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# **HHS's Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption**

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## **Briefing for Congressional Staff**

### **Senate Committee on Health, Education, Labor, and Pensions**

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# Briefing Overview

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- Introduction
- Questions
- Scope and Methodology
- Background
- Findings
- Agency Comments
- Appendixes

# Introduction

- Fragmented, disorganized, inaccessible clinical information adversely affects the quality of health care and compromises patient safety.
- Health information technology (IT)—technology used to collect, store, retrieve, and transfer health information electronically—is seen as a promising solution to this problem; however, only a small number of U.S. health care providers have fully adopted health IT.
- Financial, technical, cultural, and legal factors—including a lack of access to capital and a lack of data standards—have been identified as barriers to the adoption of health IT.
- The Department of Health and Human Services (HHS) has taken steps to address some of these barriers, but there is no comprehensive catalogue of these efforts and little is known about the nature and extent of legal barriers.

## Questions

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1. What are the major HHS initiatives for promoting the adoption of health IT by public and private health care providers?
2. What are the legal barriers to the adoption of health IT by health care providers,<sup>1</sup> and what is HHS doing to surmount them?

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<sup>1</sup>We did not address legal barriers related to the privacy and security of health information.

# Scope and Methodology

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- To describe HHS's health IT initiatives, we asked HHS to identify its major activities in this area, reviewed agency documents, and interviewed relevant HHS officials. We also incorporated information from our earlier work on health IT.
- We primarily focused on health IT used in clinical health care delivery (e.g., electronic health records (EHR)) and did not examine disease surveillance systems and telemedicine.
- Some HHS IT initiatives we describe have recently been initiated or are still in the planning stages, and so results to date are limited. In addition, the status of the initiatives is subject to change pending completion of an organizational review by the newly established HHS Office of the National Coordinator for Health Information Technology (ONCHIT).

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## Scope and Methodology (continued)

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- To identify legal barriers, we reviewed the literature and interviewed HHS and other federal officials, health care providers, health care attorneys, and other health IT experts. We did not address barriers that may be associated with privacy and security issues.
- We performed our work from May 2004 through August 2004 in accordance with generally accepted government auditing standards.

# Background

## Description of Health IT and the Electronic Health Record

- Health IT includes clinical systems, administrative and financial systems for billing and other administrative tasks, and the infrastructure to support them.
- One of the essential clinical systems is the electronic health record (EHR).<sup>2</sup>
- An EHR generally includes
  - longitudinal collection of electronic health information on the health of an individual or the care provided,
  - immediate electronic access to patient- and population-level information by authorized users,
  - decision support to enhance the quality, safety, and efficiency of patient care, and
  - support of efficient processes for health care delivery.

<sup>2</sup>EHRs are also known as electronic medical records, automated medical records, and computer-based patient records, among other names.

# Background

## Benefits of Health IT

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- In a previous study,<sup>3</sup> we found examples of reported cost savings or other benefits in 20 health IT initiatives across the United States, including
  - \$8.6 million annual savings at a teaching hospital that replaced outpatient paper medical charts with electronic health records
  - the prevention of the administration of over 1,200 wrong drugs or dosages over the period of 1 year in one rural community hospital that used bar code technology and wireless scanners to verify both the identities of patients and their correct medications
- The benefits of health IT notwithstanding, there are still significant barriers to its adoption.

# Background

## Financial, Technical, and Cultural Barriers to the Adoption of Health IT

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### Financial barriers

- Inability to access high-quality IT services at affordable prices
- Need for greater access to capital
- Inability to provide evidence of return on investment

### Technical barriers

- Complex and lengthy implementation processes
- Lack of uniform standards for data submission and reporting
- Inability to sufficiently integrate and incorporate changes to business processes

### Cultural barriers

- Need for a better understanding of best practices for IT adoption
- Lack of leadership support from the public and private sectors
- Resistance by health care providers

# Background

## Role of HHS and Other Federal Agencies in Promoting Health IT

- HHS, as a regulator, purchaser, health care provider, and sponsor of research, education, and training, has been working to promote the use of IT in public and private health care settings. Among its goals are to improve patient safety and allow quick, reliable, and secure access to information across the health care system.
- Outside of HHS, the Department of Veterans Affairs (VA) and the Department of Defense (DOD) are considered by experts to be leaders in the use of health IT, particularly with regard to the adoption of EHR systems for their constituents.<sup>4</sup>

<sup>4</sup>See appendix I for a description of existing federal EHR systems.

