



Testimony
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on Federal Financial Management, Government
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Accelerating the Adoption of
Health Information Technology

Statement of

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Chairman Coburn and Members of the Subcommittee, I am Jodi Daniel, Director of Policy and Research for the Office of the National Coordinator for Health Information Technology (ONC). Thank you for inviting me to testify today on some of the health information technology activities underway in the Department of Health and Human Services.

Setting the Context

On April 27, 2004, the President signed Executive Order 13335 announcing his commitment to the promotion of health information technology (IT) to improve efficiency, reduce medical errors, improve quality of care, and provide better information for patients and physicians. In particular, the President called for widespread adoption of electronic health records (EHRs) within 10 years so that health information will follow patients throughout their care in a seamless and secure manner. Reaching this ambitious goal requires cooperation among Federal agencies and Departments that play a role in advancing our understanding and use of health information technology: coordination across all Federal HIT programs; and coordination with the private sector. Toward those ends, the Secretary of Health and Human Services established within his office the position of National Coordinator for Health Information Technology on May 6, 2004 to advance the President's vision.

As my testimony will demonstrate, this approach is working. The Office of the National Coordinator works closely with the Centers for Medicare and Medicaid Services (CMS),

the Department of Defense, the Department of Veterans Affairs, the Office of Personnel Management (OPM), and multiple other agencies and departments to ensure synergy in our efforts and avoid unnecessary duplication.

On July 21, 2004, the Department published the “Strategic Framework: The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care.” The Framework outlined an approach toward nationwide implementation of interoperable EHRs and identified four major goals. These goals are: 1) inform clinical practice by accelerating the use of EHRs, 2) interconnect clinicians so that they can exchange health information using advanced and secure electronic communication, 3) personalize care with consumer-based health records and better information for consumers, and 4) improve public health through advanced bio-surveillance methods and streamlined collection of data for quality measurement and research. Since that time, the Department had been further developing health IT objectives and strategies while focusing on these goals and the clinical business, and technical foundations.

The Clinical Foundation: Evidence of the Benefits of Health IT

We believe that health IT can save lives, improve care, and improve efficiency in our health system. Five years ago, the Institute of Medicine (IOM) estimated that as many as 44,000 to 98,000 deaths occur each year as the result of medical errors. Health IT, through applications such as computerized provider order entry can help reduce medical errors and improve quality. For example, studies have shown that adverse drug events

have been reduced by as much as 70 to 80% by targeted programs, with a significant portion of the improvement stemming from the use of health IT.

Every primary care physician knows what a recent study in the Journal of the American Medical Association (JAMA) showed: that clinical information is frequently missing at the point of care, and that this missing information can be harmful to patients. That study also showed that clinical information was less likely to be missing in practices that had full electronic records systems. Patients know this too and are taking matters into their own hands. A recent survey by AHRQ with the Kaiser Family Foundation and the Harvard School of Public Health found that nearly 1 in 3 people say that they or a family member have created their own set of medical records to ensure that their health care providers have all of their medical information.

Current analyses examining whether health IT will produce cost savings show mixed results. Models projecting the potential savings from health IT vary widely. These estimates are based in part on the reduction of obvious errors. For example, on average, a medical error is estimated to cost about \$3,700 in 2003 dollars. But, these savings are not guaranteed through the simple acquisition of health IT. If poorly designed or implemented, health IT will not bring these benefits, and in some cases may even result in new medical errors and potential costs.

Business Foundation: The Health IT Leadership Panel Report

Recognizing that the healthcare sector lags behind most other industries in its investment in IT, HHS employed a contractor, the Lewin Group, to convene a Health IT Leadership Panel to help understand how IT has transformed other industries and how, based upon their experiences, it can transform the health care industry.

The Leadership Panel was comprised of nine CEOs from leading companies that do not operate health care businesses, but purchase large quantities of healthcare services for their employees and dependents.. They were called upon to evaluate the need for investment in health information technology and the major roles that both the government and the private sector can play in achieving widespread adoption and implementation.

The Leadership Panel identified as a key imperative that the Federal government should act as leader, catalyst, and convener of the nation's health information technology effort.

Private sector purchasers and health care organizations can and should collaborate alongside the federal government to drive adoption of health IT. In addition, the Leadership Panel members recognized that widespread health IT adoption may not succeed without buy-in from the public as health care consumer.

The Technical Foundation: Public Input Solicited on Nationwide Network

HHS published a Request for Information (RFI) in November 2004 that solicited public input about whether and how a Nationwide Health Information Network (NHIN) could be developed. This RFI asked key questions to guide our understanding around the

organization and business framework, legal and regulatory issues, management and operational considerations, standards and policies for interoperability, and other considerations.

