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I. BACKGROUND

The Consolidated Omnibus Reconciliation Act of 1996 (COBRA) has made the implementation of the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules a reality in health care over the last decade. What will the next decade bring? No one can predict the future but it is certain that 2010 and beyond will bring about reforms to both health care delivery and the legal process surrounding it.

On December 1, 2006, a series of amendments were made to the Federal Rules of Civil Procedure (FRCP). The FRCP govern court procedures for civil suits in the United States district courts. Promulgated by the United States Supreme Court according to the Rules Enabling Act, the FRCP are then approved by the United States Congress. Supreme Court modifications to the rules are based on recommendations from the Judicial Conference of the United States, the federal judiciary's internal policy-making body.

The FRCP amendments are redefining and reshaping the discovery process within federal and state courts.[1] Although the FRCP do not apply to suits in state courts, the rules of many states are being closely modeled on these and are based upon the FRCP. The enactment of the FRCP amendments has placed electronically stored information (ESI) on equal footing with paper in the eyes of the court. Perhaps unbeknownst to the body that established them, the FRCP are playing an important role in defining the functions, capabilities and capacities of the electronic health record systems (EHRs) of tomorrow.

On February 17, 2009, the Health Information Technology for Economic

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1. Seventh Circuit Electronic Discovery Pilot Program (2009), *available at* http://www.ilcd.uscourts.gov/Statement%20-%20Phase%20One.pdf, (last accessed January 4, 2010).

and Clinical Health Act (HITECH) was signed into law by President Barack Obama.[2] This groundbreaking piece of legislation was enacted as part of the American Recovery Reinvestment Act (ARRA)[3]. One of the primary goals of HITECH is to encourage the adoption of electronic health records by providing federal funding (grants and incentive payments) to providers in order to promote implementation of EHRs.

Subtitle A of HITECH established the Office of the National Coordinator (ONC) to promote adoption of health information technology and ensure the security and protection of patient health information (PHI) while improving the quality of care and reducing health care costs.

Subtitle D of HITECH includes new and far-reaching provisions concerning the privacy and security of PHI that will directly affect more entities, businesses, and individuals than ever before. Civil penalties for willful neglect will be increased under HITECH. These penalties can extend to $250,000, with repeat or uncorrected violations extending to $1.5 million. Furthermore, civil and criminal penalties that could be imposed upon providers through HIPAA have been extended to business associates.

The HITECH privacy and security changes include:

- **Accounting of Disclosures With EHR Use**: Covered entities using and disclosing PHI through an EHR are required to provide individuals with accounting, when requested, for the prior three years. Uses and disclosures of PHI through EHRs include treatment, payment and business operations.
- **Access Rights to Electronic Format**: The HIPAA Privacy Rule is amended to give individuals the right to obtain access to their PHI in electronic format, if requested and available.
- **Security Breach Notification**: This imposes breach notifications for unauthorized users and disclosures of unsecured PHI. Covered entities, business associates, and others must notify individuals and others of breaches of unsecured protected health information.
- **Health Care Operation**: By August 17, 2010, the definition of "health care operations" will be reviewed by the Secretary of the Department of Health and Human Services.
- **Sale of PHI**: Covered entities and business associates are prohibited from directly or indirectly receiving any remuneration in exchange for any protected PHI without valid authorization, except in a very limited number of circumstances.

2. The Library of Congress, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1enr.pdf, (last accessed December 30, 2009).

3. *Id.*.

- **Marketing**: Greater restrictions have been placed on the use of health information for marketing purposes.

HITECH is comprised of four major goals that advance the use of health information technology:

- **Government Oversight**: Requires the government to take a leadership role to develop standards by 2010 that allow for the nationwide electronic exchange and use of health information to improve quality and coordination of care.
- **Investment in Technological Infrastructure** : $20 billion investment in health information technology (HIT) infrastructure and Medicare and Medicaid incentives to encourage doctors and hospitals to use HIT to electronically exchange PHI.
- **Savings**: The government estimates the savings to be $10 billion, with additional savings generated throughout the health sector, through improvements in quality of care coordination of care, and reductions in medical errors and duplicative care.
- **Establishment and Enforcement of Stricter Federal Privacy and Security Laws**: To protect identifiable health information from misuse as the health care sector increases use of HIT.

