FOOD AND DRUG LAW JOURNAL

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Shana Campbell Jones
Joseph M. McMenamin
David C. Kibbe

FDLI

VOLUME 63 NUMBER 1 2008

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Shana Campbell Jones*
Joseph McMenamin**
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I. Introduction

In the effort to develop a nationwide health information technology infrastructure, the electronic health record (EHR) has been the focus of much discussion and debate. EHR advocates, EHR vendors, policymakers and standards-setting organizations will undoubtedly play important roles in defining how EHRs are implemented for years to come, but the legal system also looms as an influential factor. This article discusses potential legal issues surrounding EHRs, particularly with respect to their interoperability or ability to share and exchange data. In simple terms, interoperability allows for digitized data collected from two or more different sources to be exchanged and compared. Interoperable health records have the extraordinary potential to connect not only data but minds. As the data comprising EHRs and the norms for sharing such data ultimately will define what the national health information infrastructure looks like, the article recommends that liability should be minimized for healthcare providers adopting EHRs so that the promise of interoperable information exchange may be realized.

II. Background

For purposes of this article, the term EHR is defined as "a [digital] collection of health information that has been gathered by and is managed by an enterprise such as a doctor's office or hospital,[1] while also recognizing a related use of the term EHR as a software product or service used by these same entities to create and manage health information in electronic format. In this way, although some may argue the distinction is an artificial one, EHR may be considered separate from a personal health record (PHR), which describes a record, or the software to create such a record, containing information entered primarily by the patient.[2]

Similarly, EHRs are also distinct from but potentially inextricably intertwined with electronic prescribing (e-prescriptions or e-prescribing), which is defined by the Agency for Healthcare Research and Quality (AHRQ) as "the use of computing

* Ms. Jones is an adjunct assistant professor of political science at Old Dominion University. This article was written while she was an associate in the law firm of McGuireWoods LLP, Norfolk, Virginia.

** Dr. McMenamin is a Partner in the law firm of McGuireWoods LLP, Richmond, Virginia.

*** Dr. Kibbe was the founding Director of the Center for Health Information Technology for the American Academy of Family Physicians (AAFP), and now serves as a Senior Advisor to the AAFP.

[1] Paul C. Tang & David Lansky, *The Missing Link: Bridging the Patient-Provider Health Information Gap*, Health Affairs 24, No. 5 (2005): 1291, *available at* http://content.healthaffairs.org/cgi/content/full/24/5/1290)(last visited May 17, 2007).

[2] *Id.*

devices to enter, modify, review and output or communicate drug prescriptions."[3] Although this paper primarily refers to EHRs created and used by healthcare providers in general and physicians in particular, many of its observations apply to PHRs and e-prescribing systems as well. Regardless of the electronic record's status as an EHR, PHR or e-prescription, most advocates of healthcare connectivity appear to agree that use of standards and protocols that allow each of these records to exchange information with the others over a network is desirable to maximize patient and provider access to health-related information.[4]

Arguments for increased use of EHRs by physicians and medical practices are legion. For example, EHRs are touted as providing clinicians access to patients' complete medical histories, physical findings, and lab and imaging data; allowing for electronic reminders and alerts; reducing errors; and improving quality of care by improving communication between patients and providers.[5] On June 20, 2007, the Centers for Medicare and Medicaid Services (CMS) announced a new project to expand its "efforts to encourage Medicare beneficiaries to take advantage of Internet-based tools to track their healthcare services and provide them with other resources to better communicate with their providers" by allowing certain beneficiaries to access and use EHRs.[6] Major chip makers are working to introduce "smart cards" powered by radio frequency identification (RFID) technology, which would allow providers to "read" a patient's EHR as soon as that patient walks in the door.[7] Efficiencies related to decreased personnel costs and improved data collection are also anticipated.[8] Michael Leavitt, Secretary of Health and Human Services, estimated possible savings at $27 billion per year by means of "reduction of adverse drug events and in improved workflows" in the e-prescription context alone.[9] Not only would EHRs decrease costs of data collection, but they would also make it easier to accumulate more complete data across populations, which should in turn improve the effectiveness of measures intended to advance the health of those very populations. More broadly, EHRs are seen as the essential building blocks for population databases designed to improve public health and to react to bioterrorism.[10]

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[3] *See* Agency for Healthcare Research and Quality, Knowledge Base, *at* http://healthit.ahrq.gov/portal/server.pt ?open=514&objID=5554&mode=2&holderDisplayURL =http://prodportallb.ahrq.gov:7087/publishedcontent/publish/communities/k_o/knowledge_library/key_topics/health_briefing_03282006124741/electronic_prescribing.html (last visited May 17, 2007).

[4] *See infra* notes 11-13 and associated text.

[5] *See* U.S. Department of Health and Human Services, Health Information Technology, *at* www.hhs.gov/healthit/ (last visited May 17, 2007). *But see*, *e.g.*, Steven Reinberg, *E-Medical Records No Shortcut to Good Diabetes Care*, WASH. POST, June 7, 2007, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/06/07/AR2007060701503.html (last visited June 23, 2007).

