

Toward Implementation of Electronic Health Records: Justifications, Action, and Barriers to Adoption

KIRK BENTON KOEHLER*

ABSTRACT

An Institute of Medicine report estimated that between 44,000 and 98,000 people die each year as a result of medical errors. It is argued that the number of errors could be significantly reduced if healthcare moved from the current paper-based medical record system to an electronic health record system. President George W. Bush has set a goal of implementing electronic health records within the next ten years. In order to reach this goal, President Bush established the Office of the National Coordinator for Health Information Technology under the Department of Health and Human Services which was given the task of implementing electronic health records for the federal government and providing incentives for private sector adoption. In addition to this executive action, there has been legislative action to require electronic health records for the federal government and give incentives for private sector adoption. Finally, there are several private sector entities which have arisen to help with the adoption of electronic health records. Although there are many benefits to electronic health record adoption, there are several legal and organizational barriers to reaching that goal. Interwoven throughout all of these issues is the need for privacy and security. Electronic health records will contain very sensitive patient data, and it is important that this data is protected.

I. BACKGROUND

Many transactions in today's society are completed electronically, and most records are stored in an electronic form. As a result, information is easier and less costly to access. However, most healthcare records are still kept in paper form, especially in rural or underserved areas.¹ Arguably, keeping health records in paper form is

* Kirk Benton Koehler is a candidate for juris doctor at The Ohio State University Moritz College of Law, class of 2007. He received a bachelor of science degree in computer science from Ohio University.

¹ A medically underserved area is a rural or urban geographic area designated by the Secretary of Health and Human Services as having a shortage of health services. 42 C.F.R. § 51C.102(e) (2005). Some factors for the Secretary to consider include: health services available compared to the size of the population, health indices such as infant mortality rate,

costly in terms of lives, money, and efficiency.² In addition, there are several public health benefits to adopting electronic health records (“EHR”).³

One reason to move from paper records to electronic records is to save lives. In 1998, the Institute of Medicine initiated the Quality of Health Care in America project.⁴ The goal of the project is to increase the quality of care in the United States in the next ten years.⁵ The Institute of Medicine reported that in two studies conducted in 1984 and 1992, between 2.9% and 3.7% of hospital admissions resulted in an adverse event.⁶ Furthermore, between 53% and 58% of those adverse events were preventable.⁷ Extrapolated to 33.6 million hospital admissions, it is calculated that between “44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of

and economic factors. *Id.*; see also United States Department of Health and Human Services Health Resources and Services Administration, Guidelines for Medically Underserved Area and Population Designation, <http://bhpr.hrsa.gov/shortage/mauguide.htm> (last visited Mar. 4, 2006).

² William H. Frist, *Health Care in the 21st Century*, 352 *N. Eng. J. Med.* 267, 269 (2005) (“Widespread adoption of electronic health records will reduce errors, improve quality, eliminate paperwork, and improve efficiency.”).

³ See NEWT GINGRICH, *SAVING LIVES & SAVING MONEY: TRANSFORMING HEALTH AND HEALTHCARE* 34 (2003).

⁴ COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, *TO ERR IS HUMAN* 5 (Linda T. Kohn et al. eds., 2000).

⁵ *Id.*

⁶ *Id.* at 26 (an adverse event is “defined as injuries caused by medical management”).

⁷ *Id.* A preventable adverse event is the result of some error. An error is either “the failure of a planned action to be completed as intended [...] or the use of a wrong plan to achieve an aim [...]” *Id.* at 28 (emphasis omitted).

medical errors.”⁸ Implementing EHRs could significantly decrease the number of preventable adverse events.⁹

The cost of preventable adverse events is not only large in terms of the number of lives lost due to medical errors, but also the money spent to correct mistakes in those patients that survive. The Institute of Medicine estimates that the national cost of preventable adverse events is between \$17 billion and \$29 billion annually.¹⁰ Use of EHRs¹¹ would reduce the number of errors and therefore reduce the cost.¹²

It is also argued that it is inefficient to maintain the current paper-based system. For example, interoperable EHRs would prevent a physician from ordering the same test twice if another physician previously ordered the test. The economic benefit of this is clear; the patient or insurance company would only have to pay for one test.

In addition, there are public health benefits. First, EHRs would assist researchers by providing information that could be used to develop new healthcare technologies. Second, EHRs would allow for faster notification of public health threats, such as a disease outbreak or a bioterrorist event.¹³ Finally, EHRs would allow for the move from rewarding healthcare providers for volume-based healthcare to a

⁸ *Id.* at 26. Although these numbers are relied on heavily in support of HIT and more specifically EHRs, it is important to note that these numbers are only extrapolations of a limited study. There is some debate as to the validity of these numbers. See Clement J. McDonald et al., *Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report*, 284 JAMA 93 (2000). But see Lucian L. Leape, *Institute of Medicine Medical Error Figures Are Not Exaggerated*, 284 JAMA 95 (2000).

⁹ See GINGRICH, *supra* note 3, at 59, 116-18.

¹⁰ COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, *supra* note 4, at 27 (total national costs include lost income, lost household production, disability, and healthcare costs directly and indirectly resulting from the error).

¹¹ This article will use the term electronic health record (“EHR”) as this is the current term of art. The older term was electronic medical record (“EMR”) or electronic patient record (“EPR”). An EHR is distinguishable from a personal health record (“PHR”) discussed *infra* section VI.

¹² See GINGRICH, *supra* note 3, at 116-17, 230-31 (the Mayo Clinic in Jacksonville, Florida moved from paper records to EHRs and recognized an annual savings of between \$2.8 and \$7.1 million).

¹³ *Id.* at 34, 286-89.

pay-for-performance healthcare system, where healthcare providers are rewarded for providing quality healthcare.¹⁴

In response to these justifications, President Bush has set a goal of adopting EHRs within the next ten years.¹⁵ To reach this goal, the Office of the National Coordinator for Health Information Technology (“ONC”) was established under the Secretary of Health and Human Services (“HHS”). There has also been legislative action; both houses of Congress have developed bills to achieve EHR adoption.

Although the arguments for adopting EHRs are strong, there are several barriers to EHR adoption. These barriers can be divided into two categories: legal barriers and organizational barriers. The legal barriers include privacy, security, physician anti-kickback laws, antitrust laws, intellectual property rights, and medical professional liability. The organizational barriers are compatibility issues, the legacy of failed implementations, and financial burdens.

II. EXECUTIVE ACTION

In his 2004 State of the Union address, President Bush acknowledged the need for digital medical records.¹⁶ President Bush has set a goal of creating EHRs for most Americans within the next ten years.¹⁷ The purpose of establishing EHRs is to make the healthcare system more cost effective by reducing duplicative overhead costs in the current system and by improving healthcare

¹⁴ NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, THE DECADE OF HEALTH INFORMATION TECHNOLOGY: DELIVERING CONSUMER-CENTRIC AND INFORMATION-RICH HEALTH CARE 12 (2004), available at <http://www.hhs.gov/healthit/documents/hitframework.pdf> (“Pay-for-performance would reward clinicians for delivering the best quality of care, not the highest volume of care.”).

¹⁵ The White House, *Transforming Health Care: The President's Health Information Technology Plan*, http://www.whitehouse.gov/infocus/technology/economic_policy200404/chap3.html (last visited Mar. 3, 2006).

¹⁶ George W. Bush, President of the U.S., State of the Union Address (Jan. 24, 2004), available at <http://www.whitehouse.gov/news/releases/2004/01/20040120-7.html> (last visited Mar. 3, 2006) (“By computerizing health care records, we can avoid dangerous medical mistakes, reduce costs, and improve care.”).

¹⁷ The White House, *supra* note 15.

quality.¹⁸ On April 27, 2004, President Bush promulgated Executive Order 13,335, which established the ONC.¹⁹ ONC was established under the Secretary of HHS and is given the task of “developing a nationwide interoperable health information technology infrastructure.”²⁰ On May 6, 2004, David J. Brailer was named the first National Coordinator by HHS Secretary Tommy Thompson.²¹ Section 4 of Executive Order 13,335 required that within 90 days of the executive order, the Secretary of HHS must provide a report to the President of the ways to “promote the adoption of interoperable health information technology.”²² This section also required reports from the Director of the Office of Personal Management (“OPM”), the Secretary of Veterans Affairs, and the Secretary of Defense.²³ These reports were compiled by ONC and produced on July 21, 2004.²⁴ The report builds upon a report by Connecting for Health²⁵ which “details specific actions the public and private sectors can take to accelerate the adoption of information technology in health care.”²⁶ The ONC

¹⁸ George W. Bush, President of the U.S., Remarks at the U.S. Department of Commerce (June 24, 2004), available at <http://www.whitehouse.gov/news/releases/2004/06/print/20040624-7.html> (last visited Mar. 3, 2006).

