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

HEARING CHARTER

Standards for Health IT: Meaningful Use and Beyond

Thursday, September 30, 2010
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

I. PURPOSE

The integration of information technology (IT) with health care has the potential to improve patient care and lower escalating health care costs. Standards that enable interoperability among products developed by different vendors, as well as standards to ensure the privacy and security of electronic health care information, are central to realizing the benefits of health IT. In 2009, with the passage of the *American Recovery and Reinvestment Act*, Congress created programs and incentives to help speed the adoption of health IT, including measures to ensure the establishment of technical standards.

The purpose of this hearing is to examine the progress by the Department of Health and Human Services, the National Institute of Standards and Technology, and non-governmental health IT stakeholders in establishing standards for health IT, providing guidance for their implementation, and creating a mechanism to certify that health IT products comply with the established standards. Witnesses will also discuss future priorities for ensuring the interoperability of health IT systems, and the privacy and security of electronic health information.

II. WITNESSES

- **Dr. David Blumenthal,** *National Coordinator for Health Information Technology, Office of the National Coordinator, U.S. Department of Health and Human Services*
- **Ms. Kathleen M. Roberts,** *Associate Director for Federal and Industrial Relations, Information Technology Laboratory, National Institute of Standards and Technology*
- **Ms. Joyce Sensmeier,** *Vice President, Informatics, Healthcare Information and Management Systems Society*
- **Dr. Dick Gibson,** *President, Oregon Health Network*

- **Ms. Deven McGraw,** *Director of the Health Privacy Project, Center for Democracy and Technology*
- **Ms. Deb Bass,** *President and CEO, Bass & Associates, Inc.*

III. BRIEF OVERVIEW

Despite the potential benefits of health IT and electronic health records (EHRs) in lowering health care costs and improving patient care, the health care industry has been relatively slow to incorporate information technology into the delivery of medical services. The lack of established standards for health IT has been a key challenge hindering wider adoption of this technology. Standards ensure that information can be exchanged seamlessly between software and hardware devices developed by different vendors or put on the market at different times.

Through the *HITECH Act* [Title XIII of the *American Recovery and Reinvestment Act* (ARRA), P.L. 111-5], Congress created programs and incentives to encourage health IT adoption. In addition, the Act provided a mechanism to establish technical standards, and further provided that any health IT products purchased with ARRA funds must comply with standards established by the Department of Health and Human Services (HHS). With guidance from several advisory committees, HHS issued a final rule in July of this year identifying the standards that would support the first stage of Medicare incentive payments for health IT products (termed "meaningful use" requirements).

The initial standards established by HHS provide an important baseline of functionality for health IT products. However, many standards-related issues have not yet been fully addressed. To ensure the seamless exchange of health information among authorized entities and realize the full benefit of health IT, the health care community will need robust standards and related products for interoperability. In addition, the standards process will require coordination to ensure that standards developers are able to support the needs of the health care community as health IT technology evolves. Finally, baseline national privacy and security policies could help health IT developers and users alike maximize the benefits of the technology.

IV. BACKGROUND

The Role of IT in Health Care

Studies and statistics show that a lack of ease in information exchange and communication contributes to medical errors and duplicative tests, and other wasteful practices. For instance, one study found that nearly one out of every five doses of medication given in typical hospitals or skilled nursing facilities was somehow in error. Most often, the medication was delivered at the wrong time, but other times the dosage was wrong or the incorrect medication was

administered altogether. The study, in the *Archives of Internal Medicine,* further explained that these errors were harmful to the patient in 7 percent of cases (40 per day in a 300 patient facility)[1]. Other studies have found that miscommunication between doctors, patients, and others involved in patient care was a major factor in 80 percent of medical errors.[2] Health IT could help medical professionals, and their patients, manage complex or chronic conditions, identify harmful drug interactions or possible allergies, and provide other care support tools.

Adoption of health care IT is also widely seen as a way to stem the rising costs of health care. According to a report issued by the National Academies, an estimated half-trillion dollars per year is associated with "overuse, underuse, misuse, duplication, system failures, unnecessary repetition, poor communication, and inefficiency."[3] Although estimates vary on the actual savings that could be expected from health IT, a study published in *Health Affairs* estimated that a fully interoperable, national health IT network could save $77.8 billion a year, equal to 5 percent of annual U.S. health care spending.[4] In addition to reducing costs associated with medical errors, health IT could enable other cost-saving measures such as prompting physicians to prescribe generic drugs or making tests results more readily available, thus avoiding duplicative tests.