An explosion of primary and secondary use of data from health information systems is anticipated, especially given the HITECH goal that all hospitals implement a certified EHR system by 2015. This explosion will redefine the landscape and standards for care delivery and the management of information within the country.[4]

The primary use of an EHR is for the delivery and management of patient care. However, stakeholders today also have a vested interest in secondary uses of EHR systems for measuring quality, administrative functions, government use, marketing, and research. For example, private physicians and hospitals can query and report quality measures, public health agencies can monitor and detect population health indices, the Food and Drug Administration (FDA) can coordinate post-marketing surveillance, pharmaceutical companies can conduct focused marketing, insurance companies can allocate resources, and academia can use clinical data for comparative effective research.

On November 7, 2009, the Affordable Health Care for America Act[5] (HR

4. Office of the National Coordinator for Health Information Technology, Notice and Request for Comments. 74 Fed. Reg. 25550-25552 (May 28, 2009), *available at* http://edocket.access.gpo.gov/2009/pdf/E9-12419.pdf (last visited January 4, 2010).

5. Affordable Health Care for America, H.R. 3962, 111th Cong. (2009) *available at* http://docs.house.gov/rules/health/111_ahcaa.pdf (last visited January 4, 2010).

3962) was passed in the House of Representatives by a recorded vote of 220-215. On December 24, 2009, the Patient Protection and Affordable Care Act[6] (HR 3590) was passed in the Senate by a recorded vote of 60-39.

At the time of publication of this article, both bills are scheduled to go to the House-Senate Conference Committee, where representatives of the House and Senate will combine the measures. Both bills propose a major overhaul of America's health care system. One central difference between these bills however, is that the HR 3962 contains a government-run insurance plan, the so-called "public option," while the public option was dropped from HR 3590. Other differences include provisions over abortions and taxes.

II. THE LINK BETWEEN THE FRCP, HITECH AND HEALTHCARE REFORM

What do the FRCP, HITECH, and HR Bills 3962 and 3590 have in common? Quite simply, they share the role of significantly impacting the rules and regulations of their respective industries. Therefore, whatever final form the health care bill takes, one measure is certain: The U.S. healthcare system will undergo unprecedented change beginning in 2010.

The proposed overhaul of today's health care system is equally as significant, if not more so, than when Medicare was enacted on July 30, 1965 to cover those aged sixty-five and older and Medicaid was enacted to cover low-income families, as well as individuals with disabilities, and those on welfare.

At present, only 1.5% of U.S. hospitals have a comprehensive (a fully-integrated, enterprise-wide system) electronic-records system and 7.6% have a basic system in one or more clinical units.[7] As a result of HITECH, the implementation of certified EHRs will become a reality in the near future. The Congressional Budget Office (CBO) estimates that approximately 90% of doctors and 70% of hospitals will be using comprehensive EHRs within the next decade.[8]

On June 15, 2009, at the American Medical Association in Chicago, IL, President Barack Obama said this about the future of EHRs:

> It simply doesn't make sense that patients in the twenty-first century are still filling out forms with pens on papers that have to be stored away

6. Patient Protection and Affordable Care Act, H.R. 3950, 111th Cong. (2009) *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590as.txt.pdf (last visited January 4, 2010).

7. Ashish K. Jha et al., *Use of electronic health records in U.S. hospitals*, 360 NEW ENG. J. MED. 1628-38 (April 16, 2009).

8. Congressional Budget Office, http://www.cbo.gov/ftpdocs/99xx/doc9966/HITECHRangelLtr.pdf, (last visited Jan. 4, 2010).

