U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE AND TECHNOLOGY

HEARING CHARTER

Meeting the Need for Interoperability and Information Security in Healthcare IT

Wednesday, September 26, 2007
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

1. Purpose

On Wednesday, September 26, 2007 the Committee on Science and Technology will hold a hearing entitled *"Meeting the Need for Interoperability and Information Security in Healthcare IT"*. The hearing will examine progress toward the broad use of information technology in healthcare and the investments in technology and standards development that are needed to create a national system of secure, interoperable healthcare information technology. Witnesses will comment on barriers to the implementation of these systems, with an emphasis on the role of technical standards. They will also comment on the need for legislation to push toward the adoption of such standards. This includes a discussion of H.R. 2406.

2. Witnesses

Ms. Linda L. Kloss is Chief Executive Officer of the American Health Information Management Association (AHIMA).

Dr. David E. Silverstone is Clinical Professor at Yale School of Medicine and Assistant Chief of Ophthalmology at Yale New Haven Hospital. He serves as chairman of the Health Information Technology Committee of the American Society of Cataract and Refractive Surgery.

Mr. Michael Raymer is Vice President and General Manager for Product Strategy and New Business Initiatives at GE Healthcare Integrated IT Solutions.

Ms. Noel Williams is President of the Hospital Corporation of America (HCA) Information Technology & Services, Inc.

Mr. Justin T. Barnes is Vice President of Marketing and Government Affairs for Greenway Medical Technologies, Inc.

3. Brief overview

Information technology (IT) offers enormous potential benefits to U.S. healthcare. According to the Institute of Medicine, as many as 98,000 people die in hospitals each year from medical errors such as incorrect medications and improper diagnoses, many of which are preventable. A study by the Healthcare Information Management Systems Society found that as much as 49

percent of clinical diagnostic testing is performed because previous test results are unavailable when needed. Applications of IT to healthcare such as electronic healthcare records (EHRs), computerized ordering of prescriptions and tests, and updated medical information for clinical decision support could save thousands of lives and billions of dollars by reducing medical errors and miscommunication.

The entry of IT into the healthcare arena has been slow and disjointed. Only 12 percent of practices with five or fewer physicians, where most Americans receive their primary healthcare, have adopted EHRs. The healthcare industry spends only two percent of revenues on information technology, much lower than the 10 percent average of other information-intensive industries.

A key barrier to the adoption of a national, interoperable healthcare information technology (HIT) system is the lack of robust, widely accepted technical standards. Despite efforts at the Department of Health and Human Services (HHS) since 2004, such standards have yet to be fully developed and widely promulgated. Moreover, there is also a lack of conformance testing to ensure that products and systems comply with established HIT interoperability standards. In the absence of these standards and conformance tests, healthcare providers are reluctant to invest in HIT systems because there is no assurance that they will be able to communicate with other systems.

The federal government's lead agency for the development and promulgation of technical standards, the National Institute of Standards and Technology (NIST), has been involved with HIT standards development work since 2005. Because of its extensive expertise with issues of system interoperability, data security and privacy, and consensus standards development, NIST is well positioned to make a larger contribution to HIT standards development work and speed the deployment of a national secure and interoperable HIT system.

On May 21, 2007, Chairman Bart Gordon introduced H.R. 2406, a bill to authorize NIST to increase its efforts in support of the integration of the U.S. healthcare information enterprise. The bill: (1) directs NIST to establish an initiative for advancing HIT integration and allows it to assist healthcare representatives and organizations and federal agencies in developing technical roadmaps for HIT standards; (2) requires NIST to develop or adopt existing technology-neutral guidelines and standards to enable federal agencies to effectively select and use HIT systems that are secure, interoperable, and ensure patient privacy; (3) requires the Department of Commerce to establish a Senior Interagency Council on Federal Healthcare Information Technology Infrastructure to coordinate the development and deployment of federal HIT systems, the associated technology transfer, and federal work with private HIT standards development organizations; (4) requires NIST to establish a university grant program for multidisciplinary research in HIT-related fields; and (5) directs the National High-Performance Computing Program to coordinate federal HIT R&D programs.

