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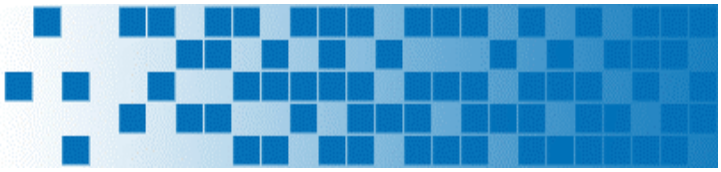

The Emerging Role of the Federal Government in Healthcare Information Technology

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This white paper is the first in a series exploring the increasing role of the Federal Government in influencing Healthcare Information Technology. It briefly covers the rationale for government involvement and its increasing role in the creation of Healthcare Information standards. Finally, It explores in more depth the Electronic Health Record (EHR) initiative, with particular attention to VistA, the Veterans Health Administration (VHA) health record.

Introduction

Many experts believe that the United States healthcare system is failing in many critical areas. They cite too many avoidable medical errors and excessive administrative costs. Many claim that these problems occur because healthcare providers do not have the necessary information technology tools required to practice high quality medicine. Without the right tools, it is argued, healthcare providers cannot find the "right information, about the right patient, at the right time" to make the best medical decisions. This, it is alleged, can lead to increased costs and decreased quality.

Based on these assertions, there appears to be an emerging consensus among leading medical experts, policy makers, and healthcare providers that information technology investment reduces the cost and increases the quality of healthcare services. Many of these same experts believe that the necessary investment in healthcare information technology will not take place without leadership by the Federal government. This paper explores the rationale for these beliefs and the Federal government's recent activity in Healthcare Information policy decisions.

Understanding Medical Errors

Quality, cost and access to healthcare services are the cornerstone of the healthcare debate. While the importance of these issues has not changed over the past decade, important new data is now fueling the debate. Most notably are the recent Institute of Medicine (IOM) reports dealing with medical errors and the importance of healthcare information technology. These IOM studies have been taken seriously by healthcare leaders and in some respects have driven the government and private sector (re: Leapfrog) initiatives. Here are some of the highpoints of those reports:

Medical Errors Effect on Quality:

- Medical errors are responsible for 44,000 to 98,000 deaths per year.
- Medical errors produce 33 million hospitalizations annually.
- Adverse events occur between 3-4% of all hospital admissions.
- Medical errors each year are responsible for more deaths than motor vehicle accidents, AIDS, and breast cancer combined.

Medical Errors Effect on Increasing Costs:

- Medical errors increase total national healthcare costs (lost income, lost household production, disability and healthcare costs) between $17 billion and $29 billion annually.
- Inpatient medication errors alone are costs over $2 billion annually.

Skyrocketing Healthcare Costs

In the United States, health care costs have historically far outstripped the overall rate of inflation. The system wastes far too much money with over 26% of US hospital expenditures or over $100 billion annually spent on claims processing and other administrative requirements. In addition, providers are now challenged to demonstrate their ability to provide high quality health care, while controlling costs. Providing better clinical outcomes (*read: reduced medical errors*) has now been thrust upon health care providers. These quality/cost concerns are really value issues. *"Do we get our money's worth for our healthcare dollar?"* Most experts say no and almost in the same sentence place much of the blame on poor information recording and transmission.

The Importance of the Electronic Health Record (EHR)

Information is critical in health care and, unfortunately, the tools necessary to manage medical information have not been widely adopted. We have a system where much vital information is still handwritten on paper; where caregivers must deal with islands of separate information systems and where providers must deal with hundreds of different billing forms and rules. The result is a serious lack of high quality, reliable health care data. In essence, the health care industry has yet to learn how to generate the necessary information to manage itself.

At the epicenter of the information crisis is the EHR. Often given many names (CPR, CPRS, EMR, EHS etc), it refers to a system that collects and transmits important data about a patient to all those who require it for the delivery of high-quality care. A key function of any EHR system is the electronic capture of the patient-physician encounter. Medical errors and costs are a direct result of physicians' decisions based on the patient-physician clinical encounter. The ability to reduce medical errors by providing real time decision support (i.e. drug-drug interactions or contraindications) is dependent on capturing the clinical encounter electronically real-time. Likewise, reducing costs by suggesting a less expensive clinical test or drug requires the same real-time capability. The importance of the EHR is underscored by the recent frenetic activity by the Federal Government to promote it.