¹⁹ Exec. Order No. 13, 335, 69 Fed. Reg. 24,059, 24059 (Apr. 30, 2004).

²⁰ *Id.* at 24,059.

²¹ Press Release, United States Department of Health and Human Services, Secretary Thompson, Seeking Fastest Possible Results, Names First Health Information Technology Coordinator (May 6, 2004), available at <http://www.hhs.gov/news/press/2004pres/20040506.html> (last visited Mar. 3, 2006).

²² Exec. Order No. 13,335, *supra* note 19, at 24,060.

²³ *Id.* (The section required that the Director of OPM should give a report on how to adopt health information technology (“HIT”) in the Federal Employee Health Benefit Program; the Secretary of Veterans Affairs and the Secretary of Defense should give a report on how they can work with the private sector to make their “health information systems available as an affordable option for providers in rural and medically underserved communities.”).

²⁴ NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, *supra* note 14, at iv.

²⁵ Connecting for Health, <http://www.connectingforhealth.org/> (last visited Mar. 4, 2006).

²⁶ NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, *supra* note 14, at iv (citing CONNECTING FOR HEALTH, ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE: A PRELIMINARY ROADMAP FROM THE NATION’S PUBLIC AND PRIVATE SECTOR HEALTHCARE

report creates four goals for improving healthcare through health information technology (“HIT”): (1) inform clinical practice (bringing EHRs into clinical practice); (2) interconnect clinicians (making EHRs interoperable among clinicians); (3) personalize care (putting the patient in control of personal healthcare decisions); and (4) improve population health (collecting and reporting data to improve healthcare).²⁷

On November 15, 2004, ONC published a Request for Information (“RFI”).²⁸ The RFI requested comments from the public concerning the adoption of interoperable EHRs. The RFI contained twenty-four questions which ranged from the definition of the National Health Information Network (“NHIN”) to implementation of NHIN. The responses were collected by ONC, and a report summarizing the responses was published on June 3, 2005.²⁹

On June 6, 2005, HHS Secretary Mike Leavitt announced the creation of the American Health Information Community (“AHIC”), a public-private collaboration that provides guidance to HHS on the adoption of interoperable EHRs.³⁰ Specifically, AHIC is charged with five tasks: (1) make recommendations on privacy and security, (2) prioritize health information technologies which will provide the greatest benefit to consumers, (3) make recommendations on a standards and certifications process, (4) make recommendations on a nationwide architecture, and (5) make recommendations on a private-

LEADERS (July 2004),

http://www.connectingforhealth.org/resources/cfh_aech_roadmap_072004.pdf).

²⁷ NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, *supra* note 14, at 9.

²⁸ Development and Adoption of a National Health Information Network, 69 Fed. Reg. 65,599 (Nov. 15, 2005).

²⁹ NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, SUMMARY OF NATIONWIDE HEALTH INFORMATION NETWORK (NHIN) REQUEST FOR INFORMATION (RFI) RESPONSES (June 2005), *available at* <http://www.hhs.gov/healthit/rfisummaryreport.pdf>; *see also* Press Release, United States Department of Health and Human Services, HHS Releases Report on Nationwide Health Information Exchange (June 3, 2005), *available at* <http://www.hhs.gov/news/press/2005pres/20050603.html> (last visited Mar. 3, 2006).

³⁰ Press Release, United States Department of Health and Human Services, Secretary Leavitt Takes New Steps to Advance Health IT (June 6, 2005) [hereinafter Press Release, Secretary Leavitt Takes New Steps], *available at* <http://www.hhs.gov/news/press/2005pres/20050606.html> (last visited Mar. 3, 2006). AHIC was formed under the Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770 (1972); Federal Advisory Committee Act Amendments of 1997, Pub. L. No. 105-153, 111 Stat. 2689 (1997).

sector organization which will succeed AHIC.³¹ AHIC has a maximum of eighteen voting members with each member having a two-year term.³² Initially, AHIC will be chaired by HHS Secretary Leavitt and will have sixteen other members from both the public and private sectors.³³

Also on June 6, 2005, HHS released four Request for Proposals (“RFP”).³⁴ These RFPs are: (1) a Standards Harmonization Process; (2) a Compliance Certification Process; (3) a Privacy and Security Assessment; and (4) a NHIN Demonstration. Three RFP contracts were awarded on October 6, 2005.³⁵ The fourth was awarded on November 10, 2005.³⁶

The Standards Harmonization Process RFP was awarded to the American National Standards Institute,³⁷ which will create the Health Information Technology Standards Panel (“HITSP”).³⁸ HITSP will develop standards that will create “interoperability among health care software applications, particularly EHRs.”³⁹

³¹ Press Release, Secretary Leavitt Takes New Steps, *supra* note 30. See also UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, AMENDED CHARTER AMERICAN HEALTH INFORMATION COMMUNITY 2, available at <http://www.hhs.gov/healthit/ahiccharter.pdf>.

³² UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *supra* note 31, at 3.

³³ Press Release, United States Department of Health and Human Services, Commissioners Selected for American Health Information Community: The Community Will Help Shape the Future of Health Care for Generations (Sept. 13, 2005), available at <http://www.hhs.gov/news/press/2005pres/20050913.html>.

³⁴ Press Release, Secretary Leavitt Takes New Steps, *supra* note 30.

³⁵ Press Release, United States Department of Health and Human Services, HHS Awards Contracts to Advance Nationwide Interoperable Health Information Technology (Oct. 6, 2005) available at <http://www.hhs.gov/news/press/2005pres/20051006a.html> [hereinafter Press Release, Contracts to Advance Nationwide Interoperable HIT].

³⁶ Press Release, United States Department of Health and Human Services, HHS Awards Contracts to Develop Nationwide Health Information Network (Nov. 10, 2005) available at <http://www.hhs.gov/news/press/2005pres/20051110.html>) [hereinafter Press Release, Contracts to Develop NHIN].

³⁷ American National Standards Institute, <http://www.ansi.org/> (last visited Mar. 4, 2006).

³⁸ Press Release, Contracts to Advance Nationwide Interoperable HIT, *supra* note 35.

³⁹ *Id.*

The second RFP was for Compliance Certification. There are many EHR products on the market; however, there is no way to identify which products are interoperable and will work in a national system. This creates a great risk in investment for a healthcare provider. The provider may invest in an EHR product and later discover the product is not interoperable. Therefore, the provider would have to invest in another product in order to join the nationwide network. To reduce this risk, the Certification Commission for Healthcare Information Technology (“CCHIT”)⁴⁰ was awarded a contract through the RFP process to develop criteria for EHR certification and an evaluation process for evaluating and certifying EHR products.⁴¹

The third RFP, Privacy and Security Solutions, was awarded to RTI International.⁴² RTI will create the Health Information Security and Privacy Collaboration (“HISPC”), “a multidisciplinary team of experts ranging from privacy and security law and health care management, as well as the National Governors Association.”⁴³ Differences in privacy and security business practices and laws present a barrier to interoperability. HISPC will address those variances and

⁴⁰ CCHIT – The Certification Commission for Healthcare Information Technology, <http://www.cchit.org/> (last visited Mar. 4, 2006).

⁴¹ The Certification Commission for Healthcare Information Technology (“CCHIT”): Certification Handbook (May 1, 2006), *available at* <http://www.cchit.org/files/certification%20process%20narrative.pdf> (CCHIT and AHIC will develop “use cases” which will create the standards of functionality to certify software. A “use case” is “a laymen and a clinical description of a patient care encounter or episode in a step-by-step form, a description of EHR and interoperability functions needed to support each step.”).

⁴² Press Release, Contracts to Advance Nationwide Interoperable HIT, *supra* note 35; *see* About RTI – RTI International, <http://www.rti.org/page.cfm?nav=6> (last visited Mar. 3, 2006) (RTI is a nonprofit corporation dedicated to improving “the human condition through objective, innovative, multidisciplinary research, development, and technical services.”); *see generally* RTI International, <http://www.rti.org> (last visited Mar. 3, 2006).

⁴³ Press Release, RTI International to Support National Health Information Security and Privacy Collaboration (“HISPC”) *available at* <http://www.rti.org/page.cfm?objectId=0AD0F1AC-B38F-4286-92481FDE5E224511> [hereinafter Press Release, RTI International to Support National HISPC]. National Governors Association, <http://www.nga.org/> (last visited Mar. 4, 2006). The National Governors Association is a “bipartisan organization of the nation’s governors--promotes visionary state leadership, shares best practices and speaks with a unified voice on national policy.” About the National Governors Association, <http://www.nga.org/portal/site/nga/menuitem.cdd492add7dd9cf9e8ebb856a11010a0/> (last visited Mar. 4, 2006).

create recommendations on how to deal with laws and business practices that create a barrier to interoperability.⁴⁴

The fourth RFP, to develop a prototype of a NHIN, was awarded to four different consortia led by: Accenture,⁴⁵ Computer Science Corporation (“CSC”),⁴⁶ International Business Machines (“IBM”),⁴⁷ and Northrop Grumman.⁴⁸ Each consortium will develop a network prototype that will share healthcare information among three healthcare providers within the same region.⁴⁹ The four consortia will also work together to make their four networks interoperable. The Accenture collaboration will work with the Eastern Kentucky Regional Health Community, CareSpark,⁵⁰ and the West Virginia eHealth Initiative.⁵¹ The CSC consortium will connect the Indiana Health Information Exchange,⁵² MA-SHARE,⁵³ and the Mendocino

⁴⁴ Press Release, RTI International to Support National HISPC, *supra* note 43.