Over 500 responses to the RFI were received. These responses yielded rich insights on how a National Health Information Network based on interoperability of health information exchange could be developed to realize our goal of the safety, quality and efficiency of care. Clear themes that emerged from this wide group of stakeholders include:

- A NHIN should be a decentralized architecture built using the Internet, linked by uniform communications and a software framework of open standards and policies.
- A NHIN should reflect the interests of all stakeholders with a governance entity composed of public and private stakeholders to oversee the determination of standards and policies.
- A key challenge will be the provision of sufficient safeguards to protect the privacy of personal health information. Others include the need for additional and better refined standards; accurately verifying patients' identity; and addressing discordant inter- and intra-state laws regarding health information exchange.
- Incentives may be needed to accelerate the deployment and adoption of a NHIN.
- Existing technologies, federal leadership, and certification of EHRs will be the critical enablers of a NHIN.

Departmental Action

Two critical challenges to realizing the President's vision for health IT are now being addressed: a) interoperability and electronic portability of health information using information technology and b) electronic health record adoption. Further, the gap in EHR adoption between large hospitals and small hospitals, between large and small physician practices, and among other healthcare providers must also be addressed. This adoption gap has the potential to shift the market in favor of large players who can afford these technologies, and can create differential health treatments and quality, resulting in a quality gap.

These challenges are being met by key actions currently underway in the ONC: harmonizing health information technology standards; promoting the certification of health IT products to assure consistency with standards; addressing variations in privacy and security policies that can pose challenges to interoperability; and developing a prototype, nationwide, Internet-based architecture for sharing of electronic health information. These efforts are inter-related, and Secretary Leavitt's federal advisory committee, the American Health Information Community, is charged with making recommendations regarding the federal government's role in responding to these challenges.

American Health Information Community

On July 14, 2005, Secretary Leavitt announced the formation of the American Health Information Community (the Community), a national public-private collaboration formed pursuant to the Federal Advisory Committee Act. The Community has been formed to facilitate the transition to interoperable electronic health systems in a smooth, market-led way. The Community is providing input and recommendations to the Secretary on use of common standards and how interoperability among Health IT systems can be achieved while assuring that the privacy and security of those records are protected. On September 13, 2005, Secretary Mike Leavitt named the Community's 17 members, including nine members from the public sector and eight members from the private sector.

At its November 29, 2005 meeting, the Community formed workgroups that were charged to make recommendations for specific achievable near-term results in the following areas:

- Consumer Empowerment - Make available a consumer-directed and secure electronic record of health care registration information and a medication history for patients.
- Chronic Care - Allow the widespread use of secure messaging, as appropriate, as a means of communication between doctors and patients about care delivery.
- Electronic Health Records - Create an electronic health record that includes laboratory results and interpretations, that is standardized, widely available and secure.

- Biosurveillance - Enable the transfer of standardized and anonymized health data from the point of health care delivery to authorized public health agencies within 24 hours of its collection.

These workgroups advanced, and the Community accepted, recommendations on May 16, and key actions related to these and future recommendations are beginning to unfold.

Health Information Technology Contracts

In addition to the formation of the Community, HHS through ONC has issued contracts, the outputs of which will serve as inputs for the Community's consideration. Specifically, these contracts focus on the following major areas:

Standards Harmonization. HHS awarded a contract to the American National Standards Institute, a non-profit organization that administers and coordinates the U.S. voluntary standardization activities, to convene the Health Information Technology Standards Panel (HITSP). The HITSP brings together U.S. standards development organizations and other stakeholders. The HITSP is developing and implementing a harmonization process for achieving a widely accepted and useful set of health IT standards that will support interoperability among health care software applications, particularly EHRs.

Today, the standards-setting process is fragmented and lacks coordination and specificity, resulting in overlapping standards and gaps in standards that need to be filled. A process was implemented where standards are identified and developed specific to real-world

scenarios, or “use cases.” As of March 2006, we have three common use cases for the standards harmonization process, which will also be used in the other contracts discussed below. In May 2006, the HITSP proposed "named standards" for the three use cases and is now developing interoperability specifications for each.

Compliance Certification. HHS awarded a contract to the Certification Commission for Health Information Technology (CCHIT) to develop criteria and evaluation processes for certifying EHRs and the infrastructure or network components through which they interoperate. CCHIT is a private, non-profit organization established to develop an efficient, credible, and sustainable mechanism for certifying commercial health care information technology products. The contract, currently scheduled for a three-year period, will address three areas of certification: ambulatory electronic health records, inpatient electronic health records, and the infrastructure components through which they could interoperate.

The CCHIT has made significant progress toward the certification of commercial ambulatory electronic health records. In February 2006, CCHIT began using its final criteria to conduct ambulatory electronic health record certification pilot tests and has been accepting applications for operational certification as of March 2006, with the goal of having certified electronic health record products in the marketplace on July 18, 2006. Certification will help buyers of HIT determine whether products meet minimum requirements.