[6] Press Release, Centers for Medicare & Medicaid Services, Medicare Testing Personal Health Records to Help Beneficiares Better Manage Own Health Care, June 20, 2007, *available at* http://www.cms.hhs.gov/apps/media/ press/release.asp?Counter=1907 (last visited July 7, 2007).

[7] Donna Fuscaldo, *Chip Makers to Personalize Health Care*, WALL STREET J. ONLINE, May 23, 2007, *available at* http://online.wsj.com/article/SB117987928600611499.html? mod=rss_whats_news_technology (last visited May 27, 2007); "Wireless Medical Devices — FDA Draft Guidance Outlines Additional Requirements," HEALTH LAWYERS WEEKLY (Jan. 26, 2007).

[8] Robert H. Miller, et al., *The Value of Electronic Health Records in Solo or Small Group Practices*, HEALTH AFFAIRS, 24, No. 5: 1127-37, *available at* http://content.healthaffairs.org/cgi/content/full /24/5/1127 ?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=Electronic+Health+Records&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT)(last visited Nov. 3, 2007).

[9] Michael O. Leavitt, Secretary of Health and Human Services, *Pilot Testing of Initial Electronic Prescribing Standards 2007*, *available at* http://healthit.ahrq.gofv/portal/server.pt/ gateway/PTARGS_0_1248_227350_0_0_18/NJ-EPAC%20Pilot%20Testing%20of% 20Electronic% 20Prescribing%20Standards.pdf (last visited June 23, 2007).

[10] W. Ed. Hammond, *The Making and Adoption of Health Data Standards*, HEALTH AFFAIRS 24, No. 5: 1205-13 (2005), *available at* http://content.healthaffairs.org/cgi/content/full/ 24/5/1205?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=%2C+%93The+Making+and+Adoption+of+Health+Data+Standards&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT (last visited May 17, 2007).

Indeed, the potential for EHRs to improve the efficacy of epidemiology efforts is great. The U.S. Department of Health and Human Services (HHS) points to "interoperable health IT," including EHRs, as bringing some of the following public health benefits: "early detection of infectious disease outbreaks around the country; improved tracking of chronic disease management; and evaluation of healthcare based on value enabled by the collection of de-identified price and quality information that can be compared."[11] Outbreaks of *E. coli* infections, for example, could be quickly identified.[12] In the event of a disaster such as pandemic influenza or a terrorist attack, a database of victims' health information would be invaluable to both responders and subsequent researchers alike.[13]

Consumers appear poised to embrace EHRs to advance the public health.[14] According to a survey conducted by The Markle Foundation, "[t]hree-quarters of Americans are willing to share their personal information to help public officials look for disease outbreaks and research ways to improve the quality of health care if they have safeguards to protect their identity."[15] And, according to a recent study, consumers believe EHRs would give them "greater access to and control over their own records, … offer them the ability to ask more informed questions of their physicians, confirm information provided by a physician, enhance their ease in accessing medical information and help them better understand choice of treatment options."[16] Indeed, given that consumers now have the ability to utilize the Internet to manage bank accounts, buy and sell stocks, auction goods, rank service providers, contribute to blogs, edit encyclopedias, or take classes and even earn degrees online, the widespread adoption of EHRs seems a natural progression.

The adoption of EHRs in healthcare has been slower than many enthusiasts would prefer. The lack of financial incentives for physicians to invest in EHRs, particularly in an era of declining physician reimbursement, is clearly one barrier.[17] The slow progress with respect to standards for health data exchange among EHRs, pharmacies and hospital systems is another.[18] It now appears, however, that there is a national consensus around the main premise that the many and various benefits of moving from paper-based health information management to computerized and networked systems of EHRs by physicians and other providers outweigh the costs, and that health care will steadily move in the direction that other major sectors of the economy, such as banking and e-commerce, have followed in adopting electronic record keeping. Moreover, as the Rand Corporation has pointed out, while enthusiasts may be frustrated with the rate of EHR adoption, EHRs are

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[11] HHS, Health Information Technology, *at* www.hhs.gov/healthit/(last visited May 17, 2007).

[12] Lawrence O. Gostin, *Health Information Privacy*, 80 CORNELL L. REV. 451, 482-84 (1995).

[13] *See* Michael Leavitt, Remarks Prepared for Delivery at the National Immunization Conference, March 6, 2006, *at* www.hhs.gov/news/speech/2006/060306.html (last visited May 26, 2007) (discussing how electronic health records could assist providers during emergencies such as pandemic influenza).

[14] *Consumers See Electronic Health Records as Important Factor when Choosing a Physician and Are Willing to Pay for the Service, Accenture Research Finds*, LIFE SCI. WEEKLY, 193 (Mar. 13, 2007).