⁴⁵ Consulting, Technology and Outsourcing Services at Accenture, <http://www.accenture.com> (last visited Mar. 3, 2006).

⁴⁶ CSC: Consulting, Systems Integration and Outsourcing, <http://www.csc.com/> (last visited Mar. 3, 2006).

⁴⁷ IBM, <http://www.ibm.com/> (last visited Mar. 3, 2006).

⁴⁸ Northrop Grumman Corporation, <http://www.northropgrumman.com/> (last visited Mar. 3, 2006). Press Release, Contracts to Develop NHIN, *supra* note 36.

⁴⁹ Press Release, Contracts to Develop NHIN, *supra* note 36 (the networks will allow “secure information sharing among hospitals, laboratories, pharmacies, and physicians.”).

⁵⁰ CareSpark, <http://www.carespark.com/> (last visited Mar. 4, 2006). CareSpark is a regional health organization covering the “Central Appalachian region.” *Id.* The Central Appalachian region covers 17 counties in southwest Virginia and Northeast Tennessee as well as counties in Kentucky and North Carolina. CareSpark – Where is the Central Appalachian Region?, http://www.carespark.com/index.php?option=com_content&task=view&id=21&Itemid=25 (last visited Mar. 4, 2006).

⁵¹ West Virginia eHealth Initiative, <http://www.wvehi.org/> (last visited Mar. 4, 2006).

⁵² Indiana Health Information Exchange, <http://www.ihie.org/> (last visited Mar. 4, 2006).

⁵³ Massachusetts Health Data Consortium: MA-SHARE, <http://www.mahealthdata.org/ma-share/> (last visited Nov. 27, 2005). The Massachusetts Health Data Consortium, Inc. (“MHDC”) was established in 1978 to improve healthcare in the Massachusetts region. MHDC: About Us, <http://www.mahealthdata.org/consortium/> (last visited Mar. 4, 2006). MHDC started the MA-SHARE program to promote the exchange of healthcare information

HRE in California. IBM will work with Taconic Health Information Network and Community⁵⁴ and the North Carolina Healthcare Information and Communications Alliance.⁵⁵ Northrop Grumman will connect Santa Cruz RHIO, HealthBridge,⁵⁶ and University Hospitals Health System.⁵⁷

III. LEGISLATIVE ACTION

In response to mounting political pressures for adopting health information technology (“HIT”) in the healthcare industry, several legislative measures have been introduced.⁵⁸ This article will focus on the Wired for Health Care Quality Act⁵⁹ (“WHCQA”), which was passed by the Senate on November 18, 2005. Under WHCQA, Congress codifies certain executive actions, establishes standards for HIT, creates incentives for private sector adoption, creates a demonstration program to integrate HIT into medical professional

through the use of information technology. MHDC: MA-SHARE Initiative – Mission, <http://www.mahealthdata.org/ma-share/mission.html> (last visited Mar. 4, 2006).

⁵⁴ Milt Freudenheim, *Doctors Join to Promote Electronic Record Keeping*, N.Y. TIMES, Sept. 19, 2005, at C4, available at <http://www.nytimes.com/2005/09/19/technology/19ehealth.html>.

⁵⁵ NCHICA, <http://www.nchica.org/> (last visited Mar. 3, 2006) (“NCHICA” stands for North Carolina Healthcare Information and Communications Alliance).

⁵⁶ HealthBridge, <http://www.healthbridge.org/> (last visited Mar. 3, 2006) (HealthBridge is a collaborative network of health care providers serving the greater Cincinnati healthcare community).

⁵⁷ University Hospitals Health System, <http://www.uhhs.com/> (last visited Mar. 3, 2006) (health system covering northern Ohio).

⁵⁸ The Senate passed the Wired for Health Care Quality Act, S. 1418, 109th Cong. (2005) on November 18, 2005. The House of Representatives passed the Health Information Technology Promotion Act of 2006, H.R. 4157, 109th Cong. (2006). Currently, the bills are in conference. See also 21st Century Health Information Act of 2005, H.R. 2234, 109th Cong. (2005); Health Information Technology Act of 2005, S. 1227, 109th Cong. (2005); Information Technology for Health Care Quality Act, S. 1223, 109th Cong. (2005); Health Technology to Enhance Quality Act of 2005, S. 1262, 109th Cong. (2005).

⁵⁹ Wired for Health Care Quality Act, S. 1418, 109th Cong. § 2 (2005) [hereinafter S. 1418, 109th Cong.], available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s1418es.txt.

curricula, mandates healthcare quality reporting, reports on the variation between the states on medical professional certification, and ensures the privacy and security of HIT.⁶⁰

A. LEGISLATIVE ADOPTION OF EXECUTIVE ACTION

WHCQA first codifies the Office of the National Coordinator and the American Health Information Collaborative.⁶¹ The bill would add Section 2902 to the Public Health Service Act⁶² which legislatively establishes the ONC under the Secretary of HHS.⁶³ The ONC is charged with coordinating among relevant federal agencies and private entities the development of a nationwide health information technology infrastructure.⁶⁴

WHCQA also codifies the American Health Information Community established by HHS Secretary Leavitt.⁶⁵ The name would be changed to the American Health Information Collaborative (“Collaborative”). The operation of the Collaborative would be similar to AHIC. The Committee Report states that “the Collaborative [would] serve the dual purpose of recommending standards for the electronic exchange of health information . . . and recommending uniform national policies facilitating the widespread adoption of interoperable health information.”⁶⁶ The Collaborative would recommend standards to the Secretary of HHS.⁶⁷ The Secretary of

⁶⁰ *Id.*

⁶¹ *See supra* Part II (the Office of the National Coordinator currently exists through executive order).

⁶² Public Health Service Act, 42 U.S.C. §§ 201-300gg-92 (2000).

⁶³ S. 1418, 109th Cong. § 2.

⁶⁴ *Id.* For a description of the current American Health Information Community (“AHIC”), *see supra* Part II.

⁶⁵ *See supra* Part II.

⁶⁶ S. REP. NO. 109-111, at 5 (2005), available at http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPaddress=162.140.64.21&filename=sr111.109&directory=/diskb/wais/data/109_cong_reports.

⁶⁷ S. 1418, 109th Cong. § 2.

HHS could then provide for adoption of the standards by the federal government.⁶⁸ Once adopted, federal agencies could only purchase HIT systems in compliance with the standards.⁶⁹ Although the Secretary of HHS adopts mandatory standards for the federal government, they are voluntary for private entities.⁷⁰ Members of the Collaborative are chosen by the Secretary of HHS from the public and private sectors.⁷¹ Members are chosen for two year terms.⁷²

Finally, WHCQA creates a Health Information Technology Resource Center (“Center”) under the Agency for Healthcare Research and Quality (“AHRQ”).⁷³ The purpose of the Center is to provide technical assistance in the adoption of HIT as well as developing effective methods for adopting, implementing, and effectively using HIT.⁷⁴ Already existing under AHRQ is the National Resource Center for Health Information Technology, which is intended to “advance[] the use of health IT . . . and stimulate investment in health IT.”⁷⁵ WHCQA allows the Secretary of HHS to modify the currently existing

⁶⁸ *Id.* at § 2 (Subsection 2903(e) is added to the Public Health Services Act (“PHSA”) to provide procedures for federal action. Additionally, the adoption of standards by the Secretary of HHS is discussed in greater detail in subsection 2903(b)).

⁶⁹ *Id.* (§ 2903(f)(1)).

⁷⁰ *Id.* at § 2 (subsection 2903(h) is added to PHSA to address voluntary adoption).

⁷¹ *Id.* at § 2 (subsection 2903(b) is added to address the composition of the American Health Information Collaborative). The bill as reported out of committee required that the committee be chaired by the Secretary of HHS and comprised of the National Coordinator, the Secretaries of Defense, Veterans Affairs and Commerce, and other members chosen by the Secretary of HHS. An amendment on the Senate floor replaced the entire text of the bill, and therefore, the value of the committee report is questionable. See 151 Cong. Rec. S13247 (daily ed. Nov. 17, 2005) (proposed amendment by Sen. Frist).