NHIN Architecture. HHS has awarded contracts totaling \$18.6 million to four consortia of health care and health information technology organizations to develop prototype architectures for the Nationwide Health Information Network (NHIN). The four consortia will move the nation toward the President's goal of personal electronic health records by creating a usable architecture for health care information. The NHIN architecture will be coordinated with the work of the Federal Health Architecture and other interrelated infrastructure projects. The goal is to develop real solutions for nationwide health information exchange by stimulating the market through a collaborative process and the development of network functions. In June 2006, the contractors submitted proposed functional requirements for the NHIN's to HHS and a public meeting will be held next week to review them.

Security and Privacy. HHS awarded a contract to RTI International working with the National Governors Association Center for Best Practices to form the Health Information Security and Privacy Collaboration (HISPC). Through this contract, healthcare stakeholders, including consumers, within and across 34 states and territories will assess variations in organization-level business policies and State laws that affect electronic health information exchange; identify and propose practical solutions for addressing such variation that will comply with privacy and security requirements in applicable Federal and State laws; and develop detailed plans to implement identified solutions.

All State and territory governors were invited to submit, or have a designee submit, a proposal for participation. States and territories that participate in the HISPC will be required to undertake certain activities that include: examining privacy and security policies and business practices regarding electronic health information exchange; convening and working closely with a wide range of stakeholders in the State, including consumers, to identify best practices, barriers and solutions; and developing an implementation plan for solutions to address organization-level business practices and State laws that affect privacy and security practices for interoperable health information exchange.

In the next six months, state consortia will produce an interim assessment of current privacy and security variations. To do this, state subcontractors will form collaborative workgroups to define this preliminary landscape. State solutions and implementation plans under this contract will be finalized in early 2007.

EHR Adoption Study

To assess progress toward the President's goal for EHR adoption, we must be able to measure the rate of adoption across relevant care settings. To date, several health care surveys have queried health care providers such as individual physicians, physician group practices, community health centers, and hospitals on their use of EHRs in an effort to estimate an overall "EHR adoption rate." These surveys indicate an adoption gap; however, the surveys and what they have measured have varied. These variations occur

from survey factors such as the type of entity, geography, provider size, type of health information technology deployed, how an EHR is defined, the survey sampling frame methodology (e.g., the source list of physicians), and survey data collection method (i.e., phone interview, mail questionnaire, internet questionnaire, etc.).

Due to the variations in the purpose and approach, these surveys have yielded varying methods of EHR adoption measurement. In particular, no single approach yields a reliable and robust long-term indicator of the adoption of interoperable EHRs that could be used for (1) bench marking progress towards meeting the President's EHR goal and (2) informing Federal policy decisions that would catalyze progress towards reaching this goal. Therefore, HHS awarded a contract to the George Washington University and Massachusetts General Hospital Harvard Institute for Health Policy to support the Health IT Adoption Initiative. The new initiative is aimed at better characterizing and measuring the state of EHR adoption and determining the effectiveness of policies to accelerate adoption of EHRs and interoperability.

Federal Health Architecture

Now that HHS has established an infrastructure to address standards harmonization, compliance certification, nationwide health information network architecture, security and privacy, and EHR adoption measurement through its contracts, there is a need to gain the Federal perspective in these and other Federal health information technology areas. To accomplish this, we are looking to the Federal Health Architecture (FHA), an OMB

line of business, established on March 22, 2004 and managed by ONC to create interoperability and increase efficiency within the public sector. To better meet the President's health IT goals, FHA as of March 2006 has been realigned to provide the federal perspective using the processes created within ONC to ensure that interoperability exists within and between the public and private sector. FHA will achieve this refined vision by providing input into the established infrastructure and guidance for implementation within the public sector. Moving forward, FHA will be representing and coordinating the federal activities in all matters relating to the President's health IT plan.

Stark and Anti-Kickback

Regulations that support adoption of e-prescribing and electronic health records were proposed last October. CMS proposed to create exceptions to the "physician self-referral" law to allow hospitals and certain health care organizations to furnish hardware, software, and related training services to physicians for e-prescribing and electronic health records, particularly when the support involves systems that are "interoperable" and thus can exchange information effectively and securely among health care providers. In a parallel action, the OIG announced proposed safe harbors for arrangements involving the donation of technology for e-prescribing and electronic health records. Arrangements for the provision of items and services that meet the requirements of the safe harbors would be exempt from enforcement action under the Federal anti-kickback statute.

Interoperable HIT as a Foundation for other Initiatives

The Department recognizes that interoperable health IT is critical in not only transforming how care may be delivered, but also in informing patients and other consumers about costs of care, and some aspects of its quality. Innovative incentive programs such as value-based purchasing could benefit from high fidelity reliable, information being available.

Conclusion

Thank you for the opportunity to update you on the progress we are making in the area of health information technology. HHS, under Secretary Leavitt's leadership, is giving the highest priority to fulfilling the President's commitment to promote widespread adoption of interoperable electronic health records, and it is a privilege to be a part of this transformation.

This concludes my prepared statement. I would be pleased to answer any questions.