Adoption of IT by the Health Care Industry and Technical Standards

The health care industry has been slow to adopt health IT, despite its potential impact. A study published in June of 2008 found that only 4 percent of U.S. physicians had a fully functional electronic health records (EHRs) system, which the authors defined as an EHR system with broad range of capabilities including clinical order entry and clinical decision support. Thirteen percent of those surveyed in the study used a basic EHR, which the study described as one with a minimum set of functionalities, such as recoding laboratory data and clinical notes and electronic prescribing.[5]

One of the key barriers to wider adoption of health IT has been the lack of robust, widely-accepted technical standards. To realize the benefits of health IT, systems must be interoperable, allowing data systems, medical devices, and software from different vendors to share EHRs, as well as electronic physician orders for lab tests and drug prescriptions, electronic referrals to specialists, electronic access to information about current treatment recommendations and research finding, and other capabilities. In addition to the need for standards to ensure that

[1] Barker, *et al*. 2002 Medication Errors Observed in 36 Health Care Facilities, *Archives of Internal Medicine*.
[2] Woolf, *et* al. 2004 A String of Mistakes: The Importance of Cascade Analysis in Describing, Counting, and Preventing Medical Errors, *Annals of Family Medicine*.
[3] Report by the National Academies, 2005 *Building a Better Delivery System: A New Engineering/Health Care Partnership*
[4] Walker, *et al*. 2005 The Value of Health Care Information Exchange and Interoperability, *Health Affairs*.
[5] DesRoches, *et al.* 2008 Electronic Health Records in Ambulatory Care—A National Survey of Physicians, *The New England Journal of Medicine*

disparate systems are interoperable, standards are needed to meet data security and privacy requirements to enable compliance with federal and state patient privacy laws.

The Science and Technology Committee held hearings on health IT in the 109th and 110th Congresses. During those hearings, witnesses identified the lack of common standards as one of the challenges facing greater health IT adoption. Witnesses claimed that, without these standards, health care providers would not have a reasonable guarantee that the systems they purchase will be able to exchange information with systems that are currently in use, or that may be installed in the future. At the hearing held in September of 2007, witnesses agreed that NIST should assist HHS in efforts to establish standards for health IT. NIST is the Federal Government's lead agency for supporting the development of technical standards and conformance testing, and has a long history of working with the private-sector, federal agencies, and other stakeholders to develop consensus-based standards in fields such as electronic commerce, manufacturing, and information security.

HITECH Act

Congress passed the *HITECH Act* as part of the *American Recovery and Reinvestment Act* (ARRA) in 2009. The *HITECH Act* established programs and incentives to boost the rate of adoption of health IT systems. It also codified the Office of the National Coordinator for Health Information Technology (ONCHIT)[6] and strengthened provisions pertaining to privacy and security of electronically stored and exchanged health information in federal law. The *HITECH Act* gave ONCHIT the role of overseeing the establishment of standards and a certification process for health IT technology, guided by recommendations from two Federal Advisory Committees—the Health IT Policy Committee and the Health IT Standards Committee—on the "implementation of a nationwide health IT infrastructure."

The *HITECH Act* charged the HIT Policy Committee with providing recommendations on areas in need of standards, implementation specifications, and certification criteria. The Act further charged the Health IT Standards Committee with "develop[ing], harmoni[zing], and recogni[zing]" standards and related material, and providing recommendations on these for consideration by ONCHIT and HHS. The *HITECH Act* directs the ONCHIT to ensure that federal funds expended toward health IT technology go toward certified EHR technology that incorporates the standards and capabilities developed by the Policy and Standards Committees, and promulgated by HHS.

[6] Federal efforts to encourage widespread health IT adoption began in 2004 when President Bush signed an executive order creating the Office of the National Coordinator for Health IT (ONCHIT) within HHS, and stated the goal of widespread EHR adoption within 10 years. ONCHIT initiated a number of activities, including work on standards and certification.

The *HITECH Act* also directs NIST to test the standards, implementation specifications, and certification criteria that emerge from the ONCHIT standards process. Additionally, the *HITECH Act* charges NIST with developing a conformance testing infrastructure, including creating technical test beds, and provided NIST with $20 million to develop this infrastructure. Conformance testing is necessary to ensure that the health IT products meet all of the requirements of the standards and that the standards are correctly implemented. To date, HHS has approved three testing and certification bodies and product certification is expected to begin shortly. In addition to supporting HHS with health IT testing and certification, NIST has assisted HHS with establishing security standards and guidance for health IT products.