[15] Press Release, The Markle Foundation, *Americans See Access to Their Medical Information as a Way to Improve Quality, Reduce Health Care Costs*, Dec. 7, 2006, *available at* http://www.markle.org/downloadable_assets/ news_release_120706.pdf (last visited May 26, 2007) (reporting survey results showing "[t]wo in three Americans (65 percent) would like to access all of their own medical information across an electronic network").

[16] David W. Bates, *Physicians and Ambulatory Electronic Health Records*, HEALTH AFFAIRS, 24, No. 5: 1180-89; Sheera Rosenfeld, et al., *Medicare's Next Voyage: Encouraging Physicians to Adopt Health Information Technology*, HEALTH AFFAIRS 24, No. 5 (2005): 1138-46.

[17] *Id.*

[18] HAMMOND, *supra* note 10, at 1206.

actually "diffusing at a rate consistent with other similar IT technologies in other industries."[19] Indeed, the Rand Corporation concludes:

Complex electronic medical records are, after a 20-year waiting period, rapidly diffusing in many segments of our healthcare system … and will reach 80 percent saturation in hospitals by 2016—or earlier if assisted by government or other organizations.[20]

If the Rand Corporation's prediction is correct, the widespread adoption of EHRs appears likely to accelerate quickly over the next 10 years. In this way, after what has seemed like slow progress, EHR adoption may well begin to move very fast. However, legal issues are likely to emerge that could hinder EHR adoption.

III. LEGAL ISSUES

To say that the healthcare system operates within a complex legal environment is an understatement. As the Robert Wood Johnson Foundation pointed out in a recent report, in order for the healthcare profession to embrace a health information technology such as EHRs, healthcare providers must conclude that the clinical, legal and economic benefits outweigh the risks.[21] Because interoperability is one of the primary potential benefits of adopting EHRs, we have focused our analysis on potential legal issues related to this important attribute.

This analysis will first describe generally what "interoperable" means in the EHR context and discuss why interoperability is desirable. It will then consider potential legal issues related to the adoption of EHRs if interoperability is achieved by some doctors and medical practices but not others, and take into account legal issues that may arise specific to interoperability itself. We believe the legal issues associated with widespread interoperable EHR fall into these areas: the doctor-patient relationship; the standard of care; statute of limitations; new theories of causation; product liability issues; exposure to fraud; and privacy. As policymakers consider how to address these issues, the premise of this article is that many of these efforts could be considerably complicated if potential sources of liability are not contained. The purpose of this paper is to begin raising and critiquing possible theories of liability that may influence the content and interoperability of EHRs in ways that may compromise their potential. Moreover, we believe that tort reform should be pursued to prevent these theories from preventing or delaying EHR's benefits from accruing to American healthcare.

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[19] Anthony Bower, Rand Corporation, THE DIFFUSION AND VALUE OF HEALTHCARE INFORMATION TECHNOLOGY xv (2005).

[20] *Id.*

[21] Robert Wood Johnson Foundation, HEALTH INFORMATION TECHNOLOGY IN THE UNITED STATES: THE INFORMATION BASE FOR PROGRESS 46 (2006), *available at* http://www.rwjf.org/files/publications/other/EHRReport0609.pdf) (last visited Apr. 24, 2007)[hereinafter "Health Information Technology "]. A final rule, that became effective October 10, 2006, provides for safe harbors to the physician self-referral statute ("Stark law") and the anti-kickback statute to allow the donation of electronic health information technology to physicians and other providers. In that rule, the Office of Inspector General for HHS specifically defined interoperability as "the ability [of the EHR software] to communicate and exchange data accurately, effectively, securely and consistently with different information technology systems, software applications and networks, in various settings, and exchange data such that the clinical or operational purpose of the data are (sic) preserved and unaltered." Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 Fed. Reg. 45110 (Aug. 8, 2006).

A. *Interoperability*

The Institute of Electrical and Electronics Engineers (IEEE) defines interoperability as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged."[22] Interoperability requires both content and technical standards. As IEEE explains in a position paper calling for interoperability in the healthcare context, interoperability "means not only that healthcare systems must be able to communicate with one another, but also that they must employ shared terminology and definitions."[23] In other words, not only must electronic files such as EHRs utilize the *same* technical protocols, but they also must utilize the *same* data-entry vocabularies, or, at the very least, be capable of mapping commonly used vocabularies and coding systems to one another in a way that preserves the meaning of the content. According to IEEE, this is the best way to make "information [such as that contained in an EHR] truly usable in the distributed clinical setting of our healthcare environment."[24] There is, of course, an inherent tension between developing such standards and stipulating the use of specific coding systems and vocabularies, while preserving individual provider and/or institutional autonomy. Some physicians may well resist conforming to such standardization. Indeed, the slow adoption of EHRs may be related, in part, to this very issue.[25]

B. *The Physician-Patient Relationship*

Interoperable health records have the extraordinary potential to connect not only data but minds. Thus, interoperability could conceivably reconstitute the physician-patient relationship as a "web" of physicians who enter into a relationship with the patient every time health-related activity occurs. One possible benefit of truly interoperable EHRs is that, as soon as a patient's EHR is updated with an information change, all of the patient's doctors could be automatically notified about that change. But who, beyond the healthcare provider who entered the information, is responsible for responding to such information, if anyone? When? As we have observed, this "web" of physicians has enormous potential to improve the quality of healthcare as well as increase efficiencies; it also has the potential to alter what the physician-patient relationship means.