⁷² *Id.* at § 2 (subsection 2903(b)(3) is added to address the term length for members of the Collaborative).

⁷³ S. 1418, 109th Cong. § 3 (for more on the AHRQ see United States Department of Health and Human Services: Agency for Healthcare Research and Quality, <http://www.ahrq.gov/> (last visited Mar. 4, 2006)).

⁷⁴ *Id.*

⁷⁵ AHRQ National Resource Center for Health Information Technology, <http://healthit.ahrq.gov/portal/server.pt?open=512&objID=562&PageID=0&parentname=ObjMgr&parentid=106&mode=2&dummy=/nrc/index/html> (last visited Mar. 3, 2006).

National Resource Center for Health Information Technology to create the Health Information Technology Resource Center required by the bill.⁷⁶

B. ESTABLISHMENT OF STANDARDS

Once the Collaborative makes recommendations to the Secretary of HHS, he will develop standards for the certification of hardware and software.⁷⁷ The purpose of these standards is to allow the interoperability of healthcare information between healthcare providers. Therefore, when a healthcare provider purchases HIT hardware or software, the provider will be sure that the hardware or software will work with other healthcare providers' systems. According to the Committee Report, "[t]he adoption of standards is an important component of establishing consistent and common content and communication between health information technology systems . . . [and is] vital [to] establishing a nationwide interoperable health information system."⁷⁸ After the Secretary of HHS adopts the standards, a federal agency cannot spend federal funds for HIT that is not in compliance with the standards.⁷⁹ The standards are voluntary for private-sector healthcare providers; however, grants or loans under the bill are conditioned on the healthcare provider using the grant or loan to purchase HIT systems compliant with the standards.⁸⁰

⁷⁶ S. 1418, 109th Cong. § 3.

⁷⁷ *Id.* (section 2940 discusses the implementation and certification of health information standards).

⁷⁸ S. REP. NO. 109-111, at 7.

⁷⁹ S. 1418, 109th Cong. § 2 (referring to amended § 2903).

⁸⁰ *Id.* (referring to the following subsections of amended § 2905: (a)(2)(D), (b)(3)(E), and (c)(2)(F)).

C. INCENTIVES FOR PRIVATE SECTOR ADOPTION

One barrier to the adoption of HIT is the high cost of implementing an HIT system.⁸¹ In addition to the cost of implementation, there are also the costs associated with maintaining the HIT system.⁸² Although there are benefits, both in cost and quality, to adopting HIT, the benefits are hard to compare against the costs of implementing HIT.⁸³ Therefore, healthcare providers have chosen to forgo the risk and keep their paper-based method. Grants by the federal government would help defray the costs of HIT adoption. WHCQA allows for three types of grants: grants to healthcare providers,⁸⁴ grants to States to create state loan programs,⁸⁵ and grants for regional or local health information technology plans.⁸⁶ Each of the grants requires matching funds provided by the recipient.⁸⁷ Additionally, each of the grant recipients will have to adhere to the standards adopted by the Secretary of HHS.⁸⁸

⁸¹ S. REP. NO. 109-111, at 8 (“The committee recognizes that . . . [a] major barrier to widespread adoption of health information technology in the U.S. health care system is the high cost of such technology.”).

⁸² *Id.*

⁸³ *Id.* (The Committee Report suggests that while the provider will bear the cost of adopting a HIT system, the savings will be realized by insurers and large healthcare systems and not small healthcare providers such as physicians practices or small community hospitals.).

⁸⁴ S. 1418, 109th Cong. § 2 (§ 2905(a)).

⁸⁵ *Id.* (§ 2905(b)).

⁸⁶ *Id.* (§ 2905(c)). In addition to these three types of grants, the bill extends the grants created by § 330L(b) of the Public Health Service Act. S. 1418, 109th Cong. § 4.

⁸⁷ S. 1418, 109th Cong. § 2 (§ 2905(a)(4); (b)(8); and (c)(5)).

⁸⁸ S. 1418, 109th Cong. § 2 (§ 2905(a)(2)(D); (b)(3)(E); and (c)(2)(F)). In general, the standards are optional for private sector healthcare providers; however, making adoption of the standards a condition of receiving grants facilitates adoption of the standards in the private sector. *See* section III(B), *supra*.

D. DEMONSTRATION PROGRAM TO DEVELOP ACADEMIC CURRICULA

The bill also allows the Secretary of HHS to award grants for the development of academic curricula “integrating [HIT] systems in the clinical education of health professionals.”⁸⁹ The Committee Report explains that the purpose of this provision is to address a cultural barrier to adoption.⁹⁰ According to the report, one reason that healthcare providers continue to use a paper-based system is because they have always used paper-based systems and adopting an electronic system might be intimidating.⁹¹ By including HIT in academic curricula, healthcare providers would be more comfortable adopting HIT systems.⁹²

E. HEALTHCARE QUALITY

A major reason to adopt HIT is to improve healthcare quality.⁹³ To this end, WHCQA directs the Secretary of HHS to develop quality measures to be used in quality reporting.⁹⁴ The quality information collected will eventually be disseminated to the public to allow the public to make choices on healthcare providers partially based on quality.⁹⁵ In addition, the information will allow researchers and public health officials to evaluate the effectiveness of the healthcare system and to make appropriate changes.⁹⁶

⁸⁹ S. 1418, 109th Cong. § 2 (§ 2906(a)).

⁹⁰ S. REP. NO. 109-111, at 11.

⁹¹ *Id.*

⁹² *Id.* (“The committee believes that exposing students and residents to effective everyday uses of health IT will lead to a greater adoption by these students and residents when they graduate and begin practicing on their own.”).

⁹³ *See supra* Part II.

⁹⁴ S. 1418, 109th Cong. § 2 (§ 2908).

⁹⁵ *Id.*

⁹⁶ *Id.*

F. MEDICAL PROFESSIONAL CERTIFICATION BARRIERS

Another barrier to adopting HIT is the differences between the states on certification of medical professionals.⁹⁷ WHCQA directs the Secretary of HHS to perform a study of state laws to determine the variation of the laws with respect to licensure, registration, and certification of medical professionals and how that variation affects the secure electronic exchange of health information.⁹⁸

G. PRIVACY AND SECURITY

According to a survey by the Markle Foundation,⁹⁹ although most Americans favor the creation of a national health information network and EHRs, the biggest concern is privacy of their information.¹⁰⁰ Section four of WHCQA specifically states that nothing in the bill is intended to affect the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") § 264,¹⁰¹ the Social Security Act §§ 1171-1179,¹⁰² or any regulations under those sections.¹⁰³ In addition,

⁹⁷ This is particularly important for determining whether a physician can render advice to a patient or physician in another state. For a more detailed analysis of this barrier, see *infra* Part V.A.4.b.

⁹⁸ S. 1418, 109th Cong. § 2.

⁹⁹ Markle Foundation, <http://www.markle.org> (last visited Mar. 4, 2006) (The Markle Foundation works to accelerate the use of emerging information and communication technologies "to address critical public needs, particularly in the areas of health and national security.").

¹⁰⁰ Press Release, Markle Foundation, Americans Support Online Personal Health Records (Oct. 11, 2005), available at http://www.markle.org/resources/press_center/press_releases/2005/press_release_10112005.php (last visited Mar. 3, 2006).

¹⁰¹ Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996); See Elizabeth Hutton & Devin Barry, *Privacy Year in Review: Developments in HIPAA*, 1 ISJLP 347 (2005) (provides background on HIPAA).

¹⁰² Social Security Act, Pub. L. 104-191, 110 Stat. 2021-2031 (1996), amended by P.L. 107-105, 115 Stat. 1007 (enacted as 42 U.S.C. § 1320d (2001)).

¹⁰³ S. 1418, 109th Cong. § 2. The Committee Report explains that the purpose of the section is to ensure that HIPAA is applied to health information stored or transmitted in electronic format. S. REP. NO. 109-111, at 12 (2005).

entities receiving grants or loans¹⁰⁴ are required to “agree to notify patients if their individually identifiable health information is wrongfully disclosed.”¹⁰⁵ One additional privacy provision not contained in WHCQA but in another proposed bill is the ability for individuals to opt-out of the nationwide health information network created under the bill.¹⁰⁶

IV. NON-GOVERNMENTAL PLAYERS

Outside the governmental action to adopt EHRs, there have been several organizations which have been working on EHR adoption. Three of the most influential organizations have been Connecting for Health,¹⁰⁷ the eHealth Initiative,¹⁰⁸ and the Center for Health Transformation.¹⁰⁹ The work of these organizations has provided guidance for the work of public bodies trying to address the same issues.

A. CONNECTING FOR HEALTH

Connecting for Health is a public-private collaborative which was established in 2002 by the Markle Foundation.¹¹⁰ Connecting for

¹⁰⁴ See *supra* Part III(C).