# Background

## Recent Actions to Promote Health IT

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- November 2001: The National Committee on Vital and Health Statistics (NCVHS), a public committee established to advise the Secretary of Health and Human Services on health data, statistics, and national health information policy, published *Information for Health: A Strategy for Building the National Health Information Infrastructure*. The study called for federal leadership to accelerate and coordinate progress on the National Health Information Infrastructure (NHII).
  - 2002: The Office of the Assistant Secretary for Planning and Evaluation started the National Health Information Infrastructure Initiative moving forward the NCVHS recommendations.
  - December 2003: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) called for 1) a Commission on Systemic Interoperability to develop a comprehensive strategy for the adoption and implementation of health care IT standards; 2) an electronic prescription drug program; and 3) uniform standards on electronic prescribing recommended by NCVHS.
  - April 27, 2004: The President issued an executive order establishing the position of the National Health Information Technology Coordinator within HHS and forming ONCHIT.
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# Background

## Recent Actions to Promote Health IT (continued)

- May 6, 2004: A National Health Information Technology Coordinator was appointed to
  - serve as the Secretary's principal advisor for health IT issues and direct HHS's health IT programs
  - ensure that HHS's health IT programs are coordinated with those of other federal agencies
  - coordinate outreach and consultation by federal agencies with public and private parties (e.g., consumers, providers, payers)
  - develop, maintain, and direct the implementation of a strategic plan to guide the nationwide implementation of interoperable<sup>5</sup> health information technology in both the public and private health care sectors that will reduce medical errors, improve quality, and produce greater value for health care expenditures

<sup>5</sup>Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged.

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# **HHS's Major Health IT Initiatives Cover a Broad Range of Activities and Participants**

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## Overview of HHS's Major Health IT Initiatives

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- HHS reported that it has 19 major health IT initiatives in operating divisions across the department.
- In fiscal year (FY) 2004, HHS provided about \$228 million for these initiatives.
- Some initiatives, reporting to the Secretary of HHS, are designed to provide overall leadership and coordination for health IT across HHS, other federal agencies, and other public- and private-sector organizations:
  - Council on the Application of Health Information Technology (CAHIT)
  - National Health Information Infrastructure (NHII)
  - Consolidated Health Informatics (CHI) Initiative
  - Federal Health Architecture (FHA)

## Overview of HHS's Major Health IT Initiatives (continued)

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- However, the majority of initiatives, and most of the funding, are for programmatic activities and grant programs administered by HHS operating divisions such as the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS). These initiatives range from support for standards development to demonstrations of interoperable health information systems.
- On July 21, 2004, the National Health Information Technology Coordinator delivered a framework for strategic action to the Secretary of HHS for promoting the adoption of health IT.

# Organization of HHS's Health IT Initiatives

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## HHS Major Health IT Initiatives Office of the Secretary

### Council on the Application of Health Information Technology (CAHIT)

An ongoing intraagency deliberative body established in June 2003 to coordinate efforts related to health IT and to promote a timely exchange of information about HHS activities and opportunities related to health IT

#### *Results to Date*

- Coordinated HHS's involvement with the Health Level Seven (HL7)<sup>6</sup> Electronic Health Record Special Interest Group; in April 2004 the group approved a draft EHR standard for trial use
- Coordinated a series of planning meetings to best position pertinent departmental health IT activities that hold the promise of accelerating EHR adoption; developed an inventory of HHS EHR activity
- Ensured the integration of Consolidated Health Informatics (CHI) standards in HHS agency activities and programs through council meetings, ad hoc activities, and staff briefings

#### *Funding*

FY 04 - No separate funding; staff resources from Office of the Secretary

FY 05 - No separate funding; staff resources from Office of the Secretary

<sup>6</sup>HL7 is a standards development organization accredited by the American National Standards Institute.