Since the passage of the *HITECH Act*, much of the work of the two advisory committees has focused on providing recommendations to the ONCHIT regarding "meaningful use." Under the *HITECH Act*, medical providers are entitled to apply for Medicare incentive payments beginning in 2011 if they adopt EHRs for their patients and meet certain requirements. Finalized in July of this year, these include 15 "core set" requirements and 10 "menu set" options. Meaningful users must meet the 15 core requirements and at least 5 of the menu set options. Core set requirements include using an EHR to record smoking status for 50 percent of patients 13 years of age or older and to maintain an active medication list for 80 percent of patients. The core set includes only one requirement related to data exchange—users must perform at least one test of an EHR's capacity to electronically exchange information. The menu set options include using health IT systems to generate a listing of patients with a specific condition or to perform at least one test data submission of immunization data to immunization registries. As specified in the *HITECH Act*, requirements will be added for future stages of meaningful use.[7]

In addition to specifying the basic functionality for certified EHRs, the final rule also included the standards, implementation specifications, and certification criteria required to be met by all certified EHRs.

National Health Information Network

In 2005, HHS began developing a National Health Information Network (NHIN). It was conceived of as a "network of networks" that would allow for the secure exchange of health information among health care providers. In 2007, HHS awarded contracts totaling $22.5 million to nine health information exchanges (HIEs) to begin trial implementation of the NHIN.

ONCHIT has continued work on developing standards and policies for a national health information exchange, whose core capabilities include the ability to look up, retrieve, and securely exchange health information; the ability to apply consumer preferences for sharing

[7] Providers who become meaningful users of EHRs beginning in 2011 are entitled to Medicare incentive payments. For providers adopting EHRs in 2014, no incentive payments will be provided. By 2015, providers not using EHRs will be penalized through reductions on Medicare payments. Additional requirements will be added in later stages of meaningful use. Note, there is a corresponding timeline for providers who become meaningful users under the Medicaid incentive program.

information; and the ability to apply and use the NHIN for other business capabilities as authorized by the health care consumer. ONCHIT has continued work on the NHIN, and is now also working on the NHIN Direct project, which will include standards, policies, and services to enable the transport of medical records between authorized providers.

Privacy and Security

A number of state and federal laws and regulations cover the confidentiality of personal health information. On the federal level, the privacy and security of medical information is protected by the *Health Information Portability and Accountability Act* (HIPPA). The *HITECH Act* expanded upon the HIPAA requirements with stricter enforcement mechanisms, requirements for breach notification, and the expansion of the privacy and security regulations to cover business associates of the health care provider.[8] The *HITECH Act* also required HHS to issues guidance on "technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals." Covered entities that follow the guidance issued by HHS but still suffer a security breach are not subject to the breach notification requirements or the stricter penalties enacted in the *HITECH Act*.

The meaningful use requirements give guidance on technologies and methodologies (such as encryption) to protect data. They also require users of health IT systems to perform a risk analysis to determine the nature and likelihood of threats, and to base their security measures on this analysis while considering the cost and complexity of needed security infrastructure.

V. ISSUES & CONCERNS

The standards adopted by HHS for meaningful use are an important step in establishing recognized standards for health IT systems and EHRs. However, while the standards provide a layer of commonality among health IT products, the final rule included only minimal provisions concerning interoperability.

At the same time, throughout the country, medical providers and states are developing electronic health information exchange networks, as well as pursuing other health IT projects. The Federal Government is also pursuing the NHIN and NHIN Direct projects. It is unclear whether, and to what extent, the standards-related components of these efforts are being coordinated to ensure interoperability in the future.

HHS has recently released an initial standards and interoperability framework. This framework will presumably guide the coordination of future standards activities, including harmonization, development, testing, and priority setting. However, HHS has not yet clearly described how it will maintain the transparency and stakeholder input that is an important component of the

[8] Relevant business associates include business partners of the provider that may provide various services, such as accounting or management, wherein individually identifiable health information is disclosed.

standards setting and development process. In addition, the framework does not specify how HHS will continue to work with NIST on health IT standards.

The *HITECH Act* strengthened privacy and security protections for patient information by requiring breach notification of readable data and implementing stricter penalties for the disclosure of personal health information. However, there is little federal guidance beyond HIPAA for implementing these stricter privacy and security measures. For example, no guidance exists on the federal level on whether individuals must opt-in to or opt-out of an electronic health exchange, or on the granularity, or degree, of patient consent needed to disclose certain types of health information. These are policy questions, often subject to individual state rules, but they impact the technology solutions that will be needed by health care providers. In addition, while the security measures adopted for EHRs allow for flexible implementation, they may prove challenging to implement, particularly among small practices.