For the risk of physician professional liability to arise, a physician-patient relationship must exist at the time the patient suffered an alleged injury. Otherwise, the physician owes no duty, and so can breach none. It is easy to establish that a physician-patient relationship exists when a patient seeks out a physician's services and that physician then provides services to that patient. The relationship is unambiguous; the duty clear. Plaintiffs may claim, however, that a physician may assume such a duty impliedly.[26] As one court has put it, the "physician-patient relationship

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[22] Position Paper, Institute of Electrical and Electronics Engineers, "Interoperability for the NationalHealthInformationNetwork," *available at* http://www.ieeeusa.org/policy/positions/ NHINinteroperability.html (last visited Nov. 3, 2007).

[23] *Id.*

[24] *Id.*

[25] Jaan Sidorov, *MarketWatch; It Ain't Necessarily So: The Electronic Health Record and the Unlikely Prospect of Reducing Health Care Costs*, HEALTH AFFAIRS 25, No. 4 (2006): 1079-85, *available at* http://content.healthaffairs.org/ cgi/content/full/25/4/1079 (last visited May 26, 2007).

[26] J. Gregory Lennon, *Easing the Medical Malpractice Crisis: Restricting the Creation of Duty Through an Implied Doctor-Patient Relationship*, 7 J. HEALTH CARE L. & POL'Y 363, 367 (2004).

may arise by implication where the doctor takes affirmative action to participate in the care and treatment of a patient."[27] What constitutes an affirmative action to participate in the care and treatment of a patient becomes, of course, the next question. Some courts have held that under certain circumstances a telephone call is enough to create an implied relationship.[28] An attempt to extend this logic from a phone call to an electronic communication by means of EHRs is not difficult to imagine. As EHRs are increasingly adopted, new questions of whether and when a physician affirmatively accepted the care of a patient may arise, and with them, claims that the physicians involved can be subject to an implied duty of care.

Similarly, with respect to the physician-patient relationship, interoperable EHRs may also raise questions of "therapeutic privileges." Traditionally, therapeutic privilege has enabled physicians to shield their emotionally unstable patients from access to those records that, in the physicians' judgment, would put such patients at risk for psychiatric decompensation.[29] The widespread adoption of EHRs has the potential to encourage such patients to expect access to all of their records, creating an expectation that may collide with the appropriate exercise of therapeutic privilege. The converse is also true. Some patients may become concerned that unauthorized individuals may more easily gain access to their records, thus disrupting the physician's therapeutic privilege as patients may not believe the records can be protected in an interoperable environment. Cases implicating the therapeutic privilege are comparatively rare, however, and the many benefits that EHRs may bring tend to overshadow the theoretical risk to a small number of patients. Nevertheless, the point remains: interoperable EHRs may have the potential not only to change when the physician-patient relationship is formed but also how it is formed.

C. *New Standards of Care*

Plaintiffs may invoke interoperability to argue that a broader standard of care should be imposed on physicians. In medical malpractice actions, the standard of care imposed on physicians and other healthcare providers is defined as the degree of skill and care ordinarily practiced by a reasonably prudent practitioner in the same field of practice and under similar circumstances at the time the case arose.[30] In some jurisdictions, such as Florida, North Carolina and Virginia, that

[27] Sterling v. Johns Hopkins Hosp., 145 Md. App. 161, 187, 802 A.2d 440, 455 (Md. App. 2002). *See also* Gross v. Burt, 149 S.W.3d 213, 222 (Tex. App. 2004)(holding "Texas courts have required an agreement between the physician and patient or some affirmative act on the part of the physician before a legal duty arises . . . [b]ut that relationship may be established with the express or implied consent of the physician."). *But see* Didato v. Strehler, 262 Va. 617, 626, 554 S.E.2d 42, 47 (2001)(holding a "physician's duty arises only upon the creation of a physician-patient relationship; that relationship springs from a consensual transaction, a contract, express or implied, general or special…and a patient is entitled to damages resulting from a breach of a physician's duty.").

[28] *See*, e.g., Cogswell by Cogswell v. Chapman, 249 A.D. 2d 865, 866, 672 N.Y.S.2d 460, 462 (N.Y.A.D. 3 Dept. 1998) (holding "a doctor-patient relationship can be established by a telephone call…when such a call 'affirmatively advis[es] a prospective patient as to a course of treatment" and it is foreseeable that the patient would rely on the advice").

