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The Effect of E-Health on Substantive Medical Malpractice Law

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Introduction

Technology is affecting health care in America. Not only is it affecting the way physicians care for patients in their office or surgical suite, but also substantive medical malpractice law. Modern medicine is seeing the introduction of computerized patient records (CPR), electronic patient records (EPR) and electronic medical record systems (EMR). Linda M. Celia, M.S.N., R.N., *Legally Speaking: Keeping Electronic Records Safe!*, 65 No. 6 R.N. p. 69 (June 2002); M. Karmel, *The Electronic Medical Record: Good Bye Paper Charts, Hello Better Patient Care*, 85(4) Minn. Med.

57-59 (April 2002); R.L. Edsall, *Toward Electronic Medical Records for the Small Practice*, 7(6) Family Practice Management 10 (June 2000); T. Worthylake and J. Garretson, 2(6) *MGMA Connexion*, 24-27 (July 2002). Advances in communication and computerized patient records are beginning to facilitate the practice of telemedicine, including real-time video consultation, teleradiology, telepathology and telemetry. Moreover, the rapid increase in the amount of medical reference materials available online and through various portable devices enables a physician to consider much more information in the diagnosis, care and treatment of patients.

Many commentators and scholars have noted that "e-health" will improve medical care in America while simultaneously increasing the efficiency and

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decreasing the cost of health care. Donald E. Kacmar, *Note: The Impact of Computerized Medical Literature Databases on Medical Malpractice Litigation: The Time for Another Helling versus Carey Wake Up Call*, 58 Ohio St. L. J. 617 (1997); Nicholas P. Terry, *An E-Health Diptych—The Impact of Privacy Regulation on Medical Error and Malpractice Litigation*, 27 Am. J. of Law and Medicine, 361, 417–419 (2001); Karmel, *supra*. at 59. However, every health care provider and attorney counseling or representing health care providers should consider how e-health will affect medical malpractice liability and how the decades-old medical malpractice principles will be applied to modern medicine.

The *prima facie* elements of a medical malpractice action are: (1) a duty owed by a physician to a patient to act pursuant to a particular standard of care; (2) a violation of the applicable standard of care; (3) a causal connection between the alleged breach of the standard of care and a patient's injury; and (4) an actual injury or damage to the patient.

Health Insurance Portability and Accountability Act of 1996

Undoubtedly, e-health has been influenced by the promulgation of regulations under the Health Insurance Portability and Accountability Act of 1996, Publ. No. 104-191, 110 Stat. 1998 (HIPAA). HIPAA signaled the federal government's recognition of the importance of protecting the privacy of health information in light of the rapid evolution of health information and health information systems and the abil-

ity to disseminate that information. The administrative simplification provisions of HIPAA, Publ. No. 104-191, Section 261, were created to improve the efficiency and effectiveness of the health care system by facilitating the electronic exchange of health and financial information. To manage the complexities of maintaining confidentiality of personal health information in an electronic data exchange system, HIPAA authorized the promulgation of standards to safeguard the privacy of individually identifiable health information (IIHI), also known as protected health information (PHI). HIPAA required the Department of Health and Human Services to adopt national standards for electronic health care transactions and to establish a uniform system of electronic exchange of health information between hospitals, physicians, health plans and other covered entities. PHI includes oral or recorded information which "relates to past, present, or future physical or mental health or condition of an individual" and identifies or could identify the individual. This broad definition would encompass a patient's clinical record, billing history, electronic communication, physician notes and other material under the protection of the new regulations.

While a detailed discussion and analysis of HIPAA and its regulations is beyond the scope and space allotted for this article, it bears noting that HIPAA does not directly regulate a computerized patient record nor does it expressly call for the adoption of Computerized Patient Record (CPR) systems. However, to the extent that CPR systems contain voluminous protected information, a CPR will certainly fall under the

HIPAA regulatory scheme. It is under this regulatory backdrop that CPR systems are evolving.

The idea of sanctions or penalties for breach of medical privacy is not new. The civil and criminal sanctions and penalties for violation of HIPAA privacy regulations are significant. Civil penalties are from \$100 to a maximum of \$25,000 annually. Criminal penalties may reach as high as \$250,000. The specter of state and federal penalties under HIPAA requires consideration of computer security issues affecting development of CPRs.