4. Issues and concerns

What is the true cost of insufficient use of information technology within the U.S. healthcare system? The burden on U.S. healthcare due to confusion, miscommunication,

insufficient or outdated clinical information and other information shortfalls is enormous. According to a study in the *Annals of Family Medicine*, miscommunication is a major cause of 80 percent of medical errors, including poor communication between physicians, misinformation in medical records and misfiled charts. Research published in the *Archives of Internal Medicine* found that there are medication errors in one in five doses given in hospitals and skilled nursing facilities, and seven percent of those errors are potentially life-threatening. A study published in the *Journal of the American Medical Association* estimates that only slightly more than half of patients receive the known "best practice" treatment for their illness. Interoperable healthcare information systems could allow physicians to share patient medical information and lab results between hospitals, labs, and clinics; order drug prescriptions; and alert patients of drug recalls much faster than by sharing paper records. While quantitative studies across the entire healthcare sector are difficult to conduct, several health associations estimate that the potential savings of greater IT adoption by the healthcare industry run into the tens of billions of dollars. A study published in the journal *Health Affairs* estimates that a fully interoperable national healthcare IT network could yield $77.8 billion per year in savings, or five percent of annual U.S. healthcare spending.

What can the federal government do to accelerate the pace of standards development and promulgation leading to interoperability of HIT systems? Are current federal efforts appropriately leveraging all resources for this effort? In April 2004, President Bush signed an executive order establishing the position of the National Health Information Technology Coordinator (National Coordinator) at the Department of Health and Human Services (HHS). The first National Coordinator announced a plan to achieve healthcare IT interoperability nationwide. As part of this plan, HHS signed a memorandum with NIST, transferring $6 million from HHS to NIST to pay for technical work in support of HIT. NIST is the primary U.S. agency for developing and promulgating technical standards in conjunction with industry, standards development organizations, and foreign governments. NIST's current HIT work under the memorandum with HHS may not be fully utilizing NIST's expertise in technical standards, data security and privacy, and electronic commerce, and its familiarity with systems interoperability and device communication issues.

How can a national, interoperable HIT system be made compatible with privacy and data security concerns? An essential feature of a practical HIT system is that it protect the privacy and confidentiality of patients' medical information. It must also have strong data security provisions, so that medical information cannot be tampered with, altered, or destroyed by unauthorized entities. HIT standards will need to incorporate privacy and security in the original standards design (as opposed to a later addition) in order to ensure that these features will be a central element of a national HIT system. Within the federal government, data security standards for all non-classified IT systems are set by NIST, under the framework established by the Federal Information Security Management Act of 2002 (FISMA). In addition, NIST has been deeply involved in the development and adoption of information-exchange standards in electronic business and electronic voting systems, which have related privacy and data-security requirements.

What can be done to improve HIT interoperability within the federal government? The federal government has not yet adopted interoperable HIT systems. The largest federal

electronic medical records systems—those of the Departments of Defense (DOD) and Veterans Affairs (VA), and the Bureau of Indian Affairs (BIA)—are not mutually interoperable or interoperable with the private sector. The federal government should set the gold standard on interoperability of HIT systems, particularly as the demands on military and veterans' healthcare infrastructures are increasing due to the wars in Iraq and Afghanistan. Demonstrating the efficiency of interoperable HIT systems in the federal healthcare system could also spur private sector adoption of these systems by providing a cost-effective model.

What research and development efforts are needed to anticipate and adapt HIT standards for the next generation of medical technologies, human-machine interfaces, and patient needs? With the current pace of biomedical research and information technology, there will doubtless be new demands on HIT systems and new opportunities for IT to play an important role in healthcare. R&D will be needed to enable the incorporation of new technologies such as voice or facial recognition into HIT systems and to modify HIT systems to respond to new medical treatments and procedures, such as remote surgery and active implantable medical devices. These R&D activities will need to span many disciplines and synthesize work in the medical, biological, engineering, information technology and computer science fields, and others.

