The Community

American Health Information Community

May 16, 2006
8:30 a.m. - 3:00 p.m.

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

American Health Information Community

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8:30 A.M.	CALL TO ORDER
8:35 A.M.	Introductory Comments
8:45 A.M.	Electronic Health Records Recommendations
10:00 A.M.	BREAK
10:15 A.M.	Chronic Care Recommendations
11:30 A.M.	LUNCH
12:15 P.M.	Consumer Empowerment Recommendations and Evolving Discussion
1:15 P.M	Biosurveillance Recommendations and Evolving Discussion
2:15 P.M.	CCHIT Presentation
2:45 P.M.	Public Input
3:00 P.M.	ADJOURN

Meeting Report

American Health Information Committee
March 7, 2006

The American Health Information Community (AHIC), a federally chartered commission formed to help advance President Bush's call for most Americans to have electronic health records within 10 years, held its fourth meeting on March 7, 2006, at the Department of Health and Human Services (DHHS), 200 Independence Avenue, SW, Washington, DC 20201.

The purpose of the meeting was to bring together the Community's 17 members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to the DHHS on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting focused on an update from the Office of the National Coordinator, a presentation on the Gulf Coast Information Task Force, and presentations from each of the four Workgroups chartered by the Community (Chronic Care, Consumer Empowerment, Electronic Health Records, and Biosurveillance).

DHHS Secretary Michael O. Leavitt chairs the Community. The remaining 16 members, selected by Secretary Leavitt, are key leaders in the public and private sectors who represent stakeholder interests in advancing the mission of the Community and who have strong peer support. Members will serve 2-year terms.

The meeting was chaired by Secretary Leavitt; however, Secretary Leavitt was unable to attend certain portions of the meeting. David Brailer, MD, PhD, National Coordinator for Health Information Technology, chaired the meeting in Secretary Leavitt's absence.

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

Call to Order

Dr. Brailer reminded Community members that at the last meeting, four workgroups were chartered and charged with achieving certain consensus recommendations. Toward that end, the Workgroups have held several meetings and have made measurable progress towards fulfilling their charges. He thanked Community members serving as Workgroup co-chairs for their work. In addition, he recognized staff from his office and from other federal agencies, thanking them for their efforts. Dr. Brailer also reminded Community members that in considering the recommendations of the Workgroups, AHIC's charter limits Community members' involvement in making recommendations about fiscal policies.

Dr. Brailer informed Community members that the next AHIC meeting, previously scheduled for April 25, 2006, has been moved to May 16, 2006. Future Community meetings are planned on the following dates:

- May 16, 2006
- June 13, 2006
- August 1, 2006
- September 12, 2006
- October 31, 2006
- December 5, 2006

Before continuing the meeting, Dr. Brailer took a moment to recognize and thank Dana Haza for her hard work and outstanding efforts in support of the AHIC. Ms. Haza is moving to accept the position of Senior Director for the National Changing Diabetes Program at Novo Nordisk. Dr. Brailer again thanked Ms. Haza and wished her the best in her future endeavors on behalf of the Community.

Joining Dr. Brailer counterclockwise around the table were:

Linda Springer, Director of the Office of Personnel Management (during part of the meeting, Ms. Springer was represented by Dan Green, Deputy Associate Director, Center for Employee and Family Support Policy, Office of Personnel Management)

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

Jonathan Perlin, MD, Under Secretary for Health, Department of Veterans Affairs and Veterans Health Administration

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

Kevin Hutchinson, CEO of SureScripts

William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs (Dr. Winkenwerder was represented by Carl Hendricks, CIO of the Military Health System, for part of the meeting)

Craig Barrett, PhD, Chairman of the Board, Intel

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

Howard Isenstein, Vice President, Public Affairs and Quality, Federation of American Hospitals (Mr. Isenstein represented Charles N. Kahn III, President of the Federation of American Hospitals—Mr. Kahn also was represented by Chantal Worzala, Senior Associate Director for Policy, Federation of American Hospitals, for part of the meeting)

Mark McClellan, MD, PhD, Administrator of the Centers for Medicare and Medicaid Services (Dr. McClellan was represented by Tony Trenkle, Director of E-Health Standards and Services, Centers for Medicare and Medicaid Services, for part of the meeting)

Gail McGrath, President and National Director of Government Affairs, National Patient Advocate Foundation (Ms. McGrath represented Nancy Davenport-Ennis, founder of both the National Patient Advocate Foundation and the Patient Advocate Foundation)

David Ayre, Senior Vice President, Compensation and Benefits, Pepsico, Inc. (Mr. Ayre was representing Steven Reinemund, CEO and Chairman of Pepsico, Inc.)

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

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention CDC), U.S. Department of Health and Human Services (Dr. Gerberding was represented by Ed Sondik, MD, Director of the National Center for Health Statistics, for part of the meeting)

Mark Warshawsky, PhD, Assistant Secretary for Economic Policy, U.S. Department of the Treasury (Dr. Warshawsky was represented by Adele Morris, Senior Economist, U.S. Department of the Treasury, for part of the meeting)

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

Office of the National Coordinator Update

Dr. Brailer discussed four major efforts currently underway: (1) Office of the National Coordinator activities, including contracts, infrastructure, and other work; (2) partners that are developing certification, developing architectures, privacy, and security; (3) the work of this Community; and (4) the new work AHIC has charged each of the four Workgroups with. Significant progress has been made in each of these four areas. Dr. Brailer noted that this meeting will present an opportunity for developing recommendations to DHHS, other federal agencies, and constituents in the private sector. The Workgroups have been challenged with making specific recommendations around the four specific charge areas; the Community in turn will be making recommendations to Secretary Leavitt. Dr. Brailer commented that to have meaningful action within the Department this calendar year, those recommendations need to be made at the next AHIC meeting (to be held on May 16, 2006). Once this first round of recommendations has been made, the Workgroups will focus on their efforts on developing recommendations on longer-term broad charges.

The Office of the National Coordinator is continuing its efforts, including the development of a strategic plan that builds on the strategic framework that was released in July 2005, and will be made publicly available this year. These efforts concentrate on the ultimate goal of incorporating an interoperable electronic health record and other health information technologies, tools, and services.

Approval of January 17, 2006, Meeting Minutes

Minutes from the January 17, 2006, AHIC meeting were distributed, reviewed by Community members, and approved unanimously with no changes.

Gulf Coast Health Information Technology Task Force Presentation

Lee Stevens, Federal Policy Director for the Southern Governors' Association (SGA), reminded Community members that the catastrophic hurricanes of 2005 revealed how vulnerable medical record data are in the United States today. For the first time in U.S. history, medical professionals were faced with tens of thousands of evacuees who had little or no knowledge of their existing medical conditions or treatment regimen. In many cases, their health history has been lost forever. Hurricanes Katrina and Rita revealed to Gulf State Governors the difference between localized emergencies and unprecedented regional catastrophes for which the health care delivery system was unprepared. Today, Governors seek to rebuild the system to respond to a catastrophe and the mass evacuation of hundreds of thousands of citizens.

Dr. Brailer approached the SGA to convene a task force to define principles for an interoperable health information exchange network. Governors immediately recognized the opportunity to prepare the health care delivery system for a catastrophe. The task force will consist of providers, payers, consumer advocates, IT professionals, business leaders, and first responders who provided medical care to victims of Hurricanes Katrina and Rita.

The SGA Gulf Coast Health Information Task Force will:

- Conduct return-on-investment studies and review current state health information technology efforts.
- Develop a set of goals to guide the work of the Task Force.
- Prepare a review of emerging national principles to guide state implementation.
- Define a set of principles for the mobilization of health records.
- Produce a communications plan to encourage support for adoption.

Dr. Roxanne Townsend, Medicaid Medical Director for the State of Louisiana, described her experiences in New Orleans in the days and nights immediately following Hurricane Katrina, noting that she saw firsthand what not having electronic information and the history of patients' medical records does to patients and to the clinicians who are trying to take care of them. For example, many nursing home residents who were moved to the Superdome in New Orleans had medical records with them that consisted of handwritten pieces of paper taped to their gowns with incomplete information in many cases, and which often did not stay with the patients for the duration of their stays in the Superdome.

Dr. Townsend thanked Dr. Brailer, the Markel Foundation, and others involved in developing Katrinahealth.org, which was up and running shortly after the hurricane. Currently, Dr. Townsend's office has a contract with the Office of the National Coordinator to create a level of interoperability and to recover and recreate many of the Katrina evacuees' medical records. She concluded her remarks by noting that the SGA has a unique perspective and can reproduce what is being done at a local level and employ it across states.

Stephen Palmer, Policy Analyst for the Texas Health Care Policy Council, noted that the Council is a new entity in the office of the Texas Governor that was established through legislation in 2005. One of the charges given to the Texas Health Care Policy Council is to coordinate and facilitate all of the technology initiatives throughout the state. Texas was among the states affected by Hurricanes Katrina and Rita, and its population saw firsthand the consequences of a paper-based health information system. Although the recent hurricanes drove home the importance of health information technology, Texas had already started down that path with health IT initiatives at both the state and regional levels. The Texas Health Care Policy Council will seek to coordinate and align these various health IT initiatives. The Council also will be working closely with the Texas Health IT Advisory Committee to serve as a health IT resource. In addition, the Council will be participating with the SGA on the Gulf Coast Health IT Task Force, charting a digital recovery for the health information infrastructure of the Gulf Coast Region.

Discussion Highlights

"KatrinaHealth [captures] the low hanging fruit, the things that were easiest to get and that was the medications…The piece we did not always have in there consistently, and it's a harder piece to capture, is allergy information…The other piece we would love to have if we're talking about just the basics is a brief problem list so anything that is not being medicated is under control." – Dr. Townsend

"Thinking about the adoption issue for those who can't use computers, the elderly…There is a segment of the population that we have to be ever-cognizant of as we move towards an electronic system, how are we going to deal with their issues and their needs? When we make recommendations we're certainly going to have to address it." – Ms. Gelinas

"It [adoption of electronic health records] is going to be an issue, but the initial adopters really need to be the provider sector and it's going to be our responsibility as providers to make that information available to other providers." – Dr. Townsend

"Have you had an opportunity to tangibalize the financial cost savings that would have accrued [if electronic health records were used]? How much money would you have saved, how many lives would you have saved? Can you tangibalize what that cost, what the return on this investment, is?" – Mr. Roob

"Specific to Katrina, I really can't tell you…one of the things that we don't know because we don't capture it electronically right now is how many errors were made in people's care based on not having the information at hand…If you look at a lot of the studies and the return on investment, things that have been looked at for health information technology, the estimate is somewhere around 30% you may save by saving redundancy." – Dr. Townsend

"I think the issue here from your perspective is you can prove the worth of this financially. I think that may be helpful to tangibalize the financial cost of not having the system. Because ultimately, it will be about the allocation of scarce resources." – Mr. Roob

"To this comment that Mitch raised, we will follow up with SGA about making sure that some evaluation can be at least considered in the work that we're doing…We've worked very closely with the Markel Foundation on an after-action evaluation of KatrinaHealth and the other health IT responses, and those should be made public soon, so that will give us all more to debate about how do we make sure that the Health Information Community is part of the solution in the future." – Dr. Brailer

Chronic Care Workgroup Presentation

Workgroup Co-Chair Dr. Craig Barrett reviewed the membership of the Chronic Care Workgroup and noted that this presentation was focused on the following specific charge:

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

Enablers to accomplish the specific charge include: (1) geography, which can leverage existing infrastructures (existing business models, multistakeholder collaborations, high awareness of HIT value); (2) clinicians who care for a high percentage of patients with chronic illnesses; (3) the availability of secure messaging (excluding open e-mail) between patients and their clinicians in physician offices with care management supports; (4) decreased malpractice risk from better documentation; and (5) reimbursement of clinician time and expertise for less costly care than that provided in office or emergency room settings.

Workgroup Co-Chair Dr. Mark McClellan presented the Workgroup's recommendations to support the enablers described by Dr. Barrett. First, the Office of the National Coordinator, through existing contracts, could define optimal solutions to address technical barriers related to interoperability, identification of users, and security. Second, the CMS can identify opportunities in existing programs and projects to evaluate the value of secure messaging. Third, AHIC should receive input regarding licensure reciprocity across state lines for purposes of secure messaging to address this legal barrier.

The following open issues face the Chronic Care Workgroup and AHIC in general:

- How can effectiveness best be defined?
- What infrastructures and programs could be leveraged, and where?
- How can secure messages that could be considered reimbursable best be defined?
- What is the most effective way to address workflow issues in the office setting?

The following next steps were identified: (1) review existing information on secure messaging—receptive environments, business infrastructures, evaluations—to support potential reimbursement policies; (2) research outcomes associated with secure messaging; (3) identify local, state, and federal entities, national organizations, and private entities that could support the recommendations; and (4) develop a conceptual framework for the transition to the Workgroup's broad charge (make recommendations to the Community to deploy widely available, secure technology solutions for remote monitoring and assessment of patients and for communication between clinicians about patients).

Discussion Highlights

"What is your [Mr. Serota's] sense about the prospects for re-emergence of payment mechanisms that move away from fee-for-service and more to group payment and prepayment?" – Dr. Winkenwerder

"I don't think the marketplace is ready to be in a risk-assumption business. The greatest difficulty we ever had in capitation was with chronically ill patients anyway. This would not be the first place I would start trying to reintroduce capitation. I am very supportive of the goal of developing reimbursable mechanisms of communication so long as…[it is] improving the outcomes. The question is how you measure that." – Mr. Serota

"The ultimate result is some kind of packaged reimbursement for service. It may not be the pure capitation model that we used before but it may be a disease-specific payment, it may be some kind of more global payment…My discussions with providers across the country would say a move back to capitation and risk assumption by the providers is not high on their list of objectives." – Mr. Serota

"There will be obviously some security features built in there and messages related to the patient's chronic conditions status and updates being included in this in those limited electronic or personal health records. We've seen some providers as part of these programs using secure e-mail to exchange information among each other to improve the coordination of care for chronically ill beneficiaries." – Dr. McClellan

"[In terms of] the use of Web-based portals for transmitting information securely...a program run by Humana called Green Ribbon Health has this secure messaging via Web portal built in they're starting to use and we're really in the phase of gathering information about how well it's working…It does open up the possibility for a lot of different participants in this process of care coordination to share information effectively…The main thing we have been focusing on now is making sure they are secure and evaluating which ones seem to work best in which circumstances." – Dr. McClellan

"Let us not forget at the end of the day if we can get the whole system electronic with full medical records everywhere, that will fully allow all of this process to occur in a seamless fashion and will allow each clinician and the patient and the consumer to deal with issues of accountability and cost and quality, et cetera…But the enabler of payment as it relates to the provider of the service as everybody here has said it will be critical. The physician community I doubt would want to go back to the days of pure capitation. – Dr. Henley

"Many physicians aren't ready to take on full capitated risk especially for their most chronically ill high-risk patients but the proposals the physician groups have developed would allow for our reimbursement systems in Medicare or health plans to provide better support for the kind of care coordination in a more manageable risk environment. That's where these kind of blended payment systems come in. So we're looking for all the opportunities we can find to get these ideas into practice and get them tested to see what kind of impact they can have." – Dr. McClellan

"You can't separate the advancement of technology from the issues of payment, but the payment issue becomes enabling to adopt the technology and to implement the technology, which is what we are about here in the Community." – Dr. Barrett

"There are approaches based on claims data reporting that physicians can use now. We started, for example, a voluntary reporting pilot program where for a set of validated clinical quality measures, physicians are essentially adding additional code reporting into the current billing systems in Medicare." – Dr. McClellan

"I think we're in a phase where we need to support both the claims-based reporting on quality measures as well as the transition to a broader use of electronic reporting because so many physicians don't have electronic records fully in place yet. We need to view this as a transitional period for both types of reporting are supported." – Dr. McClellan

"We have got to get people enough financial support to get the care they need. For many people in the health care system and for people with limited means, a health account or other types of consumer-driven care approaches that give people an opportunity to save while still giving them adequate financial support to give them the care they need is a great way, I think, to encourage the use of these kinds of services." – Dr. McClellan

"We have to focus very strongly on the small number of people who are eating up the bulk of the health care cost—that is the chronically ill." – Dr. Barrett

"There is some information that consumers can use now to help find where they can get the best care for their needs at the lowest cost…There needs to be a lot more support for consumers along those lines and it should include process measures like whether or not best medical practices are being followed, whether or not electronic records are being used." – Mr. Ayre

"I fully recognize the reimbursement issues and the incentive issues involved with payments to providers but I want to be sure that the group does not lose sight of in a very tangible way…of one of the ultimate goals which is to not only get better quality but also to lower costs for the ultimate payers for these services, which has been the great experience of the application of information technology." – Dr. McClellan

"In terms of competitive approaches, there are a number of health plans or a number of disease management groups that are available and competing for the beneficiaries to take advantage of the services that are going to tend to drive down the cost of delivering services. People choose providers that save them the most money as well as get them the best help." – Dr. Henley

"My suggestion is to focus on the implementation of these messaging systems within the existing chronic disease management, care management programs that already exist, that already have a payment structure in place, that have some measures for quality…I would suggest using that as your starting point and working out the methodology and the technology and then that can be spread to other sources." – Mr. Green

"There is a firm belief that secure electronic communication…has to make the system better and make care better." – Dr. Barrett

"Our whole focus is to leverage off existing infrastructure capabilities that demonstrate the results and then to use that as the leapfrog to get other people to do it, not to start from scratch…" – Dr. Barrett

"I think consumers would like to have one provider in charge of their health care, [but] that's just not the reality. The reality is that consumers typically are going from specialist to specialist and we just don't see that many family practitioners anymore. That's what makes it more important that consumers have input on their care, that they had the ability to access information on their care."– Ms. McGrath

"As a Workgroup focused on chronic care improvement, one of the things we need to look at is the data elements that are needed both on the provider's side as well as the patient's side to really drive an incentive for them to use it…One element we have not touched on today is medication adherence and compliance, which these tools could actually help track especially for the chronically ill, the ability to make sure patients are taking their medications and taking them as prescribed." – Mr. Hutchinson

"As the Workgroups go off and deliberate and discuss, it is our expectation that they will be able to come back with very specific recommendations that will help this group decide if they will pass that forward to the Department, other agencies in the federal government, to other entities in the private sector." – Dr. Brailer

Consumer Empowerment Workgroup Presentation

Workgroup Co-Chair Linda Springer reviewed the membership of the Consumer Empowerment Workgroup and noted that this presentation was focused on the following specific charge:

- Make recommendations to the Community so that within 1 year, a pre-populated, consumer-directed, and secure electronic registration summary is available to targeted populations. Make additional recommendations to the Community so that within 1 year, a widely available pre-populated medication history linked to the registration summary is deployed.