[29] *See* Karp v. Cooley, 349 F. Supp. 827, 835 (1972)(explaining the therapeutic privilege), *See also* Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 441 (2006) (same).

[30] *See*, e.g., Jackson v. Axelrad, 221 S.W.3d. 650, 655 (Tex. 2007)(explaining "[t]he burden of proof is on the patient-plaintiff to establish that the physician-defendant has undertaken a mode or form of treatment which a reasonable and prudent member of the medical profession would not have undertaken under the same or similar circumstances."); Palandjian v. Foster, 446 Mass. 100,

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standard is further delimited by geography.[31] As EHRs are adopted, and if their interoperability indeed reduces medical errors as predicted, plaintiffs may be emboldened to argue that a health care provider does not meet the standard of care if it does not utilize interoperable records. Providers that strive for maximum interoperability may, ironically, create a new standard of care that requires the digital accessibility of a patient's healthcare information. Moreover, given that electronic communication can and does ignore borders, its broader utilization could potentially erode the geographic bounds by which the standard traditionally was, and in some states still is, defined. In the event that the records were "transported" across state lines, issues related to which state's law would apply will likely arise as well. Plaintiffs will undoubtedly attempt to push cases into those jurisdictions perceived as more plaintiff-oriented. To the extent they succeed, physician exposure will increase. If one consequence of the promotion of EHRs is expanded professional liability exposure, physicians may understandably shy away from adopting EHRs, and the benefits of EHRs may be postponed or even missed altogether. The law should promote the growth of EHRs by sheltering physicians from potential risk of expanded liability.

Physicians should also be protected from new sources of error that could be created by software glitches or technological failures — new sources of error to which paper records are not prone.[32] Finally, policy makers should take into account the financial burden associated with developing EHRs. For a large hospital, this may not be a major stumbling block. But we should go to great lengths to avoid further burdening the solo practitioner in a rural, underserved community, or the clinic serving the urban poor, by creating some new *de facto* requirement to invest scarce resources in a tool that might be of lesser importance than many other, more conventional assets that the practice needs but lacks.

104, 842 N.E.2d 916, 920 (2006)(holding "[t]he proper standard is whether the physician, if a general practitioner, has exercised the degree of care and skill of the average qualified practitioner, taking into account the advances in the profession…"); David v. McLeod Regional Medical Center, 367 S.C. 242, 247, 626 S.E.2d 1, 3 (2006)(stating "[a] physician commits malpractice by not exercising that degree of skill and learning that is ordinarily possessed and exercised by members of the profession in good standing acting in the same or similar circumstances."); Smith v. Irving, 268 Va. 496, 501-02, 604 S.E.2d 62, 65 (2004)(holding "[t]he standard of care imposed on physicians and other health care providers in Virginia is defined as 'that degree of skill and diligence practiced by a reasonably prudent practitioner in the [same] field of practice or specialty in this Commonwealth'")(quoting VA. CODE ANN. § 8.01-581.20.).

[31] *See*, e.g., Sweet v. Sheehan, 932 So.2d 365, 368 (Fla. App. 2 Dist. 2006)(holding "Florida law unquestionably recognizes that physicians owe their patients a duty to 'use the ordinary skills, means and methods that are recognized as necessary and which are customarily followed in the particular type of case according to the standard of those who are qualified by training and experience to perform similar services in the community or in a similar community'"); McCullough v. Univ. of Rochester Strong Mem. Hosp., 17 A.D.3d 1063, 1064, 794 N.Y.S.2d 236, 237 (N.Y.A.D. 4 Dept. 2005)(observing "courts generally apply a 'locality' rule as the minimum standard in medical malpractice actions, measuring the provider's conduct against the reasonable degree of learning and skill that is ordinarily possessed by providers in the same locality, although providers must also use their best judgment and whatever superior knowledge and skill they possess, even if it exceeds that of the average provider in the locality."); Tashman v. Gibbs, 263 Va. 65, 73, 556 S.E.2d 772, 777 (2002)(defining "the standard of care in a medical malpractice action as that degree of skill and diligence exercised by a reasonably prudent practitioner in the same field of practice or specialty in Virginia"); Marley v. Graper, 135 N.C. App. 423, 428, 521 S.E.2d 129, 133-34 (N.C. App. 1999)(explaining North Carolina's "locality rule").

[32] *See*, e.g., Patrice Wendling, *Electronic Medical Record Interface Contribute to Errors*, SKIN & ALLERGY NEWS Dec. 1, 2005 (attributing that important results were not properly linked to an EHR and data entry errors).

D. *The Statute of Limitations*

As we have noted, one potential benefit of truly interoperable EHRs is that all of a patient's doctors could be automatically notified as soon as a patient's EHR is updated with an information change. Under such circumstances, does a physician-patient relationship arise, or is a dormant one renewed, every time one of the patient's physicians receives such a notification? Among other consequences, especially in jurisdictions applying the "continuing treatment rule," this could have the effect or extending the statute of limitations indefinitely.

