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CROSS-BORDER TELEMEDICINE: AN UNCERTAIN FUTURE

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I. INTRODUCTION

Imagine that technology will increase access to health care (especially for the underserved), expand utilization of specialty expertise, provide patients with rapid access to their medical records, and reduce the cost of patient care. These are just a few of the benefits touted for telemedicine.¹ Despite these benefits, the future of telemedicine, the electronic rendering of individual patient diagnoses and treatment, is uncertain. As demonstrated by its most visible form, the prescribing of ViagraTM and other drugs over the Internet, telemedicine may present significant challenges to existing regulatory frameworks. Moreover, issues such as low levels of literacy, especially health literacy, and existing ethical standards raise questions about the ultimate reach and benefits of telemedicine. Whether a legitimate trade in telemedicine services develops will ultimately depend on consumer demand and acceptance as well as whether providers can develop a viable economic model to deliver the services consumers want.

This Article will focus on two primary issues. The first is the regulatory challenge of cross-border telemedicine. The second is the issue of literacy, or the lack thereof, and the implications of low levels of health literacy for the development of telemedicine.

Telemedicine is not a self-defining term. As used in this Article, it means using information transmitted by electronic or other means to render a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient or to actually render treatment to a patient. Thus, as used here, telemedicine does not include every use of technology to exchange medical data. In addition, it does not include use of the Internet or other electronic communication forms where there has been a previously established face-to-face doctor-patient relationship. For example, it does not include every

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1. Federation of State Medical Boards, *A Model Act to Regulate the Practice of Medicine Across State Lines: An Introduction and Rationale* (April 1996), at <http://www.fsmb.org/telemed.htm> (last visited Sept. 30, 2001) [hereinafter Federation of State Medical Boards].

e-mail communication between a patient and provider and, in most instances, it does not include the transfer of medical data to consulting experts. Telemedicine acquires a cross-border character whenever the patient and physician are not located in the same state at the time the service is rendered.²

II. REGULATORY AND ETHICAL ISSUES

Except where specific statutes permit such practice, a physician practicing cross-border telemedicine could be charged with the unlicensed practice of medicine.³ Strict enforcement of these laws, which require physicians to have full and unrestricted licenses in every state where their patients are located, could seriously deter the legitimate development of telemedicine. On the other hand, allowing the practice to go unregulated seems unacceptable. A patient who receives care from an out-of-state physician should be entitled to the same standard of care as a patient receiving care from an in-state physician. In an attempt to address these issues, the Federation of State Medical Boards (FSMB), in 1996, proposed model legislation to permit cross-border medical practice under certain circumstances.⁴

The FSMB-proposed legislation would allow a physician holding a full and unrestricted license in one state to practice cross-border medicine provided that the physician obtained a special license from the board in the state where the patient is located.⁵ The physician would be subject to the jurisdiction of the board in the patient's state. Failure to appear or produce records would be a basis for suspension or revocation of the license.⁶ Importantly, medical records would be subject to all the protections provided by the state where the patient is located. The FSMB proposal would exempt cases of medical emergency, the practice of medicine on an irregular or infrequent basis, and practice done without compensation or the expectation of compensation.⁷

Notwithstanding current licensing requirements, there is at least one area of cross-border telemedicine that has flourished over the past three years—the practice of prescribing drugs over the Internet. Drugs such as Phentermine and MeridiaTM, both classified as controlled substances, as well as ViagraTM, are

2. *Id.*

3. *See, e.g.,* Illinois v. Express Today, Inc., No. 99 CH 0452 (D. Ill. filed Oct. 21, 1999).

4. *See* Federation of State Medical Boards, *supra* note 1. Few states have enacted statutes covering cross-border telemedicine. An exception is Ohio. *See* OHIO REV. CODE ANN. § 4731.296 (Anderson 2001). On the other hand, at least one state that specifically recognizes telemedicine has enacted a provision that would limit the scope of the practice of telemedicine. *See* ARIZ. REV. STAT. ANN. §§ 32-1401(25)(ss), 36-3601 et. seq. (West 2000) (prohibiting the prescribing of medications or medical devices requiring a prescription without a physical examination or previously established doctor-patient relationship).