Computerized Patient Records, Electronic Patient Records and Electronic Medical Records

More frequently, health care providers from solo physician's practices to large institutions are moving toward the computerization of patient information and electronic storage of data. To date, there is no standard definition or format for a CPR. However, most authorities agree on the general contents of a CPR as including: (1) a compilation of patient data (clinical, financial and health insurance information regarding a particular patient); (2) access to medical resources (Internet, Medline, etc.); (3) provider data entry and physician order entry; (4) communications capability; and (5) clinical decision support. Amy Jurevic Sokol and Christopher J. Molzen, *The Changing Standard of Care in Medicine—E-Health, Medical Errors and Technology Add New Obstacles*, 23 The Journal of Legal Medicine, 449 (2002); Terry, 27 Am. J. Law and Medicine at 370; Computer-Based Patient Record Institute, CPRI Workgroup on CPR

Description, Computer-Based Patient Record Description of Content (1996), available at <http://www.cpri-host.org/resources/docs/content.html> (last visited 12/19/2002). The American Medical Association Code of Medical Ethics also recognizes the importance of confidentiality and computer security. Council on Ethics and Judicial Affairs, Code of Medical Ethics, Opinion 5.05, 82-3 (1994).

In light of the threat of federal and state penalties for breaches of medical privacy and/or breach of privacy claims by patients, health care providers must pay particular attention to the security of CPRs. Worthylake and Garrettson, 2(6) MGMA Connexion at 24; Amy M. Jurevic, *When Technology and Health Care Collide: Issues with Electronic Medical Records and Electronic Mail*, 66 UMKC L. Rev. 809 (Summer 1998). CPRs contain a large volume of sensitive and confidential information in a highly searchable, legible and condensed format. Any security protocol for CPRs should address threats from physical problems such as environmental hazards, loss of communication, and power failures. Jurevic, 66 UMKC L. Rev. at 821. Computerized records are also vulnerable to attack by disgruntled employees, hackers, theft, computer viruses, hardware failures, software bugs and Trojan horses. *Id.* at 812. Any security measures should take into account these threats. Health care providers should consider chart layering and restricted access tailored to the individual health care providers' job responsibility. *Id.* at 819. Access to the CPR would conceivably be different for different types of physicians, nurses, administrators and health aides. Added security for especially sensitive records such as mental health records, substance abuse records, communicable disease records,

and genetic testing records should be considered in light of the potential for abuse and exploitation of these materials. Simple physical barriers, such as limiting access to computer terminals, networks and mainframes, are an important foundation in any security protocol. Celia, *supra.* at 70. Also, consideration of the formation of a security committee and/or security officer to implement a security policy is necessary. A security policy should address network security, personal computer security (especially security against laptop theft), mainframe system security, audit trails, disaster prevention and recovery features, security audits, authentication devices, restrictions on unauthorized software, specialized training and sanctions. Amy M. Jurevic, *When Technology and Health Care Collide: Issues with Electronic Medical Records and Electronic Mail*, 66 UMKC L. Rev. 809 (Summer 1998).

Clinical Practice Guidelines

Many scholars foresee the inclusion of clinical practice guidelines in CPRs. Nicholas P. Terry, *An E-Health Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation*, 27 Am. J. L. & Med. 361, 388 (2001). Clinical practice guidelines (CPGs) are consensus statements developed by various bodies—public and private—about what constitutes appropriate treatment for a specific condition, set of symptoms or preventative care goal. Michele M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. Pa. L. Rev. 645, 647 (January 2001). Some commentators predict that the use of CPGs will improve the medical practice. Barry R. Furrow,

Broadcasting Clinical Guidelines on the Internet: Will Physicians Tune In?, 25 Am. J. L. & Med. 403, 404 (1999).

CPGs are produced from a number of different sources, including health insurance carriers, liability insurance carriers, governmental bodies and professional societies. CPGs attempt to direct clinical care. This feature may cause CPGs to be a contentious issue in future medical malpractice litigation. Sokol and Molzen, *supra.* at 483–486. Plaintiffs and defendants in medical malpractice litigation will argue that CPGs, by directing clinical practice, set a standard of care or duty. *Id.* at 486.

The proliferation of CPGs in computerized charts and on the Internet may have the effect of replacing the locality rule with a national standard of care. Michele M. Mello, *supra.* at 655; Furrow, *supra.* at 410. Consequently, a rural physician would be held to the same level of knowledge as a metropolitan physician. However, lack of resources would affect the standard of care for a rural physician. Health care institutions would also be affected by the increased use of CPGs in computerized charting.