> somewhere. You shouldn't have to tell every new doctor you see about your medical history or what prescriptions you're taking. You shouldn't have to repeat costly tests. All that information should be stored securely in a private medical record so that your information can be tracked from one doctor to another—even if you change jobs, even if you move, even if you have to see a number of different specialists. And that will not only mean less paper-pushing and lower administrative costs, saving taxpayers billions of dollars; it will also mean all of you physicians will have an easier time doing your jobs. It will tell you, the doctors, what drugs a patient is taking so you can avoid prescribing a medication that could cause a harmful interaction. It will prevent the wrong dosages from going to a patient. It will reduce medical errors, it's estimated, that lead to 100,000 lives lost unnecessarily in our hospitals every year. So there shouldn't be an argument there. And we want to make sure that we're helping providers computerize so that we can get this system up and running.

The FRCP, HITECH and the final health care reform bill will work in triumvirate to provide model rules and standards for the functionalities of EHRs and ultimately the delivery of health care by providers.

III. THE MEANINGFUL USE AND REQUIRED FUNCTIONALITIES OF EHRS OF TOMORROW

On December 30, 2009, The Centers for Medicare and Medicaid Services posted the long awaited rule defining the "meaningful use" of EHRs to qualify for the Medicare and Medicaid incentive payments authorized under ARRA.[9] CMS also posted an interim final rule from the ONC that sets initial standards, implementation specifications and certification criteria for EHR technology. Healthcare providers, legal professionals, EHR system vendors and consumers can support the development and adoption of EHRs by reading and understand the CMS and ONC interim rules defining "meaningful use" and the standards, as well as the implementation specifications for the EHRs of tomorrow.

A certified EHR should not only provide more efficient, safer and cost effective care, but it should also comply with the legal rules that govern the discovery and admissibility of PHI into a court of law. Beginning in 2010, the functionalities and capabilities of the EHR systems of tomorrow must be designed and developed in such a way to ensure their compliance with the FRCP—if not for any other reason than to mirror the spirit and purpose of the FRCP, which is to "secure the just, speedy, and inexpensive

9. Federal Register, Interim Final Rule, *available at* http://www.federalregister.gov/OFRUpload/OFRData/2009-31217_PI.pdf (last accessed Jan. 4, 2010).

determination of every action and proceeding."[10]

EHR systems in existence today are woefully inadequate and unprepared for electronic discovery. Unless appropriate technological advancements are made, the process of the electronic discovery of EHR will be cumbersome, inefficient and very costly.

Every organization has a duty to preserve relevant information at the moment it knows about or can reasonably anticipate litigation. For example, in the landmark e-discovery case, *Zubulake v. UBS Warburg*,[11] Judge Scheindlin held that the organization's duty to preserve relevant records began at the latest when Zubulake filed her EEOC charge, but that in this case, since the relevant people at UBS anticipated litigation in April 2001, the duty to preserve evidence began at that time.

One of the many design flaws of today's EHR systems is the lack of technology to establish a legal hold on an individual's record at the time the organization knows (or should know) that it will be a target of litigation or a regulatory investigation. In addition, at present, most legal counsel are unfamiliar with EHR technology and therefore do not know how to obtain valuable data (such as system metadata) in order to argue or defend their case.

In the next decade we will see the development of commerce for the electronic exchange of health information. Rather than taking paper files or CD-ROMs from place to place, provider to provider, all information will be processed through a Health Information Exchange (HIE).

In closing, the time has come for all healthcare and legal professionals to become involved in the redesign of our new healthcare system. Healthcare and legal professionals of the next decade will be expected to possess a working knowledge of EHR and HIE systems. It behooves healthcare professionals to start educating themselves on these topics now. Reaching out to legal counsel, risk managers, health information management and information technology professionals to learn more about proposed design and implementation of their EHR systems is a wise move—as is asking an attorney about civil practice procedures and the FRCP. All of these steps ensure that healthcare professionals who do become involved in and knowledgeable about EHR systems and the FRCP will be well equipped to communicate important information for their own care as well as for in a court of law.

10. FED. R. CIV. P. 1.
11. 220 F.R.D. 212 (S.D.N.Y. 2003).