5. *See* Federation of State Medical Boards, *supra* note 1.

6. *See id.*

7. *See id.*

being prescribed by physicians over the Internet based on nothing more than a patient's answer to online questionnaires.⁸ Initially, some speculated that the questionnaires were never reviewed by a physician and that the drugs were simply being shipped to patients without any physician authorization.⁹ In the majority of investigations conducted to date, however, that has not been the case. Rather, investigators have discovered that in most cases a licensed physician reviews the questionnaires and authorizes the prescriptions.¹⁰ However, a patient who fills out an online questionnaire generally never learns the name of the physician authorizing the prescription until the prescription is received. While it might be easy to dismiss these practices as aberrations, they raise important regulatory and ethical issues that must be considered as the field develops.

Significantly, leading health associations have condemned the practice of issuing prescriptions based solely on answers to online questionnaires. The American Medical Association has taken the position that "[w]eb sites that offer a prescription solely on the basis of a simple questionnaire" do not meet appropriate standards of care for issuing a prescription.¹¹ According to the FSMB:

In order to meet a standard of practice acceptable to the state medical board, the physician should demonstrate that there has been (1) a documented patient evaluation, including history and physical examination, adequate to establish the diagnosis for which the drug is being prescribed and identifying underlying conditions and contra-indications (2) sufficient dialogue between the physician and patient regarding treatment options and the risks and benefits of treatment(s) (3) a review of the course and efficacy of treatment to assess therapeutic outcome and (4) maintenance of a contemporaneous medical

8. There are Internet pharmacies that operate legitimately over the Internet. These pharmacies typically operate like traditional "brick and mortar" or legitimate mail order pharmacies. They require valid prescriptions from licensed physicians and verify the prescriptions before dispensing the drugs. These pharmacies may provide substantial benefits to consumers, including competitive prices, access, convenience and privacy. See *Drugstores on the Net: The Benefits and Risks of Online Pharmacies Before the Subcommittee on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 3 (1999) (prepared statement of the Federal Trade Commission), available at www.ftc.gov/os/1999/9907/pharmacy_testimony.htm (last visited Sept. 30, 2001).

9. Based on FTC investigations and author's discussions with Food & Drug Administration and Department of Justice (notes on file with author).

10. *Id.*

11. *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies Before the Subcommittee on Oversight and Investigations, House Comm. on Commerce*, 106th Cong. (July 30, 1999) (statement of the American Medical Association, presented by Herman I. Abromowitz, M.D.), available at www.ama-assn.org/ama/article/1402-4136.html (last visited Oct. 8, 2001). See also American Medical Association, Report of the Board of Trustees 35-A-99, *Internet Prescribing* (1999), available at <http://www.ama-assn.org/meetings/public/annual99/reports/onsite/bot/rft/bot35.rtf> (last visited Nov. 10, 2001).

record that is readily available to patients and their other health care professionals.¹²

Applying this standard, the FSMB concluded that the “prescribing of medications by physicians based *solely* on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct.”¹³ As discussed below, it is apparent that the standard applied by the FSMB has significant implications for more than just the prescribing of Viagra™ over the Internet.

Historically, states have regulated the practice of medicine and pharmacy.¹⁴ Accordingly, a number of states have actively challenged online companies that dispense prescription drugs without a valid prescription. Kansas,¹⁵ Missouri, and Illinois have each filed actions against so-called Internet pharmacies, and Michigan issued letters of intent to sue to seventeen sites.¹⁶ In the Illinois cases, the out-of-state licensed physicians were charged with the unlicensed practice of medicine.¹⁷ Other state actions have been based on violations of state consumer protection statutes as well as on state medical and pharmacy laws.¹⁸ In addition, professional disciplinary actions have been initiated in at least a dozen states.¹⁹ For example, an Oregon physician was put on ten years probation and fined five thousand dollars for prescribing drugs online without an examination.²⁰

A case filed by the Federal Trade Commission (FTC) against an online drug dispenser illustrates at least one type of telemedicine currently being practiced.²¹ Under the Federal Trade Commission Act, the FTC can initiate

12. Federation of State Medical Boards, *Report of the Special Committee on Professional Conduct and Ethics*, Section IV (April 15, 2000), available at <http://www.fsmb.org> (last visited Sept. 30, 2001) [hereinafter Report on Professional Conduct & Ethics].