The Increasing Role of the Federal Government in Healthcare Information Technology

The Federal Government, partially because it is a major healthcare consumer (Medicare and Government Employees) and partially because its agencies fund healthcare research (NIH, ARHQ, CMS, etc.) involving all areas of information technology has inserted itself squarely in the middle of the debate. The current administration, led by the Department of Health and Human Services (DHHS) Secretary Tommy Thompson, now sees itself as increasingly responsible for assisting in the development and implementation of:

- Systems that enable users to enter analog data in digital formats,
- Systems that communicate relevant healthcare information digitally, and
- Systems that apply analytical tools to data and thereby support healthcare decision-making.

In addition to the development of the National Healthcare Information Infrastructure (NHII) to promote the above, secondary issues that are now being addressed by Federal Government initiatives include:

- Developing healthcare data standards;
- Establishing a universal methodology for identifying providers, patients, and facilities;
- Creating a common healthcare technical nomenclature;
- Promulgating clinical guidelines upon which physicians providing quality medical services can rely.

The most startling aspect of the Federal Government's increasing involvement is their approach. DHHS and its healthcare operational arm, The Center for Medicare and Medicaid (CMS) is planning to conduct demonstration projects that focus on the quality of healthcare provided, not just cost. In 2004, CMS will conduct projects in which they will pay physician practices for using information technology. This concept of *"pay for performance"* represents a dramatic paradigm shift in healthcare policy. It eschews the past decade's reliance on managed care and solely focusing on ratcheting down costs, for an approach that relies heavily on quantifying quality and determining the "best value" for healthcare expenditures.

The rationale for this approach rests with the realization that determining quality care efficiently and accurately cannot be done reliably unless the patient-physician encounter can be captured electronically. In addition, providing healthcare practitioners with real time clinical decision support to help decrease medical errors cannot be done without a computerized record system. The Federal Government recognizes this and is positioning itself to take a leadership role all Healthcare Information Technology endeavors, particularly the EHR.

The EHR Initiative

Over the past six months, the Federal Government has set in motion a very aggressive and ambitious plan. It is useful to review the chronology of the events and the major participants.

CMS Administrator Thomas Scully convened a meeting on March 17, 2003 in Washington DC to discuss how to implement the EHR in the United States. Several options that were discussed at that time are included:

- Provide financial incentives to physician practices to implement the VistA shareware system now currently in use at the Veterans Administration (VA).
- Aggressively support the open-source coding project currently in development at the American Academy of Family Physicians.
- Encourage the private sector to take the VistA system and increase its ability to serve physician practices.

The fact that CMS included the use of VistA in two of its three options was not lost on the Healthcare Information Technology community. We will take an in-depth view of VistA later in this report.

Shortly after that CMS meeting, on March 21, DHHS Secretary Tommy Thompson convened a Town Hall Meeting in Dearborn, Michigan to discuss the use of technology in healthcare. On that day, he announced that DHHS was adopting uniform standards for the electronic exchange of clinical information within the federal government.

In early April this year, CMS and the VA approached HL7, the American National Standards Institute (ANSI) standards development organization, with a request to produce *ANSI approved EHR system standards* by January 2004. HL7 agreed to the project and assigned it to the EHR Special Interest Group (SIG). The EHR SIG decided it would produce a Draft Standard for Trial (DSTU) by August 2003. Based on the DSTU response received by the Healthcare Information Technology community, it would produce a final standard for vote in January 2004.

In May of this year DHHS also requested that the Institute of Medicine (IOM), an acknowledged leader in Healthcare Information Technology policy issues, develop a *functional model* for an Electronic Health Record System (EHR-S). The IOM responded with its Letter Report "Key Capabilities of an Electronic Health Record System" dated July 31, 2003. At the insistence of DHHS, HL7 agreed to incorporate the IOM functional model into its DSTU. In August, field meetings, open to the public, were held in six major US cities to discuss the DSTU. An initial vote on these proposed standards is now being conducted by HL7 and the results of this balloting process will be announced in Sept 2003. Modifications to the EHR standards will then be made, based on this initial vote, and the final HL7 vote will be held in January 2004.

These recent events strongly suggest that in the Healthcare Information sector it is no longer "business as usual". All healthcare participants, particularly providers and vendors, will be affected. The recent focus on the EHR and the designation of VistA, the VA's EHR, are important events that must be taken seriously.

VistA

VistA, the largest integrated health information system in the world, is the centerpiece of the Veterans Administration healthcare information infrastructure. For the past 20 years, it has been used successfully in over 170 different VA facilities, from small clinics to large academic medical centers. Versions of this system are in active use in the U.S Department of Defense Military Health System, the U.S. Department of Interior's Indian Health Service, the Finnish Health System, the Berlin Heart Institute of Germany and the National Cancer Institute of Cairo University in Egypt.