The Workgroup is reviewing the following draft principles for consensus:

- Individuals should be guaranteed the right to access their own health information.

- Individuals should be able to access their personally identifiable health information conveniently and affordably.

- Individuals should know how their personally identifiable health information may be used and who has access to it.

- Individuals should have control over whether and how their personally identifiable health information is shared.

- Systems for electronic health data exchange must protect the integrity, security, privacy, and confidentiality of an individual's information.

- The governance and administration of electronic health information networks should be transparent and publicly accountable.

The Workgroup is exploring barriers and policy implications for breakthrough models. Issues to be considered include the following: (1) the need to raise consumer awareness of personal health records (PHRs), (2) confidentiality of PHRs, (3) need for patient proxies, (4) liability of providers, (5) state laws that act as barriers, (6) data standards that are not yet consistent, and (7) a lack of interoperability when sharing information. Potential breakthrough models include the use of existing regional health information exchange with a consumer interface, PHR vendor(s) linked to one or more intermediaries to get updated registration and medication information, and payer- or employer-based portals that supply information to PHRs. Possible target populations include patients who frequently utilize the system, such as those with chronic conditions. The following populations also are under consideration: (1) pediatric population, (2) older (45+) population with high medication usage, and (3) possible local/regional geographic locations with plans/providers.

There are a number of open issues that need to be addressed. For example, policies are needed to ensure that patients are in control of their health information and trust the network. Patients must be guaranteed the right to access their own personal health information. Policies also are needed to enable authorized caregivers and family members to access a patient's record. PHRs, EHRs, and relevant data sources (claims, pharmacy data) are not interoperable. In addition, mechanisms are needed to prohibit inappropriate or unauthorized secondary uses of data. Clarification is needed on how, under current laws, personal health information in PHRs is protected. Inaccurate information from PHRs could lead to medical decisions associated with bad health outcomes. A standardized approach to matching and authenticating patients to their health records is needed.

The following three next steps were identified: (1) refine and streamline principles for the specific breakthrough models; (2) refine the scope of the breakthrough models; and (3) analyze the policy, technical, and other barriers through additional research and public input.

Workgroup Co-Chair Gail McGrath noted that when this process first started, Secretary Leavitt directed Community members to reach out to as many groups and as many people as possible to obtain input from the consumer prospective. The Consumer Empowerment Workgroup has taken this direction to heart, and has included 30-40 consumer groups in its deliberations. She also noted that the Workgroup has been collaborating with the Markel Foundation. Ms. McGrath read a portion of a letter from the Markel Foundation: "The health information technology agenda will be slowed and put at risk unless the AHIC establishes a public process to develop and disseminate policies to guide the work of federal agencies and contractors and provide voluntary guidance to health information exchange efforts in the private sector."

Discussion Highlights

"You may want to consider what the accountability of the individual should be…[similar to] the concept that consumers need to be accountable for their own health record and updating it…This concept of targeting populations, like pediatrics, is a very good idea. And I think that where health care will go is eventually a changed behavior and building the behaviors in from day 1 of an individual's life…Eventually, having an electronic health record will be like a birthright." – Mr. Ayre

"In our targeted populations, the pediatric group might be a good place to target because you do have a starting point that will lead over time." – Ms. McGrath

"It's going to be critical to maintain interoperability between personal health records and EHRs…Personal health records must operate with certified EHRs. The certification process should accept those standards by which PHRs can plug and play. The vendors for PHRs in some fashion should…pay attention to the EHR certification process…If we miss that opportunity, we miss a huge opportunity in terms of the portability of data from one part of the system to the other and the accuracy of the data would be at risk." – Dr. Henley

"In the President's FY07 budget request for health information technology, there is a line item for personal health records. And as that goes through the process and comes out as an appropriation, we intend to use that to support exactly that effort of ensuring that there are standards and that there are linkages between personal health records and the rest of the health information infrastructure." – Dr. Brailer

"We [DoD and VA] both have electronic health records systems…[and with the] need potentially for a portal with just registration information, medication history, allergies, that is something we collect in both of our systems…it is an extensive reach, about a third of the doctors in the country between our populations…I wonder about creating a portal that has this basic information in it as a starting point." – Dr. Winkenwerder

"We do have not only an opportunity but a responsibility for a more public health approach." – Dr. Perlin

"I think we should take it to the Workgroup. We are working towards interoperability of our systems and moving information and already doing that in a significant way, but what strikes me with this is it's a subset of all the data that we already have that then might be more easily available to our covered populations as well as to a broader community of medical care providers." – Dr. Winkenwerder

"I want to make sure that we are not going outside of the bounds of what HIPAA has already put in place in terms of access to records and ability for providers to share in information for clinical care, for health care operations." – Ms. Worzala

"I wanted to bring up some thought processes we had with regard to the portal. We followed a path that said it should be patient's choice of entry into this personal health record world and we think a portal is a great idea. That portal could either come from your physician's office, it could come from your payer, it could come from a number of different sources." – Dr. Hutchinson

"One of the major issues I think we're going to have in this area is the various state laws that exist out there around privacy…around the view of sensitive medications, for example…there's an argument in industry that we have to address [whether] partial information [is] more damaging than being able to view the entire record of information." – Dr. Hutchinson

"Looking over the principles, [the Workgroup] clearly articulated the patient's rights, if you will, to protecting their personally identifiable information with regard to access, use, collection, security…To build trust, I think being able to clearly articulate and intelligibly communicate to the consumer is important…That should be a part of going forward. It's good if they have these rights but being able to communicate those rights to the patient I think will build that trust." – Ms. O'Neill

"There is an issue here as to what the unscrupulous [person] might do with their PHR…There is a responsibility not only on the public side but also on the health care system side to address this." – Mr. Trenkle

"We have been meeting over the past year with the leadership of the various pediatrics professional societies and children's hospitals in a group called the Pediatric Steering Committee, exploring their contribution to health information technology to the unique care environment in pediatrics." – Dr. Brailer

"The challenge is not a technical one, but the alignment of incentives, the value proposition of different players having to get involved to make this thing viable and…for this to get traction, I think we have to articulate how this helps the different entities." – Dr. Perlin

"As one moves to the concrete recommendations at the next step, I think it will be worthwhile to articulate what value accrues to whom by doing what…[For example, there may be] incentives with exercise and filling out this information so there is actual value in creating the information so that when that patient goes to someone else who has access to the information that is ultimately paid by this insurer that information leads to a more rational use of resources, ultimately achieving better health outcomes." – Dr. Perlin

"It's our hope that this meeting represents a key pivot point where the groups can go out and turn themselves to what needs to change to get this done and if they do that, refine who the populations are. Or what the delivery models would be that set that context." – Dr. Brailer

"We see [the Medicaid] population…changing primary care providers much more regularly than we do a privately insured population. So having that personal health record for that patient population, I think would add value from a health care standpoint and maybe be easier to implement than perhaps you might think." – Mr. Roob

"I'd like to raise the importance of [authenticating] patients and matching patients to their records. This will be a growing quality issue as health information flows through the system, making sure that you have the right records for the patient who is in front of you. If you don't have the right record, there could be pretty serious quality repercussions." – Ms. Worzala

"The Commission on Systemic Interoperability had a substantial discussion and set up recommendations on the question around patient authentication. It could be important input into this discussion." – Dr. Brailer

"The notion or the need for consumer confidence and trust, openness, accountability, all of that is so important in this that having a sponsorship of broad sectors of American society…is really important…I'd lean towards something that was sponsored by bigger institutions that were accountable to the public." – Dr. Winkenwerder

"There are plenty of broad coalitions of practices that are using a single EHR." – Dr. Henley

"The whole issue of portability of PHRs is extremely important. As you see more and more employers using PHRs as a way to improve employee wellness and other types of outcomes, I think that as people move from employer to employer, or move from different plans, I think it's important that we establish portability not only the interoperability between EHRs and PHRs, but also between PHRs." – Mr. Trenkle

"The Workgroups are not management bodies. They are not implementation bodies…The implementation tasks are left to the Office of the National Coordinator, federal agencies that are involved in federal efforts to support health IT, or to the contractors…We view the Workgroups…as advisory bodies." – Dr. Brailer

"We are trying to support a process that allows these recommendations to be accelerated through the discussion not just to the federal government, but to private-sector entities or others. Again, we view this Health Information Community as a steering group for many entities even though it's technically legally chartered as an advisory group to the federal government." – Dr. Brailer

"If you want to treat something that VA and DoD does as something you'd like to see happen, you should recommend it. If you just treat it as a fact and the background that's part of your thinking but in the end is not a recommendation you make, that's still valid, but it's really up to the Workgroup decide how to separate the difference between fact-finding and background information and forward-looking recommendations." – Dr. Brailer

Secretary Leavitt's Remarks

Secretary Leavitt, who was unable to attend the morning portion of the meeting, expressed his appreciation for the work being carried out by Community members. Secretary Leavitt noted that at the last AHIC meeting, he announced the creation of the Health IT Policy Council to help refine the federal government's action in responding to health IT issues as they develop. That Council is well underway and will focus on bringing the federal agencies together to facilitate and expedite the implementation of recommendations generated within the Community.

Secretary Leavitt also informed the Community that the Community has been tasked with an additional assignment this year. The *Katrina After Action Report* called for the development, within 12 months, of an efficient and effectively deployed electronic medical record or health record that could be used by first responders in the case of an emergency. In the aftermath of Katrina, 1 million people were displaced without records, pointing out how crucial having a basic health record is for first responders. This would not be a full-featured hospital emergency or electronic health record, but rather a standardized set of a very limited number of crucial elements that would be needed in an emergency situation. Secretary Leavitt noted that this task falls within the Community's mission and fits well with the progress AHIC already has made. He also asked that the SGA's Digital Health Recovery Task Force continue its work in this regard. Secretary Leavitt concluded his remarks by expressing appreciation for the work Ms. Haza has done in supporting the Community and wished her well in her future endeavors.

Electronic Health Records Workgroup Discussion

Lillee Gelinas, Electronic Health Records Workgroup Co-Chair, reviewed the Workgroup's membership and noted that this presentation was focused on the following specific charge:

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

Ms. Gelinas commented that the laboratory is emphasized in the specific charge because the availability of electronic data and clinical relevance suggests uptake is quicker and clearly could be a catalyst for broader EHR adoption. The Workgroup recommends that initial efforts be aimed at a broader group than just clinicians with EHRs; a longer-term goal involves dovetailing with PHRs. Ms. Gelinas explained

that if the patient or the consumer owns the data versus the lab or provider owning the data (which is the current system), the definition of how to proceed takes two different paths.

Dr. Perlin, Workgroup Co-Chair, described three potential models for accomplishing the group's specific charge:

- **Regional Health Information Exchanges (RHIOs).** RHIOs advance governance, primary financing, and sustainable business models while making comprehensive laboratory data from multiple sources available to authorized parties.

- **Standardized Peer-to-Peer Interfaces.** These interfaces fulfill the need for vocabulary, transmission, and implementation of technical standards, but limit access to results of tests ordered by any one provider (with an EHR).

- **Web-Based Portals.** These address market complexities and advance technical issues of patient identification, architecture, authentication, authorization, and policy issues relating to authorization (CLIA) and privacy, but may be limited to specific laboratory sources.

Dr. Perlin commented that the RHIOs model may be the optimal approach.

Ms. Gelinas discussed a number of enabling issues that need to be addressed. On the technical side, the Healthcare Information Technology Standards Panel (HITSP) review of contending standards is needed and should be supplemented as necessary with laboratory data vocabulary, transmission, and implementation guidance. Private and federal consensus is needed in the following key areas: (1) identifiers linking patients to their clinical information, (2) identifying appropriate users of patient information, and (3) patient authorization for use of data. In terms of policy issues, authorization and authentication for data use must be clearly defined and established within parameters set by the Health Insurance Portability and Accountability Act (HIPAA) and Clinical Laboratory Improvement Amendments (CLIA) for authorized use of patient data. In terms of implementing models, where a RHIO exists, measures should be taken to provide access to laboratory results through RHIO architecture, using RHIO's governance and business models to address multiple sources of laboratory results, data flow issues, and HITSP standards. Where there is not a RHIO, access to laboratory results should be implemented using HITSP standardized technologies appropriate to the market context.

Dr. Perlin noted that there also are a number of open issues/questions to be considered. For example, which environments (mature RHIOs, hospital-based systems, others) best support the specific charge? Should implementation occur first in several small areas or more broadly (with greater risks) for future success? Portals may be expeditious, but also may disincentivize further uptake of person-centric solutions. Another issue to be addressed is whether initial provider access to EHR users should be limited, or whether laboratory information should be made available to all authorized parties. Consideration also must be given to how/when to include diverse laboratory data sources (e.g., national laboratories, federal systems, hospitals, local laboratories, physician offices).

Ms. Gelinas discussed the Workgroup's next steps, which involve defining environmental characteristics for successful deployment of recommended models. A rapid environmental scan will be conducted to explore: (1) RHIO- and hospital-based processes currently available; (2) governance, financing, and value proposition in successful RHIOs (using input from Agency for Healthcare Quality and Research studies); and (3) market contexts that drive specific solutions (RHIOs, Web portals, or direct linkage to laboratory results). The Workgroup also will identify key components of a patient-driven, easy-to-use, secure authorization process, from both technical and consumer perspectives. In addition, the group will consider both technical and consumer implications of opt-in versus opt-out patient choices. Finally, the Workgroup plans to provide further recommendations for the rapid deployment of models.

