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Electronic Health Records and Medical Big Data: Law and Policy

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LAW AND POLICY

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Introduction

Electronic health record (EHR) systems are not a new idea. A short YouTube video entitled "1961 Electronic Medical Records"[1] discusses a project that Akron General Hospital in Ohio undertook in the early 1960s. The grainy black-and-white film shows the hospital's newly installed, very large computers being used by satisfied clinicians. The narrator enthusiastically asserts that thanks to the new technology, "It is going to be possible to relieve the nurses and doctors of some of their paperwork. It is going to be possible to have correlation of diseases which we have not had before. And it is going to be possible to eliminate errors in medications and tests of this kind which would have been harmful to the patients."

In truth, however, EHRs did not begin to take off until forty years later, in the early twenty-first century. On April 26, 2004, President George W. Bush announced a plan to ensure that all Americans' health records would be computerized within ten years.[2] The following day, the president issued an executive order establishing the position of National Health Information Technology Coordinator to promote implementation of a "nationwide interoperable health information technology infrastructure."[3] At the same time, many other developed countries in Europe and elsewhere undertook major initiatives to transition to use of EHR systems.[4]

[1] "1961 Electronic Medical Records"; available at: www.youtube.com/watch?v=t-aiKllc6uk (accessed February 9, 2016).
[2] The White House, "Transforming Health Care: The President's Health Information Technology Plan," in *Promoting Innovation and Competitiveness: President Bush's Technology Agenda*, April 26, 2004; available at: http://georgewbush-whitehouse.archives.gov/infocus/technology/economic_policy200404/chap3.html (accessed September 8, 2015).
[3] Exec. Order No. 13,335, *Fed. Reg.* 69: 24,059 (April 27, 2004).
[4] eHealth Stakeholder Group, "Patient Access to Electronic Health Records: eHealth Stakeholder Group," led by Illaria Passarani, European Commission, June 2013; available at: http://ec.europa.eu/digital-agenda/en/news/commission-publishes-four-reports-ehealth-stakeholder-group (accessed January 7, 2016).

Arguably, it was high time that medical professionals digitize their practices. Almost all other industries had long ago embraced computerization. Nevertheless, the rate of adoption of EHR systems was quite low at first. By 2008, only 17 percent of doctors' offices and 10 percent of hospitals had basic EHR systems in the United States.[5] In Europe, by 2007, only seven countries routinely used EHRs.[6] The transition from paper medical records to EHR systems was proving to be far more complicated, cumbersome, and hazardous than many anticipated.

In 2009, as part of President Obama's economic stimulus plan, Congress enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act.[7] This law dedicated approximately $27 billion to promoting health information technology, including incentive payments for healthcare providers who adopted and appropriately used certified EHR systems.[8] As a result, by 2013, 70 percent of US physicians had implemented at least a basic EHR system, and 76 percent of US hospitals had done so by 2014.[9] By 2015, 95 percent of hospitals and 84 percent of primary care physicians in the United States were estimated to use EHR systems, as did the vast majority of primary care physicians in other developed countries.[10]

There is no going back – we now live in a world in which computers populate the clinical setting as much as doctors, nurses, and patients do. Computers are

[5] Robert Wachter, *The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age* (New York: McGraw Hill Education, 2015), 12.

[6] World Health Organization, "Legal Frameworks for eHealth," *Global Observatory for eHealth Series* 5 (2012): 45; available at: http://apps.who.int/iris/bitstream/10665/44807/1/9789241503143 _eng.pdf (accessed January 7, 2016).

[7] Health Information Technology for Economic and Clinical Health (HITECH) Act, Pub. L. No. 111–15, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 USC).

[8] David Blumentahl and Marilyn Tavenner, "The 'Meaningful Use' Regulation for Electronic Health Records," *New England Journal of Medicine* 363 (2010): 501; Sharona Hoffman and Andy Podgurski, "Meaningful Use and Certification of Health Information Technology: What about Safety?," *Journal of Law, Medicine & Ethics* 39 (Suppl. 1) (2011): 77. Providers can receive up to $44,000 through Medicare or $63,750 through Medicaid. See Chapter 2.

[9] Dustin Charles, Meghan Gabriel, and Talisha Searcy, "Adoption of Electronic Health Record Systems among US Non-Federal Acute Care Hospitals: 2008–2014," *ONC Data Brief* 23 (2015); available at: http://healthit.gov/sites/default/files/data-brief/2014HospitalAdoptionDataBrief .pdf (accessed September 8, 2015); Dawn Heisey-Grove and Vaishali Patel, "Physician Motivations for Adoption of Electronic Health Records," *ONC Data Brief* 21 (2015); available at: www.healthit.gov/sites/default/files/oncdatabrief-physician-ehr-adoption-motivators-2014 .pdf (accessed September 8, 2015); Julia Adler-Milstein et al., "Electronic Health Record Adoption in US Hospitals: Progress Continues, But Challenges Persist," *Health Affairs* 34, no. 12 (2015): 2174.