While it has been a mainstay in the VA for several decades, it has flown "under the radar" for many of those involved in healthcare information technology. That is no longer the case and it is important to understand the history of its development. It is equally as important to understand that since VistA is in the public domain and available through the US Freedom of Information Act (FOIA), it is essentially free as software license fees are not an issue.

VistA History

In response to the Medicare legislation of 1965, several government agencies lead by the National Center for Health Services Research and Development of the U.S. Public Health Service (NCHSR&D/PHS), launched projects in health-services research. These projects explored many of the aspects of how state of the art in medical-information systems could improve the quality of care, contain costs, and provide health-services data in a consistent way across many institutions. In the mid 1970's, several hundred physicians and systems scientists from many university medical centers, research centers, and other organizations cooperated in providing suggestions and comments the features and functions needed in a state of the art medical information system. In a proof of concept demonstration project, the U.S. Navy's clinic at the Brunswick Naval Air Station deployed an early version of the system software in the form of a clinic-management and medical-record system that was "paperless". In 1978, the Veterans Administration's Department of Medicine and Surgery assembled a team to refine, test and eventually deploy the clinical-application modules developed by the Public Health Service. They chose the ANSI MUMPS computer language as their foundation and erected a framework to support their applications. In 1981, the applications were implemented in 20 VA facilities and the program was named the Decentralized Hospital Computer Program (DHCP).

Almost from its beginning the VA established that their software, derived from the PHS projects, was legally in the public domain and must be made available without proprietary or other restrictions to other government and private-sector organizations for their use. In December of 1981, Congressman Sonny Montgomery arranged for the Decentralized Hospital Computer Program (DHCP) to be written into law as the medical-information systems development program of the VA. In parallel with the VA development, the Public Health Service physicians and facility managers in the Indian Health Service were the first to deploy it throughout their hospitals and clinics. The VA adopted this PHS clinical-integration approach and incorporated it into the PHS/VA system that would be renamed the "Veterans Health Information System and Technology Architecture" (VistA) system. During the same time, The Department of Defense (DOD) modified the PHS/VA system, renamed it the Composite Health Care System (CHCS) and began to deploy it in DOD facilities.

The four major adopters of VistA (VA, DoD, IHS, and the Government of Finland) have modified the original VistA code to accommodate their unique requirements. Thus, at present the VistA code base is split four ways and therefore under ordinary circumstances would make the adoption of VistA outside of large organizations difficult. Fortunately, many of the original VistA developers have formed an organization called the Hardhats to help make the FOIA release of VA VistA more useful.

The Current VistA

The current version of VistA has been significantly enhanced with the addition of the Computerized Patient Record System (CPRS) in 1997. The CPRS not only provides a single interface for health care providers to review and update a patient's medical record, but it is flexible enough to be implemented in a wide variety of settings. In addition, VistA now provides a multi-media capability that is integrated with multiple ancillary services (Radiology, Cardiology, Pathology etc.). VistA's CPRS is designed to directly support real time clinical decision-making. Its Graphical User Interface is written in Delphi with a "look and feel" similar to many competitive commercial products. It features a "face sheet" that displays the patient's active problems, allergies, current medications, recent laboratory results, vital signs, and other important relevant medical history. Some of the other key features and functions of the CPRS include:

- A Real-Time Order Checking System that alerts clinicians during the ordering session that a possible problem could exist if the order is processed;
- A Notification System that immediately alerts clinicians about clinically significant events;
- A Patient Posting System, displayed on every CPRS screen that alerts clinicians to issues related specifically to the patient, including crisis notes, warning, adverse reactions, and advance directives;
- A Clinical Reminder System that allows caregivers to track and improve preventive health care for patients and ensure timely clinical interventions are initiated; and
- Remote Data View functionality that allows clinicians to view a patient's medical history from other VA facilities to ensure the clinician has access to all clinically relevant data available at VA facilities.

The Future VistA

The current VistA system is viewed by the VA as an interim step towards the ultimate goal of an ideal health information system to support the health needs of all veterans. The VA has stated that they plan to commit the necessary resources to achieve a system that is called "Health Vet". Health Vet consists of the integrated systems outlined below designed to address key informatics issues such as: common architecture, information security, and data quality.