In Virginia, for example, the statute of limitations ordinarily begins to run when the plaintiff's injury happens, regardless whether the plaintiff is aware of the injury or not, but the "continuing treatment rule" changes this calculus. Under the rule, "if there existed a physician-patient relationship where the patient was treated for the same or related ailments over a continuous and uninterrupted course, then the plaintiff could wait until the end of that treatment to complain of any negligence which occurred during that treatment."[33] Accordingly, for physicians to participate in an interactive web of physicians that arguably renews a quiescent physician-patient relationship every time a change is made in the patient's EHR, greater protection for physicians is essential to prevent continual extensions of the statute of limitations. Otherwise, the physician-patient relationship could be continued indefinitely, and with it the physician's liability exposure.

E. *New Theories of Causation*

To establish a medical malpractice claim, in addition to showing that a physician breached his duty, a plaintiff must also show that the physician's action or inaction caused the plaintiff's harm. If innovative health information technology such as interoperable EHRs creates new opportunities to visit liability upon providers by raising new theories of causation it may well cripple EHR adoption and innovation. It might even drive some physicians from practice. Many states have concluded that the availability of healthcare is threatened by healthcare providers' increased liability exposure.[34] Interoperable EHRs may improve what has been described as "fragmented, disorganized and inaccessible clinical information" that "adversely affects the quality of healthcare and compromises patient safety."[35] It would be a great irony, then, if the tort system, ostensibly designed in part to deter unsafe practices,[36] deters instead the adoption of EHRs based on theories that either using or not using EHRs caused the alleged harm.

"Early adopters" have already started using EHRs. Inevitably, for reasons financial, legal and personal, some providers will prove to be, or perhaps already are, "late adopters." Assuming, for the sake of argument, that EHRs will raise the standard of care, late adopters are likely to face broader liability exposure because

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[33] Grubbs v. Rawls, 235 Va. 607, 613, 369 S.E.2d 683, 687 (1988).

[34] *See* Issue Brief, National Governors Association Center for Best Practices, June 1, 2005, *at* http://www.nga.org/Files/pdf/0507MALPRACTICECOSTS.PDF)(last visited May 26, 2007)(explaining that, in a span of seventeen months, twenty-nine states "adopted some aspect of tort reform to curb the cost of medical malpractice insurance").

[35] Janet Heinrich, Government Accountability Office, Report to Committee on Health, Education, Labor and Pensions, United States Senate, *HHS's Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption*, Aug. 13, 2004)(citing CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY, The Institute of Medicine (Washington, D.C.: National Academy Press, 2001)).

[36] *See generally* G. CALABRESI, THE COSTS OF ACCIDENTS (1970).

their adversaries may claim that their hesitancy to adopt EHR has caused their practices, at least prior to adoption, to drop below the applicable standard of care. When seeking to recover in a malpractice claim, a plaintiff has to show that, but for the violation of the standard of care, the harm complained of would not have occurred. Otherwise, plaintiff is out of court for want of causation. With broader market penetration of interoperable EHRs, the argument will be this: Had the late adopter had access to the data that an interoperable system would have provided him, he would have been aware of information that, properly taken into account, would have prevented the alleged harm.

The scenarios are not difficult to imagine. For example, a physician without EHR may be accused of not *accessing* information that could have prevented an adverse medication reaction—if he had simply had access to the record of the patient's drug allergies, the ensuing harms would have been avoided.[37] Similarly, a physician without access to EHR may be accused of not *inputting* information into an EHR that could be shared with other "downstream" physicians, thus providing them with vital information. Other arguments may rest on theories of timeliness. For example, having interoperable EHR could arguably provide a physician with information that would allow him to take more aggressive diagnostic steps and discover the problem—such as a tumor—sooner. EHRs may allow for instantaneous, "real-time" information exchange. The physician who is not prepared to access the most up-to-date information may well find herself accused of "causing" an allegedly foreseeable harm.

Early adopters of EHR, however, may face their own liability risks, particularly if on a particular occasion their records are for some reason inaccessible. For example, a physician uses EHR software to store her patient's health information. Another physician requests the record but cannot access it after it is sent to him in digital format. If the timeliness of the information is ever an issue, a plaintiff might argue that the lack of interoperability of the EHR itself caused the ensuing harm, particularly as some vendors are creating mechanisms such as "CCR buttons" to allow both the import and expert of EHR and CCR files. Similarly, what happens if a physician's network goes down when an EHR is requested? What happens if an EHR becomes corrupted? Indeed, what about the emotional distress a patient might claim to suffer when she learns that her EHR is not available or cannot be read by another physician? Such situations could place an EHR early adopter in the same position as a physician who had not adopted interoperable EHRs at all, or worse, as the information that could have been relied upon is not there and the patient had the expectation that it would be.