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# HHS Major Health IT Initiatives

## Office of the Secretary

### Assistant Secretary for Planning and Evaluation (ASPE)

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#### National Health Information Infrastructure (NHII)

An initiative to improve the effectiveness, efficiency, and overall quality of health care in the United States through the creation of a comprehensive knowledge-based network of interoperable systems of clinical, public health, and personal health information

#### *Results to Date*

- Achieved National Committee on Vital and Health Statistics' (NCVHS) recommendation to develop leadership within HHS with the appointment of the National Health Information Technology Coordinator
- Sponsored annual NHII conferences and conducted outreach to public and private stakeholders

#### *Future Goals*

- Build collaboration among stakeholders
- Develop and carry out a comprehensive strategic plan encompassing public and private health IT activities

#### *Funding*

FY 04 - \$3 million

FY 05 - \$5 million requested

# HHS Major Health IT Initiatives

## Office of the Secretary

## Office of Information Resources Management

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### Consolidated Health Informatics (CHI) Initiative

An OMB e-government initiative, for which HHS was designated the lead, to establish federal health information interoperability standards as the basis for electronic health data transfer in all activities and projects and among all federal agencies

#### *Results to Date*

- Established a set of standards to be adopted by federal agencies

#### *Future Goal*

- Integrate with the Federal Health Architecture

#### *Funding*

FY 04 - No separate funding; staff resources from Centers for Medicare and Medicaid Services

FY 05 - No separate funding; staff resources from Centers for Medicare and Medicaid Services

# **HHS Major Health IT Initiatives**

## **Office of the Secretary**

### **Office of Information Resources Management**

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#### **Federal Health Architecture (FHA)**

A process begun in July 2003 that is expected to define an overarching federal framework and methodology for establishing targets and standards for interoperability and communication across the federal health community, building on the work of the CHI initiative

#### *Results to Date*

- Established governance structures to review and coordinate health IT initiatives across federal agencies
- Expanded the initial health lines of business from disease surveillance to include EHR and food safety

#### *Funding*

FY 04 - \$2.8 million

FY 05 - \$3.9 million requested

# HHS Major Health IT Initiatives Agency for Healthcare Research and Quality<sup>7</sup>

## Health Information Technology (HIT) Initiatives

Research and demonstration projects intended to achieve a better understanding of the effects of health IT on quality, safety, efficiency, and effectiveness

### *Results to Date*

- **Transforming Healthcare Quality Through IT:** Funded a series of 3-year grant programs to demonstrate the value of health IT, plan for future HIT implementation, and implement partnerships of three or more entities
- **State and Regional Health IT Demonstrations:** Issued a contract solicitation to establish and implement state and regional demonstrations of interoperable health information systems
- **Indian Health Service's (IHS) Resource and Patient Management System (RPMS):** Provided funding to IHS to support needed enhancements to the IHS-EHR in the RPMS; investment intended to create a user-friendly data system that can provide community-specific health care data as well as track the health status of the population

<sup>7</sup>This agency and its predecessor organizations have been funding research and development in medical informatics with grants since 1968.

## HHS Major Health IT Initiatives Agency for Healthcare Research and Quality (continued)

### *Future Goals*

- Solicit and evaluate grant applications to establish a state-of-the-art service center for grantees and organizations engaged in health IT diffusion activities
- Award contract for a 5-year evaluation of CMS's Medicare Care Management Performance Demonstration Project, a program that explores the integration of EHRs in the ambulatory environment
- Coordinate work with ASPE on standards and interoperability, focusing on clinical messaging and terminology standards, nomenclature for drugs and biological products, comprehensive clinical terminology and nomenclature, and research related to accelerating the adoption of interoperable health IT systems
- Explore and determine the evidence base associated with certain health IT functions over a 13-month period

### *Funding*

FY 04 - \$60 million<sup>8</sup>

FY 05 - \$60 million requested

<sup>8</sup>This funding includes \$3.2 million which AHRQ provided to the National Library of Medicine (NLM) for standards coordination.

