**Testimony of Charlene Underwood,
HIMSS EHR Vendors Association**

**Hearing on Functional Requirements for
the Nationwide Health Information Network
National Committee on Vital and Health Statistics (NCVHS)**

July 27, 2006

Thank you, Chairman Cohn and other members of the Committee for the opportunity to testify before you today on behalf of the HIMSS Electronic Health Record Vendors Association (EHRVA). My name is Charlene Underwood, Director of Government and Industry Affairs for Siemens Medical Solutions and Chair of the EHRVA. EHRVA is a trade association representing 41 of the leading ambulatory and
5   enterprise Electronic Health Record system (EHRs) vendors that addresses national efforts to create interoperable EHRs in hospital and ambulatory care settings.

The EHRVA was created to provide a forum for the vendor community to work together, where appropriate, on topics that affect the adoption of EHRs across the healthcare setting. We believe that rapid, widespread adoption of EHRs will help improve the quality of patient care and the productivity of
10   the healthcare system.

In order to realize the maximum value from EHRs, however, it will be necessary for disparate systems – whether developed by different vendors or existing in different parts of the country – to be able to share patient data accurately and securely. Coherent standards will form the basis for interoperability. Just as standards enabled different financial institutions' ATMs to talk to each other, interoperability standards will
15   enable the appropriate sharing of medical information. Although the content of healthcare records is significantly more complex, ATMs and other technologies demonstrate that the technological aspects of interoperability are clearly achievable.

We have already seen the positive impact of vendor collaboration in the creation of global HIT standards. For example, the Digital Imaging and Communications in Medicine (DICOM) standard for sharing images
20   was the result of user and vendor collaboration spanning national borders, in order to achieve "out-of-the-box" sharing of images. Diagnostic imaging vendors historically used proprietary formats which allowed CT and MR images to be shared among systems supplied by the same vendor, but not between competing systems. DICOM allowed images to move from system to system, enabled hospitals to centralize storage of images to reduce costs, and led the radiology department to move toward
25   diagnosing images on a computer screen. Significantly, DICOM was rapidly and widely adopted because it was the result of a joint effort among the radiology community and diagnostic imaging vendors rather than the product of government intervention.

The popularity of DICOM led to a desire for improving information exchange between the radiology department and other clinical IT systems in the hospital. To accomplish this, the Radiological Society of
30   North America, the Health Information Management and Systems Society (HIMSS), the American College of Cardiology, the American College of Physicians, and other professional organizations sponsor a user-led initiative known as Integrating the Healthcare Enterprise (IHE) to create a standards-based framework for clinical IT. IHE's interoperability showcases – held at major industry conferences – encourage competing vendors to build and demonstrate data exchange between their products via a collaborative
35   and transparent process. IHE's scope includes radiology images, medical summaries, laboratory results, and cardiology reports – the very information that today is often still faxed, couriered, or mailed between providers at the majority of healthcare organizations in the U.S.

EHRVA's approach to interoperability is modeled on IHE's proven methodology. By working together, vendors, providers, and industry experts can drive change and improve the processes by which
40   healthcare is delivered. EHRVA's mission is not to develop standards, but rather to help stakeholders focus their efforts, to support the work of standards development organizations such as HL7 or ASTM, and to encourage adoption of standards by our members and other stakeholders. We have also been actively involved in organizations such as the Health Information Technology Standards Panel (HITSP).

Developing standards for health IT requires an understanding of the processes to be automated and the
45   data needed to support those processes. As these activities have evolved during the past 20 years, standards are beginning to emerge in some areas. Ultimately, a single set of standards that is adopted by most (if not all) vendors is necessary to ensure connectivity.

The EHRVA Interoperability Roadmap (available at http://www.ehrva.org) was developed using input from key stakeholders to support the national goal of interoperable electronic health records by the year 2014. Recognizing that this is a complex goal, the Roadmap presents a phased approach that will deliver incremental benefits by leveraging technology that is available now and incorporating new functions as they become viable. The Roadmap is based on accepted and tested standards and allows for a variety of organizational and information-exchange models across the healthcare continuum. The organizing principle is that of empowering patients and delivering care in a patient-centric manner.

EHRVA's vision is that this Roadmap will mobilize the leadership of healthcare organizations, information technology vendors, and other relevant stakeholders to work toward the common goal of interoperability.

