

Doctor's Orders: A Shot of Information Technology

By Aileen S. McNeill

"Our grocery stores and hardware stores and paint stores are more technologically advanced than hospitals and clinics are."

Tommy Thompson,
former HHS Secretary¹

A report recently released by the Centers for Disease Control and Prevention found that less than a third of hospital emergency and outpatient departments and only 17 percent of physicians utilize electronic medical records (EMRs) in the provision of health care services to their patients.² This report provides the statistical support for what many, including former HHS Secretary Thompson, have known for years: that the health care industry lags far behind other industries in effectively utilizing information technology.

The effective use of modern information technology systems in the health care industry is important because it can significantly improve the quality of health care and reduce medical errors. In 2004 President Bush publicly announced that in 10 years he wanted the majority of Americans to have EMRs.³ President Bush also established the sub-cabinet position of National Technology Coordinator. The Coordinator was specifically directed to develop a strategic plan to oversee "the nationwide implementation of interoperable 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."⁴

On July 1, 2004, the newly appointed Coordinator, David J. Brailer, MD, PhD, released his strategic framework for accomplishing this directive entitled "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care."⁵ The four strategic goals set forth in the report were to:

- Better inform clinicians about how using information technology can reduce medical errors and duplicative work and enable clinicians to spend more time focusing on improving patient care;
- Create the infrastructure necessary to provide clinicians real-time access to critical health care information;
- Provide individuals with the information they need to manage wellness, assist in making personal health care decisions and choose providers; and
- Improve the health of the general population through the collection of timely, accurate and detailed information that can be used to evaluate health care delivery methods, provide health monitoring and to support clinical trials and research.

Active collaboration between health care providers, the private health care sector, public officials and consumers is crucial for the successful implementation of interoperable information technology in the health care industry. Several notable private sector groups have taken the lead in beginning collaborative efforts on a nationwide basis. For example, the Certification Commission for Health Information Technology was organized by three leading health care organizations for the purpose of creating a mechanism for certifying ambulatory electronic health records and other health care information technology products.⁶ The Certification Commission is expected to complete its initial certification requirements and processes during the summer of 2005.

The effort undertaken by the Certification Commission is significant because until standards have been developed and broadly adopted, large-scale investment in these systems by the private

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or the public sector is unlikely. Dr. Brailer recently remarked that "stand-alone EMRs, even if widely adopted, will not deliver the error reductions, cost savings or marketplace changes that we seek, and could even shift the market toward more fragmentation."⁷

State and local involvement in this process is also crucial. The federal government has awarded more than \$139 million in grants and contracts to regional health information exchange organizations (RHIOs) to support the adoption of health information technology systems on a regional basis. More than one hundred RHIOs have already been formed, although none have an active presence in the State of Mississippi.

While vitally important, the formation of RHIOs presents significant business and legal challenges. For example, the participation by physicians is generally believed to be integral to the success of a RHIO. However, many physicians, particularly those located in rural areas, find information technology cost prohibitive and are unlikely to have an economic incentive to invest in the development of a RHIO. However, when health care providers such as hospitals or health systems provide the necessary funding, the Federal Physician Self Referral Law (Stark Law) and the federal anti-kickback statutes may create serious legal obstacles.

The Stark Law prohibits a physician from referring Medicare patients for certain designated health services (DHS) to an entity with which the physician has a financial relationship, unless an exception applies.⁸ The Centers for Medicare and Medicaid Services (CMS) recently created a new exception that permits a hospital or other DHS entity to provide items or services of information technology to a physician that "allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health."⁹ This exception requires that the community-wide health information system (including hardware and software) be "available to all providers, practitioners, and residents of the community who desire to participate."¹⁰ Unfortunately there are ambiguities in this new exception. For example, it is not clear what obligations are created by the "community wide" requirement. CMS is currently

revising the rule in an effort to address these and other ambiguities. Until the rule is revised, reliance on this exception is not without risk.