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## HHS Major Health IT Initiatives Centers for Medicare and Medicaid Services

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### Doctors' Office Quality Information Technology

To promote the adoption and effective use of health IT through the provision by state-based Quality Improvement Organizations (QIO) of assistance to physician offices in adoption, implementation, and process redesign

#### *Results to Date*

- California's QIO is developing a methodology for provision of assistance to physician offices

#### *Future Goal*

- Begin four-state pilot program in summer 2004 and national pilot in November 2004; full national implementation expected by August 2005

#### *Funding*

FY 04 - \$5 million

FY 05 - \$5 million requested

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## **HHS Major Health IT Initiatives Centers for Medicare and Medicaid Services** (continued)

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### **Medicare Care Management Performance Demonstration**

To offer financial incentives to physician offices in four states for adopting and effectively using health IT

#### *Future Goal*

- Demonstration expected to be approved by HHS and OMB by summer 2004

#### *Funding*

FY 04 - \$2 million for administrative costs

FY 05 - \$2 million for administrative costs requested

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## **HHS Major Health IT Initiatives Centers for Medicare and Medicaid Services** (continued)

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### **Veterans Health Information Systems and Technology Architecture (VistA) - Office EHR**

To produce a version of VA's EHR system for use by non-VA physician offices

#### *Future Goal*

- First release of enhanced product planned for 2005

#### *Funding*

FY 04 - \$2 million

FY 05 - \$1 million requested

## HHS Major Health IT Initiatives Centers for Medicare and Medicaid Services (continued)

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### **E-prescribing Standards**

To test initial electronic prescribing standards and develop, adopt, recognize, or modify them

#### *Results to Date*

- Participated in National Committee on Vital and Health Statistics hearings on electronic prescribing in March and May 2004

#### *Future Goals*

- Develop, adopt, recognize, or modify initial standards by September 1, 2005
- Conduct pilot project during 2006<sup>9</sup>
- Report to Congress on pilot project by April 1, 2007
- Promulgate final standards by April 1, 2008
- Set a date that falls between April 1, 2008 and April 1, 2009 for standards implementation

#### *Funding*

FY 04 - \$600,000

FY 05 - \$700,000 requested

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<sup>9</sup>Pilot project will be conducted during 2006 unless the Secretary determines that the industry has adequate experience with such standards.

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## **HHS Major Health IT Initiatives Food and Drug Administration**

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### **Structured Product Labeling**

To develop data standards that provide information found in package inserts in a computer-readable format for use in electronic prescribing and decision support, and the maintenance and distribution of medication terminology standards

#### *Future Goal*

- Changes to regulations are under way and are scheduled to be completed within 4 years

#### *Funding*

FY 04 - \$4.6 million

FY 05 - \$4.6 million requested

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## **HHS Major Health IT Initiatives**

### **Food and Drug Administration** (continued)

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#### **Bar coding for prescription products**

To require bar codes on most prescription drugs and on certain over-the-counter drugs to address medication errors associated with drug products

#### *Results to Date*

- FDA issued a final rule on February 26, 2004 (69 *Fed. Reg.* 9120)

#### *Funding*

FY 04 - Industry funded

FY 05 - Industry funded

## **HHS Major Health IT Initiatives Health Resources and Services Administration**

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### **Shared Integrated Management Information Systems (SIMIS)/**

### **Information and Communication Technology (ICT)**

A grant program developed in 1998 to significantly improve the ability of community health centers to collect, manage, and use information in order to be more cost competitive; program may include support for a chief information officer and installation of central network hardware and software

