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United States Government Accountability Office
Washington, DC 20548

August 13, 2004

The Honorable Judd Gregg
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

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

Dear Mr. Chairman:

Studies published by the Institute of Medicine and others have indicated that fragmented, disorganized, and inaccessible clinical information adversely affects the quality of health care and compromises patient safety.¹ Health information technology (IT)—technology used to collect, store, retrieve, and transfer clinical, administrative, and financial health information electronically—is seen as a promising solution to this problem. Technologies such as electronic health records (EHR)² and bar coding of certain human drug and biological product labels have been shown to save money and reduce medical errors. However, only a small number of U.S. health care providers have fully adopted health IT. Significant financial, technical, cultural, and legal barriers to the adoption of health IT exist. These include a lack of access to capital, a lack of data standards, and resistance from health care providers.

The Department of Health and Human Services (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.³ There is no comprehensive catalogue of HHS's health IT efforts, however, and little is known about the nature and extent of the legal barriers and HHS's efforts to address them.

¹See, for example, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. (Washington, D.C.: National Academy Press, 2001).

²An EHR generally includes a longitudinal collection of electronic health information about 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.

³Outside 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 in the adoption of EHR systems for their constituents.

You asked us to review HHS's activities to promote health IT. We examined the following questions: (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, and what is HHS doing to surmount them? Enclosure I contains the briefing on the results of our study that we discussed with your staff on July 13, 2004.

To describe HHS's health IT initiatives, we asked HHS to identify its major activities in this area, reviewed agency documents, interviewed relevant HHS officials, and incorporated information from our earlier work on health IT. We primarily focused on health IT used in clinical health care delivery (e.g., EHR) and did not examine disease surveillance systems and telemedicine. Some HHS IT initiatives we describe have recently been implemented 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). 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.

Summary

HHS reported that it has 19 major health IT initiatives that cover a broad range of activities and participants. In fiscal year 2004, HHS provided about \$228 million for these initiatives. Some of them—the Council on the Application of Health Information Technology (CAHIT), the National Health Information Infrastructure (NHII), the Consolidated Health Informatics (CHI) Initiative, and the Federal Health Architecture (FHA)—are designed to provide overall leadership and coordination for health IT across HHS, other federal agencies, and other public- and private-sector organizations. The majority of initiatives and most of the funding, however, are for health IT 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 the development of standard clinical terminologies to funding of demonstrations of 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.

Various laws present barriers to adoption of health IT, and at the time of our review HHS's efforts to address these barriers had been limited in scope. 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, malpractice, and state licensing. In the area of fraud and abuse, for example, both the Physician Self-Referral (Stark) Law and the Anti-kickback Law present barriers by impeding the

establishment of arrangements between providers—such as the provision of IT resources—that would otherwise promote the adoption of health IT. Because the laws frequently do not address health IT arrangements directly, health care providers are uncertain about what would constitute violations of the 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 told us these efforts have not been sufficient to overcome the reluctance of the providers. Further, little attempt has been made by other federal agencies to address other laws that may present barriers.

Agency Comments

HHS reviewed a draft of this report and provided comments. HHS asked us to highlight other actions it has taken to advance health IT in areas such as privacy and security standards, disease surveillance systems, and telemedicine. However, as we noted in the report, our work was focused on health IT used in clinical health care delivery (EHR, for example) and not on other health IT issues. HHS emphasized that the federal anti-kickback and self-referral statutes provide important protections against fraud and abuse, and that exceptions or safe harbors from these statutes must be carefully crafted to exclude abusive arrangements. We recognize the significant role these laws play in deterring fraud and abuse, but the experts we consulted consistently told us that these laws present barriers to the adoption of health IT. In particular, we found that there was uncertainty about what would constitute a violation of the law and this uncertainty itself created a barrier for promoting beneficial health IT arrangements. HHS's written comments and our more detailed responses to them are in enclosure II. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services and other interested officials. We will also provide copies to others on request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>. If you or your staff have any questions or need additional information, please contact me at (202) 512-7119. Another contact and key contributors are listed in enclosure III.

Sincerely yours,



Janet Heinrich
Director, Health Care—Public Health Issues

Enclosures – 3

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

Briefing for Congressional Staff

Senate Committee on Health, Education, Labor, and Pensions

Briefing Overview

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

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,¹ and what is HHS doing to surmount them?

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

Scope and Methodology

- 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)

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

Background

Benefits of Health IT

- In a previous study,³ 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.

