

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

HEARING CHARTER

*Is “Meaningful Use” Delivering Meaningful Results?: An Examination of Health
Information Technology Standards and Interoperability*

**Wednesday, November 14, 2012
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building**

Purpose

On Wednesday, November 14, 2012, the Subcommittee on Technology and Innovation will hold a hearing to examine progress on the development and implementation of interoperable technical standards and conformance testing procedures for health information technology (HIT). The Subcommittee will review the activities of the Office of the National Coordinator for Health Information Technology (ONC) and the National Institute of Standards and Technology (NIST) in promoting interoperability through the development of technical standards for HIT, and will examine the implementation of the Health Information Technology for Economic and Clinical Health (HITECH) Act, including the recently announced final rule for Stage 2 meaningful use of HIT under the Act.

Witnesses

Dr. Farzad Mostashari, National Coordinator for Health Information Technology, The Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services.

Dr. Charles H. Romine, Director, Information Technology Laboratory, National Institute of Standards and Technology.

Mr. Marc Probst, Chief Information Officer and Vice President, Information Systems, Intermountain Healthcare.

Ms. Rebecca Little, Senior Vice President, Medicity.

Dr. Willa Fields, DNSc, RN, FHIMSS, Professor, School of Nursing, San Diego State University.

Overview

Effective utilization of information technology in the health care arena has the potential to lower health care costs and to improve the coordination and provision of care by reducing duplicative or unnecessary tests and procedures, preventing medical errors, and by providing clinical decision support at the point of care. Major components of HIT include portable electronic health records (EHRs) (including systems to prescribe medicine, order tests, and provide clinical support) and the development of a secure health information network to exchange information among providers.¹

Despite the pervasiveness of information technology (IT) in the public and private sectors, the healthcare industry has historically been an IT laggard.² A variety of barriers account for this, including, the lack of interoperable standards for HIT technology, the significant capital investment required, the lack of economic incentives in the health care payment structure, and the complexity and diversity of the health care arena, just to name a few.

Interoperability is critical to realizing the benefits of HIT. Interoperability allows different EHR systems to communicate, enabling a seamless flow of patient information in continuity of care among different providers. The development and application of common technical standards is critical to achieving interoperability. Simply put, interoperability is critical to realizing the benefits of HIT and technical standards are the platform upon which to build a diversity of innovative systems.

Background

Office of the National Coordinator for Health Information Technology

In 2004, President Bush signed an Executive Order creating the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Services.³ The Executive Order charged the ONC with developing and implementing a strategic plan to coordinate nationwide efforts towards interoperability standards and the electronic exchange of health information in the public and private health care sectors. The ONC drafted a framework that outlined four goals for HIT: (1) informing clinical practice by accelerating the use of EHRs; (2) connecting clinicians allowing them to exchange information in a secure environment; (3) personalizing health care by enabling consumers to participate in

¹ Redhead, C. Stephen. *CRS Report for Congress: The Health Information Technology for Economic and Clinical Health Act*. April 27, 2009.

² DesRoches, et al. 2008 Electronic Health Records in Ambulatory Care – A National Survey of Physicians, *The New England Journal of Medicine*.

³ Executive Order 13335: Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator, *available at* <http://georgewbush-whitehouse.archives.gov/news/releases/2004/04/20040427-4.html>.

their care; and (4) improving population health through public health surveillance and through the acceleration and application of health research in clinical care.⁴

The ONC's mission includes promoting development of a nationwide HIT infrastructure that allows for electronic use and exchange of information; providing leadership in the development, recognition, and implementation of standards and the certification of HIT products; HIT policy coordination; strategic planning for HIT adoption and health information exchange; and establishing governance for the National Health Information Network.⁵

The National Institute of Standards and Technology and Health Information Technology

The National Institute of Standards and Technology (NIST) has collaborated with industry and other stakeholders on healthcare information infrastructure since the early 1990s. NIST has also worked extensively with the ONC on HIT voluntary standards development since 2004.

NIST's role in HIT has been further defined in the 2009-2012 Federal HIT strategic plans and the HITECH Act to:

- Advance healthcare information enterprise integration through standards and testing.
- Consult on updating the Federal HIT Strategic Plan.
- Consult on voluntary certification programs.
- Consult on HIT implementation.
- Provide pilot testing of standards and implementation specifications, as requested.⁶

NIST is widely recognized for its technical expertise and its leadership in bringing together various stakeholders to build consensus for standards development.

Health Information Technology for Economic and Clinical Health (HITECH) Act

The HITECH Act, which was incorporated into the American Recovery and Reinvestment Act (ARRA; H.R. 1), was signed into law in 2009. The Act codified the ONC and expanded privacy and security standards for electronically stored health information. In addition, the Act established mandatory and discretionary funding programs to promote adoption of HIT products, services, and infrastructure through incentive payments, grants, and low-interest loans.

The Act provides mandatory funding through Medicare and Medicaid incentive payments (transitioning to penalties over a period of time) to encourage providers (both physicians and hospitals) to adopt and "meaningfully use certified EHRs."⁷ To qualify under "meaningful use," providers must show that they are achieving specific milestones, such as using certified HIT products to record patient data, to order prescriptions, and to make referrals to other providers.

⁴ Redhead, C. Stephen. *CRS Report for Congress: The Health Information Technology for Economic and Clinical Health Act*. April 27, 2009.

⁵ http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__onc/1200

⁶ <http://www.nist.gov/healthcare/hit/index.cfm>

⁷ ARRA § 13301.