#### *Results to Date*

- SIMIS: funded 30 networks of health care providers, supporting 91 community health centers, since 1998
- ICT: funded 6 grants, supporting 51 community health centers, since 2003

#### *Funding*

FY 04 - \$6.2 million

FY 05 - to be determined

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## **HHS Major Health IT Initiatives**

### **Health Resources and Services Administration** (continued)

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#### **Integrated Services Development Initiative (ISDI)**

To facilitate the integration of health care delivery systems and support integration efforts in five areas, one of which is information management, to improve the ability of community health centers to compete in the marketplace

#### *Results to Date*

- Funded 22 networks working on some form of information system or information technology

#### *Funding*

FY 04 - \$1.5 million

FY 05 - to be determined

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## **HHS Major Health IT Initiatives**

### **Health Resources and Services Administration** (continued)

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#### **Healthy Communities Access Program (HCAP)**

A community-based program to develop or strengthen health care safety net delivery systems; program funds may be used for a wide range of activities, including information systems

#### *Results to Date*

- Supported EHRs, eligibility determination, patient referral, and disease management

#### *Funding*

FY 04 - \$10 million

FY 05 - \$10 million requested

## HHS Major Health IT Initiatives Indian Health Service

### Indian Health Service Electronic Health Record (IHS-EHR) Initiative

To provide order entry, results reporting, encounter documentation, and other clinical functionality to IHS, tribal, and urban Indian health care providers. IHS-EHR is a component of IHS's Resource and Patient Management System (RPMS)<sup>10</sup> and is using modified components of VA's VistA system.

#### *Results to Date*

- Testing of IHS-EHR at four sites

#### *Future Goals*

- Implementation at 20 sites during FY 05
- Implementation at all sites by FY 08

#### *Funding*<sup>11</sup>

FY 04 - \$26 million

~~FY 05 - \$33 million requested~~

<sup>10</sup>See appendix I for a description of the RPMS.

<sup>11</sup>EHR costs are closely coupled with RPMS and therefore EHR funding is included as part of the annual RPMS budget.

## HHS Major Health IT Initiatives National Institutes of Health

### National Library of Medicine (NLM) Grants<sup>12</sup>

To provide research grants, contracts, and training support for advanced computer technologies and training in informatics (i.e., information sciences)

#### *Results to Date*

- Supported health informatics research and development, recently focusing on research on scalable information infrastructures for health and disaster management
- Supported training programs on clinical and bioinformatics (i.e., medical and biomedical informatics)
- Funded Integrated Advanced Information Networks (networking within academic centers), and projects to support Internet connections and access to digital libraries for health science libraries and hospitals

#### *Funding*

FY 04 - \$48 million

FY 05 - \$49 million requested

<sup>12</sup>NLM has provided these grant programs for 20 to 30 years.

## HHS Major Health IT Initiatives National Institutes of Health (continued)

### NLM's Support of Clinical Vocabularies

To provide support for, and development of, selected CHI standard clinical vocabularies<sup>13</sup> for ongoing maintenance and free use within the United States

#### *Results to Date*

- Under contract, supported Logical Observations Identifiers Names and Codes (LOINC) maintenance and dissemination
- Licensed Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT) for nationwide use
- Developed RxNORM to fill gap in drug terminology
- Supported uniform distribution and mapping of Health Insurance Portability and Accountability Act (HIPAA) code sets for electronic exchange of health-related information and other vocabulary standards within the Unified Medical Language System (UMLS)

#### *Funding*

FY 04 - \$9 million

FY 05 - \$9 million requested

<sup>13</sup>Appendix II includes a description of selected health care data and communication standards supported by NLM.