13. *Id.*

14. *E-Drugs: Who Regulates Internet Pharmacies: Hearing Before the House Comm. On Health, Education, Labor, and Pensions*, 107th Cong. (2000) (testimony of Kansas Attorney General Carla J. Stovall), available at <http://labor.senate.gov/Hearings/mar00hr/032100wt/stovall/stovall.htm> [hereinafter Stovall testimony].

15. *See, e.g.*, *Kansas v. Focus Medical Group, Inc.*, No. 99C749 (D. Kan. filed June 9, 1999).

16. *See* Stovall testimony, *supra* note 14.

17. *See, e.g.*, *Illinois v. Express Today, Inc.*, No. 99 CH 0452 (D. Ill. filed Oct. 21, 1999).

18. United States General Accounting Office, Report to Congressional Requesters, Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight, GAO-01-69 34 (Oct. 2000), available at <http://www.nascsa.org/PDF/INTERNET.PDF> (last visited Nov. 11, 2001) [hereinafter GAO Report].

19. *Id.*

20. *Internet Viagra*, PITTSBURGH POST-GAZETTE, April 2, 2000, at A-12.

21. *FTC v. Rennert*, CV-S-00-0861 JBR (D. Nev. filed July 6, 2000). *See* Federal Trade Commission, Press Release, *Online Pharmacies Settle FTC Charges* (July 12, 2000), available at <http://www.ftc.gov/opa/2000/07/iog.htm> (last visited Oct. 4, 2001) [hereinafter FTC Press Release]

civil actions against advertisers of medical products and services, including telemedicine providers and online drug dispensers, who make false or misleading claims about the products or services they provide.²² In *FTC v. Rennert*, the Commission alleged that the defendants misrepresented the services they provided.²³ In particular, the FTC claimed that the defendants' websites falsely represented that their customers were served by a clinic with physicians and an on-site pharmacy.²⁴ The FTC's complaint stated that the defendants' customers were not served by a medical clinic or an on-site pharmacy.²⁵ Instead, these defendants employed one out-of-state physician to review customers' medical questionnaires. For this service, customers were charged seventy-five dollars if the prescription was approved, and the doctor was paid ten dollars for each of the first fifty prescriptions he *approved* per week and seven dollars and fifty cents for each additional *approved* prescription request.²⁶

The first Congressional hearing on Internet pharmacies was held on July 30, 1999.²⁷ While state and federal authorities have achieved some significant victories since then, patient access to such services does not appear to have diminished. In fact, consumers can easily locate websites selling ViagraTM and other prescription drugs through common Internet search engines.²⁸ This experience suggests that state licensing boards will have a difficult time ensuring that cross-border telemedicine providers comply with the professional standards articulated by the FSMB.

22. Federal Trade Commission Act, 15 U.S.C. §§ 45(a), 52 (1994).

23. FTC Press Release, *supra* note 21.

24. Defendants' websites contained statements such as "Focus Medical Group is a full service clinic with a full time staff dealing with the treatment of sexual dysfunction. The clinic's licensed medical physicians network with an organization of physicians throughout the United States and Internationally" and "All of our prescriptions are filled on premises." *See id.*

25. *Id.*

26. In addition to prohibiting the misrepresentations alleged in the complaint, the stipulated final injunction requires certain disclosures, including the name, address and phone number of the physician, the states where the physician is licensed or authorized to practice and the states from which the entity will accept orders.