¹⁰⁵ S. 1418, 109th Cong. § 2 (referring to the following subsections of amended § 2905: (a)(2)(F), (b)(3)(D)(iii), and (c)(2)(H)).

¹⁰⁶ 21st Century Health Information Act of 2005, H.R. 2234, 109th Cong. § 3(b)(1)(B) (2005), available at http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPaddress=162.140.64.21&filename=h2234ih.txt&directory=/diskb/wais/data/109_cong_bills.

¹⁰⁷ Connecting for Health, <http://www.connectingforhealth.org/> (last visited Mar. 4, 2006).

¹⁰⁸ eHealth Initiative, <http://www.ehealthinitiative.org/> (last visited Mar. 4, 2006).

¹⁰⁹ Center for Health Transformation, <http://www.healthtransformation.net/home/> (last visited Mar. 4, 2006). This is by no means an exclusive list of private-sector organizations; rather, this list represents three of the most influential organizations whose work is frequently relied on by ONC and HHS.

¹¹⁰ Press Release, Markle Foundation, Markle Foundation Launches Initiative to Promote Adoption of Key Clinical Health Information Standards (Jun. 21, 2002), available at http://www.connectingforhealth.org/news/pressrelease_062102.html (last visited Mar. 4, 2006).

Health was “designed to improve patient care by promoting the adoption of an initial set of standards for electronic medical information, in a way that protects patient privacy.”¹¹¹ In the first phase, occurring from September 2002 to June 2003, Connecting for Health developed initial interoperable standards.¹¹² The collaborative also “[d]eveloped case studies on systems that could serve as potential models for privacy and security.”¹¹³ Finally, they defined the role of the “consumer/patient . . . in an interconnected healthcare system.”¹¹⁴ Three working groups were established to reach the goals of Phase I: the Data Standards Working Group,¹¹⁵ the Privacy and Security Working Group,¹¹⁶ and the Personal Health Working Group.¹¹⁷

In January 2004, Connecting for Health began the second phase.¹¹⁸ The first part of Phase II was to create a “roadmap” to define objectives to implementing a health information infrastructure.¹¹⁹ A

¹¹¹ *Id.*

¹¹² CONNECTING FOR HEALTH, ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE 5 (2004), available at http://www.connectingforhealth.org/resources/cfh_aech_roadmap_072004.pdf; see also Connecting for Health - Phase I, <http://www.connectingforhealth.org/aboutus/phase1.html> (last visited Mar. 4, 2006). To develop data standards, Connecting for Health established the Data Standards Working Group. Connecting for Health - Data Standards Working Group, <http://www.connectingforhealth.org/workinggroups/datastandardswg.html> (last visited Mar. 4, 2006).

¹¹³ CONNECTING FOR HEALTH, ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE, *supra* note 112, at 5.

¹¹⁴ Connecting for Health - Personal Health Working Group, <http://www.connectingforhealth.org/workinggroups/personalhealthwg.html> (last visited Mar. 4, 2006).

¹¹⁵ Connecting for Health - Data Standards Working Group, *supra* note 112.

¹¹⁶ Connecting for Health - Privacy and Security Working Group, <http://www.connectingforhealth.org/workinggroups/privacysecuritywg.html> (last visited Mar. 4, 2006).

¹¹⁷ Connecting for Health - Personal Health Working Group, *supra* note 114.

¹¹⁸ CONNECTING FOR HEALTH, ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE, *supra* note 112, at 5.

¹¹⁹ Press Release, Connecting for Health, Connecting for Health Announces Commitment to Create Incremental Roadmap for Achieving Electronic Connectivity in Health Care (Jan. 21, 2004), available at http://www.connectingforhealth.org/news/pressrelease_012104.html (last visited Mar. 4, 2006).

preliminary roadmap was released in July 2004.¹²⁰ Four working groups were established to address current barriers to health information sharing:¹²¹ the Expert Panel on Organizational and Sustainability Models for Community-Based Health Information Exchange,¹²² Working Group on Policies for Coordination Across the EHR and the PHR,¹²³ Working Group on Accurately Linking Information of Health Care Quality and Safety,¹²⁴ and the Expert Panel on Uniform Data Exchange Standards for Health Information.¹²⁵ The culmination of Phase II is the implementation of a demonstration project “to test and evaluate the working groups’ products in real-world settings.”¹²⁶

On June 1, 2005, Connecting for Health announced that it was launching a “prototype of an electronic national health information exchange.”¹²⁷ The prototype will connect the regional health

¹²⁰ CONNECTING FOR HEALTH, ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE, *supra* note 112. This preliminary roadmap states that a final roadmap will be published at some point. *Id.* at 5 (“the final version of the Roadmap . . . is set for release in September, 2004”). However, there is no indication that a final version was published or that there is intent to publish a final version.

¹²¹ Press Release, Connecting for Health, *supra* note 119.

¹²² Connecting for Health - Expert Panel on Organizational and Sustainability Models for Community-Based Health Information Exchange, <http://www.connectingforhealth.org/workinggroups/expertpanelwg.html> (last visited Mar. 4, 2006).

¹²³ Connecting for Health - Working Group on Policies for Coordination Across the EHR and the PHR, http://www.connectingforhealth.org/workinggroups/pol_coordinationwg.html (last visited Mar. 4, 2006).

¹²⁴ Connecting for Health - Working Group on Accurately Linking Information for Health Care Quality and Safety, <http://www.connectingforhealth.org/workinggroups/linkinwg.html> (last visited Mar. 4, 2006).

¹²⁵ Connecting for Health - Expert Panel on Uniform Data Exchange Standards for Health Information, <http://www.connectingforhealth.org/workinggroups/epuniformwg.html> (Although this website is given as the address of the working group, the website merely informs the visitor that more information will be forthcoming) (last visited Mar. 4, 2006).

¹²⁶ Press Release, Connecting for Health, *supra* note 119.

¹²⁷ Press Release, Connecting for Health, Prototype for a Nationwide Health Information Exchange Launched by Connecting for Health (June 1, 2005), *available at* http://www.connectingforhealth.org/news/pressrelease_060105.html.

information networks in Massachusetts, California, and Indiana.¹²⁸ Connecting for Health was part of the consortia that was awarded an RFP contract to create a prototype for the NHIN.¹²⁹

B. EHEALTH INITIATIVE

The eHealth Initiative is a group of healthcare organizations that want to improve healthcare through technology.¹³⁰ The eHealth Initiative was created to address the obstacles to HIT adoption.¹³¹ The overall goal of the eHealth Initiative is “to drive improvement in the quality, safety, and efficiency of healthcare through information and information technology.”¹³² Related to the eHealth Initiative is the Foundation for the eHealth Initiative which is a non-profit 501(c)(3) organization which “was created to serve as a national forum for the discussion of the policy issues” of HIT.¹³³

One project of the eHealth Initiative is the Connecting Communities for Better Health (“CCBH”) program.¹³⁴ CCBH is a

¹²⁸ *Id.*

¹²⁹ See Press Release, Statement of HHS Announcement of Contract to the Connecting for Health Team to Develop Nationwide Health Information Network (Nov. 10, 2005), available at http://www.connectingforhealth.org/assets/cfh_111005.pdf; see also Press Release, Contracts to Develop NHIN, *supra* note 36; see also *supra* section II.

¹³⁰ eHealth Initiative – About: Members, <http://www.ehealthinitiative.org/about/members.msp> (last visited Mar. 4, 2006). For a list of existing members, see eHealth Initiative – Members, <http://www.ehealthinitiative.org/members/members.msp> (last visited Mar. 4, 2006).

¹³¹ eHealth Initiative – About: Why eHI Was Created, <http://www.ehealthinitiative.org/about/why.msp> (According to eHealth Initiative, the barriers to adoption are “lack of health care system interoperability and widespread adoption of clinical data standards, outdated policies related to reimbursement, concerns about privacy and security, and lack of investment in innovation and technology.”) (last visited Mar. 4, 2006).

¹³² eHealth Initiative – About: Strategic Priorities, <http://www.ehealthinitiative.org/about/priorities.msp> (last visited Mar. 4, 2006).

¹³³ eHealth Initiative – About: Foundation for eHealth Initiative, <http://www.ehealthinitiative.org/about/foundation.msp> (last visited Mar. 4, 2006).