Given the above, the potential for cross-claims between providers—i.e., where one provider sues the other after a patient sues both—becomes apparent. For example, one provider makes a diagnosis of diabetes in a patient, but his EHR system is not interoperable with a second provider's system. The second provider misses the diabetes diagnosis and delays therapy that could have prevented, for example, heart failure. The patient sues both providers; the providers sue each other, each claiming that the other's EHR system caused the miscommunication. Genuinely interoperable EHR systems could prevent such a scenario, but during the transition period expected over the next decade, these questions will remain.

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[37] *See*, e.g., Laurie E. Ekstrand & Valerie C. Melvin, Government Accountability Office, Report to the Committee on Armed Services, United States House of Representatives, *DOD and VA Outpatient Pharmacy Data: Computable Data Are Exchanged for Some Shared Patients, but Additional Steps Could Facilitate Exchanging These Data for All Shared Patients* (Apr. 30, 2007).

F. *Product Liability*

Although many providers may not be familiar with product liability claims, the lack of interoperability between EHR systems could drag some providers into such actions. Product liability arises from personal injury or property damage caused by allegedly defective products in the marketplace. As discussed above, that one EHR system is not interoperable with another could potentially result in harm to a patient. Not only may a plaintiff sue the manufacturers and vendors of the EHR systems, but the providers who adopted a system that cannot communicate with other systems might be sued as well. The theory asserted against the provider might not be product liability, since the provider furnishes a service only, but the provider might not have been party to the claim at all had he not purchased and used the allegedly defective equipment. It is also possible that, even if the original complaint omits the name of the practitioner, an aggressive defendant manufacturer could file a third-party claim against the provider if it thinks it can shift some or all liability to him. Whether such a claim would be successful, of course, is another question. However, one cannot dismiss the ability of plaintiffs' counsel to create such claims.

G. *Exposure to Fraud Claims*

When adopting an EHR system, one area of concern for healthcare providers may be the possibility of increased liability under state and federal fraud laws.[38] Although HHS has created exceptions to the physician self-referral statute ("Stark law")[39] and crafted a new safe-harbor provision under the federal anti-kickback statute[40] to allow EHR and other information technologies to be donated to physicians, and even though the Internal Revenue Service (IRS) has recently directed that such donations will not place a hospital's tax-exempt status at risk,[41] some providers may nevertheless be concerned about the extent of these protections. The extent to which providers are even aware of the protections that exist is unclear.[42]

In addition, if EHRs become truly interoperable, some providers may fear that they may become associated with or even responsible for the integrity of data entered into other providers' records. Given that some allege that Medicare and Medicaid fraud accounts for at least three and perhaps as much as 10 percent of total healthcare expenditures,[43] providers may have good reason to be concerned about the quality of data entered by other healthcare professionals. If a provider suspects that certain information is false or incorrect, does that provider have a duty to correct it so that other providers do not rely upon it? Moreover, because use of EHRs "expands the accessibility of health information for government agencies and private parties," providers may be "concerned about heightened exposure to legal scrutiny due (sic) to software systems designed to detect and measure the validity of claims on a 'real time' basis."[44] Similarly, the digitizing of information may facilitate

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[38] *See* Health Information Technology, *supra* note 24, at 44.

[39] 42 U.S.C. § 1395nn (2007).

[40] 42 U.S.C. § 1320a-7b(b) (2007).

[41] Memorandum, Internal Revenue Service, Hospitals Providing Financial Assistance to Staff Physicians Involving Electronic Health Records, May 11, 2007, *available at* http://www.irs.gov/pub/irs-tege/ehrdirective.pdf (last visited May 15, 2007).

[42] *See* Health Information Technology, *supra* note 24, at 44.

[43] Tracy D. Hubbell, et al., *Health Care Fraud*, 43 AM. CRIM. L. REV. 603, 605 (2006).

[44] *See* Health Information Technology, *supra* note 24, at 45.

qui tam actions, which are "whistleblower" lawsuits brought by private individuals on behalf of the government, particularly if the data may be easily manipulated to suggest patterns of misconduct.

For all of these reasons, unless liability protections are in place providers may well perceive that adopting an interoperable EHR system is not worth the potential exposure. According to the American Medical Association, between 1997 and 2004 the median medical liability jury award increased from $157,000 to $439,400, while the average award increased from $347,134 to $606,907 during the same period.[45] Although physicians won 83 percent of the claims that went to jury verdict, the average defense cost was $93,559 per claim in cases where the defendant prevailed at trial.[46] It should come as no surprise, then, that when it comes to adopting new technologies, physicians and health providers may hesitate because of liability concerns. Given that there is broad consensus that many medical errors could be avoided if better information exchange were available, that providers would be concerned that such information could be used against them is ironic indeed.