³U.S. General Accounting Office, *Information Technology: Benefits Realized for Selected Health Care Functions*, GAO-04-224 (Washington, D.C.: Oct. 31, 2003).

Background

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

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
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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.⁴

⁴See appendix I for a description of existing federal EHR systems.

Background

Recent Actions to Promote Health IT

- 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 interoperable⁵ 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

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

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

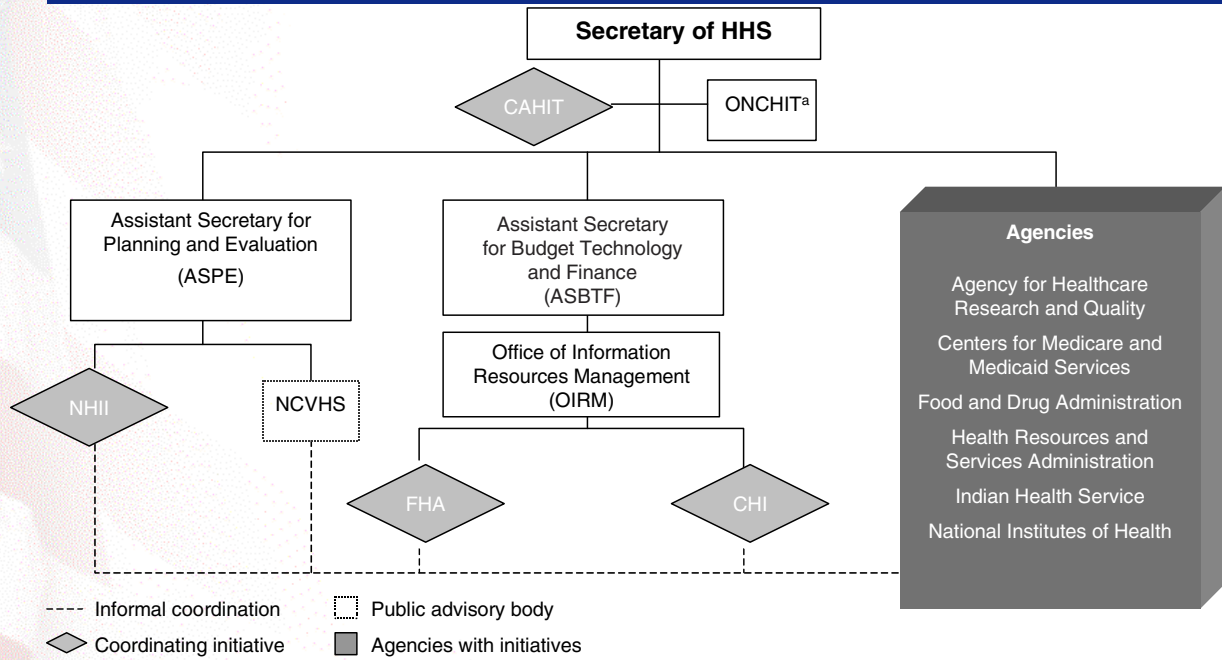
Overview of HHS's Major Health IT Initiatives

- 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.
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Organization of HHS's Health IT Initiatives



^aONCHIT was established in April 2004 and is in the process of reorganizing the reporting assignments of many HHS health IT initiatives to improve and consolidate coordination. This chart depicts the organization of HHS's health IT initiatives prior to this reorganization.

Source: GAO analysis of HHS information.

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)⁶ 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

⁶HL7 is a standards development organization accredited by the American National Standards Institute.

HHS Major Health IT Initiatives Office of the Secretary Assistant Secretary for Planning and Evaluation (ASPE)

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

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

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 Quality⁷

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

⁷This 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 million⁸

FY 05 - \$60 million requested

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

HHS Major Health IT Initiatives Centers for Medicare and Medicaid Services

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

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

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

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

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)

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 2006⁹
- 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

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

HHS Major Health IT Initiatives Food and Drug Administration

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

HHS Major Health IT Initiatives Food and Drug Administration (continued)

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

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

HHS Major Health IT Initiatives

Health Resources and Services Administration (continued)

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

HHS Major Health IT Initiatives

Health Resources and Services Administration (continued)

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)¹⁰ 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*¹¹

FY 04 - \$26 million

FY 05 - \$33 million requested

¹⁰See appendix I for a description of the RPMS.

¹¹EHR 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) Grants¹²

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

¹²NLM 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 vocabularies¹³ 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

¹³Appendix 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)

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

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

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.

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.