¹³⁴ eHealth Initiative, <http://www.ehealthinitiative.org/initiatives/ccbh/> (last visited Mar. 4, 2006).

program which provides funding to healthcare providers within a community “who are using IT and health information exchange to address quality, safety, and efficiency goals.”¹³⁵ The funding is provided by the Health Resources and Services Administration (“HRSA”)¹³⁶ and the Office of Advancement of Telehealth (“OAT”)¹³⁷ and is distributed by the Foundation.¹³⁸ The goals of the program are: (1) to provide funding for communities to adopt HIT;¹³⁹ (2) to provide an information exchange for the adoption of HIT learned through these programs; and (3) to help create a nationwide health information infrastructure.¹⁴⁰ The eHealth Initiative is also involved in creating a prototype of a NHIN with Connecting for Health.¹⁴¹

C. CENTER FOR HEALTH TRANSFORMATION

The Center for Health Transformation (“CHT”) was started in 2003 by the Gingrich Group.¹⁴² The purpose of CHT is to create

¹³⁵ CCBH Resource Center – FAQ, <http://ccbh.ehealthinitiative.org/communities/faqs.aspx?Category=150> (last visited Mar. 4, 2006).

¹³⁶ Health Resources and Services Administration, <http://www.hrsa.gov/> (The Health Resources and Services Administration (“HRSA”) is an agency in HHS that focuses on “people who are uninsured, isolated or medically vulnerable.”) (last visited Mar. 4, 2006). About the Health Resources and Services Administration, <http://www.hrsa.gov/about/default.htm> (last visited Sept. 9, 2006). Some of HRSA’s goals include: improving access to healthcare, improving quality of healthcare, eliminating healthcare disparities, improving public healthcare, and enhancing the ability of the healthcare system to respond to public emergencies. *Id.*

¹³⁷ Within HRSA is the Office for the Advancement of Telehealth (“OAT”). OAT is responsible for the coordination and promotion of telehealth technologies with HRSA as well as creating partnerships with other federal and state agencies. Office for the Advancement of Telehealth – Services, <http://www.hrsa.gov/telehealth> (last visited Sept. 9, 2006).

¹³⁸ CCBH Resource Center – FAQ, *supra* note 135.

¹³⁹ This allows for the evaluation of the cost/value of HIT.

¹⁴⁰ CCBH Resource Center – FAQ, *supra* note 135.

¹⁴¹ See Press Release, Contracts to Develop NHIN, *supra* note 36; see also *supra* Part II.

¹⁴² About CHT, <http://www.healthtransformation.net/about/History/> (last visited Mar. 4, 2006) (The Gingrich Group is a consulting firm established by former House of Representatives

solutions and policies that will lead to better healthcare.¹⁴³ Some strategies to reaching this purpose are: development of EHRs “to maximize accuracy, minimize errors, reduce inefficiencies and improve care;” development of a research database to improve research and decrease the amount of time from discovery by researchers to use by healthcare providers; and development of a network to protect the public against natural outbreaks and bioterrorism.¹⁴⁴

While Connecting for Health and eHealth Initiative focus on working with healthcare providers to adopt HIT, CHT attempts to drive the adoption of HIT at the policy level.¹⁴⁵ To reach the adoption of HIT, CHT is working with politicians to develop legislation that would help modernize healthcare, pushing for the reform of the Stark Law and the Anti-kickback Statute,¹⁴⁶ and create interoperability standards.¹⁴⁷

V. BARRIERS TO ADOPTION

There are two categories of barriers to adoption of EHRs: legal barriers and organizational barriers. The legal barriers are privacy, security, physician anti-referral and anti-kickback laws, and professional liability.¹⁴⁸ Other legal barriers to EHR adoption that are

Speaker Newt Gingrich.); About CHT: Mission, <http://www.healthtransformation.net/About/Mission/> (last visited Feb. 9, 2006).

¹⁴³ About CHT: Mission, *supra* note 142.

¹⁴⁴ About CHT: CHT Key Strategies for Health Transformation, <http://www.healthtransformation.net/About/Strategies/> (last visited Mar. 4, 2006).

¹⁴⁵ Projects – Health Information Technology (“HIT”) Project, http://www.healthtransformation.net/Projects/Health_Information_Technology/ (last visited Mar. 4, 2006).

¹⁴⁶ 42 U.S.C. § 1395nn (2000) (commonly referred to as Stark Law); 42 U.S.C. § 1320a-7b (2000) (Medicare Anti-kickback Statutes). *See infra* Part V.A.3.

¹⁴⁷ Health Information Technology – Current Activities, http://www.healthtransformation.net/projects/health_information_technology/1410.cfm (last visited Mar. 4, 2006).

¹⁴⁸ *See* CONNECTING FOR HEALTH, FINANCIAL, LEGAL, AND ORGANIZATIONAL APPROACHES TO ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE 36 (2004), *available at* http://www.connectingforhealth.org/assets/reports/flo_sustain_healthcare_rpt.pdf.

not discussed in detail in this article include intellectual property rights,¹⁴⁹ federal income taxes,¹⁵⁰ and antitrust issues.¹⁵¹ All of these are particularly important when forming Regional Health Information Organizations (“RHIOs”).¹⁵² The organizational barriers include funding and financial risk of HIT adoption, the legacy of failed implementations, and compatibility issues.

In addition to these specific barriers to adoption, there is a general barrier to adoption that is significant. The transformation from paper records is not only expensive, but it can require significant expertise.¹⁵³ It requires legal knowledge to determine applicable laws,

¹⁴⁹ Intellectual property rights are important for determining who has control and ownership of property such as the technologies used to implement EHRs or the health information contained in an EHR system. *Id.* at 36-37. *See, e.g.*, NCHICA Intellectual Property Policy, <http://www.nchica.org/AboutNCHICA/CorpInfo/IntellProp.htm> (the intellectual property policy of the North Carolina Healthcare Information and Communications Alliance) (last visited Mar. 4, 2006).

¹⁵⁰ One example of an income tax issue is “[t]ax-exempt organizations that provide financial or other benefits to private individuals may jeopardize their tax-exempt status.” *See* Letter from Janet Heinrich, Director, Health Care – Public Health Issues, U.S. General Accounting Office, to Judd Gregg, Chairman, Committee on Health, Education, Labor, and Pension, United States Senate 49 (Aug. 13, 2004), *available at* <http://www.gao.gov/new.items/d04991r.pdf>. [hereinafter Letter from Janet Heinrich]; *see also*, 26 U.S.C. § 501(c)(3) (2000). This provision would make it difficult for a tax-exempt hospital to provide HIT resources to a physician. Letter from Janet Heinrich, *supra*.

¹⁵¹ *See* CONNECTING FOR HEALTH, FINANCIAL, LEGAL, AND ORGANIZATIONAL APPROACHES TO ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE, *supra* note 148, at 37, 39 (This report mentions that anti-trust is a possible barrier but notes that many collaborations have successfully overcome this obstacle.). *See also* Letter from Janet Heinrich, Director, *supra* note 150, at 42-52. *See, e.g.*, Andrew S. Oldham, *The MedSouth Joint – (Ad)venture – The Antitrust Implications of Virtual Health Care Networks*, 14 ANNALS HEALTH L. 125 (2005).

¹⁵² A Regional Health Information Organization (“RHIO”) is a regional organization which manages or facilitates development and deployment of a regional health information system. *See* Noam H. Artz & Michael Berry, Models for Regional Health Information Systems: Ensuring Public Health’s Role, American Public Health Association Annual Meeting (Dec. 10-14, 2005), *available at* http://apha.confex.com/apha/133am/techprogram/paper_100140.htm (last visited Mar. 4, 2006). RHIOs form the foundation of the National Health Information Network (“NHIN”) discussed *supra*. *See also* Office of the National Coordinator for Health Information Technology, Regional Health Information Organizations, <http://www.hhs.gov/healthit/rhio.html> (last visited Mar. 4, 2006).

¹⁵³ *See* The Strategic Importance of Electronic Health Records Management: Checklist for Transition to the EHR, http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_024671.hcsp (Although this website attempts to provide an outline of the steps necessary to transition from paper records to EHRs, some of the steps are very complicated.

technical knowledge for the actual implementation, and medical knowledge to make the system practical.

A. LEGAL BARRIERS TO EHR ADOPTION

1. PRIVACY

In a survey by the Markle Foundation, researchers found that 72% of Americans were interested in the establishment of a nationwide health information system.¹⁵⁴ However, their greatest concern was privacy of their health information.¹⁵⁵ Although it is clear that protecting privacy is very important, it is a great barrier to adoption for reasons including the difficulty in determining the applicable state and federal laws.¹⁵⁶

a. FEDERAL LAW

First, an EHR system will have to comply with federal privacy law. For example, it is clear that any system adopted would have to

For example, under the research section, one step requires review of Rule 803(6) of the Federal Rules of Evidence to make sure the EHR being adopted meets the business record exception to the hearsay rule. This would require a legal opinion.) (last visited Mar. 4, 2006); *see also* Health IT Certification, <http://www.healthitcertification.com> (website provides certification course on adopting EHRs and HIT) (last visited Mar. 4, 2006).

¹⁵⁴ Press Release, Markle Foundation, Americans Support Online Personal Health Records, *supra* note 100.