## **HHS Major Health IT Initiatives**

### **National Institutes of Health** (continued)

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#### **National Electronic Clinical Trials and Research (NECTAR) Network**

To link clinical research information systems for sharing data and resources, augmenting performance and analysis, and accelerating the application of clinical research findings

#### *Future Goals*

- Complete inventory of current and best practices by June 2006
- Pilot and feasibility-test methods for achieving interoperability by 2006
- Continue to deploy new networks and implement best practices and applications through 2009

#### *Funding*

FY 04 - \$18 million

FY 05 - \$18.5 million requested

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## **HHS Major Health IT Initiatives**

### **National Institutes of Health** (continued)

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#### **Cancer Biomedical Informatics Grid (caBIG)**

A cancer research network of data, individuals, and organizations intended to create a common, distributed infrastructure for sharing of data and applications

##### *Results to Date*

- Conducted seminars and meetings on the development of an integrated bioinformatics infrastructure platform

##### *Future Goal*

- Complete pilot phase of development and testing of bioinformatics infrastructure within 3 years

##### *Funding*

FY 04 - \$32 million (for pilot activities and standards development)

FY 05 - \$32 million (for pilot activities and standards development) requested

# HHS IT Initiatives and Participants

IT initiative	Department of Health and Human Services								DOD	VA	Other fed	State gov	Local gov	Private sector
	OS	AHRQ	CDC	CMS	FDA	HRSA	IHS	NIH						
Council on the Application of Health Information Technology	/	/	●	●	●	●	●	●						
National Health Information Infrastructure	/	●	●	●	●	●	●	●	●	●	●	●	●	●
Consolidated Health Informatics Initiative	/	●	●	●	●	●	●	●	●	●	●			
Federal Health Architecture	/	●	●	●	●	●	●	●	●	●	●			
Health Information Technology Initiatives	●	/		●	●		●					●	●	●
Doctors' Office Quality Information Technology				/										●
Medicare Care Management Performance Demonstration				/										●
VistA – Office EHR		●	●	/	●	●	●			●				
E-prescribing Standards	●			/	●									●
Structured Product Labeling					/									●

/ Indicates lead operating division.

● Indicates participant.

Source: GAO analysis of HHS information. 41

# HHS IT Initiatives and Participants (continued)

IT initiative	Department of Health and Human Services								DOD	VA	Other fed	State gov	Local gov	Private sector
	OS	AHRQ	CDC	CMS	FDA	HRSA	IHS	NIH						
Bar coding for prescription products					/									●
Shared Integrated Management Information Systems/Information and Communication Technology						/								●
Integrated Services Development Initiative						/								●
Healthy Communities Access Program						/						●		●
IHS-EHR Initiative		●					/		●	●			●	●
NLM grants								/		●		●	●	●
Support of clinical vocabularies								/		●				●
National Electronic Clinical Trials and Research Network								/			●			●
Cancer Biomedical Informatics Grid					●			/						●

/Indicates lead operating division.

● Indicates participant.

Source: GAO analysis of HHS information.

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**Various Laws Present  
Barriers to Adoption of  
Health IT; and HHS's Efforts  
to Address These Barriers  
Have Been Limited**

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## Overview of Legal Barriers

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- Experts we interviewed indicated that beyond legal issues related to the privacy and security of health information, there are various laws—some specifically health-related and some not—that present barriers to the adoption of health IT. These laws involve
  - Fraud and abuse
  - Antitrust
  - Federal income tax
  - Intellectual property
  - Liability/malpractice
  - State licensing

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## Overview of Legal Barriers (continued)

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- Because these laws frequently do not address health IT arrangements directly, health care providers are uncertain about what would constitute violations of those laws or create a risk of litigation. To the extent there are uncertainties and ambiguity in predicting legal consequences, health care providers are reluctant to take action and make significant investments in health IT.
- HHS has attempted to address some of the legal barriers posed by the fraud and abuse laws, but experts indicated that these efforts have not been sufficient. Little attempt has been made by other federal agencies to address laws under their jurisdiction that present barriers.