Meaningful use requirements and supporting technical standards are promulgated by the Secretary of HHS, based on recommendations by the HIT Policy Committee and the HIT Standards Committee, respectively.

According to the Centers for Medicare and Medicaid Services (CMS), EHR incentive payments to providers have totaled over 7.7 billion dollars through September 2012— paid out to 158,071 physicians and hospitals. At a Health Information Management and Systems Society (HIMSS) 2012 Policy Summit, ONC National Coordinator, Dr. Farzad Mostashari, estimated that CMS would pay out around 20 billion dollars in EHR incentive payments before incentives shift to penalties in 2015.⁸

Under the HITECH Act, ONC was directed to transfer \$20 million to NIST to conduct HIT activities including technical standards analysis and establishment of conformance testing infrastructure in coordination with ONC.⁹ Specifically, NIST develops, and the ONC approves, test procedures to certify EHR product conformance. NIST also accredits private labs that perform conformance testing for HIT products, and participates in both the ONC’s HIT Policy and Standards Committees.

In addition to mandatory incentives payments, the ARRA appropriated two billion dollars in discretionary funds to ONC for HIT infrastructure investments, provider grants, and training programs. Among grant programs, HHS has dedicated grant funding for the HIT Extension Program, which established Regional Extension Centers (REC) around the country, and to the State Health Information Exchange (HIE) Program, which supports states’ and state-designated entities’ efforts in establishing information exchange ability among providers and hospitals.¹⁰

HITECH Act Meaningful Use Requirements

HITECH tasked ONC with developing meaningful use requirements for HIT. ONC has since established three meaningful use stages. Each stage consists of its own set of “core” and “menu” provider requirements determined by CMS to qualify for Medicare or Medicaid incentive payments.

Stage 1

Stage 1 aimed at introducing HIT into the healthcare industry through data capture and sharing, with the first building blocks focused on basic EHR functionality, data standardization, and privacy and security.

Stage 2

On August 23, 2012, CMS released the final rule for Stage 2. The requirements reflect a focus on improved access to information and advanced clinical processes. Previously CMS required

⁸ Diana Manos, *Mostashari: No cap on EHR incentive payouts*, HEALTHCARE IT NEWS, Sept. 13, 2012, <http://www.healthcareitnews.com/news/mostashari-theres-no-cap-ehr-incentive-payouts?topic=75,,08,12>.

⁹ ARRA § 13201

¹⁰ <http://www.healthit.gov/policy-researchers-implementers/health-it-adoption-programs>

providers to progress to Stage 2 criteria after two years under Stage 1 meaningful use requirements; the original timeline would have required Medicare providers who first demonstrated meaningful use in 2011 to meet the Stage 2 criteria in 2013. However, the final rule for Stage 2 delays the onset of Stage 2 requirements with the earliest effective date in fiscal year 2014.

Stage 3 and Beyond

Even though the final rules of Stage 2 were just recently released, ONC and CMS have started the process for developing Stage 3 meaningful use requirements. Stage 3 aims at creating improved population outcomes and individual patient engagement. Using the current timeline, Stage 3 would begin two years after a provider successfully demonstrates Stage 2 requirements—no earlier than 2016. The HIT Policy Committee’s Meaningful Use Workgroup¹¹ plans to submit their final Stage 3 recommendations to HHS by May 2013.¹²

Issues for Examination

As of May 2012, there were a total of 248,439 professional and hospital participants in the EHR incentive programs for both Medicare and Medicaid. However, while adoption of HIT products has increased since the passage of the HITECH Act, interoperability among the myriad of HIT systems has lagged. Absent interoperability, many of the potential benefits of HIT, such as improvements in coordination of care and increases in efficiency may go unrealized.

Additionally, key stakeholders, including the American Medical Association and the American Hospital Association, have expressed concern about Stage 2 meaningful use requirements.¹³¹⁴ These concerns include whether the Stage 2 rules appropriately take into account the diversity and complexity of the healthcare industry. As a result, specialists may be required to invest in systems and electronically record data that do not apply directly to their provision of care.

Witnesses were asked to address in their testimony:

What is the goal for health information interoperability under the HITECH Act? How are Stage 1 and 2 meaningful use requirements and supporting standards advancing us towards this goal?

How have the lessons learned from the implementation of Stage 1 meaningful use requirements and supporting standards been applied in drafting Stage 2 requirements and Stage 3 proposals?

¹¹ HEALTHIT.GOV, <http://www.healthit.gov/policy-researchers-implementers/federal-advisory-committees-facas/meaningful-use>.

¹² HIT POLICY COMM., MEANINGFUL USE WORKGROUP STAGE 3 – PRELIMINARY RECOMMENDATIONS (2012) 3, http://www.healthit.gov/sites/default/files/mu_stage3_rec_hitpc_meeting_01_aug_12.pdf.

¹³ <http://www.ama-assn.org/resources/doc/washington/ehr-stage-2-certification-sign-on-letter-07may2012.pdf>

¹⁴ <http://www.ama-assn.org/resources/doc/washington/ehr-stage-2-certification-sign-on-letter-07may2012.pdf>

How does the ONC engage Federal agencies and other stakeholders (National Institute of Standards and Technology, vendors, and providers) in developing the meaningful use requirements and technical standards?

How does the HIT Standards Committee balance the need for common IT standards with the diversity of the healthcare industry? How does the Committee account for technology development and innovation in its standards recommendations?

How effective have HHS and the ONC been in establishing long-term goals and benchmarks for HIT adoption, interoperability, and provision of care?

What recommendations would you make for Federal policy makers as we consider future HIT policies?