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

Overview of Legal Barriers

- 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
-

Overview of Legal Barriers (continued)

- 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.
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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.
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Legal Barriers Fraud and Abuse (continued)

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

- 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

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

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

- 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

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)

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.

Comments from the U.S. Department of Health and Human Services**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Office of Inspector General

Washington, D.C. 20201

AUG - 9 2004

Ms. Janet Heinrich
Director, Health Care – Public Health Issues
United States Government Accountability Office
Washington, D.C. 20548

Dear Ms. Heinrich:

Enclosed are the Department's comments on your draft correspondence entitled, "HHS's Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption" (GAO-04-991R). The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided several technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script, appearing to read "Dara Corrigan".

Dara Corrigan
Acting Principal Deputy Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for Government Accountability Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Department of Health and Human Services Comments on Government Accountability Office's Correspondence entitled "HHS's Efforts to Promote Health Information Technology And Legal Barriers to Its Adoption" (GAO-04-991R)

Department of Health and Human Services (HHS) Secretary Tommy G. Thompson enthusiastically supports the promotion of health information technology (HIT) and has been actively supporting it. In May and late July, he held summits on HIT, noting that "America needs to move much faster to adopt information technology in our health care system." He is moving HHS forward with the appointment of Dr. David Brailer, the release of the Framework for Strategic Action, and the launching of the slide show "Decade of HIT." GAO's proposed correspondence provides a baseline to kick-off the decade.

1. A general weakness of the slide presentation is that it focuses narrowly on the electronic health records (EHR) and does not acknowledge systems issues of interoperability among providers, the personal health record, or linkages to public health. There is also no sense of the challenge for public policy in developing appropriate incentives for the adoption of the EHR in the private sector.
2. This report does not address the efforts HHS has made to advance HIT by adopting privacy and security standards for health information, as well as standards for electronic transactions. It should be noted that HHS has adopted, under Health Insurance Portability and Accountability Act, final rules regarding the privacy and security of health information and standards for electronic transactions. The Department has begun enforcing the Privacy Rule and Transactions Rule, and will begin enforcing the Security Rule in April 2005. While there are some issues that may need to be worked out with respect to compliance with the Privacy and Security Rules in adopting HIT, these protections help address one of the President's goals set forth in his Executive Order and could help overcome significant barriers to adoption of HIT.
3. The report fails to address the risk of fraud or abuse that might arise when hospitals or other entities give valuable items or services to potential referral sources. The Federal anti-kickback statute and the Federal physician self-referral law provide important protections against fraud and abuse. In enacting these statutes, Congress sought to curb improper financial incentives that distort medical decision-making, potentially harming the Federal health care programs and their beneficiaries. Improper financial incentives can lead, directly or indirectly, to overutilization of items and services, increased costs to programs and beneficiaries, compromised medical judgment, and unfair competition.

In this regard, the first bullet on page 48 of Enclosure 1 appears to suggest, inappropriately, that "all arrangements that parties may wish to establish to promote the adoption of HIT" should be subject to a physician self-referral exception or anti-kickback statute safe harbor. In addition, on page 46 of the enclosure, GAO asserts that physician reluctance to pay for HIT is the only reason hospitals might wish to furnish physicians with HIT hardware, software, or other resources. There is legitimate concern, however, that hospitals or other providers or suppliers may provide free or deeply

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discounted HIT to physicians (particularly physicians whom they do not employ) in an effort to influence referral decisions, which may result in fraud or abuse. For example, an arrangement that links the provision of free HIT to the generation of a volume of referrals for the entity providing the HIT could result in physicians over-ordering services or inappropriately steering beneficiaries to particular providers (and potentially restricting beneficiary choice) in order to "earn" the free HIT. Similarly, larger entities with deeper pockets and greater ability to fund HIT may compete for referrals of Federal health care program business by offering free HIT, potentially disadvantaging smaller or publicly-funded entities, such as some community hospitals.

Accordingly, we believe the report should recognize that creating physician self-referral law exceptions and anti-kickback statute safe harbors requires careful consideration of the potential for fraud and abuse. Any exceptions or safe harbors would need to be crafted carefully to exclude abusive arrangements.

