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in Support of HR 2406

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Good morning. My name is Michael Raymer, and I am vice president and general manager of global product strategy for GE Healthcare Integrated IT Solutions. I want to thank the committee for giving me the opportunity to testify today.

GE supports the goal of creating a nationwide health information infrastructure. To that end, we also support initiatives to coordinate the work of various federal and state agencies and the private sector in achieving that goal. It is important, however, that this coordination does not interfere with the valuable work that has been done to date.

GE's Role in Promoting Interoperability

GE has a long history of successfully driving open, standards-based data exchange with other vendors. The earliest example is the Digital Imaging and Communications in Medicine (DICOM) standard, which has enabled diagnostic imaging devices and software systems to exchange images and related information regardless of vendor. Diagnostic imaging vendors historically created proprietary formats for the CT or MR images created by their systems. While image exchange was interoperable between systems supplied by the same vendor, this was not the case among systems supplied by competing vendors. This lock-in limited the flexibility of hospital radiology departments to utilize imaging technology in an optimum fashion. 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 towards diagnosing images on a computer screen. Consequently, DICOM enabled the creation of today's \$2 billion picture archiving and communications systems (PACS) market, while also enabling many hospitals to eliminate one of their highest expenses from their operating budgets: film. PACS has transformed the workflow within the radiology department, leading to increased efficiency and higher quality of care. Physicians at different locations can consult while simultaneously examining the same images and

comparing them with other clinical results to get a more complete picture of the patient's condition.

GE has been instrumental in HL7 standards efforts, representing users and vendors in the definition of clinical document sharing and context setting (user and patient) standards. GE's Centricity® EMR was the first major healthcare information system to provide a production- ready CCOW-compliant product. GE also worked with the HL7 board and industry vendors to define strategies for broad vendor adoption of CCOW.

And, GE is one of the founders of the Health Information and Management Systems Society (HIMSS) EHR Vendor Association (EHRVA), a group of the top 42 EHR vendors committed to making EMRs interoperable and to accelerating EMR adoption in hospital and ambulatory care settings. EHRVA is playing a pivotal role in creating and driving a single set of standards for electronic health records interoperability, similar to the role NEMA played in transforming diagnostic imaging interoperability in the 1990s. Standards for electronic medical records are complex, because they involve multiple types of data and terminologies that are not 100 percent congruent from one specialty to the next - or even from one hospital to the next.

GE is a coauthor of the *EHRVA Interoperability Roadmap* - an effort to articulate an achievable path to interoperability. The roadmap sets out a phased timeline for the interoperability needed to implement a nationwide health information infrastructure (NHIN). The first phase of that roadmap was demonstrated at the HIMSS Conference in 2006, with GE joining 37 other IT vendors, including the VA and DOD, in showcasing multiple interoperability use-cases. One of the NHIN pilot implementations used several aspects of the roadmap, and GE and EHRVA are reaching out to other stakeholders to encourage further implementation and convergence of the roadmap.¹

Don Woodlock, GE Healthcare's General Manager of Imaging Solutions, was the only speaker at the Secretarial Summit on Health Information Technology, July 21, 2004, to advocate open, standards-based interoperability. And numerous GE employees contribute their time and energy to establishing and staffing bodies, including the Certification Commission for Health IT (CCHIT) and the Health Information Technology Standards Panel (HITSP).

IHE: A Proven Interoperability Development Process

GE has also been a long-term leader in Integrating the Healthcare Enterprise (IHE), an industry-led initiative that is creating a standards-based framework for clinical IT. IHE was established in 1998 by the Radiological Society of North America (RSNA) and HIMSS. At that time, the popularity of DICOM led to the desire to improve imaging information exchange beyond the radiology department to other clinical IT systems in the hospital. Early on IHE recognized that solving healthcare interoperability problems sometimes requires multiple standards, and established a process that

¹ The EHRVA interoperability roadmap can be found at http://www.himssehrva.org.

allowed multiple standards to be profiled and specified in a precise manner to resolve workflow challenges while maintaining plug-and-play capabilities.

IHE defines precise interoperability specifications to ensure truly compatible implementations by different vendors. IHE couples these specifications with a comprehensive testing process, the IHE Connectathon. These interoperability showcases, held at major industry conferences, encourage competing vendors to build and demonstrate data exchange between their products, in a collaborative and transparent process. This includes laboratory results, radiology images, medical summaries, and cardiology reports - the very information that today is often still faxed, couriered, or mailed between the majority of healthcare organizations in the U.S. Beginning with the 2005 HIMSS Conference IHE Cross-Enterprise Showcase, 14 companies - including seven EHRVA members and NIST - demonstrated the document-sharing health information exchange concept using medical summary information, lab reports, static text reports (.pdfs), and structured information. The product demonstrations focused on use cases that would enable plug-and-play interoperability with the types of clinical information that patients and clinicians utilize in typical medical settings.

IHE's implementation and testing process has been leveraged by many countries and regions around the world, including the United States (through HITSP), France, Canada, Austria, Italy, and Japan. In the spring of 2005, for example, 16 European vendors participated in the IHE-Europe Connectathon for cross-enterprise information exchange; this has since grown to more than 70 companies participating in the North American and European IHE Connectathon process. The IHE Cross-Enterprise Document Sharing (XDS) profile and associated integration profiles achieved connectivity between inpatient and ambulatory EHR systems (including products from different EU countries) that had not previously communicated. By establishing a larger-scale market for HIT interoperability, IHE helps reduce the cost of achieving interoperability and makes the inherent technology risk more acceptable for vendors. The backbone of the HITSP health information exchange infrastructure utilizes many of the same IHE interoperability specifications that are already recognized and being deployed around the world.