¹⁵⁵ *Id.*

¹⁵⁶ In adopting EHRs, the developers should keep in mind the five core principles of privacy protection: (1) notice/awareness; (2) choice/consent; (3) access/participation; (4) integrity/security; and (5) enforcement/redress. Fair Information Practice Principles, <http://www.ftc.gov/reports/privacy3/fairinfo.htm> (last visited Mar. 4, 2006). Each of these principles leads to several questions which need to be addressed in creating EHRs and a nationwide interoperable network: who will have physical control (storage) of the data; who will have access to the data; whether patients can opt-in or opt-out of the network; whether patients will have access to their EHR; what kind of security standards are required to protect the data; and what rights patients have when their privacy is compromised.

comply with HIPAA.¹⁵⁷ In addition, the system would have to comply with two rules promulgated under HIPAA: the Privacy Rule¹⁵⁸ and the Security Rule.¹⁵⁹ HIPAA was enacted to reduce administrative costs in the healthcare industry and allow for the easy exchange of healthcare information, while protecting that information.¹⁶⁰ The Privacy Rule is a “federal floor” of privacy protection for health information in the United States.”¹⁶¹ The Privacy Rule “define[s] and limit[s] the circumstances in which an individual’s protected health information may be used or disclosed by covered entities.”¹⁶² The Security Rule provides security standards for the maintenance and exchange of electronic health information.¹⁶³ It is clear that the information contained in an EHR would clearly fall within the scope of protected health information covered by the Privacy Rule. Therefore, an EHR system would have to comply with the requirements of the Privacy Rule.

b. STATE LAW

In addition to complying with federal privacy law, an EHR system will have to comply with the applicable state privacy laws.¹⁶⁴ This

¹⁵⁷ Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) [hereinafter HIPAA].

¹⁵⁸ Privacy Rule, 45 C.F.R. § 164 (2005). See Hutton & Barry, *supra* note 101 (for a background on the privacy rule).

¹⁵⁹ 45 C.F.R. § 164 (2005).

¹⁶⁰ Hutton & Barry, *supra* note 101.

¹⁶¹ Electronic Privacy Information Center (“EPIC”), Medical Privacy, <http://www.epic.org/privacy/medical/> (last visited Mar. 4, 2006).

¹⁶² OFFICE FOR CIVIL RIGHTS, U.S. DEPT. OF HEALTH & HUMAN SERVICES, SUMMARY OF THE HIPAA PRIVACY RULE 4 (2003), available at <http://www.hhs.gov/ocr/privacysummary.pdf>.

¹⁶³ 68 Fed. Reg. 8334, 8334 (Feb. 20, 2003) (the purpose of the Security Rule is to provide “national standards for safeguards to protect the confidentiality, integrity, and availability of electronic protected health information.”).

¹⁶⁴ Health Privacy Project, *State Health Privacy Laws* (2d ed. 2002), available at http://www.healthprivacy.org/info-url_nocat2304/info-url_nocat.htm (last visited Mar. 4, 2006); see also Hutton & Barry, *supra* note 101, at 372-73.

becomes even more complicated when designing an interoperable nationwide network for the exchange of health information between healthcare providers in different states because the transfer will have to comply with the state laws of both states.

2. SECURITY/INTEGRITY

Related to the issue of privacy are the issues of security and integrity. The privacy and accuracy of the health information stored on a system depends on the security of the system.¹⁶⁵ Assuming the healthcare provider adopting the EHR system is a covered entity under HIPAA,¹⁶⁶ the HIPAA Security Rule will apply.¹⁶⁷ Security is important for several reasons. First, security protects the privacy of the health information maintained within the system. Second, security is one element in guarding the integrity of the system.¹⁶⁸ The integrity of the system is important for making sure that the information is practically useful¹⁶⁹ as well as legally useful.¹⁷⁰

Security will become even more important if a nationwide interoperable health information network is implemented. In order to maintain the security of the entire system, each member of the network will have to maintain a minimum level of security because the security of the entire network is based on the security of the weakest member.

¹⁶⁵ Security is one of the five core principles of privacy protection. Fair Information Practice Principles, *supra* note 156.

¹⁶⁶ HIPAA § 1173.

¹⁶⁷ See 45 C.F.R. § 164.

¹⁶⁸ The other element, which is beyond the scope of this article, is the integrity of the system itself. This is left to the software engineers to make sure that the system properly stores the data.

¹⁶⁹ For example, the system would not be very beneficial if the data was incorrect.

¹⁷⁰ An unsecured system would probably not be considered trustworthy under the business record exception to hearsay; therefore, the record might not be admissible in court. FED. R. EVID. 803(6).

3. PHYSICIAN ANTI-KICKBACK AND ANTI-REFERRAL LAWS

Another legal barrier to EHR adoption is anti-kickback and anti-referral statutes. Under federal law, these are the Anti-kickback Statute¹⁷¹ and the Stark Law.¹⁷² In general, the Anti-kickback Statute provides for criminal liabilities to anyone who gets remuneration when referring patients under Medicare, Medicaid, or any federally funded health plan.¹⁷³ The Stark Law is broader and prevents physicians from referring patients to other healthcare providers in which the physician has a financial interest.¹⁷⁴ Under state law, it is significantly more difficult to determine what state laws are applicable.

Following the creation of Medicare and Medicaid in 1965, complicated schemes arose where physicians would refer patients to other healthcare providers in which the physician had a financial interest; therefore, the physician would benefit from the referral.¹⁷⁵ In 1972, Congress enacted an anti-kickback statute to stop this practice.¹⁷⁶ Violation of this statute is a felony and can result in up to five years imprisonment, a \$25,000 fine, or both.¹⁷⁷ There are several exceptions to this statute,¹⁷⁸ referred to as "safe harbors."¹⁷⁹ The Stark Law is broader than the Anti-kickback Statute because it covers all physician referrals and is not limited just to referrals involving

¹⁷¹ 42 U.S.C. § 1320a-7b(b) (2000).

¹⁷² 42 U.S.C. § 1395nn (2000).

¹⁷³ Alissa M. Nann, *Health Care Fraud*, 42 AM. CRIM. L. REV. 573, 582 (2005).

¹⁷⁴ *Id.* at 605.

¹⁷⁵ John J. Farley, *The Medicare Antifraud Statute and Safe Harbor Regulations: Suggestions for Change*, 81 GEO. L.J. 167, 168-69 (1992).

¹⁷⁶ *Id.* at 170 (citing Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329 (1972)). The current statute can be found at 42 U.S.C. § 1320a-7b(b).

¹⁷⁷ 42 U.S.C. § 1320a-7b(b)(1).

¹⁷⁸ *Id.* at § 1320a-7b(b)(3).

¹⁷⁹ P. Greg. Gulick, *E-Health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural, and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs*, 12 ALB. L.J. SCI. & TECH. 351, 389 (2002).

Medicare or Medicaid.¹⁸⁰ In addition, the Stark Law does not provide criminal liability, but rather civil liability.¹⁸¹ There are several exceptions to this law as well.¹⁸²

Many scholars and private organizations have suggested that this is a barrier to the adoption of HIT, and they suggest that safe harbors or exceptions should be created to encourage HIT adoption.¹⁸³ For example, physicians might be discouraged from joining a Regional Health Information Organization ("RHIO") with other healthcare providers in a region because doing so might create a financial relationship, and then they could not refer patients to providers within the RHIO without being subject to criminal or civil liabilities.¹⁸⁴ In addition to the federal anti-kickback and anti-referral laws, it is necessary to determine applicable state laws.¹⁸⁵ This can become even more complicated if the relationship involves entities in more than one state.

4. PROFESSIONAL LIABILITY

In adopting EHRs, there are several medical professional liability issues which need to be addressed. First is the effect of EHR adoption on the legal standard of care. Second, the adoption of EHR with relation to telemedicine has the potential to create liabilities for physicians.

¹⁸⁰ See 42 U.S.C. § 1395nn.

¹⁸¹ *Id.* at § 1395nn(g).

¹⁸² *Id.* at §§ 1395nn(c)-(e).

¹⁸³ See, e.g., Gulick, *supra* note 179, at 389-91 (2002) (The author explains that e-commerce uses the promotional tool of "per click" arrangements which reward websites for generating traffic through ads placed on their websites. This could not be implemented in the healthcare context because it would violate the anti-kickback statute.).

¹⁸⁴ CONNECTING FOR HEALTH, ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE, *supra* note 112, at 51.