4. We disagree with the assertion that "[b]ecause [fraud and abuse laws and other laws] frequently do not address HIT arrangements directly, health care providers are uncertain about what would constitute violations of those laws or create a risk of litigation" (page 3 of the report and page 45 of Enclosure 1). We disagree that Federal health care program fraud and abuse laws are unclear or that parties do not understand what the laws prohibit. The fact that these and other laws do not specifically address HIT arrangements does not mean that their applicability to such arrangements is unclear or unpredictable.
5. We disagree with the suggestion in the third bullet on page 48 of Enclosure 1 that an Office of Inspector General (OIG) advisory opinion is of limited practical value. A favorable advisory opinion ensures that the recipient will not be subject to OIG sanctions. We believe the bullet would be more accurate if it stated that "such case-by-case guidance is not an appropriate mechanism for addressing broader industry concerns." We believe this statement more clearly reflects the intent of the bullet point.
6. Also on page 46 of Enclosure 1, it should be noted that the Centers for Medicare and Medicaid Services (CMS) has accepted public comments and is currently engaged in rulemaking with respect to the community-wide HIT exception, including the definition of the term "community-wide."
7. The report concludes in several places that the Federal physician self-referral law and anti-kickback statute inhibit arrangements between physicians and hospitals or other entities that would promote adoption of HIT. We think it worth noting that barriers exist unrelated to these statutes, including cost and physician resistance to the use of HIT.
8. We do not believe that there is unanimous agreement that hospitals should pay for HIT used by physicians who are not employed by hospitals and who will use the IT resources in the context of their own office practices.

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9. We note that the report appears to suggest that HHS has failed to address antitrust, tax, intellectual property, malpractice liability, and state licensing laws. HHS has no legal jurisdiction over those laws.
10. The report neglects to mention the role of the National Committee on Vital Health Statistics (NCVHS) as specified in the Medicare Prescription Drug, Improvement and Modernization Act, and progress to date. NCVHS is mentioned later in several places, but there is no context for this information.
11. GAO provided guidance that telehealth/telemedicine initiatives should be excluded in the inventory of programs. Health Resources and Services Administration's program incorporates many of the goals and activities described in the GAO slides. Therefore, it may now be relevant to include information about the Telehealth Network Grant Program.

GAO's Responses to HHS's Comments

HHS provided 11 specific comments about various issues in the draft report, and our response to these comments is as follows:

Background and Scope of Work

HHS commented that our briefing slides had a narrow focus and did not acknowledge other actions it has taken in areas such as interoperability, privacy and security standards for health information, and telehealth/telemedicine (comments 1, 2, and 11). We were specifically asked by our requestor to focus our work on health IT used in clinical health care delivery (e.g., EHR) and not on other health IT issues. In addition, we were asked to look at specific legal barriers to the adoption of health IT that did not include privacy and security concerns. HHS also said that besides the self-referral and anti-kickback laws, there are other barriers to the adoption of health IT, including cost and physician resistance (comment 7). We described those barriers on page 12. HHS provided additional information about the role of the National Committee on Vital and Health Statistics as specified in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (comment 10). We added this information to the background section of our briefing slides.

Legal Barriers

HHS stated that we failed to address the risk of fraud and abuse when hospitals or other entities give valuable items or services to potential referral sources (comment 3). We recognize the role the federal fraud and abuse laws play in deterring such health care violations but experts consistently told us that these laws present a barrier to the adoption of health IT. We revised our report in response to HHS's comment that is difficult to craft appropriate safe harbors that would prevent fraud and abuse.

HHS disagreed that fraud and abuse and other relevant laws are unclear and that health care providers are uncertain about what may constitute violations of those laws or create risks of litigation (comment 4). However, health care providers, attorneys, and other experts consistently told us that they were uncertain about the application of the laws to health care IT and what may constitute statutory violations or create risks of litigation. This uncertainty constitutes a barrier for promoting beneficial health IT arrangements.

HHS disagreed with our conclusion that an Office of Inspector General advisory opinion is of limited practical value and suggested alternative wording (comment 5). We revised the wording as suggested. In its technical comments, HHS also noted that the Secretary can issue an advisory opinion on whether a health IT arrangement would violate the self-referral law, and we added this information to our report. We also revised our report to reflect that CMS has accepted public comment on the March 26, 2004 interim rule and is currently engaged in rulemaking with respect to the definition of "community-wide" (comment 6).

HHS said that there is not unanimous agreement that hospitals should pay for health IT used by physicians who are not employed by hospitals and who will use the IT resources in their office practices (comment 8). We did not suggest that hospitals should pay for health IT for physicians. Experts told us that if hospitals want to develop such arrangements, the fraud and abuse laws may be barriers.

Finally, HHS clarified that HHS has no legal jurisdiction over antitrust, tax, intellectual property, malpractice liability and state licensing laws and therefore cannot address these barriers (comment 9). We revised our report to make this distinction clear.

GAO Contact and Staff Acknowledgments

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