Nationwide Health Information Network (NHIN) has the potential to significantly reduce health care losses due to improper documentation and fraud.[4]

ES.3 Methodology and Rationale

In late 2006, ONC contracted with RTI International for a project involving three tasks: (1) develop recommendations for functional requirements for EHR-S that would enhance data by reducing the incidence of improper payment and assisting in fraud management, (2) validate the recommendations through public comment, and (3) work with appropriate HIT organizations to encourage adoption of the recommendations.

The basis for this project followed a subset of the 10 Guiding Principles[3] outlined in the September 2005 *Report on the Use of Health Information Technology to Enhance and Expand Health Care Anti-Fraud Activities* by the American Health Information Management

[3] The 10 Guiding Principles are listed in Appendix B.

Association's (AHIMA's) Foundation of Research and Education (FORE).[4] First, the NHIN policies, procedures, and standards must proactively prevent, detect, and support prosecution of health care fraud rather than be neutral toward it. Second, EHR standards must define requirements to promote fraud management and minimize opportunities for fraud and abuse, consistent with the use of EHRs for patient care purposes. Third, data required from the NHIN for monitoring fraud and abuse must be derived from the NHIN's operations and must not require additional data transactions. In addition to these three principles, one of this project's important decisions was that fraud management requirements also can be used to improve the accuracy and quality of documentation for the large majority of clinicians who are not involved in fraudulent activity.

The project's first task involved the creation of the Model Requirements Executive Team (MRET), which brought together industry experts from various private and public stakeholder groups with multiple backgrounds in order to develop a set of recommendations for enhanced accuracy and fraud management requirements for Electronic Health Records (EHRs). The MRET worked in two groups, one that focused on prevention functions and another that focused on prospective and retrospective functions. Prevention functions are those that occur prior to and during the documentation process in an EHR. Prospective functions are those that occur after EHR documentation occurs but before a payment is made on any claim based on the EHR documentation. Retrospective functions are those that occur after a claim has been paid. Following the Guiding Principles outlined above, all requirements were constructed based on their ability to enable prevention of fraud management rather than remain neutral toward it, their ability to do this without impeding delivery of timely services to the patient, and to the extent possible, their ability to minimize EHR software programming and administrative costs associated with the recommended functions.

The next task validated the MRET recommendations through a public comment process by which the recommended requirements were released to the public using online tools to gather feedback from all interested parties. The majority of public comments fell into one of five categories:

- Ability to Detect or Deter Fraud
- Practicality of and Timeline of Implementation
- Cost Issues
- Burden and User Issues
- Patient and Privacy Issues

In response to the public comments, the MRET eliminated or modified requirements as necessary and developed a final set of recommendations for the requirements. These

requirements were supported by the vast majority of public responders and achieved high consensus among the members of the MRET.

Finally, the project staff worked closely with the leadership of the Health Information Technology and Security Standards Panel (HITSP) and the Certification Commission for Health Information Technology (CCHIT) to determine the most appropriate procedures for considering the recommended requirements in upcoming review cycles of each group. Each organization emphasized the importance of balancing the needs of enhancing accuracy, fraud management, and risk reductions that might enhance EHR-S against concerns that might inhibit EHR adoption. Productive conversations about both the costs and benefits of the recommended requirements led to feasible and actionable solutions that encouraged strong consideration within both groups.

ES.4 Recommendations

The recommended requirements for EHR-S developed herein provide the initial building blocks for increasing accuracy and fraud management within the health care system. Great efforts have been made to ensure the privacy and security of EHR data, but a deliberate effort to build these functional requirements into EHR-S and the NHIN could also increase data quality and reduce exposure to new and ever-evolving forms of electronically enabled health care fraud.[4]

This project produced 14 recommended functional requirements that, if included in EHR-S, would increase data accuracy and would aid in fraud management:

1. Audit Functions and Features
2. Provider Identification
3. User Access Authorization
4. Documentation Process Issues
5. Evaluation and Management (E&M) Coding
6. Proxy Authorship
7. Record Modification after Signature
8. Auditor Access to Patient Records
9. EHR Traceability
10. Patient Involvement in Anti-Fraud
11. Patient Identity-Proofing
12. Structured and Coded Data
13. Integrity of EHR Transmission
14. Accurate Linkage of Claims to Clinical Records

Each of these requirements was linked to current or planned CCHIT and Health Level 7 (HL7) criteria♦ where applicable. Twenty-two percent of the recommended requirements developed by the MRET map closely to existing CCHIT criteria. Another 45% of the requirements had some foundation in the current or planned criteria, but would require additions or modifications to support an active stance against fraud in EHR-S. Finally, 33% of the recommendations were found to have no match to current or planned criteria. These findings indicate that there is a significant base in current standards and certification requirements upon which to build proactive fraud management capabilities, but further work is required. Updating these current criteria would certainly provide a significant win for reducing costs associated with this current and growing problem.

The overwhelming majority of clinicians do not commit fraud and should not be burdened by mechanisms aimed solely at the few who do. Therefore, the recommended requirements also are directed at helping the majority, as they support quality of care through reduced errors and promote good documentation practices, as well as assist in fraud management, including protections against unmerited accusations of fraud and strengthened proofs of legitimacy. It is recommended that these requirements be considered among the many other improvements to be built into the emerging generation of EHR-S that are interoperable in the NHIN.

ES.5 Moving Forward

The activities undertaken in this project are simply the latest steps in an ongoing process to develop and integrate effective anti-fraud measures in the evolving HER-S requirements. Our efforts to date were constrained by time and resources and were not intended to produce a comprehensive solution to the fraud problem. Instead, our efforts are intended to raise awareness of the need to be proactive regarding the problems of fraud, rather than neutral or passive, and to encourage a dialogue between all parties interested in enhancing the accuracy of data in EHR-S.

At the conclusion of this project, the following suggestions are provided to ensure a continual, long-term approach to ensuring the integrity, validity, and accuracy of health record data. A full supporting explanation for each suggestion is provided in Chapter 5 of the report.

1: Current processes that are shaping the direction of HIT must be guided to advance health care information validity, accuracy, and integrity protections, including health care fraud management, in order to meet their future goals and objectives.

♦ The CCHIT roadmap establishes the areas of focus for the workgroups for future certification cycles by establishing future milestones.

1.1: ONC should include fraud management as one of its basic tenets in the next version of the Strategic Framework.

1.2: ONC must articulate the need to advance health information validity, accuracy, integrity, and fraud management functionalities to the American Health Information Community (AHIC) so that the appropriate use cases may be developed for HITSP and CCHIT.

1.3: Guidelines should be developed for both vendors and users of EHR-S regarding the appropriate use of documentation techniques to ensure complete, accurate, and quality documentation.

2: Given that this project narrowly focused on anti-fraud requirements for EHR-S; fraud management requirements for HIE/NHIN infrastructure and plans for their deployment should developed.

3: Greater efforts should be made to understand the concerns and opinions of all affected stakeholder groups regarding requirements that discourage fraud within EHR-S.

4: Further analysis is required to better quantify and characterize the current fraud activity as it relates to EHR-S, either as a tool for fraud or a potential source for fraud management. This should include an investigation into ways in which the appropriate entities in health care can work with law enforcement to communicate to providers how fraud schemes and fraud “rings” operate.

5: Stimulate advancements in the data aggregation process beyond the institutional level so that advanced analytics can detect trends and anomalies.

6: Increase consumer awareness of health care fraud and the role HIT, such as EHRs and PHRs, play in its reduction.

7: Educate health care stakeholders to a greater degree on the benefits of EHR-S containing requirements on health information validity, accuracy, and integrity and the impact these requirements will have on fraud management.

8: A designated position and supporting staff within ONC should be created to:

8.1 oversee and encourage the adoption of the recommended requirements developed under this project within CCHIT, HITSP, and other organizations responsible for the evolving NHIN;

8.2 develop future contracts to evolve and refine the functional requirements; and

8.3 oversee future research and analysis in this area.