27. *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies Before the House Commerce Comm. Subcomm. on Oversight and Investigations*, 106th Cong. (July 30, 1999) (prepared statement of the Honorable Tom Bliley), available at <http://com-notes.house.gov/chear/hearings106.nsf>.

28. A search conducted on September 25, 2001, using the Lycos search engine, located numerous domestic websites selling Viagra and other prescription medications and offering online consultations. These sites were listed in the first twenty-five hits or on the initial link to "featured" websites: <http://usa-pharmacy.com/viagra/index.htm>; <http://weight-loss-pharmacy.net/>; <http://www.at-cost-drugs.com>; <http://www.1-viagra-purchase.com>; <http://www.drugs-express.com/a/11722/viagra.html>; <http://www.medscripemd.com/html/viagra.html>; <http://buy-phentermine-online.com/?dom=gotoviagra>; <http://e-scripts-md.com/index.asp?referrer=10760>; <http://www.a1viagra.com>; and <http://valuehealthonline.com>.

Enforcement of existing legal and professional standards in the face of consumer demand and the technology of the Internet presents significant challenges.²⁹ One significant factor is resources. State regulatory bodies are already overloaded and may lack the expertise to investigate and prosecute violations.³⁰ Some of the most significant problems include identifying the physicians involved and the limited ability and authority of state medical boards to investigate and act against physicians once they are identified.³¹ Moreover, state unlicensed practice of medicine laws, allowing for injunctive actions and minor criminal penalties, may not be an efficient enforcement vehicle. In the absence of physical injury, or other direct threats to health, local prosecutors may not see these cases as priorities. All of these considerations raise further questions about the ability of states to regulate an expanding cross-border telemedicine practice.

As noted above, both the AMA and the FSMB have condemned the prescribing of drugs based solely on the answers to online questions.³² In addition, FSMB has published standards for issuing prescriptions online.³³ Certain of these standards—a documented patient evaluation, including a history and physical examination adequate to establish the diagnosis for which the drug is being prescribed, identifying underlying conditions and contraindications, and ensuring a sufficient dialogue between the physician and patient regarding treatment options and the risks and benefits of treatment—could pose significant obstacles to cross-border telemedicine. While technological solutions may exist or may be developed to address at least some of these concerns, until fully developed and implemented, serious questions will remain.

Some providers may try to limit the type of medical services they provide (or not provide certain medications at all) in order to comply with professional standards. Such limitations on standard medical practice should be fully disclosed to patients. For example, the health Internet ethics organization, Hi-Ethics, Inc., states that health professionals practicing online should inform patients about the limitations of online health care.³⁴ Other providers may claim that they are not providing medical services. Again, this practice raises

29. Report of the President's Working Group on Unlawful Conduct on the Internet, *The Electronic Frontier: The Challenge of Unlawful Conduct Involving the Use of the Internet*, App. D: Internet Sale of Prescription Drugs and Controlled Substances (Mar. 2000), available at <http://www.usdoj.gov/criminal/cybercrime/append.htm> (last visited Sept 29, 2001).

30. GAO Report, *supra* note 18, at 16.

31. *Id.*

32. See *supra* text accompanying notes 11-13.

33. Report on Professional Conduct & Ethics, *supra* note 12.

34. Hi-Ethics, *Health Internet Ethics: Ethical Principles for Offering Internet Health Services to Consumers*, available at <http://www.hiethics.org/Principles/index.asp> (last modified Sept. 29, 2001) (discussing the disclosure of limitations in principle thirteen).

difficult disclosure issues, which might conflict with reasonable patient expectations and unless done successfully, create risks for both the physician and the patient.