Fostering collective agreement through a collaborative process

While vendors are not bound by EHRVA's recommendations, there are acknowledged reasons to follow a common Roadmap. Interoperability succeeds only to the extent that the majority of vendors implement a common technical framework. In the long run, it is in the interests of vendors and other stakeholders to face ongoing challenges and make compromises for the greater good of all care providers and, in the end, patients. Achieving interoperability will require coordinated strategies that help providers achieve optimum workflow with reasonable investment, while building toward an increasingly consumer/patient centric model of healthcare. Without this, we will perpetuate the current Babel of incompatible systems that are difficult and costly to implement, and we will fail to realize the benefits that the NHIN can provide.

ERHVA has worked extensively not only with member vendors but with a variety of other stakeholders in developing its Roadmap, in order to promote broad adoption. We have worked in conjunction with:

- Standards development organizations (SDOs) at both the national and international level;
- International standards adoption organizations;
- HIT advocacy organizations such as Connecting for Health;
- Several national health information technology (HIT) program organizations; and
- Professional societies representing clinicians spanning diverse clinical specialties.

The experience of EHRVA members worldwide indicates that most of the interoperability components needed for national HIT programs in clinical information are common to a high degree across national boundaries. Relatively few areas require specific national customization, and those that do can be more easily implemented as national extensions to the underlying standards, rather than as separate (and possibly competing) standards. Because diseases do not recognize national borders, surveillance for bioterrorism or epidemics such as avian flu will be more effective if systems are interoperable across those borders as well. U.S. status with various international organizations may ultimately be affected by how well we can respond to these challenges as part of a global paradigm. Further, the ability of U.S. IT vendors to compete in a global market will be fostered by international standards.

Articulating the desired outcome and value to the healthcare system

Widespread adoption of HIT is necessary to achieve the vision of an electronic health record. Only when caregivers' processes are demonstrably improved, and quality and cost benefits realized, will significant private investment be made in technology. The Roadmap considers this and defines the value needed to facilitate adoption of technology. This value, along with the direction given by the American Health Information Community (AHIC), drives the logical sequence of components defined within the Roadmap.

Defining the Core Technical Framework and approach to interoperability

The Roadmap defines essential elements and requirements of the proposed nationwide health information network (NHIN) as well as any local or regional health information organization (RHIO). These elements include:

- Utilize "thin" architecture for the core NHIN and its subnetworks, and leverage the functionality of the edge systems that connect to it;

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- Create an architecture with the necessary flexibility to support centralized or distributed data repositories within the NHIN and its subnetworks without the need for multiple boundary interfaces to edge systems; and

- Simplify the infrastructure by limiting the number of core functions that are included within the NHIN and its subnetworks (see next section).

100 In this context, it is important to recognize that the role of the NHIN and its subnetworks is as a set of communications services that enable information to be shared or exchanged among applications such as EHRs or lab or pharmacy systems. The NHIN and its subnetworks are not applications or systems. The significance of this distinction is to ensure that the focus remains on the needs of the clinical end-users and the information they exchange.

105 Building the NHIN as a thin infrastructure and allowing it to leverage the capabilities of existing edge systems (EHRs and others) will be more cost-effective than duplicating edge system functionality within the core. Thin architecture can evolve more easily, without creating additional barriers to future evolution of the edge systems. Keeping the infrastructure simple, rather than building a lot of functionality into it, means that users will be able to access the NHIN from a variety of different types of edge systems. It would not require that every provider have a full EHR in order to access the NHIN.

110 In this model, the functional requirements of the NHIN would focus on ensuring transparency at the boundaries between core and edge systems, and at the boundaries between edge systems. The role of the infrastructure would be to move data from one system to another, with a minimum of data actually stored within the core. This provides necessary flexibility to support subnetworks of the NHIN (RHIOs) regardless of whether their data is centralized or distributed. This flexibility will reduce the cost of 115 development for edge systems by avoiding a proliferation of interfaces: a vendor can rely on a single solution that will work within either a centralized or distributed environment.

Similarly, limiting the core functions of the NHIN will lead to more uniformly robust edge systems, without the need to market many different variations.