¹⁸⁵ For a comprehensive table of state statutes that are similar to the federal anti-kickback or Stark laws, see MICHAEL K. LOUCKS & CAROL C. LAM, PROSECUTING AND DEFENDING HEALTH CARE FRAUD CASES 575 (2001).

a. STANDARD OF CARE

Over the past two centuries, the legal standard of care for physician accountability has evolved.¹⁸⁶ The “locality” standard was established by courts during the middle of the 19th Century as a solution to the variances in physician skill level caused by the vast differences in resources and access to new technology from area to area.¹⁸⁷ The “locality” standard compared each physician to other physicians in the same community.¹⁸⁸ After World War II, as travel and information sharing improved, the “locality” standard was replaced with a “national” standard.¹⁸⁹ The “national” standard, which is the current standard, holds a physician to the same “degree of care and skill which is expected of a reasonably competent practitioner in the same class to which [the physician] belongs, acting in the same or similar circumstances.”¹⁹⁰ With the recent exponential growth in medical knowledge, the use of EHRs and HIT will increase the standard of care required by physicians throughout the country. In addition to the dissemination of general information, EHRs will compile targeted information concerning the procedures and policies of physicians throughout the country, further increasing the “national” standard of care.

b. EHR AND TELEMEDICINE

Another potential issue in medical professional liability that poses a barrier to EHR adoption is through the use of EHRs in telehealth.¹⁹¹

¹⁸⁶ Amy Jurevic Sokol & Christopher J. Molzen, *The Changing Standard of Care in Medicine: E-Health, Medical Errors, and Technology Add New Obstacles*, 23 J. LEGAL MED. 449, 473 (2002).

¹⁸⁷ *Id.* at 473-475.

¹⁸⁸ *Id.* at 474.

¹⁸⁹ *Id.* at 475.

¹⁹⁰ *Shilkret v. Annapolis Emergency Hosp. Ass’n*, 349 A.2d 245, 254 (1975).

¹⁹¹ Telehealth includes the term telemedicine but telehealth is broader than telemedicine. DEPARTMENT OF VETERANS AFFAIRS, REPORT ON APPROACHES TO MAKE HEALTH INFORMATION SYSTEMS AVAILABLE AND AFFORDABLE TO RURAL AND MEDICALLY UNDERSERVED COMMUNITIES 19 (2004), reprinted in NATIONAL COORDINATOR FOR HEALTH

Telehealth is “the provision of health care services [through electronic media] when patient and provider are separated in time and/or place.”¹⁹² Telehealth involves “the use of electronic information and telecommunications technologies to support long-distance clinical healthcare, patient and professional health-related education, public health and health administration.”¹⁹³ A key component of telehealth is EHRs because for telehealth to be effective, it is necessary that the remote physician be able to look at the patient’s health record. Therefore, the use of telehealth would theoretically increase the adoption of EHRs. However, a barrier to the adoption of telehealth is physician licensure.¹⁹⁴ Physicians are generally required to have a license in a state in which they practice, and it is unclear whether a physician is considered practicing in a state when the physician is in another state performing telehealth.¹⁹⁵

B. ORGANIZATIONAL BARRIERS TO EHR ADOPTION

In addition to the legal barriers to EHR adoption, there are several organizational barriers: compatibility issues, legacy of failed implementations, and financial risks.

INFORMATION TECHNOLOGY, THE DECADE OF HEALTH INFORMATION TECHNOLOGY: DELIVERING CONSUMER-CENTRIC AND INFORMATION-RICH HEALTH CARE, at 110 (July 21, 2004), available at <http://www.hhs.gov/healthit/documents/hitframework.pdf>.

¹⁹² *Id.*

¹⁹³ Office for the Advancement of Telehealth, *supra* note 137. The Office for the Advancement of Telehealth (“OAT”) was established by the Health Resources and Services Administration, which is under HHS, to lead the adoption of telehealth. *Id.*

¹⁹⁴ Gulick, *supra* note 179, at 365.

¹⁹⁵ *Id.*; see also The Center for Telehealth and E-Health Law, <http://www.ctel.org/> (last visited Mar. 4, 2006). The Center for Telehealth and E-Health Law, formerly called the Center for Telemedicine Law, created a report for the Office of the Advancement of Telehealth on physician licensure. See CENTER FOR TELEMEDICINE LAW, TELEMEDICINE LICENSURE REPORT (2003), available at <ftp://ftp.hrsa.gov/telehealth/licensure.pdf>.

1. COMPATIBILITY ISSUES

Compatibility is necessary so that healthcare providers can exchange records with one another.¹⁹⁶ Much of the executive action, through the Office of the National Coordinator, and the legislative bills that have been proposed have focused on creating national standards for interoperable EHRs. Interoperable simply means systems are compatible with each other. The goal is to eliminate compatibility issues. Aside from establishing standards of interoperability, there is another potential compatibility issue. Many healthcare providers have already implemented an EHR system or are in the process of implementing a system. For these providers, there is no guarantee that their current system will be compatible with the standards that are yet to be adopted. Depending on the amount of money these providers have invested in their current system, it might not be financially feasible for them to move to a system which is interoperable until they can afford to replace their current system. This could mean that providers which are currently technologically advanced may end up being technologically behind.

2. LEGACY OF FAILED IMPLEMENTATIONS

Successful EHR adoption will require overcoming the legacy of failed implementations. According to a Connecting for Health report, “[e]fforts to institute electronic medical records and clinical health information networks date back at least to the 1960s, but they have been unable to overcome formidable structural and financial barriers.”¹⁹⁷ Organizations involved in failed attempts at implementing EHRs may be reluctant to try again. In order to overcome this barrier, it is necessary to look at the reasons the implementations failed and attempt to avoid those problems in the future.

¹⁹⁶ See PRESIDENT’S INFORMATION TECHNOLOGY ADVISORY COMMITTEE, REVOLUTIONIZING HEALTH CARE THROUGH INFORMATION TECHNOLOGY 14-15, 24-25 (2004), available at http://www.nitrd.gov/pitac/reports/20040721_hit_report.pdf.

¹⁹⁷ CONNECTING FOR HEALTH, ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE, *supra* note 112, at 1.

3. FINANCIAL BURDEN

There are also financial burdens which present a barrier to EHR adoption. First, “[m]any healthcare organizations . . . believe that EHRs are a poor investment.”¹⁹⁸ In addition, several studies have found that EHR adoption is low because most healthcare providers lack adequate funding.¹⁹⁹ This lack of funding is further exacerbated because providers do not see any current benefit in adopting EHRs that would make adoption worthwhile even if they did have adequate funding.²⁰⁰

VI. PHR v. EHR

While the federal government and many private-sector entities work toward interoperable EHRs, some patients have already collected their medical records into a personal health record (“PHR”).²⁰¹ A PHR, like an EHR, contains a patient’s entire health record; however, a PHR is collected and maintained by the patient whereas an EHR is collected and maintained by a healthcare provider.²⁰² The justifications for creating a PHR are generally the same as for adopting EHRs, except there is no benefit to the public, such as through research and public health surveillance. Rather the benefits are personal to the patient creating the record.²⁰³ A PHR can be either digital or paper-based.²⁰⁴ There are a wide variety of software and

¹⁹⁸ CONNECTING FOR HEALTH, FINANCIAL, LEGAL, AND ORGANIZATIONAL APPROACHES TO ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE, *supra* note 148, at 21.

¹⁹⁹ *Id.*

²⁰⁰ *Id.* at 22.

²⁰¹ CONNECTING FOR HEALTH, ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE, *supra* note 112, at 27.

²⁰² *Id.* at 25.

²⁰³ See myPHR.com – Why Start a PHR?, http://www.myphr.com/your_record/why_start.asp (last visited Mar. 4, 2006).

²⁰⁴ myPHR.com – Additional Resources, http://www.myphr.com/your_record/keeping.asp (last visited Mar. 4, 2006).

services available to help create and maintain a PHR.²⁰⁵ One advantage of PHRs over EHRs is that the patient could completely control the security of the PHR by regulating who has access to the record. In contrast, a patient could not control who had access to their EHR.²⁰⁶ Further, if the PHR was kept at an online PHR service provider, if the patient was unsatisfied with the service provider, including security considerations, the patient could change service providers. The patient would not have the same control over an EHR. However, an EHR in a hypothetical nationwide interoperable system would be available anywhere at the point of care in an emergency situation. A PHR would require the patient to grant consent for the physicians to use the PHR, which might not be possible in an emergency.

VII. CONCLUSION

Moving from paper-based healthcare records to EHRs would provide a great benefit by reducing preventable errors, lowering the cost of healthcare, and improving the efficiency and quality of healthcare. While there are many benefits to the adoption of EHRs, there are also many barriers to adoption. The barriers include both legal and organizational barriers that need to be addressed before adoption of EHRs can be effective. EHRs have the potential to transform the healthcare system; however, the path to EHR adoption will require hard work and collaboration among many public and private organizations.

²⁰⁵ See myPHR.com – Research PHR Tools and Services, http://www.myphr.com/resources/phr_search.asp (last visited Mar. 4, 2006).

²⁰⁶ Of course, HIPAA places some limitations on who has access to a patient's health information. See Hutton & Barry, *supra* note 101, at 350-51.