The question arises, then, whether professional standards should be relaxed for telemedicine. While a compelling case can probably be made for certain exceptions, such as emergencies and, perhaps, to serve populations that would not otherwise receive adequate medical treatment, the justifications seem lacking for lowering standards across the board. Lowering standards for telemedicine would mean that patients utilizing these medical services would be entitled to less protection than patients using “brick and mortar” medical services. From a public health perspective, there seems to be little impetus to go in this direction. Of course, it is possible that lowering standards for telemedicine could increase pressure to lower standards for other types of medical services. In this instance, the prudent policy seems to be to apply existing professional standards, if for no other reason, than to encourage the development and broad-based implementation of compliant technology.

III. HEALTH LITERACY

Current e-health information and Internet services rely on text-based applications written at college literacy levels, which make them of limited use to a significant portion of our population. The implications of limited literacy, particularly limited health literacy, are significant both for telemedicine and other health information providers. Some have suggested that once the quality of e-health information matures and search costs are eliminated, informed consent will become redundant.³⁵ While this may be possible for a few, it does not take into account more than ninety million Americans who have difficulty understanding basic health information.³⁶ Many people lack sufficient skills to comprehend written health education materials,³⁷ and health information on the Web is commonly written at levels beyond the understanding of a majority of readers.³⁸ With one in five adults reading below a fifth grade level and only

35. Nicolas P. Terry, *Structural and Legal Implications of E-Health*, 33 J. HEALTH L. 607, 607-08 (2000).

36. Peter Brandt, *Engaging the New Consumer: a Pfizer Perspective*, in COLUMBIA UNIVERSITY HEALTH CARE FORUM: THE FUTURE HEALTH CARE CONSUMER 30 (Francoise Simon & Lothar Krinke eds., 2000), available at <http://www.hfflr.com/adobe/columbia.pdf>.

37. See Terry, *supra* note 35, at 608.

38. See *id.* at 607.

about half reading at levels necessary to understand basic health information,³⁹ the lack of basic literacy presents a significant problem.⁴⁰

At least for the immediate future, telemedicine will rely almost exclusively on textual material to convey important information to patients. In addition to requirements that currently exist, such as informed consent, others are likely to exist in the future, such as privacy disclosures required pursuant to Health and Human Service rules implementing the Health Information Portability and Accountability Act (HIPAA). In any case, telemedicine providers will be faced with the challenge of insuring that patients understand disclosures, including limitations on services, and patient instructions, all without the benefit of visual cues available in face-to-face consultations. This problem will be particularly difficult to resolve given the complexity of the patient information and privacy disclosures that may be required. Moreover, it is likely that the legal system, as it should, will place the burden on the providers when there is a miscommunication. After all, selling health services is not the same as selling toasters. There is, and should be, a higher standard for health providers.

Most, if not all, of these concerns can be addressed through technology and sensitivity to the literacy problem. Providers could present material at a textual level consistent with the user's ability to read and comprehend, and video, audio, and graphics can be used in many cases instead of text. The first step in solving a problem is recognizing that it exists. Too often, in the area of consumer protection, problems of literacy have been ignored, in part because there was no good solution. The Internet may present us with novel ways to address this difficult challenge.

IV. CONCLUSION

Telemedicine presents exciting opportunities and challenges for the twenty-first century. Its future will depend on consumer demand and the economics of providing telemedicine services. There is no reason to doubt that innovative technologies will develop to address existing professional obstacles. But telemedicine, particularly cross-border telemedicine, presents significant regulatory challenges that cannot be easily addressed. Thus far, however, a comprehensive, effective strategy to address cross-border telemedicine has not emerged.

39. SCI. PANEL ON INTERACTIVE COMMUNICATION & HEALTH, OFFICE OF DISEASE PREVENTION & HEALTH PROMOTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., *WIRED FOR HEALTH AND WELL-BEING: THE EMERGENCE OF INTERACTIVE HEALTH COMMUNICATION* 40 (Thomas R. Eng & David H. Gustafson eds., 1999).

40. Of course, the literacy problem is not limited to health information on websites. For example, privacy notices are frequently written at college reading levels. See John Schwartz, *Privacy Policy Notices Are Called Too Common and Too Confusing*, N.Y. TIMES, May 7, 2001, at A1.