The Role of NIST Today

The National Institute of Science and Technology (NIST) is charged with developing and promoting measurement, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life. While NIST's portfolio is not specific to healthcare, much of the research done at the NIST Laboratories with respect to advancing the nation's technology infrastructure is directly applicable to the creation of an NHIN. Further, virtually all of NIST's projects are conducted in cooperation with a wide variety of public and private stakeholders.

Within the healthcare realm, NIST Information Technology Laboratory has been involved with IHE on the development of XDS, which was adopted by EHRVA as the approach to electronic health information sharing for the *Interoperability Roadmap*.

NIST provided a test environment for vendors to test their implementations, and coordinated specification development with the web-services standards development organization OASIS that provided the standards used to implement XDS.

NIST is also an invaluable resource in the area of data security and privacy. Because of the sensitivity of personal medical information, consumer opposition to an NHIN largely centers on concern about unauthorized access to and misuse of medical records. Among the methodologies pioneered by NIST is role-based access control technology that limits the type of information that can be viewed by any individual depending on that individual's function. So, for example, hospital-billing clerks would be authorized to see only the parts of a patient's medical record necessary to generate invoices for a specific admission, while physicians with access to the same system would be able to see the patient's entire medical history. NIST's expertise in data security can both accelerate the process of achieving an NHIN, and enhance public confidence in those efforts.

A Future Role for NIST

HR 2406 envisions an expanded role for NIST in the development of HIT. GE supports NIST's increased involvement - but not at the expense of processes that are already working well, such as HITSP. We note also that NIST has not yet been allowed to fulfill its role under the 2005 Memorandum of Understanding (MOU) between the Department of Health and Human Services (HHS) and the Department of Commerce (DoC).

The areas where we believe NIST can be most valuable are:

• Facilitate coordination among federal agencies.

The 2005 MOU charges NIST with the responsibility for strategic, policy, and program coordination among federal agencies. While such an effort is often likened to "herding cats," we believe that NIST has the capability and should be given the opportunity to fulfill this mandate.

The federal government is the largest healthcare payer in the country, and therefore stands to benefit the most from the increased efficiencies and costsavings that can be garnered through HIT. NIST's role would not be to create or certify standards, but to work with other government agencies to ensure that existing standards are being implemented appropriately.

• Enhance the already effective HITSP process.

HITSP represents a best practice in public/private collaboration. We should be wary of any action that would result in diminishing the effectiveness of this group. That said, we believe it is possible to build on the current successes of HITSP (and of CCHIT), and NIST can play an important role in doing so. To ensure this, we suggest that HITSP be specifically recognized in this legislation. As a facilitator and coordinator among other federal agencies, NIST can help to accelerate the HITSP process by working between meetings to achieve consensus among the public sector participants. And NIST's authority to enforce federal agency compliance with standards implementation should be strengthened.

NIST's track record of promoting collaboration through IHE demonstrates that it can also play an effective facilitation role in the private sector.

Finally, NIST can serve as a resource to state governments, helping to disseminate information about technology roadmaps and other information that is available to support local HIT efforts.

• Provide coordination for testing interoperability standards.

The utility of interoperability testing is to demonstrate that products comply with a defined set of standards. Over the past 10 years, the IHE Connectathon has proven to be an effective, transparent testing process. Development of a parallel testing process, as CCHIT has proposed, covering the same standards can be done only to the detriment of the industry. We should not waste certification resources on duplicative efforts, and we should not ask vendors who have already contributed to creation of the IHE process - to pay a second time, in the form of increased CCHIT certification costs. And if the parallel processes yield disparate results for the same product, it would undercut the underlying rationale for certification.

To the extent there are testing processes not within the scope of the Connectathon, there is room for CCHIT or other entities - either alone or in the context of a public/private collaboration - to develop their own testing processes. NIST could help to oversee these efforts and ensure that there is no duplication. NIST's position within the DoC makes it uniquely suited to drive global standards harmonization.

In other industries, NIST has effectively served as a single clearinghouse for testing tools, whether they were created by NIST or by another entity. We suggest that NIST should be given the same responsibility with respect to interoperability standards, working in conjunction with HITSP.

• Focus research on areas not currently covered by HITSP and other public/private sector activities.

There is certainly room amid all these other activities for NIST's extensive research capabilities, especially in areas where the agency has particular expertise. These include:

- 1. Investigating the information technology necessary to support payfor-performance program.
- 2. Harmonization of security standards and practices, especially with respect to the "four As" identified by HISPC (authentication,

authorization, access, and audit), and making robust authentication more accessible to the consumer.

3. Working with the private sector and HHS to provide clarity in HIPAA security regulation guidance.

Summary

NIST has played, and can continue to play, an effective role in coordinating the efforts of the public and private sectors toward developing HIT. Our support for expanding NIST's participation in these activities is contingent on the agency leveraging its strengths, and not duplicating or reinventing the good work that is currently being carried out by other public/private entities. NIST's research activities should be directed to the areas where there are currently gaps, such as data security.

With respect to HISTP, we believe that NIST's highest and best use is to facilitate communication and consensus among the government entities represented. NIST can also help coordinate efforts in the private sector with respect to the efficiency and effectiveness of interoperability testing.