Identification of the Fundamental Requirements and Infrastructure

120 The phased approach of the Roadmap defines and delivers required infrastructure to facilitate cross-enterprise and constituent communication, including:

- Security and access control;

- Patient/provider identity management;

- Persistent information management (storing/sharing aggregated records from uncoordinated 125 sources across time, *e.g.*, medical summaries);

- Dynamic information access (direct request/response interactions to specific target systems, *e.g.*, query of immunization registry); and

- Workflow and quality (cooperative work distributed across entities, *e.g.*, ordering and results of lab tests or prescriptions).

130 (Appendix A defines how these functions support the NCVHS functional categories.)

Of these five functions – which have both edge-to-edge and edge-to-core components – the first two are foundational to the NHIN; without these, nothing else can be accomplished.

Once those have been established, the first priority should be persistent information management. Also referred to as "document sharing" by analogy with the world of paper records, the fundamental

135   characteristic of persistent information management is to allow the longitudinal aggregation of a health record with incrementally added content from uncoordinated multiple sources over time. Each electronic "document" includes both specific medical information about the patient plus sufficient context to provide a level of confidence in the data – for example, the prescribed medications associated with a recorded medical history and the known allergies at the time care was provided for the diagnosed problems – in a

140   form which can be both read by a provider and processed by a computer. Each source is responsible for maintaining its own contribution to the record, which can include medical summaries (problems, medications allergies, etc.), radiology reports or images, laboratory results, or any other data that may be collected about the patient. All of the AHIC/ONC use cases identified to date rely on such document sharing.

145   Again, the structure of the NHIN needs to be flexible enough to allow persistent data to reside either in the core or in the edge systems. RHIOs should be the decision-makers about where their data is stored. In this way, the NHIN will be able to accommodate the largest variety of edge systems.

In the phased approach that EHRVA is proposing (explained in more detail below), document sharing comprises Phase 1, while dynamic queries and workflow are later priorities that are part of Phase 2. The

150   model allows for some temporal overlap between the phases, so that some simplified areas of workflow (*e.g.*, delivery of lab results to ordering providers) could be in place before Phase 1 is completed.

Implementation Plan and Timeframe

The EHRVA Interoperability Roadmap is based on three specific architectural and process assumptions for implementing a nationwide health information network:

155   - Healthcare applications are "edge" systems connected to a "thin" NHIN.

- The NHIN should be deployed by encouraging sub-networks managed by sub-network organizations (e.g. RHIOs). All sub-networks must use the same "common framework" of interoperability standards and policies to ensure reuse of products, experience, and easy flow of nationwide health information.

160   - The NHIN should be deployed utilizing an approach that allows the incremental deployment of functions to provide healthcare information exchange.

EHRVA expects the Interoperability Roadmap to be delivered in four phases, each driven by use cases that explain why information exchange is necessary. These phases build on each other and provide increasingly rich functionality to deliver the electronic health record within President Bush's requested

165   timeframe.

- **Phase 1: Share Care Status Information:** Structured medical summaries support transition of care among providers.

- **Phase 2: Share Diagnostic Results and Therapeutic Information:** Adds patient-created information and emergency summaries plus e-Lab and e-Prescription, with selected coded

170   information.

- **Phase 3: Advanced Clinical Support and Access Control:** Extends access control, exchange of continuity of care documents and dynamic queries for medications and allergies with extensively coded information.

- **Phase 4: Collaborative Care, Active Quality Reporting and Health Surveillance:** Introduces

175   workflow-oriented collaborative services and the second generation of public health surveillance and quality reporting.

Extensive work, representing hundreds of person-years, has already been undertaken by a wide range of HIT vendors, providers, and other stakeholders worldwide to advance the interoperability solutions presented in the Roadmap. Full specifications for Phase 1 are contained in the current version of the EHRVA Interoperability Roadmap. Early implementations of Phase 1 functionality were introduced in early 2006 and were demonstrated to provide interoperability among more than 20 different electronic health record (EHR) systems, ancillary IT systems, and IT infrastructure components. Several regional projects in the U.S., as well as regional and national projects in other countries, will deploy later in 2006. Specification of Phase 2 integration profiles is under way, with testing planned for 2007. Hundreds of person-years of work have been and continue to be invested by HIT vendors (i.e., not only EHR vendors), providers and other stakeholders world-wide to advance the interoperability solutions presented in this Roadmap.

