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Introduction - Symposium Issue on Health Data Security Systems

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INTRODUCTION

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The health care industry in the United States is undergoing a fundamental change. Medical practices are replacing traditional hard-copy medical files with electronic health record (EHR) systems. This transition has accelerated in the last few years because the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act[1] dedicated billions of dollars to the promotion of health information technology (HIT). Individual clinicians who adopt and meaningfully use certified EHR systems can receive up to $44,000 through Medicare or $63,750 through Medicaid, totaling $27 billion over ten years.[2] According to a recent report, approximately 30-40% of primary care doctors have already implemented basic EHR systems.[3] HITECH's stated goal is "[t]he utilization of an electronic health record for each person in the United States by 2014."[4]

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1 See Health Information Technology for Economic and Clinical Health (HITECH) Act, Pub. L. No. 111-5, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

2 David Blumenthal & Marilyn Tavenner, *The "Meaningful Use" Regulation for Electronic Health Records*, 363 New Engl. J. MED. 501, 501 (2010); *see also* Sharona Hoffman & Andy Podgurski, *Meaningful Use and Certification of Health Information Technology: What About Safety?*, 39 J. L. MED. & ETHICS 77, 77 (Supp. 2011).

3 David Brailer, *David Brailer and Farzad Mostashari: Two National Health IT Czars Compare Notes*, 31 HEALTH AFFAIRS 475, 475 (2012).

4 42 U.S.C. 300jj-11(c)(3)(A)(ii).

Given that record keeping in most other industries is fully computerized, health care appears to be far behind in terms of data processing.   However, the digitization of health information is extremely complex and raises a dizzying array of concerns and challenges.[5]   Both the potential benefits and the potential risks of health information technology are numerous; the transition ushers in great promise and considerable difficulties.[6] A primary area of focus has been safeguarding the confidentiality and security of EHRs.[7] In addition, numerous other important issues have emerged.

The editors of the *Houston Journal of Health Law & Policy* have assembled an impressive group of authors for this symposium issue on Data Collection and Health Information Technology.   They explore a variety of novel and important topics, and their articles make significant contributions to the growing HIT literature.

The symposium issue opens with an article by Professors Mark Rothstein and Gil Siegal. They grapple with the question of whether HIT will impact physicians' duty to notify patients of new medical developments, such as the discovery of severe drug side-effects, medical device recalls, or modified dietary recommendations for those with particular illnesses.[8] Professor Rothstein is the Herbert F. Boehl Chair of Law and Medicine and the director of the Institute for Bioethics Health Policy and Law at the University of Louisville School of Medicine.   Professor Siegal is a professor of law at the University of Virginia School of Law and chair of the Center for Health Law and Bioethics at Kiryat Ono Academic College in Israel.

The authors note that EHR systems will greatly facilitate

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5 Sharona Hoffman & Andy Podgurski, *Finding A Cure: The Case for Regulation and Oversight of Electronic Health Record Systems*, 22 Harv. J. L & TECH. 103, 119-26 (2008) (discussing the challenges of EHR implementation); see also Sharona Hoffman & Andy Podgurski, *E-Health Hazards: Provider Liability and Electronic Health Record Systems*, 24 BERKELEY TECH. L. J. 1523, 1533-62 (2009) (analyzing liability concerns associated with EHR system use).

6 See Hoffman & Podgurski, *Finding A Cure*, supra note 5, at 112-26; Hoffman & Podgurski, *E-Health Hazards*, supra note 5, at 1530-62.

7 See e.g. Mark A. Rothstein, *Debate Over Patient Privacy Control in Electronic Health Records*, Bioethics Forum, Feb. 17, 2011, *available at* http://www.thehastingscenter.org/ Bioethicsforum/Post.aspx?id=5139; *see also* Nicolas P. Terry & Leslie P. Francis, *Ensuring the Privacy and Confidentiality of Electronic Health Records*, 2007 U. ILL. L. REV. 681, 702 (2007).

8 Mark A. Rothstein & Gil Siegal, *Health Information Technology and Physicians' Duty to Notify Patients of New Medical Developments*, 12 HOUS. J. HEALTH L. & POL'Y 93 (2012).

communication between doctors and patients through electronic communication, social networks, and use of mobile phones as information portals. Professors Rothstein and Siegal argue that, as a consequence, physicians should be ethically and legally bound to inform patients of significant new medical developments that will be of clear benefit to these patients. Furthermore, patients who are harmed by a failure to notify should have a common law cause of action that enables them to seek redress. Professors Rothstein and Siegal develop detailed recommendations for the scope and application of their proposed notification duty.