- **The VA Health Data System** incorporates a Health Data Repository (HDR) to create a longitudinal healthcare record including data from VA and non-VA sources. This system will also support research, facilitate patient access to data, and improve data quality and data security.
- **The VA Healthcare Provider Systems** are designed to support healthcare providers and the care process. The key components of this system include: CPRS, Imaging, Blood Bank, Pharmacy, Laboratory, Federal Health Information Exchange (FHIE), and Scheduling.
- **The VA Management/Financial Systems** include four applications that are each ten or more years old and will be replaced: the Financial Management System, Billing and Accounts Receivable (AR), and Fee Basis (paying providers).
- **The VA Information and Education Systems** rely on the Internet and the emerging concepts of "e health". "They include: prescription refills, appointments and My HealtheVet, which provides the veteran population with access to their health records, online health assessment tools; and high quality health education information.
- **The VA Registration, Enrollment and Eligibility Systems** will be developed as a single, department wide data system and demographic database including a Master Patient Index (MPI) as well as up to date eligibility information.

VistA-Pros and Cons

When CMS indicated that they would pay practices to implement VistA, the Healthcare Information Technology landscape changed dramatically. Those involved in making IT decisions now must thoroughly understand the perceived strengths and weakness this “free” software. Since VistA is based on MUMPS, it is important to address the key issues of the “MUMPS debate”.

What is MUMPS?

MUMPS (alternative name: 'M') is a computer language, database and operating system all rolled into one. Devised at Massachusetts General Hospital in the 1960's, it forms the basis, even today, of many commercial medical information systems, such as those sold by Eclipsys and Meditech. MUMPS is characterized by the way it integrates disk I/O and process control into the very syntax of the language, in a high-level way. Early M implementations were generally closed systems that required programmers to build their own tools and application frameworks from scratch. Keeping this early environment in mind will help explain the nature of the VistA architecture.

Using the flexibility and power of MUMPS, the VA constructed a generic, highly portable foundation and framework. The DHCP designers constructed the architecture in interlocking layers:

- MUMPS Technology - The M language and database.
- FileMan - Database Management System written in MUMPS
- Kernel - Application framework, based on MUMPS and FileMan, providing services such as user management, menus, device selection, background task scheduling, etc.
- Application - End-user software. VistA supports the development of these applications by providing a framework of Kernel, FileMan and MUMPS.

VistA development is guided by software standards that have allowed developers dispersed across the VA to build health-care modules that integrate seamlessly with pre-existing data structures, either at individual VA sites, or across the entire system.

VistA’s reliance on MUMPS will always spark a debate among those who believe that MUMPS is antiquated technology that does not perform as well as current relational and vector database technology. Notwithstanding this debate, there are other pro’s and con’s regarding VistA that are identified below:

Pros:

- VistA has a new GUI front-end that works well and has been tested extensively in a real-world medical environment.
- The source is free from the government under the freedom of information act. Anyone can get it and sell it.
- Bug fixes are potentially available courtesy of the government.
- An object-oriented layer of M/MUMPS, which VistA is built on, is available and is open source.

Cons:

- No web interface.
- It requires closed-source components such as an M/MUMPS interpreter, although an open source M/MUMPS may be available in the near future.
- Some of the client GUI code is written in Delphi, which is not open source.
- Not all of VistA is available such as security and authorization parts.
- Since VistA was developed for the VA. Environment, it is not always clear how it can best be used in a given environment. The applications tend to be so highly integrated that it is difficult to use only a small subset of its components.
- It is difficult to integrate VistA with non-MUMPS based applications.

Summary

Research studies show that information technology investment sharply reduces medical errors. The availability of computer-based clinical information at the time of care delivery, together with clinical decision support systems, reduces many medical errors.

The Veterans Health Administration believes in investing in information technology and currently spends about $180 million annually to maintain its existing VistA system. Commercial IT vendors (Siemens, McKesson, IDX, Cerner, Epic) with comparable and competitive products have also invested and continue to invest heavily in healthcare IT, especially the EHR.

Other government agencies recognize the value of IT in reducing medical errors and lower costs and are joining forces to influence all facets if medical informatics. Most notably, DHHS is seriously considering paying practices to install the VA's VistA system with the anticipation of reducing medical errors and lower over all healthcare costs. As these projects move forward, the healthcare industry can look forward to increased Federal Government participation in choosing a comprehensive medical vocabulary, laboratory standards, medication database standards as well as their acknowledged involvement in privacy, confidentiality and security.

More in-depth information about the VistA system and about the Mumps environment may be found in the VistA technical appendix.