Discussion Highlights

"Let's assume I have a favorite portal company that I have my e-mail with and I have some music I buy and I tend to do some electronic shopping there and I have my instant messaging and I keep my photos there and they have a window that says 'health record.' And I have registered and that's the portal that I would like. Is that part of this vision?" – Secretary Leavitt

"The idea is you would have a sort of generic viewer and be able to get the information. Someone used a good analogy earlier. Do you go online to bank with your favorite bank? You might have a different account with another bank and do transactions through their viewer or manage your money in one of these programs, [like] Quicken, that actually goes behind the scenes and reaches out to the same companies and gets that information and while not necessarily part of this specific vision, it's a sort of derivation that would allow one to get information that lives somewhere else." – Dr. Perlin

"Let's say that portal was 'Quicken for health care.' And I would assume it would use the AHIC standards and go off to the lab company and say…Mike Leavitt ordered a lab request there and send it to this place on my Quicken for health care record." – Secretary Leavitt

"Your 'Quicken for health care' is an absolutely fabulous vision. The challenge we have at the moment is that we need to set up the relationships…so we can transact online before we put the program, the 'Quicken for health care' in between. But it's a great vision." – Dr. Perlin

"We've proven that with KatrinaHealth…where we have labs highly stratified across national laboratory companies, local regional laboratory companies, and hospital/doctor office laboratories, the consolidation and unification is a massive challenge for the industry. So the focus here is how do we get the data to the doctor and thinking that the next step to achieve this is then to take it out to the patient to follow that medication solution once we can consolidate it." – Dr. Brailer

"You can have the Web portal in a regional model, where you can get one access, one view of all the lab data for one patient regardless of who originated it, or you can have it in an enterprise model where each lab, each hospital, can have a portal and you have to figure out which portal they have. Same thing from peer to peer." – Dr. Brailer

"Could you use the fact that the health care ultimately is paid for, attach it to the paying function and then and create a mechanism for bringing the information together? In practical terms, it would be somewhat difficult to operationalize…we don't typically share the basic lab data with the payer." – Dr. Perlin

"In a portal model…any physician providing care to that patient could ultimately do a query and…see the results of those tests that have been performed, to prevent multiple tests from being performed and ordered by multiple physicians because they are unaware the test was performed the day before by another physician." – Dr. Hutchinson

"Let's just roll this forward for 5 or 10 years and assume we have made lots of progress we haven't yet made, and we live in a world where electronic health records are much more common. [Assume that] we've got all the standards we need and the question now is, how do we initiate and determine who keeps our electronic health record?" – Secretary Leavitt

"The pivotal question in our presentation is whether the data is lab-centric. That is, does it reside in the number of sites because it's a lab element produced by a particular lab or does it in some way follow the person so that when the person moves, the person goes to different doctors, that it follows them…The value of the electronic health record from our experience is that if I have chest pain and I show up at the Washington VA and I'm giving a talk in Baltimore tomorrow and I have chest pain, they can actually know my past record and so they don't have to know which doctor I went through." – Dr. Perlin

"I think the elephant in the room here is that we are talking about data that has already been vetted and now is 'part of the past history.' What is of concern…is what do we do with the data that was just ordered, has been completed in the lab, and hasn't yet been vetted in terms of an abnormal value? Should the patient have free and open access to that positive HIV test that I ordered, and yet there hasn't been a conversation between the patient and the physician or other clinician as to what that test means because it's abnormal?" – Dr. Henley

"I see a difference between the record and the information. I don't see why there needs to be any change from today as far as who owns or creates and owns the information. I think we're asking for another level of complexity we don't need to get into. Your doctor has information. The electronic health record is the thing that makes that information useable outside of the doctor's office. And then there can be competition as to who has the best or most useful, efficient health record for different purposes." – Mr. Green

"Who owns the record? If my doctor hasn't explained [a test result] to me yet, do I own it before he explains it or after he explains it?" – Secretary Leavitt

"If I want to use a client server on my laptop at home that's integrated to my health care organization, that's great. If I want to use CVS, who is supplying a free personal health record, I understand there is some limitation to that. They may not have access to all the various different networks that have information on me. It may be a much more limited record. But I think that's ultimately going to be the consumers' choice." – Mr. Hutchinson

"The lab industry has been supplying this technology to physicians' offices for quite some time but it's not integrated into their workflow, and that's the biggest challenge…One of the biggest challenges that the labs are most interested in is the order process, and that order process is not been standardized on a lab-by-lab basis…so orders are still going paper [and] results are coming back electronic. I would challenge all of us as we look at this particular process, especially as an EHR subgroup, that we focus on the entire lab process of how we get orders electronically and how we receive the results as electronically as well." – Mr. Hutchinson

"[The VA] has a rule that if there are things like new diagnosis of cancer or HIV or something of that sort, then that data doesn't go forward until the physician has indicated or the clinician has indicate they had provided counseling." – Dr. Perlin

"Can the patient who gets care in one environment have the results available to another clinician in another environment and to themselves in a third environment? Maybe the insurer actually gives the patient an insurance discount because they have a health record and they share their health record with their insurance company and the insurance company gives that patient information about better control of their diabetes or exercise and nutrition." – Dr. Perlin

"Standardized peer-to-peer fits the bill of allowing electronic orders ideally to come in with electronic data coming back but it doesn't fill the need of totally integrating with the rest of the care experience elsewhere. The portal is the 'Google' model…but it doesn't necessarily resolve the issue of getting that order electronically to the lab company. It may have more effectiveness as a viewing engine. The third model…the RHIOs…[can] result in greater efficiencies and higher safety, higher quality. [There is] value to each. Each actually brings the adoption curve forward, with specific opportunities and specific challenges. Clearly the RHIO is by far the most complex." – Dr. Perlin

"From the consumer perspective, certainly we want the provider to be able to read our lab results and tell us what the problem is. We'd also like to be able to easily get that information. But more importantly, we'd like to know that that information is not going to be used against us. For example, if we think we may have a genetic predisposition to something, I'd like to feel comfortable that I could go in and have that test without becoming uninsurable." – Ms. McGrath

"[The] broad charge to us was to speed the adoption of electronic health records and in fact...I think there is a market dynamic that helps them to move forward and ultimately the market forces will help determine which are best approaches." – Dr. Perlin

"We can do better. We can be safer. We can offer higher quality. We can improve the efficiency and in fact, with these sorts of systems we can protect the privacy in ways that you can't ensure with faxes back and forth and phone calls and voice mails." – Dr. Perlin

"It is important to think about that incremental change over time…the peer-to-peer interface lays groundwork to the bigger vision and it really is to get to the standardized part and there is nothing about moving forward to that that would prevent further development of greater ability to share. So I think it is a good starting point." – Ms. Worzala

"The two greatest barriers to adoption of electronic health records by physicians and others are cost and lack of interoperability. The focus of the Workgroup at present on laboratory interoperability, laboratory data interoperability, is an excellent focus in terms of immediate results. All three models are important and when you go from lab to the entire EHR, all three models have to exist in the system to assure interoperability based upon geography and different populations" – Dr. Henley

Biosurveillance Workgroup Presentation

Dr. Julie Gerberding, Biosurveillance Workgroup Co-Chair, reviewed the Workgroup's membership and noted that this presentation was focused on the following specific charge:

- Make recommendations to the Community so that within 1 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.

Dr. Gerberding discussed enablers to accomplish this specific charge, such as starting with a minimum dataset that can be readily captured from the health care delivery system. Data linkers can protect privacy and provide event-level data to public health to facilitate analysis and follow-up investigations as needed. In addition, existing local, state, and federal biosurveillance programs sharing biosurveillance data should be built on, to help meet public health needs. To support these enablers, data should flow simultaneously to local, state, and federal health departments. There should be a focus on a narrow scope of data across a broad geographic scope to maximize coverage and detection of public health threats. As feasible, intermediaries or RHIOs can capture data from providers and then share with local, state, and federal health departments.

Open issues include addressing the following key questions:

- Do local and state health departments have the capacity to receive, analyze, and act on steady stream of electronic data?

- A lack of standards impedes data sharing with public health—how can we standardize the format of data?

- Beyond altruistic early participants, how can we incentivize health care providers to participate?

- If voluntary participation is not sufficient, are there other options?

- What are the future roles of RHIOs and the Nationwide Health Information Network as a means of providing public health data to local, state, and federal partners, and who pays for this service?

Dr. Gerberding discussed the Biosurveillance Workgroup's next steps, which include the following: (1) develop a short- and longer-term scope, (2) analyze barriers and recommend ways to overcome them, and (3) evaluate complementary technologies supporting interpersonal communication and traditional case reporting to ensure coordination and integration.

Mr. Roob, Biosurveillance Workgroup Co-Chair, thanked the Workgroup members for all of their work and support, noting that "we have not allowed the perfect to be the enemy of the good here." Creating the minimum data set took an enormous amount of effort, but having it gives the Workgroup the "what." The "who" are the emergency departments and associated ambulatory care facilities. The "how" involves moving that data through RHIOs back to the CDC for quick analysis. Mr. Roob expressed optimism that the Workgroup would meet its deadlines.

Mr. Roob noted that there has been some degree of consternation among the traditional public health communities, and the Workgroup has reached out to many in the public health community, particularly at the state level, to obtain their input in terms of how those data are moved. State health commissioners want data for people who live in their states to quickly get into their state systems; Dr. Roob emphasized the necessity of this activity. If a RHIO model is adopted that is designed around a multi-state facility, that RHIO will have to be able to feed data to multiple state health departments as they feed the data to CDC as well. Although not an insurmountable barrier, it represents a key point to keeping the state health commissioners onboard in this effort.

Discussion Highlights

"What you want is within 24 hours the results of the prior day…What part of the health care system already has some form of electronic record keeping or electronic health records which are ultimately searchable because they are big databases? How big a sample do you need from those existing databases to have an adequate measure of a pandemic, something to be able to differentiate between the onset of flu with the first day of hunting season and a real pandemic? How big a database do you need?" – Dr. Barrett

"The problem I think will be that if you get a plane landing and you disburse that population, [they are] outside the boundaries of a RHIO. Unless you pull that together, the only person that will see that is going to be Dr. Gerberding because they're going to arrive in emergency departments in ones and twos." – Mr. Roob

"Just how big a database do you need and don't we already have enough of these existing EHRs in that are searchable today?" – Dr. Barrett

"We are talking about finding 5 in a universe of 5 million and that becomes the place where we want to catch it. A sample of 5 million might only require 1,000 different pieces of information but it won't find the 5." – Secretary Leavitt

"If we are looking for a few cases of serious food borne toxic illness in the population…with people coming in with diarrheal illness every day, we've got to have a very sensitive system with a lot of data elements in it and a lot of trend…But if we are looking for a signal above background…for example if we are just looking for an increase in influenza-like illness in the population, then we don't need to have such a comprehensive set of data elements in the system because the number of events we are seeking for is large. It really does depend on exactly what we are expecting the system to be able to define for us." – Dr. Gerberding

"Is the problem divisible? Can it be partitioned into two pieces? If you're looking for five needles in the United States haystack, that's one issue. If you're looking for onset of a more common disease or flu or pandemic…you don't need such a large population…There are some pretty sophisticated databases today and I'm not sure we have an integrated system to search those databases as opposed to starting with some something new. I'm all for building on what we have." – Dr. Barrett

"That's why we will go through the RHIOs, which in many cases have this system existing today. So we won't build this new. This is not a *de novo* system. This takes existing data elements and analyzes them more effectively. Thank goodness some company developed a really effective processor for churning through all this data because the amount of data that we capture here is just unbelievable." – Mr. Roob

"Right now the DoD and the VA contribute many of these data elements to CDC in a 24-hour time frame, so we are including already a catchment of information from the federal health care facilities in the sort of prototype of the surveillance system we have under development" – Dr. Gerberding

"Wouldn't the 'hub-and-spoke model,' the rapid deployment of data to the different elements serve [some] value? Because isn't it possible that something could be going on in my neighboring community and I'm unaware of it because of the sequential nature? Wouldn't it be available to come back to me and wouldn't that kind of close the value loop?" – Dr. Perlin

"The downside of this is the reality of our public health system…in many cases…where there really is no capacity to make use of the information as it comes in, we have to rely on the nearest neighbor or the state to take on the responsibility for some of the local jurisdictions where they just simply don't have the investment to develop the capacity. Fortunately that's not true in every location. We have some marvelous local health departments large and small that are able to do this already." – Dr. Gerberding

"We believe the value proposition is there in speed, in sensitivity, and in getting the treasured epidemiologists that we do have to be doing something about the problem rather than spending their time acquiring the information and manually looking at it. That can be an automated process and decision tools and algorithms can be built in to warn people without them having to go to the computer to look at the data so they spend their time in…action to respond and try to prevent the problems." – Dr. Gerberding

Closing Discussion Highlights

"There is high optimism that the Biosurveillance Workgroup will, by the end of this year, be able to provide a broad set of data from existing databases that can in fact be accumulated, assembled to those local health departments who have the capacity to handle and use it, and beyond that at the Centers for Disease Control where it can begin to be processed and learned and refined." – Secretary Leavitt

"Let me add the states. I would be remiss if I didn't." – Mr. Roob

"[The Electronic Health Records Workgroup] will meet in March. You've defined some very important questions…we still have the pure vision in our sights, but there are some interim steps that we can accomplish this year…if I can get peer-to-peer, ultimately I can build on that and different models will emerge through the market…but the first step is getting peer-to-peer with standards that make the data exchangeable." – Secretary Leavitt

"[The Electronic Health Records Workgroup] came out with the feeling that our specific charge is to have a medication record and a restoration summary and have recommendations on that by May. Along with that, we felt very strongly there should be consumer principles applied for privacy. We're feeling comfortable that by May we will have some very definite recommendations on what we can propose, along with certain population groups that could be tested." – Ms. McGrath

"Very similar to the other Workgroups, [the Chronic Care Workgroup] believes that you need to build off an existing base and then leverage that base and demonstrate that in fact you can increase the quality of care at lower costs for people with chronic illness…So if you want something by the end of the year, it has to be built off of that existing base and probably some subset of that to demonstrate there is increased quality, decreased cost, increased efficiency. We had a long discussion about…incentives…We have a lot of work yet to do in that space." – Dr. Barrett

"I know there is a lot of work going on in the Workgroups and I want to express appreciation for that. I also want to keep the sense of urgency that I feel in front of you. I've made a commitment on HHS's part

that we intend to take these standards and to convert them to rule making which will in fact empower HHS, specifically Medicare and Medicaid, and other health care entities within HHS to begin implementing them." – Secretary Leavitt

"We all want to move forward on this together but the power of this Community is our ability to move the market in a responsible way…If we wait too long, the opportunity will pass us by." – Secretary Leavitt

Public Input Session

Speaker Number 1 – Jason Dubois, American Clinical Laboratory Association. Mr. Dubois commented that achieving the pure vision related to the Electronic Health Record Workgroup's charge is possible; one of the major steps needed in taking this forward is standards development. Currently, no standards have been recognized by HHS for results reporting. A consensus-driven effort, known as "E-Links," is being housed at the California Health Care Foundation. The current version includes approximately 95% of the top 100 commonly ordered tests; Version 1.0 was adopted by the Certification Commission. Ultimately, this or a similar effort would need to be adopted by HITSP and the Department. Mr. Dubois concluded his remarks by noting that adopting the peer-to-peer approach can help reach the pure vision—helping advance standards development in terms of peer-to-peer and using a product such as E-Links would be a major step in the right direction.

Speaker Number 2 – Dr. Alan Zuckerman, American Academy of Pediatrics (AAP) representative on the Certification Commission for Healthcare Information Technology's Interoperability Working Group and Co-Chair of the Consumer Empowerment Youth Case Committee within HITSP. He expressed appreciation that the Community focused a large amount of discussion on targeting the pediatric population, but reminded AHIC members that children grow into teenagers. He urged the community to confront the issue of when the ownership of a child's record transfers to the child from their parents and what rights teenagers will have within their records. He also noted that many of AAP's members now are sharing PHRs from their EHR systems with their patients; however, an unexpected problem has arisen in that when these are brought, either hand-carried or on Web pages to various hospitals and emergency rooms, local security systems sometimes defeat access to them.

Dr. Zuckerman reminded the group that some of the current commercial payers are sharing not only laboratory result values but also ICD9 diagnoses from claims. The issue of direct sharing from claims data and including laboratory results to patients needs to be addressed within this process. Many of those portals for laboratory data are run by hospitals and hospital laboratories. A great deal of attention has been paid to moving data on medication lists between the ambulatory and inpatient setting. There also is a need to make hospital laboratory data available within small offices. He commended the Community for keeping portability in mind and recognizing that the ability to change providers for both EHRs and PHRs will be a critical factor in adoption.

Speaker Number 3 – Dr. Carol Bickford, American Nurses Association. Dr. Bickford commented that there was a discussion about laboratories being the model in the EHR Workgroup and pharmacies serving as the model for the Consumer Empowerment Workgroup. She commented that this gives the impression that there are two "silos," and asked whether this is the case.

Dr. Brailer noted that this question will be posed to the Workgroups, adding that these breakthroughs are necessarily segmented to create a clear path for the Workgroups to find a solution. Although they had to be isolated, one of the challenges facing AHIC and the Office of the National Coordinator is ensuring an integrated solution.

Closing Remarks

Before adjourning the meeting, Secretary Leavitt thanked all members of the Community and those who provided public comments.

May 9, 2006

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

Dear Mr. Chairman:

The American Health Information Community has identified and prioritized several health information technology applications, or "breakthroughs," that could produce specific tangible value for healthcare consumers. To address one of these breakthrough areas, the Electronic Health Records (EHR) Workgroup was formed and given the following broad and specific charges:

> **Broad Charge for the Workgroup:** Make recommendations to the Community on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers.
>
> **Specific Charge for the Workgroup:** Make recommendations to the Community so that within one year, standardized, widely available, and secure solutions for accessing current and historical laboratory results and interpretations are deployed for clinical care by authorized parties.

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

1. The need to support all of the necessary steps in the evolutionary path toward a patient-centric flow of laboratory results data
2. The urgent need for endorsed, adopted, and interoperable vocabulary, messaging, and implementation standards that can be applied to enable the exchange of laboratory results data
3. The potential barriers posed by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations that may hinder electronic laboratory results data exchange in a patient-centric manner, particularly in States that have more stringent privacy laws
4. Technical considerations relating to privacy and security with respect to patient and provider authorization and authentication, including accurate patient identification and linkage to patient specific information
5. The need for an aligned business case and incentives for the multiple stakeholders involved
6. The need for assessment, monitoring, and research of the experiences of early adopters and identification of best practices.

This letter provides both context and recommendations for how these issues can be addressed to enable widespread access to both current and historical lab data in a patient-centric fashion.