[10] Robin Osborn et al., "Primary Care Physicians in Ten Countries Report Challenges Caring for Patients with Complex Health Needs," *Health Affairs* 34, no. 12 (2015): 2104–12; available at: http://content.healthaffairs.org/content/34/12/2104.full?keytype=ref&siteid=healthaff&ijkey= Wvt51Tp9QSL/g#T4; HealthIT.gov, "Health IT Quick Stats"; available at: http://dashboard .healthit.gov/quickstats/quickstats.php (accessed December 28, 2015).

a standard feature in the examination room and at the bedside. But this change does not please everyone. I am sure I'm not alone in having witnessed a clinician curse the computer during an office visit or in feeling at times as though doctors are paying more attention to their data-input duties than they are to me during our encounters.

EHR systems are central not only to clinical care but also to medical research, public health initiatives, quality-improvement efforts, and other health-related endeavors. EHRs enable the creation of "medical big data," that is, very large electronic data resources that can be put to secondary, nonclinical uses. Medical big data can have tremendous benefits as a tool for scientific discoveries and other advances, but the creation and use of vast EHR databases raises acute concerns about privacy breaches and consequent harm to data subjects.

Just as the transition to EHR systems has had a profound impact on the delivery of medical care, research, and health data analysis, so too it has changed the laws and regulations of the healthcare industry. Countless legal questions are raised by the new technology. For example, how can privacy best be protected when medical records are stored electronically? Does use of EHR systems increase or decrease clinicians' vulnerability to medical malpractice claims? How can complex and ever-changing EHRs be transformed into discoverable documents that are accessible to plaintiffs? Should medical research regulations respond in any way to the increasing prevalence of EHR-based research? Are American anti-discrimination laws strong enough to protect individuals when employers and others may discover private health information on the Internet?

This book's purpose is to analyze the intersection of law and health information technology. It will evaluate what EHR systems and big data have to offer and what their shortcomings are. It will also explore how the law has responded to the advent of EHR systems so far, highlight gaps in the current legal framework, and develop detailed recommendations for future regulatory, policy, and technological improvements. A central premise of the book is that the law is a vital tool for safeguarding and enhancing the quality and security of EHR systems. Although the US Department of Health and Human Services has engaged with the need to oversee the new technology and has implemented a series of regulations, they are far from comprehensive. While this book largely focuses on regulations and policies in the United States, much of the analysis is applicable to other regions of the world, and the text is often enriched with references to international studies and doctrine.

A Note about Terminology. For the sake of consistency, I use the term "electronic health record" (EHR) rather than "electronic medical record"

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(EMR) in this book. I do not believe that there is a substantive difference between the two, and I mean EHR to encompass any digital version of a patient's medical chart. The term "electronic health record (EHR) system," as I use it here, means a system that adds to EHRs information management tools such as clinical alerts and reminders, decision aids, tools for data analysis, and more.[11]

Discussions of the law in this book focus on legal concerns arising from the use of EHR systems. Thus I do not assess many other legal-medical challenges that are important to contemporary patients. For example, I do not devote space to general health privacy interests or to provisions of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule that do not relate specifically to electronically stored information. Likewise, discussion of medical big data in this book focuses on government or private-entity databases that draw data from EHRs or healthcare providers. Therefore I generally do not address big data that is obtained from nontraditional sources such as social media, consumer purchasing records, or website searches.

This book proceeds in two primary parts. The first part focuses on EHR systems as they are used in clinical settings to treat patients. The second part is devoted to medical big data that is derived from EHRs and used for research and other nonclinical, secondary purposes.

More specifically, this book covers a wide array of EHR system and medical big data topics. Part I begins with a chapter that details the capacities of EHR systems and analyzes their benefits and shortcomings. It proceeds to a discussion of the federal "meaningful use" and certification regulations that govern EHR systems and assesses their efficacy. Chapter 3 is devoted to EHR data security and the HIPAA Security Rule. Chapter 4 focuses on the liability risks that EHR systems generate and the effects that record digitization will have on discovery in medical malpractice cases. Part II of this book begins with a discussion of what medical big data is and what benefits it offers. Chapter 6 probes the privacy and autonomy concerns that medical big data research raises. It is followed by a discussion of the data-quality problems and analytical challenges that analysts working with medical big data may face. Finally, Chapter 8 explores the emerging phenomenon of open medical data, that is, health information that is publicly available to anyone with Internet access and that may or may not be thoroughly deidentified. Many of these chapters conclude with a set of proposals to address the challenges that they highlight.

[11] Edward H. Shortliffe and James J. Cimino, eds., *Biomedical Informatics: Computer Applications in Health Care and Biomedicine* (New York: Springer, 2006), 937.

My hope is that readers gain an in-depth understanding of EHR systems and medical big data. This book serves not only as a general primer but also analyzes the many legal, ethical, and policy implications of EHRs and big data and the relationship between law and medical technology. It also formulates a large body of recommendations to improve the technology's safety, security, and efficacy for both clinical and secondary uses. The field of medicine is now firmly rooted in the digital age. This book, which is up-to-date as of July 2016, is devoted to illuminating both its promise and its perils.