Support for AHIC "Breakthrough" implementation

AHIC has published four key areas of focus for the industry as it relates to HIT. These "breakthrough" use cases are biosurveillance, chronic care, consumer empowerment, and EHRs. As the HITSP interoperability specifications are refined, EHRVA expects that the Phase 1 and Phase 2 communication services of this Roadmap will offer many of the required interoperability elements.

Enabling the Transformation: Next steps

No single stakeholder can achieve implementation of interoperable electronic health records. Thus, a collaborative process that actively involves and serves to unite HIT vendors, providers, standards development organizations and other stakeholders is a prerequisite to success of the NHIN. The process, as illustrated by the Interoperability Roadmap, should:

1. Acknowledge and access the experience of industry stakeholders in an open dialogue that values the contribution of all stakeholders;

2. Utilize a pragmatic business case-oriented approach to planning; and

3. Evaluate and harmonize national and private sector initiatives.

What we have not included in the Roadmap is the wholesale development of more standards. We recommend instead an accepted, collaborative effort to determine where standards are needed, review existing standards, and agree which can be applied to HIT. If there are no directly applicable standards, the next step would be to expand on existing standards – including those from outside the healthcare industry. New standards should be developed only as a last resort. Our goal should be to arrive at the minimum number of standards in order to simplify the realization of interoperability.

In any transformation, both the journey and the destination are significant. EHRVA's vision of the destination is a thin, flexible, cost-effective infrastructure that leverages existing edge functionality and supports the greatest variety of edge systems. We need not – and must not – wait until we arrive there to start reaping the benefits, however. Incremental implementation of defined milestones will serve as a foundation for further achievements, ultimately hastening completion of the entire network. More importantly, incremental implementation will deliver immediate and ongoing benefits for both patients and providers in terms of both quality of care and productivity of the healthcare system.

On behalf of EHRVA, Mr. Chairman, I want to express my gratitude for the opportunity to share with you our perspective on creating the nationwide health information network. I would be happy to answer any questions you and the Committee might have.

EHRVA
HiMSS Electronic Health Record Vendors Association

APPENDIX A:
Comparison of NHIN Functional Categories with
EHRVA Roadmap Category of Communication Services

Comparison of NHIN Functional Categories with EHRVA Roadmap Category of Communication Services

The Category of Communication Services is defined in the EHRVA Roadmap (www.himssehrva.org) on pages 21 through 23

NHIN Functional Categories	Category of Communication Services	Edge HIT System Role	NHIN Role (Core)
Audit and logging	Security and Identity	Shared	Shared
Authentication	Security and Identity	Primary	Secondary
Authorization	Security and Identity	Primary	Secondary
Confidentiality	Security and Identity	Shared	Shared
Credentialing	Security and Identity	Primary	Secondary
Data access and update	Persistent Information Management (retrieve, replace and append)	Primary	See Record Location
Data access and update	Dynamic Information Access (Query)	Primary	See Data routing
Data content	Persistent Information Management	Primary	No, except to set content standards
Data filtering	Persistent Information Management	Primary	Secondary: See record location
Data mapping/translation	Persistent Information Management	Primary	No, except terminology mapping services
Data quality/data integrity	Persistent Information Management	Primary	No, but shall preserve integrity
Data rendering	Persistent Information Management	Primary	No
Data retrieval (pull)	Persistent Information Management	Primary	Secondary, See persistent data storage
Data routing	Dynamic Information Access / Workflow	Secondary	Primary
Data source	Persistent Information Management / Workflow / Dynamic Information Access	Primary	No
Data transmission (push)	Persistent Information Management (provide document and register)	Primary	Secondary See Record Locator and Persistent Data Storage
Data transmission (push)	Workflow / Dynamic Information Access	Primary	Secondary, See Data Routing
Data usage	Persistent Information Management / Workflow / Dynamic Information Access	Primary	No (Public Health are edge systems)
Identity/information correlation	Security and Identity	Secondary	Primary
Persistent data storage	Persistent Information Management	Either shall have the possibility of being Primary	
Record location	Persistent Information Management (Document locator service)	Secondary	Primary
Transient data	Workflow / Dynamic Information Access	Primary	Secondary, See Routing