BACKGROUND AND DISCUSSION

Widespread EHR Adoption and Availability of Historical Laboratory Results

In his January 2004 State of the Union Address, President George W. Bush highlighted the importance of information technology in health care when he stated, "By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care." In April 2004, the President issued Executive Order 13335, calling for widespread adoption of interoperable EHRs within 10 years, and established the position of National Coordinator for Health Information Technology.

The effective use of EHRs has the potential to positively influence both the quality and cost of health care for the Nation. It presents clinical information and comprehensive patient data to clinicians at the point of care, facilitating more informed decisions in a shorter time frame. In addition, the cost of care can be decreased by streamlining data collection, decreasing the likelihood and associated cost of medical errors, and reducing resources used for duplicative or unnecessary information capture and testing.

Despite these benefits, the Nation has been slow to adopt EHRs, as highlighted in the recent work of the Health IT Adoption Initiative. This group evaluated both the quality and the results of all EHR adoptions surveys and found that overall physician adoption was approximately 17 percent[1]. A recent Agency for Healthcare Research and Quality (AHRQ)-sponsored report that reviewed 286 studies focused on HIT adoption identified a large number of barriers to the implementation of HIT. These barriers were classified as:

- **Situational barriers,** including the high cost of purchasing and implementing EHRs as well as developing the necessary interfaces between EHRs and other Health Information Technology (HIT) systems on a custom basis
- **Cognitive or physical barriers,** including users' physical disabilities and insufficient computer skills
- **Liability barriers,** including confidentiality concerns
- **Knowledge and attitudinal barriers.**[2]

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[1] *The HIT Adoption Initiative. Report to the Office of the National Coordinator: an environmental scan of the current state of EHR adoption measurement in the United States*. Boston, MA: The George Washington University School of Public Health and Health Services; Institute for Health Policy at MGH/Partners HealthCare System; Division of Internal Medicine at the Brigham & Women's Hospital; Clinical and Quality Analysis Group of Partners HealthCare System. In press.

[2] Shekelle PG, Morton SC, Keeler EB, et al. *Costs and benefits of health information technology, evidence report/technology assessment,* no. 132. Rockville, MD: Agency for Healthcare Research and Quality; April 2006. AHRQ Publication No. 06-E006. Available at: http://www.ahrq.gov/downloads/pub/evidence/pdf/hitsyscosts/hitsys.pdf. Accessed May 8, 2006.

Another short-term barrier is the lack of comprehensive electronic data on any one individual. Laboratory results have the unique feature of currently existing in electronic format, though they are generally transmitted to physician offices by fax. Since these results are a component in 70 percent of clinical decisions, timely and easy access to comprehensive laboratory information is of high value to clinicians.

The ability to easily access this information through an EHR at the point of care would enhance the value of the EHR to the clinician greatly. Unfortunately, the current environment precludes this type of easy access to comprehensive information. Indeed, many States prohibit labs from providing results to anyone other than the ordering clinician. Moreover, while results exist in electronic format, they cannot be transmitted directly to an EHR without customized and expensive interfacing, and there are no clear technological solutions for how patients determine the degree to which their laboratory information can be made available to multiple providers. Addressing these barriers would realize significant value to the purchasers and users of EHRs and, therefore, increase adoption.

RECOMMENDATIONS

I. Provider- and Patient-Centric Models

The ultimate goal is to make laboratory data available in a patient-centric model, where a patient's laboratory results data are available to all authorized providers of care regardless of where or when the information is generated. This would enable patients to benefit from more coordinated and complete health care delivery, and it would reduce the cost associated with duplicate and unnecessary tests. Thus, the patient-centric model extends availability of information beyond the existing business environment, where laboratory data results are available in a provider-centric model (i.e., only the laboratory data ordered by a specific provider for a specific patient are available for review). The Workgroup recognizes that an evolutionary path from the provider-centric model to the patient-centric model requires the adoption and use of data standards that allow more efficient flow of information. This will enable the suppliers and users of electronic laboratory results data to use standards that promote interoperability and lower costs of specialized interfaces to meet the needs of the current environment, while adopting the tools and technologies to support the patient-centric model as they are developed and implemented. A patient-centric model also will require addressing both technical and legal privacy and security issues.

> **Recommendation 1.0: The U.S. Department of Health and Human Services (HHS) should take immediate steps to facilitate the adoption and use of endorsed standards and incentives needed for interoperability of lab results within the current provider-centric environment. The Office of the National Coordinator for Health Information Technology (ONC) shall work with multiple stakeholders to develop a detailed workplan to achieve patient-centric information flow of laboratory data by March 31, 2007.**

II. Standards

Systems must be able to receive electronic lab test results when requested by a patient or authorized health care provider. The lack of easily implemented, usable standards is a primary barrier to this flow of critical information. By incorporating Health Information Technology Standards Panel (HITSP)-endorsed standards and implementation guides into its certification process for EHRs, CCHIT certification can reduce the cost of laboratory interface development, which is a significant barrier to EHR adoption. Laboratory-to-practice connectivity has been an elusive goal that has prevented leveraging the benefits of HIT interoperability in the small practice setting and has frustrated clinicians and vendors seeking to implement EHR systems. Much has been blamed on the high cost of custom interfaces, which are estimated at $30,000 to $50,000 per laboratory and $20,000 per interface in a group practice office.[3]

Once HITSP has endorsed standards for laboratory results vocabulary, messaging, and implementation, Federal health care delivery systems should begin adopting these standards in a reasonable time frame. Although this is not mandating their use, doing so should help to promote further adoption within the private sector. In addition, Federal agencies should positively incentivize adoption of HITSP-endorsed standards and implementation guides in their contracts.

Recommendation 2.0: HITSP should identify and endorse vocabulary, messaging, and implementation standards for reporting the most commonly used laboratory test results by September of 2006, so as to be included in the CCHIT interoperability criteria for March 2007 certification. HITSP should consider CLIA and HIPAA regulatory requirements as appropriate.

Recommendation 2.1: Federal health care delivery systems (those which provide direct patient care) should develop a plan to adopt the HITSP-endorsed standards for laboratory data interoperability by December 31, 2006.

Recommendation 2.2: Federal Agencies and Departments with health lines of business should include/incentivize the use of HITSP-approved standards in their contracting vehicles where applicable.

III. CLIA/HIPAA Options

The HIPAA Privacy Rule generally permits the disclosure of protected health information (PHI) by covered entities to health oversight agencies, other health care providers, and other covered entities and their business associates for purposes of disease management and chronic care improvement. However, the HIPAA Privacy Rule does not pre-empt more stringent Federal or State laws governing the release of such information. Regulations promulgated under CLIA require that clinical laboratories disclose test results only to "authorized persons" – defined as individuals authorized under State law to order tests or receive test results, or both, and, if applicable, the individual responsible for using the test results and the laboratory that initially

[3] Walker J, Pan E, Johnston D, Adler-Milstein J, Bates DW, Middleton B. *The value of health care information exchange and interoperability*. Health Affairs Web Exclusive. Available at: http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.10/DC1. Accessed January 19, 2005.

requested the test, e.g., reference laboratories. Many States require that clinical laboratories disclose test results only to the ordering physician or his/her designee and are silent on disclosure of test results to others caring for the patient.

In order for electronic historical laboratory results to be available in a patient-centric fashion to authorized providers of care, various architectural models (Web portals, RHIOs, etc.) must be evaluated with respect to CLIA and HIPAA. In addition, specific guidance from CLIA should be pursued on permitting the use of a patient's authorization as a means of enabling the release of lab data.

Recommendation 3.0: By September 30, 2006, ONC should review the possible models for the exchange of both current and historical lab information and determine which would require CLIA/HIPAA guidance, regulatory change, and/or statute change.

Recommendation 3.1: Based of the findings from Recommendation 3.0, by December 31, 2006, ONC should engage the National Governors Association and other State-based organizations to resolve variations in "authorized persons" under the various State statutes, regulations, policies, and practices as a resource for clinical laboratories seeking to define access rights to electronic laboratory data.

IV. Privacy and Security

Health information can be accessed only with adequate security and privacy mechanisms if there are clear standards and means for the following:

- **Identification.** Accurate identification of patients is particularly important in a digital environment, where it is essential for treatment, safety, and payment accuracy and to ensure that PHI is not misdirected to misidentified individuals. While the most accurate identification can be achieved through the use of unique patient identification numbers, cultural and political considerations make such an approach infeasible, at least in the near future. That being the case, other technologies, policies, and procedures must be developed or identified and implemented to ensure the lowest possible patient identification error. An alternative to creating unique personal identification for everyone is to define a national standard set of authenticating information required to receive health care. Unambiguously identifying patients and linking their information from multiple sources is a major challenge both within and across clinical enterprises. Unless caregivers are able to access linked information on a given patient across the continuum of care, proper and cost-effective care cannot be rendered. Similarly, the ability to link patient data in a secure fashion is critical to the anonymized use of information for national research, public health surveillance, and bio-preparedness.

- **Authentication.** For the health care delivery system to realize the greatest benefit from digitization, clinicians and patients must be able to authenticate that each person using an EHR is who he/she says he/she is. An environment of trust based on secure authentication allows for buy-in from clinicians, patients, and other healthcare entities.

- **Authorization.** The existence of contradictions within the patchwork of State privacy laws also inhibits authorized individuals from connecting health care information. HIPAA set a minimum national privacy standard, but many States have augmented those standards. This results in a jumble of State laws that are fundamentally inconsistent; what is mandated in one State is prohibited in another.

  Recommendation 4.0: The Community should create a consumer empowerment subgroup comprised of privacy, security, clinical, and technology experts from each Community Workgroup. The subgroup should frame the privacy and security policy issues relevant to all the Community charges and solicit broad public input and testimony to identify viable options or processes to address these issues that are agreeable to all key stakeholders. The recommendations developed should establish an initial policy framework and address issues including but not limited to:

  - **Methods of patient identification**
  - **Methods of authentication**
  - **Mechanisms to ensure data integrity**
  - **Methods for controlling access to personal health information**
  - **Policies for breaches of personal health information confidentiality**
  - **Guidelines and processes to determine appropriate secondary uses of data**
  - **A scope of work for a long-term independent advisory body on privacy and security policies.**

V. Advancing Adoption

As the health care industry travels this evolutionary path of adoption from provider-centric to patient-centric historical laboratory data exchange, it is imperative that the unique needs of and impact on all stakeholders are carefully considered. Although much discussion has taken place regarding the potential benefits, cost savings, cost shifting, and increased costs of interoperable lab results data, a full examination and development of the business case, including identification of incentives for all stakeholders, is required.

Recommendation 5.0: HHS, in collaboration with all key stakeholders, should both assess the value proposition and develop the business case for current and historical laboratory results data sharing across all adoption models, considering the unique needs and alignment of incentives for all stakeholders.

VI. Assessment, Monitoring, and Research

The provision of patient-centric laboratory data resources has the potential to improve the quality and efficiency of patient care. However, it is necessary to prove that these benefits are actually being achieved in practice. It is also important to consider that implementations may vary in their effectiveness and that best practices need to be identified and disseminated as early as possible.

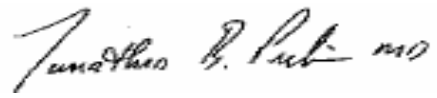
Recommendation 6.0: By March 31, 2007, AHRQ, in collaboration with the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS), should develop a proposed study methodology to measure the extent and effectiveness of the adoption of the first stage of HITSP standards, as well as the adoption and utilization of aggregated patient-centric data as they become available.

Recommendation 6.1: By December 31, 2007, AHRQ, in collaboration with the CDC and CMS, should research best practices in the implementation and utilization of patient-centric laboratory data stores and how to implement this knowledge.

These recommendations are supported by information obtained through research and testimony to the Electronic Health Records Workgroup, which is contained in the supporting documents available at http://www.hhs.gov/healthinformationtechnology/.

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,



Jonathan B. Perlin, M.D., Ph.D.
Co-chair, Electronic Health
Records Workgroup

Sincerely yours,

Lillee Smith Gelinas, R.N., M.S.N.
Co-chair, Electronic Health
Records Workgroup

May 9, 2006

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

Dear Mr. Chairman:

The American Health Information Community members identified and prioritized several health information technology applications, or "breakthroughs", that could produce specific tangible value to healthcare consumers. To address one of these breakthrough areas, a Chronic Care Workgroup was formed and given the following broad and specific charges:

> **Broad Charge for the Workgroup:** Make recommendations to the Community to deploy widely available, secure technology solutions for remote monitoring and assessment of patients and for communication between clinicians about patients.
>
> **Specific Charge for the Workgroup:** Make recommendations to the Community so that within one year, widespread use of secure messaging, as appropriate, is fostered as a means of communication between clinicians and patients about care delivery.

While concentrating on deployment of the specific charge, the Workgroup identified five significant issues which could either preclude or enable successful implementation of both charges. The Workgroup's recommendations presented in this letter address these five issues:

1. Reimbursement
2. Medical Liability and Licensure
3. Systems Supporting Patient-Clinician Secure Messaging
4. Consumer and Clinician Access
5. Patient Identification, Authentication and Security

BACKGROUND AND DISCUSSION

Chronic Illness and Patient-Clinician Secure Messaging

Approximately 50-60 million Americans live stably with at least one chronic condition and most have more than one. This 20 percent of the US population interprets care which is safe, safe, effective, efficient, timely, patient-centered, and equitable (the aims of the Institute of Medicine) broadly -- given that most of the care management occurs outside of the professional setting. Patients with stable chronic conditions manage a good part of their care themselves while monitoring diets, controlling weight, checking blood sugars, adjusting blood thinners, and titrating asthma medications.

This population, above and beyond almost any other, requires frequent and easy communication with their clinicians for guidance and timely decisions so that their chronic condition can be better and more tightly managed in their home, work, and school environments with minimal disruption. Further, as technology continues to find new and better ways to gather and transmit information through monitoring and communication devices, there will be even greater opportunity to meet patients' needs for care wherever and whenever they require the time and expertise of their physician or clinician.

Early efforts in this area of enhanced patient-clinician communication suggest that patients benefit from better health outcomes and that overall cost savings are realized. As the use of more robust communication technologies expands, the value of those communications to consumers (e.g., time savings, access, more engagement with their clinicians) and clinicians (e.g., time savings, convenience, better understanding of patient needs) can be better quantified and used to guide new developments and policies.

Technology alone, however, will not lead to better care and outcomes. Critical components of success include how the technology is adopted, how it is used, as well as the financial and social policies which either incent or disincent the adoption and use by both clinicians and consumers. The following recommendations which address technical, financial, and social barriers are specific to secure messaging between patients and their physicians and clinicians. These recommendations are, however, applicable to all types of telehealth communications.

Secure Messaging -- Definition and Common Functionalities

Secure patient-clinician messaging refers to communications between patients and clinicians who have an explicit measure of responsibility for the patient's care. In addition to online consultation, secure messaging between patients and their clinicians may be used for:

- Requesting Prescription Refills
- Scheduling Appointments
- Requesting Referrals
- Receiving Routine Test Results
- Receiving Reminders and Instructions

Secure messaging may occur through a secure unique portal, may be part of a shared electronic health record system, may be accessed through a delivery system's architecture or may be part of encrypted attachments to traditional email. Independent of the vehicle, secure messaging is characterized by clear guidelines for use, published by the American Medical Association (AMA) and American Medical Informatics Association (AMIA), and a clear methodology for assessing value developed by the Institute of Medicine and the American Telemedicine Association.

Adoption by the practicing clinical community has, however, been limited. The following recommendations address the major barriers:

RECOMMENDATIONS

I. Reimbursement

While up to 80 percent of chronic care management takes place outside of the clinician's office, the practitioner is only reimbursed for time and expertise if the patient makes the effort to make and keep an appointment for an office visit. Explanations on how to best manage the changing patterns of atrial fibrillation, to modulate insulin in a brittle diabetic, to monitor of blood pressure and to titrate medications all require office visits in order for clinicians to be compensated, though much of this information and guidance could be provided through remote communication. Lack of reimbursement for clinician time and expertise rendered outside of the office setting is the major barrier to widespread adoption of the use of secure messaging between clinicians and their patients. In situations where lack of compensation is not a barrier (salaried clinicians or fee for service reimbursement for secure messaging) both a positive return on investment and improved quality of care have been noted by the entity holding responsibility for the costs of care.

There are, however, multiple methods of reimbursement. Fee for service payments, capitation, salary, bundling of services, and pay-for-performance have each been observed to produce different behaviors in practicing clinicians. In a system where any one clinician is subjected to multiple methodologies, he or she will determine which workflows and practice approaches are likely to produce the best return on their time and effort. As an example, it has been demonstrated that clinicians must be able to offer the ability to communicate via secure messaging with at least 20 to 30 percent of their patients before they find it worthwhile to change office workflows and practices to maximize its effectiveness.

Lastly, reimbursement for virtually any service has attendant guidelines that should be clearly defined.