# Legal Barriers Fraud and Abuse

## Physician Self-Referral (Stark) Law

- The law prohibits physicians from referring patients to an entity for certain health services if the physician (or an immediate family member) has a financial relationship (i.e., has an ownership interest in or receives compensation from) with the entity, and prohibits entities from billing for any services resulting from such referrals, unless an exception applies. 42 U.S.C. § 1395nn (2000).
- The law presents a barrier by impeding the establishment of arrangements that promote the adoption of health IT. Specifically, because many physicians find health IT cost-prohibitive, hospitals or other providers are sometimes willing to provide physicians with hardware, software, or other resources. Parties have been reluctant to establish such arrangements, however, out of concern that if the physician subsequently makes a referral to that provider, they may be viewed as having violated the law.
- Violation may result in parties having to return any payments they received for services resulting from the prohibited referral, being excluded from participation in federal health care programs, and having to pay civil penalties.

# Legal Barriers

## Fraud and Abuse (continued)

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### Anti-kickback Law

- The law prohibits an individual or entity from knowingly and willfully offering or accepting remuneration of any kind to induce a patient referral for or purchase of an item or service covered by any federal health care program. 42 U.S.C. § 1320a-7b(b) (2000).
- Like the self-referral law, it presents a barrier by impeding the establishment of certain arrangements that promote the adoption of health IT. Physicians may be reluctant to accept IT resources from a hospital or other provider, knowing that the resources may be viewed as remuneration and that any referrals the physician subsequently makes to the provider may be viewed as having been made in return for such resources in violation of the law.
- Violation may result in civil or criminal penalties, including exclusion from participation in federal health care programs and imprisonment.

# Legal Barriers

## Fraud and Abuse (continued)

### HHS's Efforts to Address Barriers Presented by Self-Referral and Anti-kickback Laws

- There are various statutory and regulatory exceptions to the self-referral and anti-kickback laws, but none are sufficient to cover all arrangements that parties may wish to establish to promote the adoption of health IT. In its comments on a draft of this report, HHS noted the difficulty in crafting safe harbors that exclude abusive arrangements.
- The Medicare Prescription Drug, Improvement and Modernization Act of 2003 requires HHS to establish additional limited exceptions under both laws to facilitate electronic prescribing. HHS officials are currently developing regulations to implement this requirement.
- On March 26, 2004, CMS issued an interim rule with comment period creating a new exception under the self-referral law for “community-wide health information systems,” but experts say it does not cover many health IT arrangements and there is a lack of clarity about what “community-wide” means. Additionally there is no parallel exception under the anti-kickback law. An HHS official said that parties can request an advisory opinion to determine whether an arrangement they are contemplating would violate the anti-kickback law. In response to a draft of this report, HHS noted that advisory opinions can also be obtained for the self-referral law. However, the process is time-consuming and such case-by-case guidance is not an appropriate mechanism for addressing broader industry concerns.
- The comment period for the interim rule ended on June 24, 2004. CMS is currently engaged in revising the rule based on the comments including clarifying the term community-wide.

### State Self-Referral and Anti-kickback Laws

- Many states have laws analogous to the federal self-referral and anti-kickback laws, some of which are stricter or have fewer exceptions or both.

# Legal Barriers Antitrust

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- Some experts are concerned that certain arrangements that may promote the adoption of health IT may be viewed as anticompetitive and thereby violate antitrust laws. 15 U.S.C. §§ 1 et seq. (2000).
- An official from the Department of Justice told us that to the extent that the benefits of such arrangements can be shown to outweigh any anticompetitive impact, they are not likely to violate federal antitrust laws.
- However, given the uncertainty about the impact of health IT arrangements on competition and what constitutes a violation, antitrust laws still present a barrier to the adoption of health IT.

## **Legal Barriers Federal Income Tax**

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### **Private Inurement/Benefit**

- Tax-exempt organizations that provide financial or other benefits to private individuals may jeopardize their tax-exempt status. Some experts are concerned that the provision of IT resources by tax-exempt hospitals to physicians may be viewed as providing just such benefits to private individuals. 26 U.S.C. § 501(c)(3) (2000).