The federal anti-kickback statute prohibits an individual or entity from knowingly or willingly offering or accepting remuneration of any kind in exchange for referring or recommending the referral of items or services to be paid for by a federal health care benefit program.¹¹ The Department of Justice has advised HHS that "to the extent that the benefits of such arrangement can be shown to outweigh any anticompetitive impact, they are not likely to violate the federal antitrust laws."¹² However, the specific facts and circumstances relevant to the methods by which the RHIO is structured and operated will be crucial in determining the associated anti-kickback risk. For example, anti-kickback risk would be significantly increased if access to the network was conditioned on referrals or was otherwise designed to provide an advantage to some providers against others. Care should be taken in structuring RHIOs because the

language of the anti-kickback statute is very broad and uncertainty remains about the impact of these arrangements on competition and what constitutes a violation of the anti-kickback statutes.

In addition to the Stark Law and the federal anti-kickback statute, RHIOs must comply with the Health Insurance Portability and Accountability Act of 1986 (HIPAA) and state privacy laws, to the extent that they are not "contrary" to a provision or requirement of HIPAA.¹³

Protected health information (PHI) may be used and disclosed to RHIOs by covered entities (CEs), such as providers, physicians and payors, without patient consent provided that such disclosure is related to one of the core health care activities: "treatment", "payment" and/or "health care operations."¹⁴ RHIOs are considered to be "business associates" and CEs must enter into business associate agreements with their RHIO.¹⁵

Notwithstanding the legal challenges presented, the formation of a RHIO is a

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useful way to garner the collaborative support of health industry participants that is necessary to implement interoperable information technology systems in the health care industry.

While there are no RHIOs active in the State of Mississippi, the Mississippi State Department of Health recently awarded a grant of almost \$1 million to the Epidemiology Program at The University of Mississippi Medical Center.^{xvi} The purpose of the grant is to implement TheraDoc® computer programs for hospital epidemiology, antibiotic usage, and antibiotic resistance surveillance. These programs, if successful, could be a catalyst for the formation of a RHIO in the State of Mississippi.

Health care providers, together with their legal advisors, should look for ways to foster collaboration within the health care industry so that hospitals and clinics will no longer lag behind grocery, hardware and paint stores in utilizing information technology.

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- 1 A copy of the transcript from the State Office of Rural Health Conference Call with Tommy Thompson, former Secretary of the United States Department of Health and Human Services (HHS) on June 19, 2001 is available at www.ruralhealth.hrsa.gov.
- 2 "Use of Computerized Clinical Support Systems in Medical Settings: United States, 2001-2003", March 15, 2005. A copy of the full report is available at www.cdc.gov.
- 3 A copy of President Bush's remarks entitled "Transforming Health Care for Americans with Information Technology" is available at www.hhs.gov.
- 4 Executive Order issued by President George W. Bush on April 26, 2004, a copy of which is available at www.whitehouse.gov.
- 5 A copy of the full report is available at www.os.dhhs.gov.
- 6 The Certification Commission was formed by The American Health Information Management Association, Healthcare Information and Management Systems Society, and The National Alliance for Health Information Technology (Alliance). See www.himss.org.
- 7 A copy of Dr. Brailer's remarks at the HIMSS Conference in Dallas, Texas, on February 17, 2005 is available at www.hhs.gov.
- 8 42 USC §1395nn.
- 9 42 CFR §411.357(u).
- 10 *Id.*
- 11 15 USC §§1 *et seq.*
- 12 See HHS Report titled "HHS's Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption" made to the Senate Committee on Health, Education, Labor and Pensions, a copy of which is available at www.gao.gov.
- 13 45 CFR Parts 160, 162 and 164. The HIPPA Privacy Rule compliance deadline was April 14, 2003 while the Security Rule compliance deadline, for most "covered entities", is April 21, 2005.
- 14 45 CFR 164.501.
- 15 45 CFR 164.504(e).
- 16 See http://medicine.umc.edu/Divisions/Infectious_Diseases/