> **Recommendation 1.0: The U.S. Department of Health and Human Services (HHS) should develop and regularly update the evidence base for informed reimbursement policies with respect to secure messaging between clinicians and their patients. This should include monitoring and reporting the effect of secure messaging on cost, quality of care, patient and caregiver satisfaction, and medico-legal issues.**
>
> **Recommendation 1.1: HHS should compile and assess the effect of various reimbursement methodologies for secure messaging on clinician workflow in various care models, and report on best practices.**
>
> **Recommendation 1.2: Public and private payers, including the Centers for Medicare & Medicaid Services (CMS), should contribute to the evidence for and information base on reimbursement strategies through direct reimbursement, pilot or demonstration studies, or coverage analysis for Internet-based patient/clinician encounters in accordance with guidelines developed by the American Medical Informatics Association, the American Medical Association, and the Massachusetts**

Health Data Consortium for structured secure messaging, including, but not limited to, encounters that qualify under CPT code 074T.

II. Medical Liability and Licensure

Existing State licensing laws prohibit a practitioner licensed in one State from providing advice/care/education using a remote communication modality to any of his or her patients residing in another State. Licensing alternatives, such as licensure by reciprocity, for the purpose of permitting reimbursable secure messaging between patients and clinicians across State lines should be considered.

In addition to providing better care to patients with chronic illness, patient/clinician communication may be critical in the event of a man-made (e.g., anthrax) or natural (e.g., H5N1 influenza) bio-event. Immediate, secure communication will provide information that can affect diagnostic, therapeutic and isolation decisions to avoid further spread. State licensing laws should not prohibit our ability to diagnose and treat individuals who have been exposed to fast-spreading, possibly deadly, biological agents.

Recommendation 2.0: HHS should convene the appropriate State agencies and professional societies to develop and adopt new licensing alternatives which will address the ability to provide electronic care delivery across State boundaries while still ensuring compatibility with individual State requirements.

III. Standards for Secure Patient-Clinician Messaging and Supporting Systems

Secure technology solutions for communication about chronic care delivery among clinicians, and between clinicians and patients, and for remote monitoring and assessment of patients, must be based on standard transactions before they can be widely deployed as a means of chronic care improvement. A solution will be effective only if the clinical data can be appropriately shared between parties with legitimate needs for the data. Web portals currently offer feasible solutions for secure messaging among clinicians and patients; however, their effectiveness is limited by a lack of standardization and interoperability. Certification of secure message transactions and portals by a recognized certification body has the potential to encourage more widespread utilization.

Recommendation 3.0: The Office of the National Coordinator for Health Information Technology (ONC) should direct the Health Information Technology Standards Panel (HITSP) to define standards for secure patient-clinician messaging transactions so that they may be interoperable with electronic health records.

Recommendation 3.1: ONC should direct the Certification Commission on HIT to establish certification criteria for system interoperability with patient-clinician secure messaging.

IV. Consumer and Clinician Access

The benefits of HIT, particularly transactional functions, are of recognized value to consumers. However, several studies have suggested that certain populations are less likely than others to access health information services electronically than others. A number of factors have been identified that may contribute to this disparate use. In order to minimize disparities in health care related to use of health information technology, it is necessary to identify and confirm barriers to use and strategies to ensure that secure messaging can be a viable technology for all population groups.

Providers also have variable access to HIT, particularly in areas where broadband is not available.

Recommendation 4.0: The Agency for Healthcare Research and Quality (AHRQ) should conduct a synthesis of current knowledge from existing studies of health information technology use by elderly, ill, and underserved populations including an analysis of barriers and drivers. The barrier and driver analysis should elucidate for which subpopulations barriers can be overcome and how.

Recommendation 4.1: HHS will work with appropriate organizations to report on secure messaging availability to providers across the country and report on a plan and timetable to make securing messaging available uniformly.

V. Privacy and Security

Accurate, verifiable, unique patient identification and authentication is a foundational requirement both for supporting secure messages between patients and clinicians as well as incorporating the documents created into electronic health records. The records include both those maintained by health care organizations as well as personal health records, which may be maintained by patients. The methodology for identifying and authenticating patients must be constructed in such a way as to promote patient trust in the process, transparency in the use of information provided, and adequate patient control over who may or may not access this information. Ideally, patient-identifying components and the method for cross-matching these components between systems should be standardized to facilitate matching patient identification across multiple systems, multiple provider environments, and multiple health-care sectors -- as long as patients have a full understanding of the potential risks and benefits of this capability and voluntarily chose to allow this level of interoperability.

Authentication is the first step to enabling a patient, or the patient's proxy, access to his or her health information electronically and having a high level of assurance that the sender of health information is in fact the authoritative source for the information. The technologies that are developed should facilitate the identification/authentication process, provide a more acceptable level of security, and create opportunities for structured data entry not routinely available in common e-mail systems. The e-authentication industry is advanced and authentication is an existing technology that healthcare can leverage.

Recommendation 5.0: The Community should create a consumer empowerment subgroup comprised of privacy, security, clinical and technology experts from each Community Workgroup. The subgroup should frame the privacy and security policy issues relevant to all the Community charges and solicit broad public input and testimony to identify viable options or processes to address these issues that are agreeable to all key stakeholders. The recommendations developed should establish an initial policy framework and address issues including but not limited to:

- **Methods of patient identification**
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- **Policies for breaches of personal health information confidentiality**
- **Guidelines and processes to determine appropriate secondary uses of data**
- **A scope of work for a long-term independent advisory body on privacy and security policies.**

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

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.

May 9, 2006

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

Dear Mr. Chairman:

The American Health Information Community has identified and prioritized several health information technology applications, or "breakthroughs," that could produce specific tangible value for healthcare consumers. To address one of these breakthrough areas, the Consumer Empowerment Workgroup was formed and given the following broad and specific charges:

> **Broad Charge for the Workgroup:** To make recommendations to the Community to gain widespread adoption of a personal health record (PHR) that is easy to use, portable, longitudinal, affordable, and consumer centered.
>
> **Specific Charge for the Workgroup:** To make recommendations to the Community so that within one year, a pre-populated, consumer-directed, and secure electronic registration summary is available to targeted populations. Make additional recommendations to the Community so that within one year, a widely available pre-populated medication history linked to the registration summary is deployed.

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

1. Privacy and security safeguards and consumer control of personal health information related to medication history and registration summary need to be established and enforced.
2. There is no widely accepted standard definition or functional specification for the features of a PHR.
3. There are no standards or functional specification for populating medication history and registration summary tools.
4. Appropriate incentives to encourage consumer and provider use of PHRs must be identified and supported.
5. Currently, consumers have little to no access to their electronic medical records.
6. Generally, consumers are unaware of the availability and value of medication histories and electronic registration summaries and, therefore, of the potential value to them of a PHR.

This letter provides both context and recommendations for how most of these issues can be addressed by enabling access to electronic registration summaries and medication histories in target populations.

BACKGROUND AND DISCUSSION

Many people believe that successfully deploying some form of easily accessible, personal health information could be one of several important ways to encourage individual involvement in self-care and care management. Consumer commitment to PHRs could increase efficiency in the healthcare system, lower overall costs, and improve health care information access.

PHRs and related tools, such as medication histories and registration summaries, have few standards for data content, format, functionality, interoperability, use guidelines, privacy or security policies, development, deployment, education, and outreach. Traditionally, consumers have had limited exposure to PHRs and the process for enrollment. As a result, there is low demand for, and little common understanding of, the usefulness and purpose of these tools. Instead, current interest in PHRs is found largely among employers, health plans, and vendors. Nonetheless, many health care experts believe widespread use of user-friendly, consumer-centric health information may have short- and long-term benefits for consumer health and health care utilization. Potential users of these tools have legitimate concerns about managing data access and ensuring privacy and security as well as with the lack of interoperability, lack of user support, and general unavailability of tools needed to manage a registration summary and medication history.

While some PHRs are sold to providers who make them available to their patients, few of these are automatically populated with patient-specific information from the provider's system. More often, PHRs and related tools are "shells" to be populated by the individual or a caregiver who must spend many hours entering relevant data. There is little consistency in how the populated tools can be accessed by providers. Likewise, the availability of the information to a sponsoring provider in his or her office is limited, because providers may not have computers on their desks or in their patient exam rooms, and many providers do not have access to the internet in their offices.

In addition, some PHRs are populated with data from health insurance claims. For example, employers are increasingly offering PHRs to their employees; in one case brought to the attention of the Workgroup, a vendor imports claims data from various health plans under contract to an employer to populate the PHR tool. There is concern that providers cannot access the claims data and that the data cannot be electronically transmitted to patients. Similarly, there is concern that claims data do not include current health status or health history, because such data represent singular events and lag behind the actual encounters within the health care system.

In many discussion groups and forums, interest in PHRs (including medication history) is based on the ability to:

1. Secure information consistently from all providers
2. Make available medical information to all providers consistently (common source for the same data)
3. Track medications (prescriptions, over-the-counter medicines, and supplements)
4. Track diagnoses, conditions, test results, hospitalizations, comprehensive treatments, and enrollment in clinical trials

5. Give providers, family members, or other caregivers emergency access to health information.

The Workgroup notes that in order to give target populations access to electronic registration summaries and medication histories, it is necessary for consumers to choose one of many different types of PHR sponsors including vendors that offer Web-based tools for the storage and management of their personal health information. The Workgroup also recognizes that most enablers for registration summaries and medication histories are the same as those for PHR adoption. Thus, many of the Workgroups' evolving recommendations inevitably address the broad charge in order to achieve the short-term goal. We expect to continue to refine many recommendations related to PHRs after the Workgroup hears additional testimony and deliberates on more complex issues pertaining to the broader charge. For the purposes of the specific charge, the following objectives were agreed upon to guide the development of recommendations.

Primary Objectives:

1. Create measurable value for consumers, patients, and families for improved health outcomes, cost, and convenience.
2. Ensure privacy and security protections and consumer control of their medication history and registration summary.

Secondary Objectives:

3. Create measurable value for health system participants.
4. Establish an initial "building block" for supporting expanded PHR availability and portability.
5. Enhance interoperability among PHRs and other digital health information systems such as electronic health records (EHRs) and other PHRs.

The Workgroup recognizes that there are many key policy issues/barriers that must be addressed to assure the general public that a personal health record can be developed that will provide for privacy and security of the consumer's information as it moves forward to realize these Primary and Secondary Objectives. The following recommendations will be subject to periodic review and possible revision as the Workgroup continues to work on both its broad charge and its specific charge from the Community.

RECOMMENDATIONS

The Workgroup identified the following actionable recommendations to meet the specific charge.

I. Interoperability

The Community acknowledges that the minimum dataset required for the breakthrough project's registration summary and medication history is a small subset of a more comprehensive PHR. Furthermore, the Workgroup recognizes the importance of establishing a technical, policy, and business infrastructure to enable widespread adoption of registration summary and medication history exchange, while supporting innovation in the PHR space. We encourage the use of an underlying PHR infrastructure for maintaining and exchanging PHR-related information that goes beyond the minimum dataset. We envision that vendors and PHR sponsors will want to provide these extended services by using both standardized data and images and, in some cases, unstructured data or "free text." These efforts to extend PHR functionality will lead to further expansion of the fully adopted PHR minimum dataset and exchange standards that will undergo the same specification and certification process as is being developed in the first version of our efforts. We support trading partner exchange of data that fall outside the minimum dataset if they follow the principles and precepts established for the initial scope of the consumer empowerment breakthrough.

> **Recommendation 1.0: The Health Information Technology Standards Panel (HITSP) should identify the technical and data standards to enable the availability of a core registration dataset and medication history (with comprehensive review of recommendations for registration and medication history provided to HITSP by the Workgroup), including vocabularies, messaging, authentication, security standards, and appropriate documentation, by September 30, 2006.**

II. Demonstrating Value

The Workgroup considered various target populations for the specific charge to meet the primary objective of creating measurable value for consumers, patients, and families for improved health outcomes, cost, and convenience. Patients with chronic conditions requiring frequent use of the health care system are most likely to derive value from the availability of an electronic registration summary and medication history. Examples can be found in the pediatric community where health status can be documented starting at birth and within the Medicare populations where chronic conditions require the use of multiple concomitant medications. We gave particular consideration to pediatric populations, because there are opportunities to use longitudinal PHRs to follow patients over their lives, while demonstrating to families and providers of well and chronically ill children the short term value of registration summaries and medication histories.

> **Recommendation 2.0: The U.S. Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), the Agency for Healthcare Research and Quality (AHRQ), other interested Federal agencies, and private-sector partners, should pilot programs that measure and demonstrate the value of an electronic registration summary and medication history to patients with chronic disease. The sponsoring organizations should strive to implement pilot programs that meet all the objectives identified by the Workgroup no later than**

December 30, 2006, and an evaluation of the initial results should be reported to the Community by June 30, 2007.

Also, the Workgroup believes education and outreach for providers about the availability and benefits of electronic registration summary and medication history information will be necessary to encourage participation in the breakthrough initiative. Additionally, outreach will be necessary to confirm consumer and patient use of PHRs.

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

Targeted outreach needs to be culturally sensitive and available in a variety of forms to meet consumer needs. For the breakthrough initiative, consideration should be given to foreign languages, health literacy, and basic Internet skills. In addition, while it is important to make electronic registration summaries and medication histories readily available, consumer and provider use of these data is essential to achieving their benefits.

Recommendation 2.1: In the next 6 months, HHS agencies sponsoring pilots for an electronic registration summary and medication history should work with appropriate private-sector health organizations, such as patient advocacy organizations and medical professional societies, to promote provider and consumer participation in a breakthrough project through a targeted outreach initiative.

III. Privacy and Security

Each breakthrough workgroup identified policy issues to establish public trust and ensure successful adoption and implementation of recommendations. The consumer empowerment group recognizes its work is expected to bring 300 million new users into a nationwide health information network, raising numerous questions about privacy, data security, consumer control, and trust. Survey data and early user experience confirm that Americans believe that their personal health information is highly sensitive, and they demand strong protections regarding its proper management, sharing, and use.

Privacy and security policy issues are essential to achieving the four workgroups' specific charges. As a result, it makes sense to create a consumer empowerment subgroup comprised of existing Workgroup members who are most knowledgeable about privacy and security policy issues and their practical application. The subgroup's charge would be to make recommendations to the Community on the most pressing privacy and security issues that need to be addressed for implementation of the breakthroughs. The subgroup's mission would be to build public trust by ensuring structured public input, including written and oral testimony from consumer groups, privacy advocates, technology experts, clinicians, and population health experts to enable

balanced discussions of all issues. Consensus recommendations will be made based on broad public input. The Workgroup recognizes the need for a long-term multi-stakeholder policy advisory body to develop and recommend long-term privacy and security policies in addition to a thorough and deliberative shorter-term work group process to address the needs for implementation of the breakthroughs.

> **Recommendation 3.0: The Community should create a consumer empowerment subgroup comprised of privacy, security, clinical, and technology experts from each Community Workgroup. The subgroup should frame the privacy and security policy issues relevant to all the Community charges and solicit broad public input and testimony to identify viable options or processes to address these issues that are agreeable to all key stakeholders. The recommendations developed should establish an initial policy framework and address issues including, but not limited to:**
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> - **Methods of patient identification**
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These recommendations are supported by information obtained through research and testimony to the Consumer Empowerment Workgroup which is contained in the supporting documents available at http://www.hhs.gov/healthinformationtechnology/.

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,

Linda Springer
Co-chair, Consumer Empowerment Workgroup

Sincerely yours,

Nancy Davenport-Ennis
Co-chair, Consumer Empowerment Workgroup

May 9, 2006

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

Dear Mr. Chairman:

The American Health Information Community has identified and prioritized several health information technology applications, or "breakthroughs," that could produce a specific tangible value to healthcare consumers. To address one of these breakthrough areas, the Biosurveillance Workgroup was formed and given the following broad and specific charges:

> **Broad Charge for the Workgroup:** Make recommendations to the Community to implement the informational tools and business operation to support real-time nationwide public health event monitoring and rapid-response management across public health and care delivery communities and other authorized government agencies.
>
> **Specific Charge for the Workgroup:** Make recommendations to the Community so that within 1 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.

The Workgroup's deliberations highlighted a number of key needs that must be addressed to meet the group's specific charge, including the following:

1. Define the necessary steps to determine the data and technical specifications needed to support key public health functions.
2. Share data in a way that supports all levels of public health while ensuring that traditional public health roles are maintained.
3. Protect patient confidentiality.
4. Define clear goals, metrics, and rigorous program evaluations to inform recommendations for new programs, ongoing programs, and the broader charge.

This letter provides both context and recommendations for how these issues can be addressed to enable the transmission of ambulatory, emergency department, and lab data from electronically enabled health care systems to public health systems.

BACKGROUND AND DISCUSSION

The threat of significant naturally occurring or manmade health events is a critical issue for the Nation. The ability to detect events rapidly, manage the events, and mobilize resources

appropriately in response can save lives. Information from hospital emergency departments can be electronically reported and monitored without identifying patients and serve to provide a real-time view of the health of our communities. These data can be shared with and among local, State, and Federal public health agencies to support shared and unique needs at all levels of the public health system. Likewise, information from public health agencies can be shared in real-time with clinical providers in emergency departments to improve their ability to respond to rapidly evolving events.