### **Unrelated Business Income**

- Tax-exempt organizations that generate income from business activities not substantially related to the role that qualified them for tax-exempt status must pay income tax on that income. Some experts are concerned that any charges tax-exempt hospitals impose on others for using IT resources that the hospitals have financed and developed may be taxable. 26 U.S.C. §§ 501(b) and 513(a) (2000).

# Legal Barriers Intellectual Property

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## Copyright Protection

- Hospitals and other entities that are investing (or considering investing) significant financial resources in the development of health IT systems are concerned that copyright protections applicable to such systems may be inadequate to prevent unauthorized use and they will be unable, as a result, to recoup their investments. 17 U.S.C. § 106 (2000).

## Legal Barriers Liability/Malpractice

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- Some physicians are concerned that the more information they have access to through health IT, the more information they will be held responsible for knowing and that this will increase their risk of being held liable for malpractice.
- Physicians are generally responsible, however, for obtaining relevant information from patients to provide proper treatment, and the adoption of health IT may make it easier for physicians to obtain all relevant information and provide better care, which may reduce the risk of malpractice.

## Legal Barriers State Licensing

- Physicians generally must be licensed to practice medicine in any state in which they practice, and state licensing requirements vary from state to state. If physicians provide medical advice electronically or engage in telemedicine across state boundaries, there is concern that they may be viewed as practicing medicine in a state where they are not licensed to do so.

# Appendix I

## Federal Electronic Health Record Systems

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The Department of Veterans Affairs' (VA) Veterans Health Administration consists of 21 regional networks that support 158 hospitals, 133 nursing homes, and 698 community-based outpatient clinics.

- VA has had an automated information system, the Decentralized Hospital Computer Program (DHCP), in its medical facilities since 1985.
- In 1996 DHCP evolved into the Veterans Health Information Systems and Technology Architecture (VistA).
- The Computerized Patient Record System (CPRS) is the interface that integrates all clinical VistA data, providing clinicians with a complete EHR and supporting patient care in both inpatient and outpatient settings.

## Appendix I (continued)

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The Department of Defense (DOD) operates a worldwide health care program that consists of 75 hospitals and 461 outpatient clinics.

- Implementation of the Composite Health Care System II (CHCS II) began in March 2003 and is expected to be completed by 2008.
- CHCS II interfaces with military health care systems to provide an integrated EHR for care provided in DOD outpatient medical facilities.

HHS's Indian Health Service (IHS) consists of 36 hospitals, 61 health centers, 49 health stations, and 4 residential treatment centers.

- IHS's Resource and Patient Management System (RPMS) is a decentralized automated information system with integrated software applications.
- RPMS consists of patient-based administrative applications, patient-based clinical applications (e.g., IHS-EHR), and financial and administrative applications.

# Appendix II

## Selected Health Data and Communication Standards Developed, Supported, Mapped and/or Distributed by NLM

Health Level (HL7) messaging standards	Comprehensive standards for the exchange of data for the purpose of simplifying the implementation of interfaces between health care software applications and various vendors, so as to reduce the need for custom interface programming.
Health Insurance Portability and Accountability Act (HIPAA) code sets	Transactions and code sets for electronic exchange of health-related information to perform billing or administrative functions.
Logical Observations Identifiers Names and Codes (LOINC)	A standard set of universal names and codes for identifying individual laboratory and clinical results and allows users to merge clinical results from many sources into one database for patient care, clinical research, or management.
RxNorm	A clinical nomenclature that provides standard names for clinical drugs (e.g., active ingredient, strength, dose form) and for dose forms as administered.
Systemized Nomenclature of Medicine Clinical Terms (SNOMED CT)	A comprehensive clinical terminology formed by the convergence of SNOMED RT® and the United Kingdom's Clinical Terms Version 3 (formerly known as the Read Codes).
Unified Medical Language System (UMLS) Metathesaurus	A large, multi-purpose, multi-lingual vocabulary database built from the electronic versions of many different thesauri, classifications, code sets, and terminologies, including HIPAA and CHI standards.