In a second article, Deven McGraw and Alice Leiter offer a framework for using electronic health data for quality improvement purposes.[9] Mr. McGraw is the Director of the Center for Democracy & Technology's Health Privacy Project. Ms. Leiter is the Director of Health IT Policy at the National Partnership for Women & Families. The authors call for the development of policies that will promote the use of EHR data to analyze and improve the quality of health care in the United States. However, maximizing the benefits of HIT in the realm of quality improvement will require some normative shifts. Specifically, traditional reliance on informed consent and patient autonomy will need to be diminished and replaced with "strong data stewardship" practices and more comprehensive regulatory oversight. Mr. McGraw and Ms. Leiter also explore how quality analytics can be enhanced in practical terms, and they recommend the use of decentralized, distributed networks across multiple institutions rather than the creation of a central data repository.

The authors explicitly limit their proposal to quality improvement activities. By coincidence, my co-author Andy Podgurski and I recently published an article in which we independently crafted similar recommendations for observational research studies using large-scale EHR databases.[10] Mr. McGraw and Ms. Leiter thus have identified and analyzed a problem that crosses into several fields of endeavor: how do we best realize the benefits of

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9 Deven McGraw & Alice Leiter, *A Policy and Technology Framework for Using Clinical Data to Improve Quality*, 12 HOUS. J. HEALTH L. & POL'Y 137 (2012).

10 Sharona Hoffman & Andy Podgurski, *Balancing Privacy, Autonomy, and Scientific Needs in Electronic Health Records Research*, 65 SMU L. REV. 85, 127-44 (2012).

secondary use[11] of EHR data without alienating patients who may no longer be asked for data use authorization and without compromising patient confidentiality?

The third symposium piece, written by Professor Leslie P. Francis, focuses on privacy and confidentiality concerns related to a very specific EHR feature: participative technologies that enable patients to interact with their EHRs.[12] Professor Francis is the Alfred C. Emery professor of law and professor of philosophy at the University of Utah S.J. Quinney College of Law. She holds adjunct appointments at the University's medical school and political science department.

Professor Francis explains that some systems now include portals that allow patients to access their EHRs, submit information to them, communicate with providers, and download portions of their records. Her analysis highlights new privacy concerns arising from this advanced EHR system capability. Professor Francis cautions that patients must understand that any information they enter through patient portals may become permanently embedded in their medical records and thus be shared with other clinicians. In addition, to effectively safeguard health information confidentiality, the technology must be capable of authenticating users and limiting the scope of information to which different users have access. Such limitations may be particularly important when the patient is a minor, as state law grants adolescents and their parents different health care information rights. Professor Francis's evaluation of these and other privacy risks that are associated with interactive technologies is a valuable addition to HIT privacy literature.

The symposium articles will give readers new insight into the far-reaching implications of EHR system adoption. The articles highlight the benefits and risks of EHR systems for patients,

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11 Secondary use can be defined as "non-direct care use of ... [data] including but not limited to analysis, research, quality/safety measurement, public health, payment, provider certification or accreditation, and marketing and other business including strictly commercial activities." Charles Safran et al., *Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper*, 14 J. Am. Med. Informatics Ass'n 1, 4 (2007).

12 Leslie P. Francis, *When Patients Interact with EHRs: Problems of Privacy and Confidentiality*, 12 HOUS. J. HEALTH L. & POL'Y 171 (2012).

physicians, and other stakeholders. The new technology may enable patients to receive valuable information through electronic notification. At the same time, this capability could impose new responsibilities on doctors and potentially create additional malpractice vulnerabilities. EHRs may also create opportunities for extensive quality analytics and health care improvements. However, in order to enable such advances, patients may need to tolerate diminished control of how their information is used outside the clinical setting. Finally, interactive technologies can empower patients to become increasingly engaged in their own health care and to communicate regularly with providers. Predictably, however, such features also intensify privacy concerns.

As HIT becomes evermore prevalent, it is important to anticipate and probe the numerous novel questions that the technology raises. The authors of this symposium issue have unearthed several of them, and their well-crafted recommendations should be seriously considered by clinicians and policy-makers alike.