At the onset, the Biosurveillance Workgroup agreed that the biosurveillance functions to be supported with advanced, enhanced, or real-time transmission of electronic health data are initial event detection, situational awareness, outbreak management, and response management. Accomplishing these functions requires a coordinated effort across Federal, State, and local public health agencies, along with partnerships with the clinical care delivery system.

In order to get a better understanding of the potential for local and State public health agencies to participate in a biosurveillance breakthrough, the Workgroup solicited input from the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO). In April 2006, ASTHO and NACCHO surveyed the State, Territorial, and large (>200,000 population) local health departments across the Nation regarding their capacity to receive, in electronic format, clinical care data to support biosurveillance efforts.

Responses to the ASTHO survey were received from 29 States, three Territories, and the District of Columbia. Several important findings emerged from this survey:

- The majority of State public health agencies have the capacity and the need to participate in biosurveillance efforts. These results emphasize the need for public health to be actively engaged in the electronic exchange of health information.
- Eighty-two percent of all responding agencies indicated that they are receiving, or plan to receive within the next 6 months, electronic data from clinical care settings for one or more biosurveillance capabilities.
- Eighty-nine percent of all respondents reported that they have an active relationship with some clinical partners to develop capacity for electronically receiving, processing, and using data for either notifiable disease reporting or biosurveillance efforts.
- Eighty-two percent of all respondents indicated a lack of funding, and 70 percent of all respondents indicated a lack of trained personnel as the primary obstacles for participating in a nationwide biosurveillance project.

Responses to the NACCHO survey were received from 93 large (>200,000 population) local public health agencies. The key findings from this survey include the following:

- The majority of the large local public health agencies have the capacity and the need to participate in biosurveillance efforts.
- Sixty-eight percent of all responding agencies indicated that they are receiving, or plan to receive within the next 6 months, electronic data from clinical care settings for one or more biosurveillance capabilities.

- Ninety-eight percent of all respondents reported that they have an active relationship with clinical partners for local preparedness planning.
- Sixty-eight percent of all respondents indicated a lack of funding, and 51 percent of all respondents indicated a lack of a technology infrastructure as the primary obstacles for participating in a nationwide biosurveillance project.

These findings informed the preliminary recommendations with respect to the specific charge as described below.

RECOMMENDATIONS

I. Data Strategy

A minimum dataset is necessary to meet the specific charge to obtain data in a biosurveillance program to enable key public health functions including initial event detection, situational awareness, outbreak management, and response management. The types of data necessary for the specific charge were recognized by the Workgroup, but not at the level of detail needed for the implementation of a program. The Workgroup acknowledged that it might not be feasible to get all of the data elements in the minimum dataset from every emergency department, laboratory, or ambulatory care setting. This led to consideration of two strategies for data collection. One data strategy would target receiving the minimum dataset from a limited number of clinical data providers and would support initial event detection, situational awareness, outbreak management, and response management. The second data strategy would be based on data that are easily obtained and potentially provide broader geographic coverage while still supporting at least one of the public health functions. For both strategies, data may need to be filtered with consideration given to usefulness in public health functions balanced with sensitivity of information.

> **Recommendation 1.0: By June 30, 2006, the U.S. Department of Health and Human Services (HHS), in collaboration with State and local governmental public health agencies and clinical care partners, should establish, convene, and oversee a Data Steering Committee to carry out the activities described in the recommendations below.**
>
> **Recommendation 1.1: The Data Steering Committee will identify the data elements and the appropriate filtering of data from ambulatory care settings, emergency departments, and laboratories as well as hospital utilization data needed to enable the key public health functions, as outlined above. The Health Information Technology Standards Panel (HITSP) should identify the technical specifications for these initial data requirements by September 30, 2006. The Centers for Disease Control and Prevention (CDC) and others should provide the HITSP with the public health expertise and funds needed to perform this task.**

Recommendation 1.2: By August 15, 2006, the Data Steering Committee should identify the data sources and requirements necessary to allow for collection of a more limited set of data across a broader geographic area.

II. Roles of Local, State, and Federal Public Health Agencies

The Workgroup recognizes that public health investigations are typically led by local health departments, with assistance from state health agencies if the investigation exceeds local capacity. State health agencies lead investigations when local health department capacity does not exist and assist in multi-jurisdictional outbreaks. Variations in the relationship between local health departments and state health agencies do occur across the country. Local and state jurisdictions may ask CDC to participate in an investigation when necessary. CDC becomes involved in investigations that cross state or national jurisdictional boundaries.

Recommendation 2.0: For the purposes of the Biosurveillance Breakthrough Initiative, the CDC should establish memoranda of understanding to enable simultaneous data flow from data providers to local, State, and Federal public health entities while preserving traditional investigation roles at local and State public health levels, whereby local and State jurisdictions continue to have lead roles in public health investigations. State and local public health agencies should ensure such memoranda of understanding are put into place and supported.

III. Protecting Patient Confidentiality

Data from clinical encounters are very important to public health authorities for the purposes of biosurveillance. Critical in the use of these data are the need to protect patient privacy and support initial detection and authorized public health investigation of critical health events. Although the Health Insurance Portability and Accountability Act of 1996 (HIPAA) allows for named reporting of appropriate public health data, important concerns remain about protecting patient privacy. HIPAA "de-identification" relates to data used for public release and other purposes such as scientific research. Some of these data, such as general localizing information, are critical for public health to establish that an event is occurring and how it may threaten the general population. So, while full HIPAA de-identification may provide maximum protection from a privacy and security perspective, it makes it virtually impossible for public health authorities to have information needed to identify, monitor, and respond to public health emergencies.

At the other end of the spectrum, public health authorities, at times, get named data as required by State or local law to allow follow-up on notifiable diseases. For biosurveillance, a significant amount of public health value can be derived from data that do not include obvious identifying information; therefore, it is not necessary to use named data for these broader biosurveillance purposes. The Workgroup agrees that identifiers, such as medical record numbers or patient names, should not be included in this biosurveillance breakthrough. However, data providers should ensure the ability to re-identify individuals for public health agencies in the event of an authorized public health investigation.

ASTHO has reported that some States and local jurisdictions believe that explicit State-level authorization might be necessary to permit the exchange of data for biosurveillance.[1] Data collected under a biosurveillance breakthrough would not be available for public release. The only data that should be shared with public health entities are those that are necessary to meet the core public health functions.

Recommendation 3.0: By August 30, 2006, HHS should develop sample data use agreements to facilitate the sharing of data from health care providers to local, State, and Federal public health agencies. HHS also should offer practical implementation guidance to data providers and State and local public health agencies to address HIPAA concerns about transmitting data (with obvious identifiers removed) for public health purposes.

Recommendation 3.1: HHS, in collaboration with privacy experts, State and local governmental public health agencies, and clinical care partners, should develop public communication materials to educate the general public about the information that is used for biosurveillance including the benefits to the public's health, improved national security, and the protection of patient confidentiality by September 30, 2006.

IV. Program Evaluation

The Biosurveillance Workgroup recommendations include strategies that build on existing programs and capacity in local, State, and Federal health departments to implement a biosurveillance program to transmit data from electronically enabled clinical care settings across the country simultaneously to local, State, and Federal public health agencies as feasible. Clear, measurable metrics are needed to guide the implementation, monitoring, and evaluation of this effort in the short and long-term. Program evaluation should be designed and implemented by public health officials experienced in biosurveillance programs.

Recommendation 4.0: The CDC, State and local governmental public health agencies, and clinical care partners with firsthand experience in managing ongoing biosurveillance programs should design and conduct evaluations of the biosurveillance breakthrough. These parties should establish goals, develop outcome measures, and establish metrics for evaluation of the breakthrough by September 30, 2006.

Recommendation 4.1: The Data Steering Committee will monitor the progress continuously, interpret the results of program evaluations, and assess the value of the data. The Data Steering Committee will use the results of program evaluations; taking into account the minimum data necessary for public health purposes to inform recommendations for modifications to the program. The Data Steering Committee should consider large-scale implementations and suggest modifications

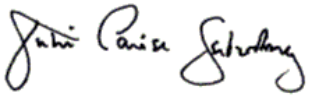
[1] Association of State and Territorial Health Officials. *The impact of the HIPAA privacy rule on syndromic surveillance.* 2004. Available at: http://www.astho.org/pubs/29724_ASTHO.pdf

to data collection when sufficient evidence exists that demonstrates the value of the information derived or lack thereof. The Data Steering Committee should monitor adherence to the protection of patient confidentiality.

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

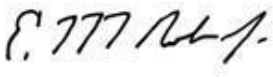
Thank you for giving us the opportunity to submit these recommendations. We look forward to discussing these recommendations with you and the members of the American Health Information Community.

Sincerely yours,



Julie Gerberding, M.D.
Co-chair, Biosurveillance Workgroup

Sincerely yours,



E. Mitchell Roob
Co-chair, Biosurveillance Workgroup

Sincerely yours,

Charles N. Kahn, III
Co-chair, Biosurveillance Workgroup

Certification Commission
for Healthcare
Information Technology

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May 5, 2006

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

Dear Mr. Secretary:

Thank you for inviting me, in your capacity as Chair of the American Health Information Community, to appear at the Community's May 16th meeting to report on the progress of the Certification Commission for Healthcare Information Technology (CCHIT).

I am pleased to report that CCHIT, a public/private initiative working under contract HHS-P23320054102EC, recently achieved an important milestone. On May 1, CCHIT published its first release of consensus-based criteria for the certification of ambulatory Electronic Health Records. Attached to this letter is a summary of the criteria, which define required capabilities in functionality, interoperability, and security so that EHR systems will improve care, make health records interoperable, and protect the privacy of personal health information. The complete criteria documents, available on our website at www.cchit.org , provide additional details including specific standards applicable for each item, the evidence upon which the criteria were based, and a roadmap showing which criteria become effective in May 2006, May 2007, and May 2008.

This work was accomplished through a broad consensus-based, public/private collaborative effort. Although CCHIT operates in the private sector, we have generally adopted the stringent requirements for governmental activities with regard to openness and transparency. Our Board of Commissioners has a defined composition that ensures representation from all stakeholder groups. Our volunteer workgroups are each led by two co-chairs who must come from different industry sectors, and the membership of every workgroup includes diverse stakeholders. From the private sector, our representation include physicians, hospitals, and other care providers such as safety net facilities; health IT vendors; payers and purchasers of healthcare; quality improvement organizations; standards development organizations; informatics experts; consumer organizations; and others. From the public sector, we have enjoyed participation by representatives of Federal agencies including HHS/ONC, CMS, VA, CDC, and NIST.

Besides involving a broad array of stakeholders, we have also adopted processes to ensure openness and transparency. During the 18 months of criteria development, we published interim and proposed final work products at every step and invited public comment. During three such cycles, we received and responded publicly to over 1500 comments from a wide spectrum of physicians, hospitals, payers, vendors, and other stakeholders. Our communications and outreach program has included several large Town Hall presentations with attendances in the 500-1000 range at Healthcare Information and Management Systems Society

conferences, as well as more than thirty presentations to physician associations, payer associations, HIT vendor groups, safety net providers, health journalists, and organizations such as NCVHS, ANSI-HITSP, and JCAHO. We also conducted six public Town Call teleconferences, each typically attended by 100-200 people, to explain the work in progress and gather questions and feedback. All work products, presentations, and meeting minutes are published promptly on our website.

To further validate the criteria, a Pilot Test was conducted from December 2005 through February 2006. Following an open call for participation, six EHR products was randomly selected from among those who volunteered to participate, and the compliance criteria and inspection process were subjected to a thorough evaluation. Any criteria not fully validated by the Pilot Test (fewer than 10% fell in this category) will be subject to further refinement and revalidation before becoming part of the required set.

Moving forward, CCHIT will use the same consensus-based process, with discussion among all stakeholders, to refine and update these criteria annually. This will give us the opportunity to include support for the Breakthrough Use Cases as soon as possible after they are finalized. Consistent with the scope of our contract, our first set of criteria covers EHR systems used in ambulatory care. Next year we will introduce criteria for certifying EHR systems in hospital settings, and the following year we will develop criteria for the networks that interconnect EHRs.

I will be honored to attend the May 16th meeting to present this information to the Community, and I look forward to answering any questions you and the Community may have about our work.

Respectfully yours,

Mark Leavitt, MD, PhD
Chair, CCHIT

Functionality Criteria		
Criteria #	**Category**	**Specific Criteria**
1	**Identify and maintain a patient record:** Key identifying information is stored and linked to the patient record. Both static and dynamic data elements will be maintained. A look up function uses this information to uniquely identify the patient.	1. The system shall create a single patient record for each patient.
2		2. The system shall associate (store and link) key identifier information (e.g., system ID, medical record number) with each patient record.
3		3. The system shall store more than one identifier for each patient record.
4		4. The system shall use key identifying information to identify (look up) the unique patient record.
5		5. The system shall provide more than one means of identifying (looking up) a patient.
6		6. The system shall provide a field which will identify patients as being exempt from reporting functions.
7		7. The system shall provide the ability to merge patient information in a controlled method when appropriate.
8	**Manage patient demographics:** Contact information including addresses and phone numbers, as well as key demographic information such as date of birth, gender, and other information is stored and maintained for reporting purposes and for the provision of care.	1. The system shall capture and maintain demographic information as part of the patient record.
9		3. The system shall provide the ability to include demographic information in reports.
10		4. The system shall maintain historic information for prior names and addresses.
11		5. The system shall provide the ability to modify demographic information about the patient.
12		6. The system shall store demographic information in the patient medical record in separate data fields, such that data extraction tools can retrieve these data.
13	**Manage problem list:** Create and maintain patient specific problem lists.	1. The system shall display all current problems associated with a patient.
14		2. The system shall maintain a history of all problems associated with a patient.
15		3. The system shall provide the ability to maintain the onset date of the problem.
16		4. The system shall provide the ability to record the chronicity (chronic, acute/self-limiting, etc.) of a problem.
17		5. The system shall record the user ID and date of all updates to the problem list.
18		6. The system shall provide the ability to associate orders, medications, and notes with one or more problems.
19		7. The system shall provide the ability to maintain a coded list of problems.
20		8. The system shall provide the ability to display inactive and/or resolved problems.
21		9. System shall provide the ability to manually order / sort the problem list

22	**Manage medication list:** Create and maintain patient specific medication lists- Please see DC.1.3.1 for medication ordering as there is some overlap.	1. The system shall create and maintain medication lists.
23		2. The system shall record the prescribing of medications including the identity of the prescriber.
24		3. The system shall maintain medication ordering dates.
25		4. The system shall maintain other dates associated with medications including start, modify, renewal and end dates as applicable.
26		5. The system shall display medication history for the patient.
27		6. The system shall capture medications entered by authorized users other than the prescriber.
28		7. The system shall provide the ability to enter non-prescription medications, including over the counter and complementary medications such as vitamins, herbs and supplements.
29		8. The system shall provide the ability to exclude a medication from the current medication list (e.g., marked inactive, erroneous, completed, discontinued) and document reason for such action.
30		9. The system shall store medication information in discrete data fields such as dose, route, sig, dispense amount, refills, associated diagnoses, etc.
31		10. The system shall provide the ability to print a current medication list.
32		11. The system shall provide the ability to display current medications only.
33		12. The system shall include standard medication codes associated with items in the medication list.
34		13. The system shall provide the ability to enter uncoded or free text medications when medications are not on the standard medication list or information is insufficient to completely identify the medication.
35		14. The system shall alert the user at the time a new medication is prescribed that drug interaction and allergy checking will not be performed against the uncoded or free text medication.
36		15. The system shall provide the ability to enter or further specify in a discrete field that the patient takes no medications.
37		16. The system shall capture and display the identity of the user and date of changes made to the medication list for the patient.
38	**Manage allergy and adverse reaction list:** Create and maintain patient specific allergy and adverse reaction lists.	1.The system shall capture and store lists of medications and other agents to which the patient has had an allergic or other adverse reaction.
39		2. The system shall provide the ability to specify the type of allergic or adverse reaction.
40		3. The system shall provide the ability to remove an item from the allergy and adverse reaction list.
41		4. The system shall provide the ability to specify the reason for removing an allergy/allergen from the allergy list.