5. Background

Although the United States is the most technologically advanced nation in the world, the U.S. healthcare system continues to rely on pen and paper for the bulk of its information needs. From patient medical histories, to prescriptions, to hospital charts, handwritten notations are the basis for patient care information. This system is costly, antiquated, and prone to dangerous or life-threatening medical errors. More than 98,000 Americans die and more than one million patients suffer injuries each year as a result of broken healthcare practices and system failures. According to the National Academies, between 30 and 40 percent of healthcare costs—more than half a trillion dollars per year—is spent on "overuse, underuse, misuse, duplication, system failures, and unnecessary repetition, poor communication, and inefficiency".

Information technology offers enormous potential benefits to improve the functioning and efficiency of U.S. healthcare. A fully realized national interoperable healthcare IT (HIT) system could reduce errors, improve communication, help eliminate redundancy, and provide numerous other benefits that would protect patients and save up to tens of billions of dollars per year. The central challenge to achieving such a system is interoperability—the ability of data systems, medical devices and software from different vendors based on a diverse array of platforms to share patient electronic healthcare records (EHRs), electronic physician orders for lab tests and drug prescriptions, electronic referrals to specialists, electronic access to information about current recommended treatments and research findings, and other information.

In February 2006, the Subcommittee on Environment, Standards and Technology of the Committee on Science held a field hearing in Portland, Oregon, titled "Health Care Information Technology: What are the Opportunities for and Barriers to Inter-operable Health Information Technology Systems?". Representatives David Wu and Dave Reichart oversaw the proceedings, whose purpose was to review the potential benefits of IT to both patients and the healthcare

industry, and to determine what actions federal and state governments and the private sector should take to speed the adoption of interoperable HIT systems. Witnesses stressed the need for standardization in the HIT industry, and encouraged strong investment by the federal government, especially NIST, in standards development and education and training activities for healthcare providers.

6. Bill summary of H.R. 2406

Section 1. Findings

Establishes Congressional findings that the National Institute of Standards and Technology (NIST) is well equipped to address HIT enterprise integration because of its experience with electronic commerce, security, and privacy, as well as healthcare business through its Malcolm Baldrige National Quality Program.

Section 2. Healthcare Information Enterprise Integration Initiative

Directs NIST to establish an initiative to advance HIT enterprise integration nationally, building on existing efforts at NIST and involving government and industry consortia. Technical activities of this program may focus on standards and interoperability analysis and the development of technical testbeds, software conformance and certification, security and privacy, medical device communication, data management and retrieval architecture, conformance testing infrastructure, and healthcare information usability and decision support. The initiative may also include assistance to outside organizations and federal agencies in developing technical roadmaps for HIT enterprise integration, relying on voluntary consensus standards where possible. The Director shall report to Congress annually on these activities.

Section 3. Federal Healthcare Information Technology Systems and Infrastructure

Directs NIST to develop new or adopt existing technology-neutral HIT guidelines and standards for use by federal agencies within 6 months of enactment. The guidelines and standards shall enable agencies to select HIT systems that provide security and privacy and are interoperable. They shall promote the use of commercial HIT systems by federal agencies, include conformance-testing procedures, provide privacy profiles, establish interoperability specifications, and include validation criteria to enable agencies to select appropriate HIT systems. NIST will report annually on the progress toward and barriers to adoption of interoperable, secure and private HIT systems by federal agencies. Directs the Department of Commerce to establish a Senior Interagency Council on Federal Healthcare Information Technology Infrastructure, with responsibilities to coordinate development and deployment of HIT systems across the federal government, associated technology transfer, and federal funding for and participation in private standards-development organizations as related to HIT.

Section 4. Research and Development Programs

Directs NIST, in consultation with NSF, to establish a grant program for institutions of higher education partnering with businesses, non-profits and government laboratories to establish

Centers for Healthcare Information Enterprise Integration. Grants shall be awarded on a competitive, merit-reviewed basis. The Centers will generate innovative approaches to HIT enterprise integration by conducting research on the interfaces between human information and communications technology systems, voice-recognition systems, interoperability software, software dependability, metrics of the impact of information technology on healthcare, healthcare information enterprise management, and information technology security and integrity. Grant applications shall include descriptions of proposed projects, efforts to foster multidisciplinary collaboration, and technology transfer and education activities. The National High-Performance Computing Program established by the High-Performance Computing Act of 1991 shall coordinate federal R&D programs related to HIT.