If a hospital adopts guidelines for post-surgical care or other substantive medical care, it may be at higher exposure for direct liability or corporate liability. Plaintiffs would seek to hold the hospital directly liable for an improper or inadequate guideline. *Thompson v. Nason Hospital*, 527 Pa. 330, 591 A.2d 703 (1991). Moreover, the institution would take one step closer to the actual delivery of health care as opposed to the delivery of health care through its employees, agents or ostensible agents. *Id.*

Evidentiary and admissibility issues will be the major battleground involving CPGs. CPG admissibility will be impacted by whether the litigation is controlled by federal or state evidence rules. The Federal Rules of Evidence adoption of this hearsay

exception for barred treatises would make it easier to admit CPRs into evidence. If a particular state does not apply an evidence code similar to the Federal Rules in this regard or otherwise recognize the learned treatise exception, admission of CPRs will be more difficult. Plaintiffs assert that the CPG itself sets forth a particular standard of care, thereby relieving the plaintiff of the burden of proving a particular standard of care through expert testimony. This argument would increasingly be made against hospitals, health systems and other institutions which adopt policies to direct clinical care. Conversely, defendants will argue that compliance with a particular CPG is exculpatory in and of itself. See generally, Mello, *supra*. at 662–667. Obviously, careful consideration should be given to the content and type of CPG included in a computerized chart.

Effects of Telemedicine

Many are already familiar with the most common type of telemedicine, the telephone consultation. The increased use of real-time video consultation, teleradiology, telepathology and telemetry will create “duty” and “breach” issues and venue issues in medical malpractice cases. Sokol and Molzen, *supra*. at 455–456.

The first element of any medical malpractice case is whether a physician-patient relationship exists between the defendant-physician and the plaintiff. Case law has established that a telephone consultation may establish a physician-patient relationship. Phyllis F. Grande, *Medical Malpractice Issues Related to The Use of Telemedicine—An Analysis of the Ways in Which Telecommunications Affect the Principles of Medical Malpractice*, 73 N. Dak. L. Rev. 65, 69 n. 17 (1997). Courts analyze the following factors in determining whether a consultation creates a physician-patient relationship: (1) whether

the consulting physician created a chart for the patient; (2) whether the consulting physician charged for the consultation; (3) whether the consulting physician signed a consultation note in a hospital chart; (4) whether the consulting physician charged for the services rendered; (5) whether the consulting physician was advised of the patient’s name; (6) whether the consulting physician reviewed the patient’s records; and (7) whether the consulting physician examined the patient. *Id.* at 69; *Fortino v. Stouffer*, 17 Pa. D.&C.4th 526 (Cumberland 1993). Obviously, this analysis is fact-intensive and the ultimate determination will vary from case to case. A court reviewing these factors will examine the quality as well as the quantity of the factors involved.

Telemedicine may also affect the standard of care analysis in medical malpractice cases. As technology facilitates specialty consultations from physicians located at extended distances from the primary care physician, the primary physician may be criticized for failing to utilize telecommunications technology to seek out a specialist consultation. Grande, 73 N. Dak. L. Rev. at 90. Similarly, telemedicine may move more jurisdictions in the direction of a single standard of care that does not differentiate between rural and metropolitan medical care. *Id.* Also, telemedicine by creating greater access to specialized medical care may ultimately improve the delivery of health care while simultaneously decreasing medical malpractice litigation. *Id.*

Finally, telemedicine may give rise to more jurisdictional and choice of law issues in medical malpractice litigation. Until recently, most medical care was rendered within the same general geographic location and normally within the same state. *Id.* at 84. However, as indicated above, telemedicine will enable primary care physicians to engage the services of specialists

from outside his or her geographic region and state. Conflicts of law analysis provide that jurisdiction will rest where the injury occurred or in the state that has the most ties to the issues involved. *Id.* at 84 *citing* Restatement (Second) Conflicts of Laws Section 146. Moreover, more medical malpractice cases may be brought in federal courts assuming federal diversity of citizenship requirements is met. Health care providers must be aware that the patient’s state is not the only location in which a suit may be initiated. The physician’s home state may have sufficient ties to serve as a suitable forum for a medical malpractice plaintiff. Whenever the laws of more than one jurisdiction may be applied to a case, forum shopping may result. *Id.* Several jurisdictions have enacted statutory caps in medical malpractice cases or have enacted other tort reforms that may affect physician liability and/or a plaintiff’s recovery. *Id.* See also 2A N.J.S.A. 53A-27 (requirement of affidavit of lack of care in action for professional malpractice or negligence); the Medical Care Availability and Reduction of Error (Mcare) Act, 40 P.S. §1303.101 *et seq.* (Purdons 2002). Plaintiffs will obviously prefer a jurisdiction without tort reform legislation and no statutory caps on damages. Defense counsel will want to consider the potential of application of medical malpractice law incorporating tort reform and statutory caps.

Conclusion

Legal and medical practitioners will need to remain aware of the advances in technology, especially as they relate to the practice of medicine. While the medical community may not incorporate technology into the day-to-day practice of medicine as rapidly as other industries, technology will more frequently impact physicians and lawyers.