42		5. The system shall record the removal of items from the allergy list, including the ID of the user who removed the item and attributes of the items removed.
43		6. The system shall provide the ability to review the allergies for a patient and record the date the review was performed and the ID of the user who performed it.
44		7. The system shall provide the ability to explicitly indicate that a patient has no known drug allergies.
45		8. The system shall provide the ability to display information which has been removed from the list or prior information that has been modified.
46		9. The system shall capture non-drug agents to which the patient has had an allergic or other adverse reaction.
47	**Manage patient history:** Capture, review, and manage medical, procedural/surgical, social and family history including the capture of pertinent positive and negative histories, patient reported or externally available patient clinical history.	1. The system shall capture, store, display, and manage patient history.
48		2. The system shall provide the ability to capture structured data in the patient history.
49		3. The system shall provide the ability to update a patient history by modifying, adding, removing, or inactivating items from the patient history as appropriate.
50		4. The system shall provide the ability to capture patient history as both a presence and absence of conditions, i.e., the specification of the absence of a personal or family history of a specific diagnosis, procedure or health risk behavior.
51		5. The system shall capture history collected from outside sources.
52		6. The system shall capture patient history in a coded form.
53	**Summarize health record**	1. The system shall create and display a summary list for each patient that includes, at a minimum, the active problem list, current medication list, medication allergies and adverse reactions
54	**Manage clinical documents and notes:** Create, correct, authenticate, and close, as needed, transcribed or directly entered clinical documentation.	1. The system shall create clinical documentation or notes (henceforth "documentation").
55		2. The system shall display documentation.
56		3. The system shall save a note in progress prior to finalizing the note.
57		4. The system shall provide the ability to finalize a note, i.e., change the status of the note from in progress to complete so that any subsequent changes are recorded as such.
58		5. The system shall record the identity of the user finalizing each note and the date and time of finalization.
59		6. The system shall provide the ability to cosign a note and record the date and time of signature.
60		7. The system shall provide the ability to addend and/or correct notes that have been finalized.

61		8. The system shall record and display the identity of the user who addended or corrected a note, as well as other attributes of the addenda or correction, such as the date and time of the change.
62		9. The system shall provide the ability to enter free text notes.
63		10. The system shall provide the ability to filter, search or order notes by the provider who finalized the note.
64		11. The system shall provide the ability to filter, search or order notes by associated diagnosis within a patient record.
65		12. The system shall capture patient vital signs, including blood pressure, heart rate, respiratory rate, height, and weight, as discrete data.
66		13. The system shall capture other clinical data elements, such as peak expiratory flow rate, size of lesions, severity of pain, as discrete data.
67		14. The system shall associate standard codes with discrete data elements in a note.
68		15. The system shall provide templates for inputting data in a structured format as part of clinical documentation.
69		16. The system shall provide the ability to customize clinical templates.
70		17. The system shall provide templates for displaying medical summary data in a structured format.
71		18. The system shall display patient-disputed information such that a user could identify it as being disputed.
72		19. The system shall link disputed information to the original entry.
73		20. The system shall identify patient completed information.
74		21. The system shall provide the ability to graph height and weight over time.
~~**75**~~		Removed.
76	**Capture external clinical documents:** Incorporate clinical documentation from external sources.	1. The system shall provide the ability to capture and store external documents.
77		2. The system shall receive, store in the patient's record, and display discrete lab results received through an electronic interface.
78		3. The system shall provide the ability to save scanned documents as images.
79		4. The system shall receive, store in the patient's record, and display text-based outside reports.
80		5. The system shall provide the ability to save radiologic images, slides or other visual data as images.
81		6. The system shall accept, store in the patient's record, and display clinical results received through an interface with an external source.
82		7. The system shall accept, store in the patient's record, and display medication details from an external source.

83		8. The system shall accept, store in the patient's record, and display structured text-based reports received from an external source.
84		9. The system shall accept, store in the patient's record, and display fully structured, codified data received from an external source.
85	**Generate and record patient specific instructions:** Generate and record patient specific instructions as clinically indicated.	1. The system shall provide access to patient instructions and patient educational materials, which may reside within the system or be provided through links to external sources.
86		2. The system shall provide access to medication instructions, which may reside within the system or be provided through links to external sources.
87		3. The system shall provide access to test and procedure instructions that can be customized by the physician or health organization. These documents may reside within the system or be provided through links to external sources.
88		4. The system shall provide the ability to record that patient specific instructions or educational material were provided to the patient.
89		5. The system shall provide the ability to create patient specific instructions.
90	**Order medication:** Create prescriptions or other medication orders with detail adequate for correct filling and administration.	1. The system shall create prescription or other medication orders with sufficient information for correct filling and administration by a pharmacy.
91		2. The system shall provide the ability to set required fields to enforce generation of a complete prescription.
92		3. The system shall record user and date stamp for prescription related events, such as initial creation, renewal, refills, discontinuation, and cancellation of a prescription.
93		4. The system shall capture the identity of the prescribing provider for all medication orders
94		5. The system shall provide the ability to cosign medication orders
95		6. The system shall update the medication history with the newly prescribed medications.
96		7. The system shall provide a list of medications to search from, including both generic and brand name.
97		8. The system shall maintain a coded list of medications.
98		9. The system shall capture common content for prescription details including strength, sig, quantity, and refills to be selected by the ordering clinician.
99		10. The system shall check for daily dose outside of recommended range for patient age (e.g., off-label dosing).
100		11. The system shall provide the ability to select a drug by therapeutic class.
101		12. The system shall display and store information received through electronic prescription eligibility checking.

102		13. The system shall display and store information received through health plan/payer formulary checking.
103		14. The system shall provide the ability to reorder a prior prescription without re-entering previous data (e.g. administration schedule, quantity).
104		15. The system shall provide the ability to print and electronically fax prescriptions.
105		16. The system shall provide the ability to re-print and re-fax prescriptions.
106		17. The system shall provide the ability to submit prescriptions electronically.
107		18. The system shall display a dose calculator for patient-specific dosing based on weight, age, and/or renal function.
108		19. The system shall display patient specific dosing recommendations based on weight, age, and renal function.
109		20. The system shall have the ability to display information about the patient's financial responsibility for the prescription.
110		21. The system shall identify medication samples dispensed, including lot number and expiration date.
111		22. The system shall provide the ability to prescribe fractional amounts of medication (e.g. 1/2 tsp, 1/2 tablet).
112		23. The system shall provide the ability to prescribe uncoded medications.
113		24. The system shall alert the user at the time a new medication is prescribed that drug interaction, allergy, and formulary checking will not be performed against the uncoded medication.
114		25. The system shall provide the ability to update drug interaction databases.
115		26. The system shall alert the user if the drug interaction information is outdated based on the frequency of updates.
116		27. System shall allow the user to configure prescriptions to incorporate fixed text according to the user's specifications and to customize the printed output of the prescription.
117		28. The system shall provide the ability to associate a diagnosis with a prescription.
118		29. The system shall provide the ability to display the problem or diagnosis (indication) on the printed prescription.
119		30. The system shall provide links to general prescribing information at the point of prescribing.
120		31. The system shall provide the ability to create provider specific medication lists of the most commonly prescribed drugs with a default dose, frequency, and quantity.

121		32. The system shall provide the ability to add reminders for necessary follow up tests based on medication prescribed.
122	**Order diagnostic tests:** Submit diagnostic test orders based on input from specific care providers.	1. The system shall provide the ability to order diagnostic tests, including labs and imaging studies.
123		2. The system shall provide the ability to associate a problem or diagnosis with the order.
124		3. The system shall capture the identity of the ordering provider for all test orders.
125		4. The system shall capture applicable co-signatures for all test orders.
126		5. The system shall capture appropriate order entry detail, including associated diagnosis.
127		6. The system shall provide instructions and/or prompts to the ordering user when placing orders for diagnostic tests so that the user supplies all required information.
128		7. The system shall relay orders for a diagnostic test to the correct destination for completion.
129		8. The system shall provide a view of active orders for an individual patient.
130		9. The system shall provide a view of orders by like or comparable type, e.g., all radiology or all lab orders.
131	**Manage order sets:** Provide order sets based on provider input or system prompt, medication suggestions, drug recall updates.	1. The system shall provide the ability to define a set of related orders to be subsequently ordered as a group on multiple occasions.
132		2. The system shall provide the ability to modify order sets.
133		3. The system shall provide the ability to include in an order set orders for medications, laboratory tests, imaging studies, procedures and referrals.
134		4. The system shall provide the ability to display orders placed through an order set either individually or as a group.
135		5. The system shall provide the ability for individual items in an order set to be selected or deselected.
136	**Manage results:** Route, manage, and present current and historical test results to appropriate clinical personnel for review, with the ability to filter and compare results.	1. The system shall indicate normal and abnormal results based on data provided from the original data source.
137		2. The system shall display numerical results in flow sheets and graphical form in order to compare results.
138		3. The system shall display non-numeric current and historical test results as textual data.
139		4. The system shall notify the relevant providers (ordering, copy to) that new results have been received.
140		5. The system shall filter or sort results by patient, type of test, and date.
141		6. The system shall provide the ability to forward a result to other users.
142		7. The system shall provide the ability to transfer the responsibility to perform follow up actions from clinical to other clinical personnel.

143		8. The system shall link the results to the original order.
144		9. The system shall provide the ability to enter a free text annotation to a result.
145		10. The system shall provide the ability to associate one or more images with a result.
146		11. The system shall provide the ability for a user to whom a result is presented to acknowledge the result.
147	**Manage consents and authorizations:** Create, maintain, and verify patient treatment decisions in the form of consents and authorizations when required.	1. The system shall capture scanned paper consent documents (covered in DC 1.1.7).
148		2. The system shall generate both on-line and printable consent forms.
149		3. The system shall store and display administrative authorizations (e.g. privacy notices).
150		4. The system shall store and display authorizations associated with a specific clinical activity (e.g., treatment, surgery) along with that event in the patient's electronic chart.
151		5. The system shall provide the ability to chronologically display consents and authorizations.
152	**Manage patient advance directives:** Capture, maintain, and provide access to patient advance directives.	1. The system shall provide the ability to indicate that a patient has completed advanced directive(s).
153		2.The system shall provide the ability to indicate the type of advanced directives, such as living will, durable power of attorney, or a "Do Not Resuscitate" order.
154		3. The system shall provide the ability to indicate when advanced directives were last reviewed.
155	**Support for standard care plans, guidelines, protocols:** Support the use of appropriate standard care plans, guidelines, and/or protocols for the management of specific conditions.	1. The system shall provide access to standard care plan, protocol and guideline documents when requested at the time of the clinical encounter. These documents may reside within the system or be provided through links to external sources.
156		2. The system shall provide the ability to create site-specific care plan, protocol, and guideline documents.
157		3. The system shall provide the ability to modify site-specific standard care plan, protocol, and guideline documents obtained from outside sources.
158	**Capture variances from standard care plans, guidelines, protocols:** Identify variances from patient-specific and standard care plans, guidelines, and protocols.	1. The system shall provide the ability to record variances from care plans, guidelines, and protocols.
159		2. The system shall provide the ability to record the reason for variation from care plans, guidelines, and protocols.
160	**Support for drug interaction:** Identify drug interaction warnings at the point of medication ordering	1. The system shall check for potential interactions between medications to be prescribed and current medications and alert the user at the time of medication ordering if potential interactions exist.
161		2. The system shall check for potential interactions between medications to be prescribed and medication allergies and intolerances listed in the record and alert the user at the time of medication ordering if potential interactions exist.

162		3. The system shall provide the ability to prescribe a medication despite alerts for interactions and/or allergies being present.
163		4. The system shall provide the ability to set the severity level at which drug interaction warnings should be displayed.
164		5. The system shall check for duplicate therapies by pharmaceutical class and alert the user at the time of medication ordering if such exist.
165		6. The system shall provide the ability to document reasons for overriding a drug interaction warning.
166		7. The system shall provide alerts indicating to the prescriber that certain lab test results may be impacted by a patient's medications.
167		8. The system shall provide the ability to check whether a medication being prescribed has been noted to be ineffective for the patient in the past, and alert the user at the time of medication ordering if noted ineffectiveness exists.
168		9. The system shall provide the ability to display, on demand, potential interactions on a patient's medication list, even if a medication is not being prescribed at the time.
169		10. The system shall provide drug-disease interaction alerts.
170		11. The system shall provide the ability to view the rationale for a drug interaction alert.
171		12. The system shall provide the ability to check for potential interactions between a current medication and a newly entered allergy.
172		13. The system shall generate alerts based on patient age.
173	**Support for medication or immunization administration or supply:** To reduce medication errors at the time of administration of a medication, the patient is positively identified; checks on the drug, the dose, the route and the time are facilitated. Documentation is a by-product of this checking; administration details and additional patient information, such as injection site, vital signs, and pain assessments, are captured. In addition, access to online drug monograph information allows providers to check details about a drug and enhances patient education.	1. The system shall provide the ability to document medication administration.
174		2. The system shall provide the ability to document immunization administration.
175		3. The system shall document immunization, dose, time, route, site, lot number, expiration date, manufacturer, and user ID as structured documentation.
176		4. The system shall provide the ability to indicate a reaction to a specific immunization administration.
177		5. The system shall alert a user at the time of ordering that the patient had a prior adverse reaction to that immunization.
178	**Support for non-medication ordering (referrals, care management)**	1.The system shall create referral orders with detail adequate for correct routing.
179		2. The system shall record user ID and date/time stamp for all referral related events.

180	**Present alerts for disease management, preventive services and wellness:** At the point of clinical decision making, identify patient specific suggestions/reminders, screening tests/exams, and other preventive services in support of disease management, routine preventive and wellness patient care standards.	1. The system shall provide the ability to establish criteria for disease management, wellness, and preventive services based on patient demographic data (minimally age and gender).
181		2. The system shall display alerts based on established guidelines.
182		3. The system shall provide the ability to establish criteria for disease management, wellness, and preventive services based on clinical data (problem list, current medications).
183		4. The system shall provide the ability to update disease management guidelines and associated reference material.
184		5. The system shall provide the ability to update preventive services/wellness guidelines and associated reference material.
185		6. The system shall provide the ability to override guidelines.
186		7. The system shall provide the ability to document reasons disease management or preventive services/wellness prompts were overridden.
187		8. The system shall provide the ability to modify the guidelines.
188		9. The system shall provide the ability to document that a preventive or disease management service has been performed based on activities documented in the record (e.g., vitals signs taken).
189		10. The system shall provide the ability to document that a disease management or preventive service has been performed with associated dates or other relevant details recorded.
189a		11. The system shall provide the ability to be customized to address specific patient situations.
190	**Notifications and reminders for disease management, preventive services and wellness:** Between healthcare encounters, notify the patient and/or appropriate provider of those preventive services, tests, or behavioral actions that are due or overdue.	1. The system shall identify preventive services, tests, or counseling that are due on an individual patient.
191		2. The system shall display reminders for disease management, preventive, and wellness services in the patient record.
192		3. The system shall provide the ability to identify criteria for disease management, preventive, and wellness services based on patient demographic data (age, gender).
193		4. The system shall provide the ability to identify criteria for disease management, preventive, and wellness services based on clinical data (problem list, current medications, lab values).
194		5. The system shall provide the ability to modify the guidelines that trigger the reminders.
195		6. The system shall provide the ability to notify the provider that patients are due or are overdue for disease management, preventive, or wellness services.

196		7. The system shall provide the ability to produce a list of patients who are due or are overdue for disease management, preventive, or wellness services.
197		8. The system shall send an electronic reminder to the patient of services that are due.
198	**Clinical task assignment and routing:** Assignment, delegation and/or transmission of tasks to the appropriate parties.	1. The system shall provide the ability to create and assign tasks by user or user role.
199		2. The system shall provide the ability to present a list of tasks by user or user role.
200		3.The system shall provide the ability to re-assign and route tasks from one user to another user.
201		4. The system shall provide the ability to designate a task as completed.
202		5. The system shall provide the ability to remove a task without completing the task.
203		6. The system shall provide the ability to escalate incomplete tasks to the appropriate supervisor or authority.
204	**Inter-provider communication:** Support secure electronic communication (inbound and outbound) between providers in the same practice to trigger or respond to pertinent actions in the care process (including referral), document non-electronic communication (such as phone calls, correspondence or other encounters) and generate paper message artifacts where appropriate.	1. The system shall provide the ability to document verbal/telephone communication into the patient record.
205		2. The system shall provide the ability to incorporate paper documents from external providers into the patient record.
206		3. The system shall support messaging between users.
207	**Pharmacy communication:** Provide features to enable secure and reliable communication of information electronically between practitioners and pharmacies or between practitioner and intended recipient of pharmacy orders.	1. The system shall provide electronic communication between prescribers and pharmacies or other intended recipients of the medication order.
208		2. The system shall electronically communicate from the prescriber to the pharmacy an initial medication order as well as changes to or renewals of an existing order.
209		3. The system shall capture any acknowledgments, prior authorizations, renewals, inquiries and fill notifications provided by the pharmacy or other participants in the electronic prescription.
210	**Provider demographics:** Provide a current directory of practitioners that, in addition to demographic information, contains data needed to determine levels of access required by the EHR security and to support the practice of medicine.	1. The system shall maintain a directory of all clinical personnel who currently use or access the system.
211		2. The system shall maintain a directory which contains identifiers required for licensed clinicians to support the practice of medicine including at a minimum state medical license, DEA, NPI, and UPIN number.
212		3. The system shall maintain a directory that stores user attributes required to determine the system security level to be granted to each user.
213		4. The system shall allow authorized users to update the directory.