H. *Privacy*

There is little question that some privacy advocates see the adoption of EHRs as a threat to patient privacy.[47] The concern that EHR could lead to legal exposure associated with the accidental or intentional disclosure of information may well be another reason health care providers are slow to adopt EHRs.[48] Although there is little reason to assume that paper records are more secure than digitized records,[49] the fact remains that, because of the Internet, the ability for someone to disseminate electronic records to a large audience in a short time is a very real issue. Indeed, the bad press associated with the accidental public posting of patient health information may be enough to give some health providers pause.[50]

Assuming that a provider is a covered entity, the provider must comply with the privacy rules established under the Health Insurance Portability and Accountability Act (HIPAA)[51] regardless whether its practice is a "paper" practice or an "electronic" one.[52] Part of this compliance involves ensuring that all "business

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[45] American Medical Association, MEDICAL LIABILITY REFORM – NOW! 3 (2006), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/-1/mlrnow.pdf) (last visited July 5, 2007).

[46] *Id.*

[47] *See*, e.g., Laura Dunlop, *Electronic Health Records: Interoperability Challenges Patients' Right to Privacy*, 3 SHIDLER J. L. COM. & TECH. 16 (2007); Peter A. Winn, *Confidentiality in Cyberspace: The HIPAA Privacy Rules and the Common Law*, 33 RUTGERS L.J. 617 (2002).

[48] *See* Health Information Technology, *supra* note 24, at 45.

[49] June M. Sullivan, *Recent Developments and Future Trends in Electronic Medical and Personal Health Records*, 19 HEALTH LAW 16, 17 (2007).

[50] *See*, e.g., *Private medical records of Colorado residents exposed on Internet* (Minnesota Public Radio broadcast, May 22, 2007), *available at* www.minnesota.publicradio. org/collections/special/columns/wavlength/archive/2007/05/private_medical_records_of_col.shtml (last visited May 26, 2007); Henry K. Lee, *Alameda County Kaiser Sues Fired Worker for Leaking Data, Confidential Patient Information Linked on Blog, Suit Says*, SAN FRAN. CHRON., B3 (Mar. 19, 2005).

[51] 65 Fed. Reg. 82,462 (2000).

[52] As a recent report points out, however, some providers are under the mistaken assumption that a "paper" practice insulates them from potential legal burdens under HIPAA because of the great attention given to electronic records. *See* Health Information Technology, *supra* note 24, at 45.

associates,"[53]comply with the HIPAA Privacy Rule as well.[54] Although a provider may have a "business associate" contract with an EHR vendor, that vendor may have contracts with entities, server farms (groups of networked servers that are housed in one location), for example—to store the EHR data, and the providers may be concerned about liability that may ensue from any breach of privacy by these parties.

On the other hand, the late adopter may well rely on paper records to his detriment. The Robert Wood Johnson Foundation has pointed out that, although utilizing EHR does not increase a provider's responsibilities under HIPAA, "because of the attention given to *electronic* records, many health professionals may mistakenly believe that they are insulated from possible legal ramifications [under HIPAA] by remaining a 'paper' practice."[55] Put simply, avoiding EHR is no protection. Moreover, as noted, paper records are not necessarily more secure than digitized records and, indeed, may be less so, as EHRs allow for security features such as passwords.[56] Paper records are often out in plain view and are subject to being misplaced. Consequently, a provider not adopting an EHR may find himself at greater risk of liability when a paper breach occurs, records are lost in the mail or records are destroyed.

IV. CONCLUSION

The potential for interoperable EHRs to improve health and provide efficiencies is real. Good medical decisions cannot be made without access to good information, and both providers and patients could benefit by having digital access to a patient's complete medical history or even a standardized summary of that history that is up-to-date and accurate. The purpose of this article is to raise ways in which potential sources of liability surrounding a key component of EHRs—interoper-

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[53] 45 C.F.R. § 160.103 (2007) provides that, "business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.…

[54] 45 C.F.R. § 164.504(e)(1)(ii)(2007)(providing "[a] covered entity is not in compliance with the standards in § 164.502(e) and paragraph (e) of this section, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation…"). If termination of the contract or agreement is not feasible, a covered entity is required to report the problem to the HHS Office for Civil Rights (OCR). *Id.*

[55] *See* Health Information Technology, *supra* note 24, at 45.

[56] *See* SULLIVAN, *supra* note 53, at 17.

ability—could complicate EHR adoption efforts, so that policymakers may begin to consider how to address these issues. A variety of legislative solutions present themselves: providing for the therapeutic privilege in the EHR context; abolishing the "continuing treatment" rule or limiting "continuing treatment" to actual in-person consultation given by a physician to a patient; and protecting physicians from liability when they rely on data inputted by the patient and other providers. The exemptions to physician self-referral laws, anti-kickback statutes and IRS donation rules should be expanded, and, equally important, physicians should be educated about the existence and effects of such protections.

This is a new area, and the extent to which EHRs will produce new theories of liability remains to be seen. Given past experience, however, the authors anticipate that new theories of liability are likely if not inevitable. Accordingly, the authors hope to begin a conversation about how such liability might be contained so that providers—and not the legal system—ultimately define EHR standards and what our nationwide health information technology infrastructure looks like.