214		5. The system shall maintain a directory of clinical personnel external to the organization who are not users of the system to facilitate communication and information exchange.
215	**Scheduling:** Support interactions with other systems, applications, and modules to provide the necessary data to a scheduling system for optimal efficiency in the scheduling of patient care, for either the patient or a resource/device.	1. The system shall display a schedule of patient appointments, populated either through data entry in the system itself or through an external application interoperating with the system.
216	**Report Generation:** Provide report generation features for the generation of standard and ad hoc reports	1. The system shall provide the ability to generate reports of clinical and administrative data using either internal or external reporting tools.
217		2. The system shall provide the ability to generate reports consisting of all or part of an individual patient's medical record (e.g. patient summary).
218		3. The system shall provide the ability to generate reports regarding multiple patients (e.g. diabetes roster).
219		4. The system shall provide the ability to specify report parameters (sort and filter criteria) based on patient demographic and clinical data (e.g., all male patients over 50 that are diabetic and have a HbA1c value of over 7.0 or that are on a certain medication).
220		5. The system shall provide the ability to access reports outside the EHR application.
221		6. The system shall provide the ability to produce reports based on the absence of a clinical data element (e.g., a lab test has not been performed or a blood pressure has not been measured in the last year).
222		7. The system shall provide the ability to save report parameters for generating subsequent reports.
223		8. The system shall provide the ability to modify one or more parameters of a saved report specification when generating a report using that specification.
224	**Health record output:** Allow users to define the records and/or reports that are considered the formal health record for disclosure purposes, and provide a mechanism for both chronological and specified record element output.	1. The system shall provide the ability to define one or more reports as the formal health record for disclosure purposes.
225		2. The system shall provide the ability to generate hardcopy or electronic output of part or all of the individual patient's medical record.
226		3. The system shall provide the ability to generate hardcopy and electronic output by activities and events on a chosen date and/or date range (e.g., all hospital discharge summaries).
227		4. The system shall provide the ability to de-identify protected health information (PHI) on the hardcopy and electronic output, but leave the actual PHI data unmodified in the original record.

228		5. The system shall create hardcopy and electronic report summary information (procedures, medications, labs, immunizations, allergies, and vital signs).
229		6. The system shall provide support for disclosure management in compliance with HIPAA and applicable law.
230	**Encounter management:** Manage and document the health care delivered during an encounter.	1. The system shall provide the ability to document a patient encounter.
231		2. The system shall provide the ability to document encounters by one or more of the following means: direct keyboard entry of text; structured data entry utilizing templates, forms, pick lists or macro substitution; dictation with subsequent transcription of voice to text, either manually or via voice recognition system.
232		3. The system shall provide the ability to associate individual encounters with diagnoses.
233		4. The system shall provide filtered displays of encounters based on encounter characteristics, including date of service, encounter provider and associated diagnosis.
234	**Rules-driven financial and administrative coding assistance:** Provide financial and administrative coding assistance based on the structured data available in the encounter documentation.	1. The system shall provide a list of financial and administrative codes.
235		2. The system shall provide the ability to select an appropriate CPT Evaluation and Management code based on data found in a clinical encounter.
236		3. The system shall provide assistance in selecting appropriate billing codes based on codified clinical information in the encounter.
237		4. The system shall prompt for data required to determine appropriate administrative (evaluation & management) codes if such data is not present in encounter data.
238	**Eligibility verification and determination of coverage**	1. The system shall display medical eligibility obtained from patient's insurance carrier, populated either through data entry in the system itself or through an external application interoperating with the system.
239		2. The system shall store and display information received through electronic prescription eligibility checking.
240	**Manage Practitioner/Patient relationships:** Identify relationships among providers treating a single patient, and provide the ability to manage patient lists assigned to a particular provider.	1. The system shall identify by name all providers associated with a specific patient encounter.
241		2. The system shall provide the ability to specify the role of each provider associated with a patient, such as encounter provider, primary care provider, attending, resident, or consultant.
242		3. The system shall provide the ability to specify the primary or principal provider responsible for the care of a patient within a care setting.
243		4. The system shall create a list of all patients who have had an encounter with a given provider.

244	**Clinical decision support system guidelines updates:** Receive and validate formatted inbound communications to facilitate updating of clinical decision support system guidelines and associated reference material	1. The system shall provide the ability to update the clinical content or rules utilized to generate clinical decision support reminders and alerts.
245		2. The system shall provide the ability to update clinical decision support guidelines and associated reference material.
246	**Entity Authorization:** Manage the sets of access control permissions granted to entities that use an EHR-S. Enable EHR-S security administrators to grant authorizations to users for roles, and within contexts. A combination of the authorization levels may be applied to control access to EHR-S functions or data within an EHR-S, including at the application or the OS level.	1. The system shall provide the ability to designate certain note types, medications, tests, etc. as confidential and only make those values accessible by appropriately authorized users.
247	**Enforcement of confidentiality:** Enforce the applicable jurisdiction's patient privacy rules as they apply to various parts of an EHR-S through the implementation of security mechanisms.	1. The system shall audit the date/time and user of each instance when a patient chart is printed
248		2. The system shall provide the ability for the patient to review, and for patient-disputed information to be documented in, the chart.
249		3. The system shall identify all users who have accessed an individual's chart over a given time period.
250		4. The system shall provide the ability to identify certain information as confidential and only make that accessible by appropriately authorized users.
251		5. The system shall provide the ability to prevent specified user(s) from accessing a designated patient's chart
252	**Data retention, availability, and destruction:** Retain, ensure availability, and destroy health record information according to organizational standards. This includes: Retaining all EHR-S data and clinical documents for the time period designated by policy or legal requirement; Retaining inbound documents as originally received (unaltered); Ensuring availability of information for the legally prescribed period of time; and Providing the ability to destroy EHR data/records in a systematic way according to policy and after the legally prescribed retention period.	1. The system shall retain data until otherwise purged, deleted, archived or otherwise deliberately removed.
253		2. The system shall provide a method for archiving health record information.
254		3. The system shall provide the ability to support retention periods as determined by applicable local, state or federal requirements.
255	**Audit trail:** Provide audit trail	1. The system shall provide the ability to audit information exchange.

256	capabilities for resource access and usage indicating the author, the modification (where pertinent), and the date and time at which a record was created, modified, viewed, extracted, or removed. Audit trails extend to information exchange and to audit of consent status management (to support DC.1.5.1) and to entity authentication attempts. Audit functionality includes the ability to generate audit reports and to interactively view change history for individual health records or for an EHR-system.	2. The system shall audit the receipt of documents.
257	**Extraction of health record information:** Manage data extraction in accordance with analysis and reporting requirements. The extracted data may require use of more than one application and it may be pre-processed (for example, by being de-identified) before transmission. Data extractions may be used to exchange data and provide reports for primary and ancillary purposes.	1. The system shall provide the ability to export (extract) pre-defined set(s) of data out of the system
258		2. The system shall provide the ability to import data into the system
259		3. The system shall provide the ability remove discrete patient identifiers.
260		4. The system shall provide the ability to track the intended destination of the extracted information.
261	**Concurrent Use:** EHR system supports multiple concurrent physicians through application, OS and database.	1. The system shall provide the ability for multiple users to interact concurrently with the EHR application.
262		2. The system shall provide the ability for concurrent users to simultaneously view the same record.
263		3. The system shall provide the ability for concurrent users to view the same clinical documentation or template.
264		4. The system shall provide record level protection to maintain the integrity of clinical data.

Interoperability Criteria		
Criteria #	**Category**	**Specific Criteria**
1	**Laboratory and Imaging**	Receive lab results (no specified format) – self attestation
2		Receive general laboratory results using common vocabulary with inbound interface optionality removed
3		Send orders to lab systems
4		(1) Create and share sets of digital medical images managed by PACS (2) create and share imaging reports like EKGs (3) web access to digital medical images and reports from EHRs
5		Order and schedule radiology tests
6	**Medications**	Transmission of prescriptions
7		**Use Standardized Communication of Sig instructions in e-prescribing.**
8		Query and receive medication information
9		(1) Query and receive eligibility information - (2) Distribute Formulary and Benefits Information
10		Receive medication fulfillment history
11	**Immunizations**	Report patient immunizations
12		**Retrieve immunization history from registry**
13	**Clinical Documentation**	Register documents with registry: Basic RHIO functionality
14		**Query registry for documents:** Basic RHIO functionality
15		**Send documents to repository:** RHIO functionality (with repository)
16		**Refer or transfer clinical care of patient**
17		**Communicate data to PHRs**
18		**Receive data from PHRs**
19	**Secondary Uses of Clinical Data**	**Public Health Disease Reporting**
20		**Quality Improvement reporting**
26		**Practice Management System Communication Revenue Cycle Related Transactions Query and receive electronic eligibility information**
21	**Administrative and Financial Data**	**Enable patient & user identity correlation.** Coordinate patient information
22		**Patient administration**
23		**Scheduling**
24		**Receive electronic authorization for referral (from payor)**
25		**Clinical Trials**

Security Criteria		
Criteria #	**Category**	**Specific Criteria**
S1	**Security: Access Control**	The system shall enforce the most restrictive set of rights/privileges or accesses needed by users/groups (e.g. System Administration, Clerical, Nurse, Doctor, etc.), or processes acting on behalf of users, for the performance of specified tasks.
S2		The system shall provide the ability for authorized administrators to assign restrictions or privileges to users/groups.
S3		The system must be able to associate permissions with a user using one or more of the following access controls: 1) user-based (access rights assigned to each user); 2) role-based (users are grouped and access rights assigned to these groups); or 3) context-based (role-based with additional access rights assigned or restricted based on the context of the transaction such as time-of-day, workstation-location, emergency-mode, etc.)
S4		The system shall support revocation of the access privileges of a user without requiring deletion of the user.
S5.1	**Security: Audit**	The system shall be able to generate an audit record when auditable events happen, including but not limited to the following (success, attempt, and failure): User Login/Logout, Chart created/viewed/updated/deleted, and System Security Administration.
S5.2		The system shall be able to generate an audit record when auditable events happen, including but not limited to the following (success, attempt, and failure): system start/stop, User Login/Logout, Chart created/viewed/updated/deleted, Scheduling, Query, Order, Node-authentication failure, Signature created/validated, PHI export (e.g. print), PHI import, and System Administration.
S6		The system shall record within each audit record the following information when it is available: (1) date and time of the event; (2) the component of the information system (e.g., software component, hardware component) where the event occurred; (3) type of event (including: data description and patient identifier when relevant); (4) subject identity (e.g. user identity); and (5) the outcome (success or failure) of the event.
S7		The system shall provide authorized administrators with the capability to read all audit information from the audit records in one of the following two ways: 1) The system shall provide the audit records in a manner suitable for the user to interpret the information. The system shall provide the capability to generate reports based on ranges of system date and time that audit records were collected. 2) The system shall be able to export logs into text format and correlate records based on time (e.g., UTC synchronization).
S8.1		The system shall be able to provide time synchronization using NTP/SNTP, and use this synchronized time in all security records of time.

S8.2		The system shall record time stamps using UTC based on ISO 8601-2000. Example: "1994-11-05T08:15:30-05:00" corresponds to November 5, 1994, 8:15:30 am, US Eastern Standard Time.
S9		The system shall prohibit all users read access to the audit records, except those users that have been granted explicit read-access. The system shall protect the stored audit records from unauthorized deletion. The system shall be able to prevent modifications to the audit records.
S10		The system shall continue normal operation even when security audit facility is non-functional. (For example, if the audit log reaches capacity, the system should continue to operate and should either suspend logging, start a new log or begin overwriting the existing log.)
S11		The system shall allow an authorized administrator to set the inclusion or exclusion of audited events based on organizational policy & operating requirements/limits.
S12	**Security: Authentication**	The system shall authenticate the user before any access to Protected Resources (e.g. PHI) is allowed including when not connected to a network e.g. mobile devices.
S13		When passwords are used, the system shall support password strength rules that allow for minimum number of characters, and inclusion of alpha-numeric complexity.
S14		The system upon detection of inactivity shall prevent further viewing and access to the system by initiating a session lock that remains in effect until the user reestablishes access using appropriate identification and authentication procedures. The inactivity timeout shall be configurable.
S15		The system enforces a limit of [Assignment: organization-defined number] consecutive invalid access attempts by a user during a [Assignment: organization-defined time period] time period. The information system shall protect against further malicious user authentication attempts using an appropriate mechanism (e.g. locks the account/node until released by an administrator, locks the account/node for an [Assignment: organization-defined time period], or delays next login prompt according to [Assignment: organization-defined delay algorithm])
S16.1		When passwords are used, the system shall provide an administrative function that resets passwords.
S16.2		When passwords are used, user accounts that have been reset by an administrator shall require the user to change the password at next successful logon.
S17		The system shall provide only limited feedback information to the user during the authentication.
S18		The system shall support case insensitive usernames that contain typeable alpha and numeric characters in support of ISO-646/ECMA-6 (aka US ASCII).

S19		When passwords are used, the system shall allow an authenticated user to change their password consistent with password strength rule **(#13)** that allow for minimum number of characters, and inclusion of alpha-numeric complexity.
S20		When passwords are used, the system shall support case sensitive passwords that contain typeable alpha and numeric characters in support of ISO-646/ECMA-6 (aka US ASCII).
S21		When passwords are used, the system shall not store passwords in plain text.
S22		When passwords are used, the system shall prevent the reuse of passwords within a specific timeframe.
S23		The system shall include documentation that covers:Method used to create, modify, and remove user accounts.
S24	**Security: Technical Services**	The system shall support protection of confidentiality of all Protected Health Information (PHI) delivered over the Internet or other known open networks via encryption using triple-DES (3DES) or the Advanced Encryption Standard (AES) and an open protocol such as TLS, SSL, IPSec, XML encryptions, or S/MIME or their successors.
S25		The system shall support protection of integrity of all Protected Health Information (PHI) delivered over the Internet or other known open networks via SHA1 hashing and an open protocol such as TLS, SSL, IPSec, XML digital signature, or S/MIME or their successors.
S26		When passwords are used, the system shall not display passwords while being entered.
S27		If the system provides a web (HTTP) interface, then it shall provide an SSL configuration mechanism. (E.g. This might be a manual that describes the proper configuration steps.)
S28		The system shall support protection of integrity of all Protected Health Information (PHI) delivered over the Internet or other known open networks via SHA1 hashing and an open protocol such as TLS, SSL, IPSec, XML digital signature, or S/MIME or their successors.
S29		The system shall support ensuring the authenticity of remote nodes (mutual node authentication) when communicating Protected Health Information (PHI) over the Internet or other known open networks using open protocol (e.g. TLS, SSL, IPSec, XML sig, S/MIME).
R1	**Reliability: Backup / Recovery**	The system shall generate a backup copy of the application data, security credentials, and log/audit files.
R2		The system restore functionality shall result in a fully operational and secure state. This state shall include the restoration of the application data, security credentials, and log/audit files to their previous state.
R3		If the system claims to be available 24x7 then the system shall have ability to run a backup concurrently with the operation of the application.
R4	**Reliability: Documentation**	The vendor shall provide documentation on known issues regarding the use of off-the-shelf malware detection and eradication software.

R5		If the system includes hardware, then the system shall include documentation that covers: Expected physical environment necessary for proper secure & reliable operation of the system including: electrical, HVAC, sterilization, and work area.
R6		Removed
R7		The system shall include documentation that covers: The services (e.g. php, web service) and network protocols/ports (e.g. hl7, http, ftp) that are necessary for proper operation and servicing of the system, including justification of the need for that service and protocol. This information may be used by the healthcare facility to properly configure their network defenses (firewalls and routers).
R8		The system shall include documentation of known conflicts with security services (e.g. antivirus, intrusion detection, malware eradication, host based firewall, etc.) and the resolution of that conflict.
R9		The system shall include documentation that covers: The steps needed to confirm that the installation was properly completed and that the system is operational.
R10		The system shall include documentation that covers: The patch (hot-fix) handling process the vendor will use for EHR, operating system and underlying tools. (e.g. specific web site where patch notices are, approved patch list, special instructions for installation, and post installation test).
R11		The system shall include documentation that explains system error or performance messages to users and administrators, with actions required.
R12		The system shall have documentation of product capacities (e.g. number of users, number of transactions per second, number of records, network load, etc.) given a baseline representative configurations (e.g. number or type of processors, server/workstation configuration and network capacity, etc).
R13		The system shall include documented procedures for product installation, start-up and/or connection.
R14	**Reliability: Technical Services**	The system, including installation media, shall be free of currently, well-known malware.
R15		Removed
R16		The system shall include documentation of the minimal privileges necessary for each service and protocol necessary to provide EHR functionality and/or serviceability.
R17		The system shall be configurable to prevent corruption or loss of data already accepted into the system in the event of a system failure (e.g. integrating with a UPS, etc.).
R18	**Reliability: Documentation**	The system shall include documentation that covers: Guidelines for proper configuration of the EHR security controls (e.g. users, roles management, password management, audit logs) necessary for proper secure and reliable operation of the system.
R19		Removed